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# Influence of Maternal Past Dental Experience and Child's Temperament on Behavior Management Problems in Dental Office

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## Abstract

**Introduction:** Children are all unique and special in their own way, and as pediatric dentists, we recognize that children cannot all be treated the same. The child's behavior on every dental visit depends on variables such as parental behavior, parental anxiety, past medical/dental history, the awareness of their dental problem, type of dental procedure, the behavior management, and the procedural techniques followed by the dentist. The aim of the following study was to assess the following background variables with a view to estimate their influence on behavior management problems using a structured interview and analyzing their separate and combined predictive power: (1) Mother's previous dental experience and (2) Child's temperament.

**Materials and Methods:** A total of 100 children of the age group 6-8 years, who reported for their first dental appointment with their mothers, were included in the study. An assessment of the behavior exhibited by each child was made using the four-point scale of Frankl, and their mothers were asked to rate their own past dental experiences. Children were also categorized according to temperament.

**Results:** Out of 13 children, whose mothers had a pleasant past dental experience, 11 children (84.62%) displayed positive behavior. On the contrary, only 4 children (28.57%) of mothers with unpleasant dental experience exhibited positive behavior, and this difference was statistically significant ( $z = 2.9283$ ,  $P = 0.0038$ ). Furthermore, children with negative temperament generally exhibited negative dental behavior.

**Conclusion:** In this study, a correlation between maternal anxiety, child anxiety, and negative behavior in the dental office was observed. Appropriate use of management techniques not only helps us to efficiently perform dental treatment but also instills a positive dental attitude in the child, which ensures desired behavior even on successive visits.

**Key words:** Behavior management problem, Child emotionality, Maternal anxiety, Positive dental behavior, Temperament

## INTRODUCTION

The foundation of practicing dentistry on children is the ability to guide them through their dental experiences while instilling in them a positive attitude toward dentistry. Behavioral dentistry is an interdisciplinary science, the

objective of which is to develop in a dental practitioner an understanding of the interpersonal social forces that influence a patient's behavior.

Children are all unique and special in their own way, and as pediatric dentists, we recognize that children cannot all be treated the same. The initial consultation appointment allows the dental team to not only establish treatment needs but just as important, determine how to manage behavior. The child's behavior on every dental visit depends on variables such as parental behavior, parental anxiety, past medical/dental history, the awareness of their dental problem, type of dental procedure, the behavior management, and the procedural techniques followed by

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the dentist.<sup>1</sup> Furthermore, children's developmental age and the corresponding level of cognition and emotionality play a prominent role in clinical behavior.<sup>2</sup> Interwoven with these primal characteristics is the child's temperament, broadly embraced and defined as how a child responds to novel environments and strangers.<sup>3</sup> Temperament is thought to have a genetic basis, and some aspects of the temperament domain significantly influence children's behavior in clinical settings including dental offices. For example, shy or withdrawn, non-approachable, and moody children generally may not be cooperative for routine dental procedures.<sup>4</sup>

The issue of dental fear and anxiety has been studied extensively and presents a significant problem to patients and dentists alike. It appears that a common method of anxiety assessment is for clinicians to use their clinical judgment and experience in determining anxiety levels. This is the method used by the majority of UK dental practitioners, and therefore, is highly relevant.<sup>5</sup>

The aim of the following study was to assess the following background variables with a view to estimate their influence on behavior management problems using a structured interview and analyzing their separate and combined predictive power:

1. Mother's previous dental experience
2. Child's temperament.

## MATERIALS AND METHODS

The study was conducted in the Department of Pedodontics and Preventive Dentistry, Buddha Institute of Dental Sciences and Hospital, Patna, India. About 100 children of the age group 6-8 years, who reported for their first dental appointment with their mothers, were included in the study. An assessment of the behavior exhibited by each child was made using the four-point scale of Frankl, which has been found reliable by various authors.

The criteria for scoring were as follows.

- Rating 1: Definitely negative: Refusal of treatment, crying forcefully, fearful, or any overt evidence of extreme negativism.
- Rating 2: Negative: Reluctant to accept treatment, some evidence of negative attitude but not pronounced.
- Rating 3: Positive: Acceptance of treatment, at times cautious, willingness to comply with the dentist, at times with reservation but patiently follows cooperatively.
- Rating 4: Definitely positive: Good rapport with the dentist, interested in the dental procedures, laughing and enjoying the situation.

In addition, the mothers were asked to rate their own past dental experiences as follows:

- Group A: Pleasant.
- Group B: Indifferent (neither pleasant nor unpleasant).
- Group C: Unpleasant.
- Group D: No prior dental exposure.

Children were categorized into following groups according to temperament (Thomas and Chess, 1977).<sup>6</sup>

- Group 1: Easy child (adaptable, playful, responsive to adults).
- Group 2: Slow-to-warm-up child (slow adaptability, takes longer to elicit positive behavior).
- Group 3: Difficult child (fussy, difficult to soothe, has problems sleeping and eating).

Data were statistically analyzed, frequency tables of variables were generated, and cross tabulations were derived where necessary. The Chi-square test was employed to determine the association between variables.

## RESULTS

The frequency distribution of the mother's past dental experiences is shown in Table 1.

It was noted that quite a high percentage of the mothers had no prior dental experience.

Out of 13 children, whose mothers had a pleasant past dental experience, 11 children (84.62%) displayed positive behavior. On the contrary, only 4 children (28.57%) of mothers with unpleasant dental experience exhibited positive behavior, and this difference was statistically significant ( $z = 2.9283$ ,  $P = 0.0038$ ). 9 children (64.28%) exhibited negative behavior and 1 child (7.14%) showed signs of definitely negative behavior (Table 2).

Among mothers with indifferent experience, 16 children (59.26%) revealed negative behavior, 1 child (3.7%) exhibited definitely negative behavior, and 10 children (37.04%) showed positive behavior.

About 24 children (52.17%), whose mothers did not have any prior dental experience, exhibited positive behavior, 3 children (6.52%) children exhibited definitely negative behavior, and 19 children (41.31%) demonstrated the negative behavior (Graph 1).

From Table 3, it is safe to conclude that significantly higher number of children, whose mothers had a pleasant past dental experience displayed positive behavior when compared with other groups.



Frequency distribution of temperaments of children as reported by their mothers is shown in Table 4.

Assessment of children's behavior according to temperament is demonstrated in Table 5 as well as Graph 2, where it can be observed that majority of children of Group 1 showed positive behavior, whereas all the children of Group 3 showed negative behavior.

**Table 1: Mother's past dental experience**

Group	Mother's past dental experience	Percentage
Group A	Pleasant	13
Group B	Indifferent	27
Group C	Unpleasant	14
Group D	No prior exposure	46

**Table 2: Behavior rating of children**

Group	n (%)			
	Rating 1	Rating 2	Rating 3	Rating 4
Group A (n=13)	0 (0)	2 (15.38)	11 (84.62)	0 (0)
Group B (n=27)	1 (3.7)	16 (59.26)	10 (37.04)	0 (0)
Group C (n=14)	1 (7.14)	9 (64.28)	4 (28.57)	0 (0)
Group D (n=46)	3 (6.52)	24 (52.17)	19 (41.31)	0 (0)

**Table 3: Comparison between various groups**

Groups compared (for positive behavior)		P value	Significance
Group A	Group B	0.0048	Statistically significant
Group A	Group C	0.00338	
Group A	Group D	0.00578	
Group B	Group C	0.5892	The difference was not statistically significant
Group B	Group D	0.71884	
Group C	Group D	0.38978	

**Table 4: Children's temperament**

Group	Temperament	Percentage
Group 1	Easy child (adaptable, playful, responsive to adults)	31
Group 2	Slow-to-warm-up child (slow adaptability, takes longer to elicit positive behavior)	43
Group 3	Difficult child (fussy, difficult to soothe, has problems sleeping and eating)	16

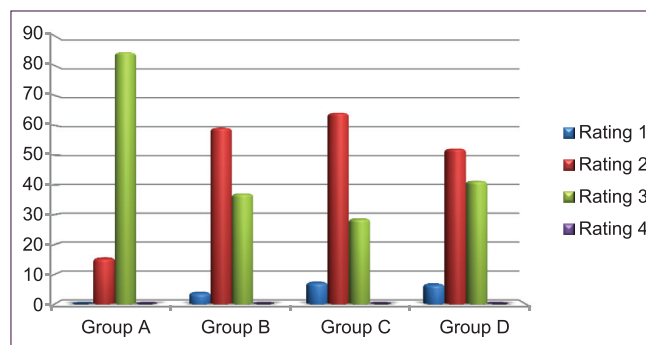
**Table 5: Behavior exhibited by children of different temperament**

Behavior rating	n (%)		
	Group 1 (n=31)	Group 2 (n=43)	Group 3 (n=16)
Positive (Rating 3 and 4)	28 (90.32)	16 (37.21)	0 (0)
Negative (Rating 1 and 2)	3 (9.68)	37 (86.05)	16 (100)

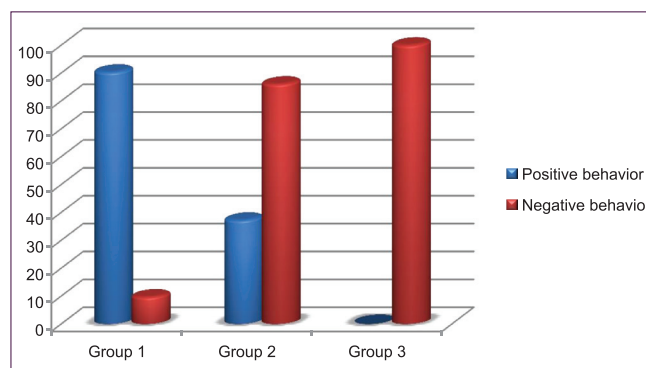
## DISCUSSION

The origin of dental fears is numerous, complex, and multifactorial, being associated with age, socioeconomic status, oral health status, and dental pain experience.<sup>7</sup> A few of the determinants of dental fear includes dental behavior management problem (DBMP), mother-child relationship, temperament, predictability, and controllability.<sup>8</sup> DBMP is a collective term for behaviors resulting in the delay or cancellation of treatment as determined by the treating dentist or dental staff. DBMP has been discussed in a multifactorial context where personal, environmental, and situational factors interact. Children and adolescents vary in age, competence, temperament, personality, intellectual capacity, and maturity. They also differ greatly in life experience, family situation, and cultural background. All these aspects affect the child's or adolescent's ability to tolerate dental examinations and treatment.<sup>9</sup>

According to Finn, one of the ways by which a child can acquire dental fears is subjective, based on information from others without the individual having experienced the situation himself.<sup>10</sup> Incorporation of attitudes and behavior patterns from parents and siblings is as common as contracting measles from family members or friends, and thus, is referred to as behavior contagion. Data have



**Graph 1: Behavior rating of children**



**Graph 2: Behavior exhibited by children of different temperament**

revealed that fearful dental patients come from families that have had previous unfavorable dental experiences and in particular where these attitudes are typically expressed.<sup>11</sup>

Hawley *et al.* (1974) reported that there was significant negative behavior in children who had interacted with someone with an unpleasant dental experience. Similarly, frightening comments made by other children and adults have resulted in children reacting unfavorably at the dental clinic.<sup>12</sup>

Most of the characters of the child such as behavior, personality, anxiety, and reaction to stress are directly influenced by the parents' characters. Both the parents play an important role in child's psychological development, but more emphasis is placed on the mother, since mothers generally have more intimate contact with the child since prenatal period. The quality of maternal interactive behavior with infants influences the physiological and behavioral response to stress, including expression of fearfulness.<sup>11</sup> This was in agreement with our study, where children whose mothers had unpleasant past dental experience also exhibited fearful behavior.

According to Hane,<sup>13</sup> the function of maternal behavior was different across the two general trajectories (maternal positivity and negativity), and these influenced the development of social withdrawal in childhood. Maternal negativity is associated with poor social functioning in children who have an established history of social withdrawal, whereas maternal positivity is associated with better social outcome for preschoolers who are viewed as temperamentally shy.

Research on the role of parental fearfulness and modeling in children's fear has revealed that children of fearful mothers who often expressed their fears were very fearful themselves. A mother who bears anxieties as a result of her own previous dental experience can transmit it to her offspring, and this may produce a phobia of dental treatment in the child with preconceived notions even before the actual visit.<sup>14</sup>

Bankole established that there exists a correlation between maternal anxiety, child anxiety, and negative behavior in the dental office, which indicated a disruptive influence caused by an anxious mother,<sup>11</sup> and this finding concurred with the results of the current study.

There is clear evidence of relationships between temperament and dental fear and anxiety. As with internalizing problems, it is more connected with temperamental traits such as shyness, inhibition, and negative emotionality.<sup>15</sup> Temperament has become

an increasingly important concept in developmental psychology and psychopathology. With the growth of developmental psychopathology as a discipline, a renewed interest in the transaction between the child's inborn tendencies (e.g. temperament, neurological vulnerability) and the caregiving environment has followed. Over the last decade, the interest in temperament in terms of reactivity (i.e. how quickly and intense, different parts of the nervous system reacts to external stimuli) has been supplemented with an interest in temperamental aspects of the regulation of affect and behavior (i.e. how well the child is able to regulate his or her activated nervous system).<sup>16</sup>

Although there is some evidence that temperament is stable over time, there are some factors that affect some types of temperament. Martin and Fox (2006) suggested that these factors include sex of the child (inhibited girls are more likely to change than inhibited boys), children's participation in out-of-home care (children who receive outside child care become less inhibited over time), parental characteristics (over controlling parents have children who remain inhibited over time), sibling relationships, and stress.<sup>6</sup>

Negative emotionality, a tendency to become easily and intensely upset, especially when frustrated, may also influence children's ability to cope with dental treatment, since it leads to aggressive and/or refusal behavior. This could be seen in our study as well, in cases of children of difficult temperament, who exhibited negative behavior in the dental office.<sup>9</sup>

The association of dental anxiety with a history of dental pain in children less than five years of age may be explained by the notion that dental fear is closely related to invasive procedures. This suggests that the fear of pain is a factor to be considered, investigated, and controlled in dental practice, particularly in pediatric dentistry, since it constitutes the first experience of oral health care.<sup>17</sup>

## CONCLUSION

Successful pediatric dentistry depends not only on technical skills but also on our ability to acquire and maintain a child's cooperation. Proper assessment of children's behavior helps the dentist to plan appointments and render effective and efficient dental treatment. One of the most challenging aspects of dental practice is working with the difficult, challenging, or uncooperative children, whose primary emotions on entering a dental office are anxiety and fear. It is during these times that the dentist's clinical and patient management skills are most thoroughly tested, and success requires a personal knowledge of the patient and an

understanding of human behavior and development. In this study, a correlation between maternal anxiety, child anxiety, and negative behavior in the dental office was observed. Appropriate use of management techniques not only helps us to efficiently perform dental treatment but also instills a positive dental attitude in the child, which ensures desired behavior even on successive visits.

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# Diagnostic Yield of Bronchoscopy in Lower Lung Field Tuberculosis

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## Abstract

**Background:** Pulmonary tuberculosis (PTB) in the adult may present with unusual X-ray patterns that may lead to diagnosis in the direction other than TB. When TB is confined to the lower lung fields, it often presents as pneumonia and the correct diagnosis gets delayed. Early diagnosis and treatment help in the prevention of complications and hospital stay. This 2 years prospective study was designed to study clinical profile, outcome, and role of bronchoscopy in sputum negative cases.

**Materials and Methods:** All the patients of PTB with lesions below an imaginary line across the hila in the chest radiograph were included. HIV testing, sputum for acid-fast bacilli (AFB), blood sugar, and other relevant investigations were performed in each patient. The yield of bronchoscopy in bacteriologic diagnosis in sputum negative cases was noted.

**Results:** Out of 1811 cases of PTB patients, 42 cases had lower lung field TB (LLFTB). It was more common in females 28 (66%). The majority of patients 27 (64%) were in the 16-40 years age group. Unilateral disease was more common 29 (69%) and the right side was more frequently affected 31 (73.8%). Consolidation 28 (66.6%), cavitation 9 (21.4%), and nodular opacities 5 (11.9%) were the main radiological findings. Fiberoptic flexible bronchoscopy yielded AFB in 18 (42.9%) cases.

**Conclusion:** Diagnosis requires a high index of suspicion. Diabetes mellitus, HIV, and lung cancer increase the risk of LLFTB. Fiberoptic flexible bronchoscopy helps in diagnosis in sputum negative cases.

**Key words:** Fiberoptic flexible bronchoscopy, HIV, Lower lung field tuberculosis, Sputum negative pulmonary tuberculosis

## INTRODUCTION

An important preventable and treatable cause of death causing a major health problem worldwide is pulmonary tuberculosis (PTB). In the year 2011, there are 8.7 million new cases of TB (13% co-infected with HIV) and 1.4 million people died from TB including almost one million deaths among HIV-negative individuals and 430000 among people who were HIV-positive.<sup>1,2</sup>

PTB commonly affects upper lobe, however, lower lung field cannot be ruled out easily. This often causes great confusion in the diagnosis, especially in non-resolving pneumonia. HIV/AIDS epidemic has considerably

increased the incidence of middle and lower lung field TB (LLFTB)<sup>3</sup> which is frequently associated with negative sputum smear due to lower bacillary load.<sup>4</sup>

Since Laennec's era, lower lobe TB was a rare entity.<sup>5</sup> In 1866, Kidd stated that "apex of lower lobe is very prone to tubercular disease and may be attacked before the apex of the upper lobe."<sup>6</sup> When TB affects lower lung fields, it confuses clinicians as pneumonia and hence delays accurate treatment and increases cost and hospital stay of patients. Therefore, a high index of suspicion is the key to the diagnosis of LLFTB.

LLFTB is defined as "TB disease found below an imaginary line traced across the hila and including the para-hilar regions on a standard posterior-anterior chest x-ray without the concomitant involvement of upper lobe."<sup>7</sup>

Anatomically, this includes the right middle lobe and lingula, in addition to the lower lobes.

The proposed pathogenesis is the ulceration of a bronchus by a lymph node with spillage into the bronchus. Many

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authors believe it may be a continuum of primary TB or soon after, in the post-primary phase.<sup>8</sup>

Detecting patients with active LLFTB help in giving early appropriate treatment and render these patients non-infectious. Under the World Health Organization (WHO)<sup>9</sup> program, which implemented successfully in high burden countries including India's Revised National TB Control Program (RNTCP),<sup>10</sup> the diagnosis of PTB is based on sputum smear examination. Sputum microscopy is a highly specific test, a low-cost and appropriate technology and is an essential component of the directly observed treatment.

However, in patients with LLFTB sputum smears do not reveal acid-fast bacilli (AFB) in all patients. Mycobacterial cultures take at least 6-8 weeks' time for confirming the diagnosis and thereby a valuable time is lost. Sputum smear-negative (SSN) TB still remains a common problem faced by the clinicians. This is particularly true in the case of children, those with HIV, and diabetes patients.

Flexible fiberoptic bronchoscopy (FOB) and bronchoalveolar lavage and sample for AFB staining have helped in early identification with LLFTB. Since early diagnosis and treatment play an important role in the prevention of TB, therefore, a proper understanding about its clinical, radiological, and bacteriological presentations, as also the outcome of treatment is very essential.

## MATERIALS AND METHODS

This study was conducted in tertiary care hospital from July 2012 to June 2014. There were a total of 1811 patients diagnosed as cases of PTB during the study period. Patients who had pulmonary, extra PTB, or both were considered as cases of PTB and included in this study. PTB was diagnosed by detailed history, clinical examination, chest radiograph, and sputum for AFB examination by Ziehl-Neelsen method and culture on LJ media. Those patients, whose sputum was negative for AFB by direct smear and by culture, were diagnosed as cases of sputum negative PTB (SSN-PTB). Definitive diagnosis was made by recovery of AFB in the sputum or flexible FOB and bronchial lavage for AFB. Whenever the patient was sputum negative, FOB was done to make a definitive diagnosis. Informed consent was taken from all patients for the study and during the bronchoscopy procedure. After the procedure, the bronchoscope was properly checked according to guidelines for appropriate sterilization to avoid false positive cases.

An arbitrary horizontal line on chest radiograph postero-anterior view across the hila was taken as the

dividing line between upper and lower lung fields. A total of 42 patients had lower lung field TB.

Exclusion criteria included patients with age <16 years, cases involving either ipsilateral or contralateral involvement of both upper and lower lung fields, pleural effusion, and thickening unless associated with parenchymal lesions in the area involved. HbA1C level, fasting and post-prandial blood sugar levels were used to diagnose diabetes. HIV testing was done according to the NACO guidelines.<sup>11</sup> All patients were treated with short course chemotherapy according to the WHO guidelines.<sup>4</sup>

## RESULTS

During the study period from July 2012 to June 2014, there were 1811 cases with PTB of which 42 had lower lobe TB (LLT). The incidence of lower lung field TB was 2.3% Table 1. It was more common in females 28 (66%) than in males 24 (34%). The youngest patient during our study was 16-year-old, and oldest was 71 years. The highest incidence was observed in 16-45 years age group patients 27 (64%).

The presenting symptoms were a cough, with or without expectoration, in all patients (100%), followed by fever in 23 (54.7%), chest pain (49%), hemoptysis (11%), and weight loss in 13% patients. Risk factors were seen in 26 patients of which diabetes in 18 patients, HIV in 5, pregnancy and lung cancer 3 cases each (Table 2).

Radiological observation seen was consolidation in 28 (66.6%), cavity in 9 (21.4%) followed by non-homogeneous opacities in 11.9% patients. Cavitation was less common finding in HIV-infected patients. In diabetic patients, consolidation was commonly seen. Right lung involvement

**Table 1: Incidence of LLFTB**

Authors	Total tuberculosis cases	Subjects with LLT	Incidence of LLT (%)
Berger <i>et al.</i> <sup>7</sup>	386	27	7
Hamilton <i>et al.</i> <sup>15</sup>	349	10	3
Parmer <sup>8</sup>	1455	50	3.4
Viswanathan <sup>13</sup>	638	41	6.4
Present study	1811	42	2.3

LLFTB: Lower lung field tuberculosis, LLT: Lower lobe tuberculosis

**Table 2: Clinical features of patients with LLT**

Authors	Cough (%)	Fever (%)	Chest pain (%)	Hemoptysis (%)	Weight loss (%)
Berger <i>et al.</i> <sup>7</sup>	25 (1.3)	22 (82)	16 (59)	12 (44)	12 (44)
Hamilton <i>et al.</i> <sup>15</sup>	10 (100)	2 (20)	8 (80)	5 (50)	
Viswanathan <sup>13</sup>	41 (100)	6 (15)	7 (17)		
Present study	42 (100)	29 (69)	17 (40.4)	6 (14)	5 (11.9)

LLT: Lower lobe tuberculosis

was more frequently affected in 31 (73.8%) patients. Left lung was involved in 8 (19.1%) patients, and bilateral involvement was there in 3 (7.1%) patients. Sputum was positive for AFB in 24 (57.1%) patients. Fiberoptic flexible bronchoscopy was used to diagnose when there was a strong suspicion of TB. Bronchoscopy washings yielded AFB in 18 (42.9%) cases.

## DISCUSSION

Kidd first reported the case of LLFTB in 1886. The incidence of LLFTB varies from reports from different parts of the world.<sup>12-14</sup> It varies from 0.63%<sup>12</sup> to 6.4%.<sup>13</sup> In our study, we observed an incidence of 2.3%.

All studies, including our study except a few, showed female predominance.<sup>8,12</sup> The probable explanation being that females have costal type of respiration resulting in poor ventilation of and hence higher chances of TB.<sup>13,14</sup> In our study, the patients with LLFTB 27 (64%) were in the age group of 16-45 years. This was also found in other studies.<sup>15-17</sup>

About 5 of our patients had HIV with lower lobe TB. In HIV persons based on CDC counts presentation differs. With lower immune status, favors mid and lower lung zone TB<sup>3,4</sup> and cavitation is less common. In a study by Purohit *et al.*<sup>18</sup> had also reported mid and LLFTB in more than 50% cases. Diabetes mellitus was associated in 18 cases. Studies have shown<sup>15-17,19</sup> higher incidence of LLFTB in diabetics.

The common symptoms were a cough (100%) followed by fever, hemoptysis, chest pain, and weight loss. This finding was also observed in other Indian studies.<sup>8,13,17</sup> Weight loss was prominent in HIV patients. The right lung was more predominantly involved in 60% patients was also seen in other studies.<sup>8,13,15</sup> The right side of the lung is more common than left due to anatomical factors. There is a higher incidence of right-sided hilar lymphadenopathy which may rupture through any bronchus and can cause lower zone infection.<sup>18</sup>

Microbiological study of sputum yielded AFB 24 (57.1%) and flexible FOB in 18 (42.9%) cases whenever sputum was negative, and a high index of suspicion was present. Flexible FOB increases the recovery rate of AFB, and microscopic examinations of bronchoscopic specimens were found positive for AFB in 48-67%. A study by Wilcox and Wongthim showed bronchial washes increases the diagnostic yield in PTB.<sup>18,20</sup>

All the patients were treated according to the WHO Guidelines.<sup>4</sup> Success was similar to that in classical upper lung field TB. There were no deaths in our study.

## CONCLUSION

LLFTB is frequently confused with the commonly seen pneumonias. TB has to be considered as one of the possible diagnosis especially in diabetics, elderly, HIV, immunocompromised and when the radiologic picture suggests unresolved lower lobe pneumonia or bronchiectasis. The early diagnosis helps in prevention of severe sequelae. Repeated and extensive investigations are necessary to look for non-resolving pneumonia and to confirm the diagnosis in doubtful cases.

LLFTB is not uncommon finding in clinical practice. The absence of upper lobe involvement cannot rule out lower lobe TB and lack of symptoms, initial negative sputum smears, and culture for AFB and/or a negative initial tuberculin skin test do not entirely rule out the possibility of TB. The flexible FOB has been a wonderful tool in obtaining secretions and tissue specimens for definite diagnosis but also in assessing the severity of the endobronchial lesions and as a guide for early surgical intervention. Performing FOB and subjecting the bronchoscopic secretions to conventional diagnostic methods of AFB smear, mycobacterial culture and histopathology appear to be helpful in the diagnosis of SSN-PTB. The FOB may also offer the additional advantage of the confirmation of the diagnosis of several non-TB conditions that may mimic PTB as well.

In developed countries with no limitations on resources/ diagnostic facilities, early use of FOB seems to be the best course of action in a patient with suspected SSN-PTB. Prognosis is similar to those cases involving upper lobe.

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# Evaluation of Palpable Breast Lumps under the Age of 35 Years with Triple Assessment

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## Abstract

**Introduction:** Breast is an important feature of female anatomy and representing femininity. Breast complaints are one of the most common reasons for surgical consultation. A quick, reliable, non-invasive or minimally invasive means of diagnosis helps to lessen the anxiety and aids in instituting early definitive care. Triple assessment has been considered the best combination of tests.

**Aims:** To study the pattern of age, duration, and pathology, the mode of onset and clinical manifestations, and to identify - malignant disorders of palpable breast lumps using triple assessment.

**Materials and Methods:** It is an observational cross-sectional study conducted in Mandya Institute of Medical Sciences from March 2015 to March 2016. All female patients below 35 years presented to the surgical outpatient department (OPD) with palpable breast lumps are assessed by triple assessment.

**Results:** Total of 80 patients were included in the study, among which mean age of presentation is 26.62 with standard deviation of 6.09, 42 had lumps in right breast (52%), 36 patients in left breast (45%), 14 out of 80 patients had positive axilla with palpable lymph nodes. 6 out of 80 patients had significant family history of breast carcinoma. The triple assessment was in favor of benign diagnosis in 41 (51.25%) patients while as the malignant diagnosis was made in 14 (17.5%) patients.

**Conclusions:** Triple assessment is a very useful diagnostic tool to evaluate patients with breast lumps and to detect patients with breast cancers with an overall accuracy of 99.3%. When the lumps are palpable clinically and of size more than 2 cm fine-needle aspiration cytology itself has a sensitivity of 100%. The triple assessment did not require hospitalization, can be performed on OPD basis, without any complications and it is the gold standard diagnostic tool for the palpable breast lumps in early detection of malignancy avoiding biopsies.

**Key words:** Palpable breast lump, Triple assessment, Ultrasonography of breast

## INTRODUCTION

Mammary glands or breasts are a distinguishing feature of mammals.<sup>1</sup> Breast is an important feature of female anatomy and representing femininity. From puberty to death, the breast is subjected to constant physical and physiological alterations that relate to menses, pregnancy, gestation, lactation, and menopause. This is unique because

its development and growth are under the control of numerous hormones.

Breast masses in young women are common and cause much anxiety. The majority of these lesions are benign. In the modern society, females as they are more educated with increased medical awareness, they are more worried about any physiological or pathological changes in the breast, which causes more psychological and emotional trauma to the patients, when the patient suspects it may be a malignancy.

A quick, reliable, non-invasive or minimally invasive means of diagnosis helps to lessen the anxiety and aids in instituting early definitive care. Triple assessment has been considered the best combination of tests.

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The triple assessment is an evaluation of palpable breast masses by clinical breast examination (CBE), imaging and tissue sampling. Because of their mammographically dense breasts and the fear of exposing them to repeated radiation, ultrasonography (USG) is the first choice imaging method in young women (<35 years) with palpable breast masses.

## MATERIALS AND METHODS

It is an observational cross-sectional study conducted in Mandya Institute of Medical Sciences from March 2015 to March 2015. All female patients below 35 years presented to surgical/oncosurgery outpatient department (OPD) with palpable breast lumps are assessed taking a detailed history regarding lump, pain, nipple discharge, menstrual history, obstetric history, history of oral contraceptive pills. General physical examination done. A detailed local and systemic examination was carried out, and clinical diagnosis was made.

Patients were subjected to USG of breast and fine-needle aspiration cytology (FNAC)/core biopsy.

## RESULTS

Figure 1 shows the mean age of presentation is 26.62 with a standard deviation of 6.09 with mean duration

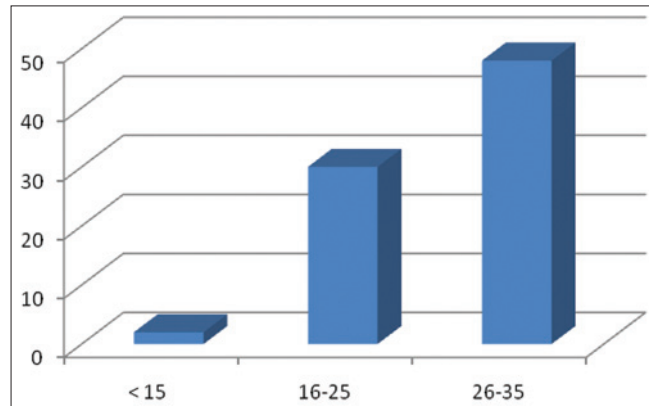


Figure 1: Age

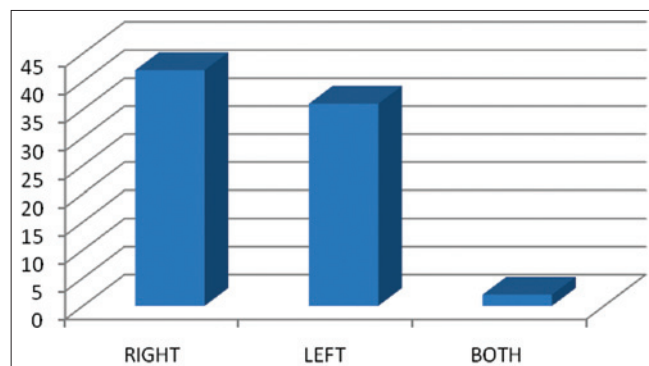


Figure 2: Site

of complaints 3.79 months with standard deviation of 2.75 months.

Out of 80 patients, 42 had lumps in right breast (52%), 36 patients in left breast (45%), and 2 patients had lumps in both breasts (Figure 2).

About 59 out of 80 patients had lump in the upper outer quadrant (73.75%) and the remaining in other quadrants (Figure 3).

Chief complaints being palpable breast lumps in 53 patients (66.25%) with associated symptoms 27 patients (33.75%).

About 53 out of 80 had non-tender lumps and 14 out of 80 patients having significant changes over the skin (Figure 4).

About 52 out of 80 palpable lumps are of the firm in consistency, 23 being hard, and 5 being cystic (Figure 5).

All the 80 patients were subjected to HR-USG of the breast. Out of 80 patients, 45 (56.25%) patients had fibroadenoma, 18 (22.5%) had well defined solid masses, 5 (6.25%) had cystic lesion, and breast abscess in 8 (10%)

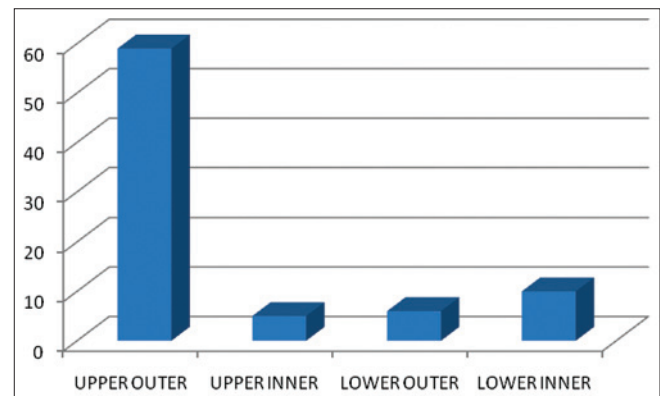


Figure 3: Distribution

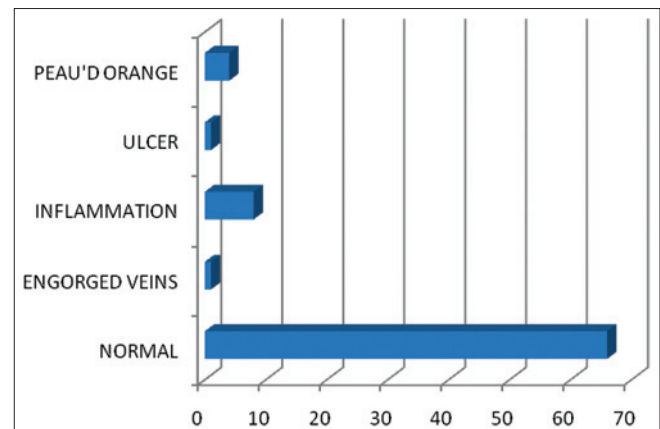


Figure 4: Skin changes

patients. Rests of patients were diagnosed as antibioma, lipoma, and galactocele (Table 1 and Figure 6).

All the 80 patients were taken for FNAC. Fibroadenoma was the most common FNAC diagnosis seen in 41 (51.25%) patients. Fibroadenosis was seen in 6 (7.5%) cases with galactocele in 5 patients, breast abscess in 7 patients, and

ductal cell carcinoma of the breast in 14 (17.5%) patients (Figure 7).

The result of triple assessment was in favor of benign diagnosis in 41 (51.25%) patients while as the malignant diagnosis was made in 14 (17.5%) patients. Histopathology diagnosed fibroadenoma in 41 (51.25%) cases, breast abscess in 7 (8.75%) cases, infiltrating ductal cell carcinoma in 14 (17.5%) cases, and fibroadenosis in 6 (7.5%).

Table 2 shows physical examination when compared with histopathology had a concordance of 97.3%, positive predictive value (PPV) of 80%, negative predictive value (NPV) of 99.3%, sensitivity of 85.3%, and specificity of 82.7%. *P* value was significant (0.001).

Table 1 shows USG when compared with histopathology had a concordance of 96.7%, PPV of 66.7%, NPV of 100%, sensitivity of 85.8%, and specificity of 96.4%. *P* value was significant (0.001).

Table 3 shows FNAC results when compared with histopathology results showed a concordance of 97.3%, PPV of 73.3%, NPV of 100%, sensitivity of 98.5%, and specificity of 97.1%. *P* value was significant (0.001).

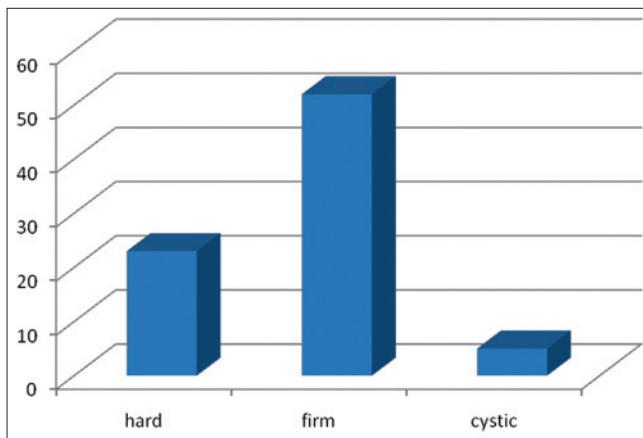


Figure 5: Consistency

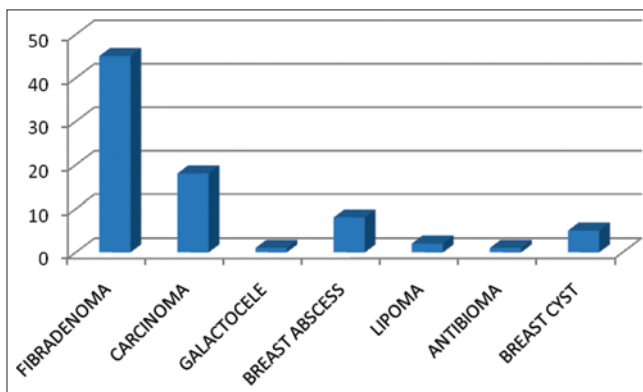


Figure 6: Ultrasonography

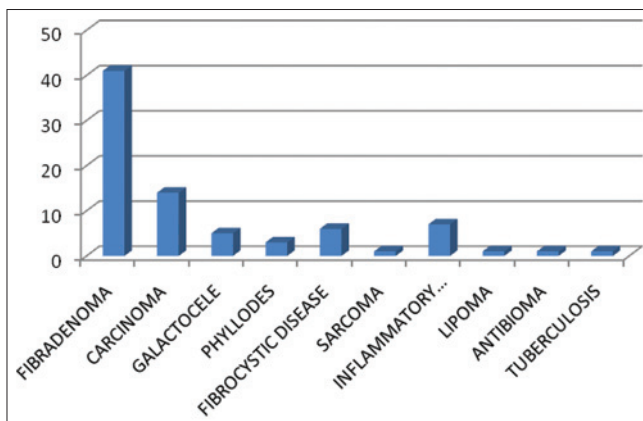


Figure 7: Fine-needle aspiration cytology diagnosis

**Table 1: Contingency analysis of final diagnosis by ultrasound**

Count	AB	CA	FA	PT	FCD	GAL	TB	SA	BA	LIP	Total
AB	1	0	0	0	0	0	0	0	0	0	1
BC	0	0	0	0	0	4	1	0	0	0	5
CA	0	13	1	2	1	0	0	1	0	0	18
FA	0	1	40	2	2	0	0	0	0	0	45
GAL	0	0	0	0	0	1	0	0	0	0	1
BA	2	0	0	0	0	0	0	0	6	0	8
LIP	0	0	0	0	1	0	0	0	0	1	2
Total	3	14	41	4	4	5	1	1	6	1	80

AB: Antiboma, CA: Carcinoma, FA: Fibroadenoma, PT: Phylloides tumor, FCD: Fibrocystic disease, GAL: Galactocele, TB: Tuberculosis, BA: Breast abscess, LIP: Lipoma, SA: Sarcoma

**Table 2: Contingency analysis of final diagnosis with clinical diagnosis**

Count	AB	CA	FA	PT	FCD	GAL	TB	SA	BA	LIP	Total
AB	2	1	0	0	0	0	0	0	1	0	4
CA	0	12	3	1	1	0	1	1	0	0	19
FA	0	1	38	2	1	1	0	0	1	1	45
PT	1	0	0	1	0	0	0	0	0	0	2
FCD	0	0	0	0	2	0	0	0	0	0	2
GAL	0	0	0	0	0	3	0	0	1	0	4
BA	0	0	0	0	0	1	0	0	3	0	4
Total	3	14	41	4	4	5	1	1	6	1	80

*P* < 0.001, AB: antibioma, CA: Carcinoma, FA: Fibroadenoma, PT: Phylloides tumor, FCD: Fibrocystic disease, GAL: Galactocele, TB: Tuberculosis, BA: Breast abscess, LIP: Lipoma, SA: Sarcoma

**Table 3: Contingency analysis of final diagnosis with FNAC/core biopsy**

Count	AB	CA	FA	PT	FCD	GAL	TB	SA	BA	LIP	Total
AB	1	0	0	0	0	0	0	0	0	0	1
CA	0	14	0	0	0	0	0	0	0	0	14
FA	0	0	40	1	0	0	0	0	0	0	41
PT	0	0	0	3	0	0	0	0	0	0	3
FCD	0	0	1	0	4	0	0	0	1	0	6
GAL	0	0	0	0	0	5	0	0	0	0	5
BFH	0	0	0	0	0	0	0	1	0	0	1
TB	0	0	0	0	0	0	1	0	0	0	1
BA	2	0	0	0	0	0	0	0	5	0	7
LIP	0	0	0	0	0	0	0	0	0	1	1
Total	3	14	41	4	4	5	1	1	6	1	80

AB: Antiboma, CA: Carcinoma, FA: Fibroadenoma, PT: Phylloides tumor, FCD: Fibrocystic disease, GAL: Galactocoele, BFH: Benign fibrous histiocytoma, TB: Tuberculosis, BA: Breast abscess, LIP: Lipoma, FNAC: Fine-needle aspiration cytology, SA: Sarcoma

## DISCUSSION

The mammary glands are modified sweat glands and are ectodermal in origin. The epithelial lining of ducts and the alveoli are derived from ectoderm and supporting fatty tissue and blood vessels by mesenchyme.

The greater part of the breast, about 2/3<sup>rd</sup> rests on pectoralis major muscle and 1/3<sup>rd</sup> on serratus anterior muscle. At its lower medial quadrant, the gland rests on the aponeurosis of the external oblique which separates it from the rectus abdominis, the axillary tail is deep to deep fascia although the breast proper is superficial to axillary fascia, the axillary tail is deep to deep fascia although the breast proper is superficial to axillary fascia,<sup>2</sup> the deep fascia covers pectoralis major muscle, serratus anterior, and chest wall muscle.<sup>3</sup>

The physiological changes occur in three stages:<sup>4</sup>

1. Growth and involution related to age
2. Changes associated with menstrual cycle
3. Changes due to pregnancy and lactation.

A comprehensive classification which puts all the processes of physiological changes growth Development and involution into a single framework called Aberrations of Normal Development and Involution.

Apart from congenital anomalies and inflammatory conditions, the benign breast diseases consist of benign breast tumors such as fibroadenoma, fibrocystic change, sclerosing lesions, and papillary lesions. Epithelial proliferative disease and rarely miscellaneous section.<sup>5</sup>

Virtually, every woman of reproductive age has occasional breast discomfort. Indeed, histological changes in breast tissue can be found in nearly all women of reproductive age.<sup>6</sup>

Epidemiological studies that clarify the etiology of benign breast diseases are few.

Classification of benign breast diseases:<sup>7</sup>

- I. Developmental disorders
- II. Inflammations
- III. Fibrocystic changes
- IV. Proliferative breast disease
- V. Benign tumors
- VI. Others.

Fibroadenomas may present of any age, but the peak incidence is in the 3<sup>rd</sup> decade.<sup>8</sup>

Whether fibroadenomas are neoplasms or aberrations of lobular development is an unsettled issue.<sup>9</sup> The benign nature of the general class of epithelial tumors of the breast was recognized 100 years ago by Sir Astley Cooper, who called them “chronic mammary tumors.”<sup>10</sup>

Muller first found the term “cystosarcoma phylloides,” this tumor is neither cystic nor sarcomatous, and thus the designation should be abandoned in favor of the term “phylloides tumor”<sup>11</sup> or in the case of malignant transformation, “phylloides sarcoma.” The term phylloides come from Greek word “phyllon,” which means “leaf.”

Breast cancer is the most common site-specific cancer in women and is the leading cause of death for women aged 20-59 years. It accounts for 26% of all newly diagnosed cancers in females and is responsible for 15% of the cancer-related deaths in women.<sup>12</sup>

## Types of Breast Cancer

### *Carcinoma in situ*

Cancer cells are *in situ* or invasive depending on whether or not they invade through the basement membrane.<sup>13,14</sup> In 1941, Foote and Stewart published a landmark description of lobular carcinoma *in situ*, which distinguished it from ductal carcinoma *in situ*.<sup>14</sup>

Invasive breast cancers have been described as lobular or ductal in origin.<sup>15-18</sup>

The study entitled “evaluation of palpable breast lumps under the age of 35 years with triple assessment” was a prospective study conducted in the Department of Surgery, MIMS Mandya on outpatient and inpatient basis. A total 80 patients with breast lump were included in the study to determine the number of patients having breast cancer. This study was carried out over a period of 1-year from March 2015 to March 2016. Currently, a combination of three tests, i.e., clinical examination, radiological imaging (USG), and FNAC (pathology) together called as triple



assessment is used to accurately diagnose all palpable breast lumps. The triple assessment is taken positive if any of the three components is positive for malignancy and negative only if all of its components are negative for malignancy. Physical examination was in favor of malignant disease in 18 patients. However, histopathology confirmed malignancy in 14 patients only and 4 patients proved to be benign. Similarly, benign diagnosis was made on physical examination in 62 patients. However, histopathology confirmed the benign diagnosis in 66 patients only with the remaining 4 patients being diagnosed as malignant. Thus, histopathology confirmed malignant breast disease in 14 patients. USG was in favor of malignant diagnosis in 16 patients, out of which 14 turned out to be malignant on histopathology.

The sensitivity, specificity, PPV, and NPV of my study are shown in Tables 4-7.

When compared to the other study done in University of Nairobi, "Diagnostic Value of Modified Triple Test for Evaluation of Palpable Discrete Breast Masses In Young Women" the sensitivity, specificity, PPV, and NPV was 100%, 92.3%, 60%, and 100%, respectively, on CBE; 100%, 94.2%, 66.7%, and 100%, respectively, on ultrasound; and 100%, 98.1%, 83.3%, and 100%, respectively, on FNAC. Combinations of CBE and ultrasound and CBE and FNAC had sensitivity, specificity and PPV and NPV of 100%.

Whereas my study shows equal correlation with this study.<sup>19</sup>

Component	Clinical	USG	FNAC	Clinical+USG
Sensitivity	85.7	92.85	100	92.85
Specificity	89.3	92.42	100	92.42
PPV	65	72.2	100	72.2
NPV	3.2	1.6	-	1.6

NPV: Negative predictive value, PPV: Positive predictive value, USG: Ultrasonography, FNAC: Fine-needle aspiration cytology

Yang *et al.* (1996) found a sensitivity, specificity, and PPV for clinical examination as 88%, 92%, 67%, respectively.<sup>20</sup>

Thus, the concordance for histopathology was 96.7%, sensitivity was 100%, and specificity was 96.4%. PPV was 66.7% and NPV was 100%. Pande *et al.* (2003) found that sensitivity, specificity, PPV, and NPV for USG was 95%, 94.10%, 95.50%, 93.75%, respectively (45). Yang *et al.* (1996) found that sensitivity, specificity, and PPV for USG was 97%, and 85%.<sup>20</sup>

Ariga *et al.* (2002) found that FNAC had a sensitivity of 99%, PPV of 99%, and specificity of 99%, respectively (41). Mohammed *et al.* (2005) found that fine-needle aspiration biopsy had a PPV of 100%, sensitivity of 90.6%, and specificity of 100%.<sup>21</sup>

**Table 4: Correlation of clinical diagnosis**

Clinical	HPE	
	Malignant	Benign
Malignant	12	7
Benign	2	59

Sensitivity - 85.7%, Specificity - 89.3%, PPV - 65%, NPV - 3.2%, NPV: Negative predictive value, PPV: Positive predictive value, HPE: Helicobacter pylori eradication

**Table 5: Correlation of USG with final**

USG	HPE	
	Malignant	Benign
Malignant	13	5
Benign	1	61

Sensitivity - 92.5%, Specificity - 92.4%, PPV - 72%, NPV - 1.6%, NPV: Negative predictive value, PPV: Positive predictive value, USG: Ultrasonography, HPE: Helicobacter pylori eradication

**Table 6: Correlation of FNAC with final**

FNAC	HPE	
	Malignant	Benign
Malignant	14	0
Benign	0	66

Sensitivity - 100%, Specificity - 100%, PPV - 100%, PPV: Positive predictive value, HPE: Helicobacter pylori eradication, FNAC: Fine-needle aspiration cytology

**Table 7: Combined CBE+USG**

USG+clinical	HPE	
	Malignant	Benign
Malignant	14	5
Benign	0	61

Sensitivity - 92.85%, Specificity - 92.42%, PPV - 72.2%, NPV - 1.6%, NPV: Negative predictive value, PPV: Positive predictive value, USG: Ultrasonography, HPE: Helicobacter pylori eradication, CBE: Clinical breast examination

Ahmad *et al.* (2007) found that the sensitivity of triple test was 100%, and specificity was 100%.<sup>22</sup>

In comparison with the available studies, Manisha *et al.* study on palpable breast lumps with triple assessment our study has values equal to it in benign disease, but the malignant percentage when compared to him is more. His study had a malignancy rate of 5.5% when compared to our study it is 18.75%.<sup>23</sup>

## CONCLUSION

Triple assessment is a very useful diagnostic tool to evaluate patients with breast lumps and to detect patients with breast cancers with an overall accuracy of 99.3%. When the lumps are palpable clinically and of size more than 2 cm FNAC itself has a sensitivity of 100%. When the lumps are <2 cm CBE + USG has a sensitivity of 92.8%. It was found that when clinical examination, USG, and FNAC

were all negative for malignancy in a patient with a breast lump, the patient can be safely observed, obviating the need for histology (surgical biopsies). Triple assessment did not require hospitalization, can be performed on OPD basis, without any complications and it is the gold standard diagnostic tool for the palpable breast lumps in early detection of malignancy avoiding biopsies.

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# Hepatitis B- and Hepatitis C-infected Cases and Their Correlation with Liver Function Test in Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh India

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## Abstract

**Introduction:** Hepatitis B and Hepatitis C are the major cause of inflammation of the liver. Hepatitis B virus (HBV) belongs to the Hepadnaviridae family and has a circular, partially double-stranded DNA. HBV and Hepatitis C virus (HCV) are the most common cause of chronic liver diseases worldwide.

**Materials and Method:** It is a type of prospective study, and it was conducted in the Department of Microbiology. Among the patients suffering from HBV and HCV who visited Teerthanker Mahaveer Medical College and Hospital, Moradabad, from March 2015 to January 2016 after obtaining written and informed consent from each patient.

**Result:** In our study, the total number of 250 cases of Hepatitis B and Hepatitis C were taken. Out of them, the number of positive cases was 172 and negative cases was 78. In our study, among positive and negative cases of hepatitis, the male cases were 134 (53.60%) and 46 (58.97%), respectively, and the female cases were 116 (46.40%) and 32 (41.02%). According to this study, the mean total bilirubin levels of HBV, HCV, and both HBV and HCV were  $3.50 \pm 5.78$ ,  $3.32 \pm 13.76$ , and  $1.35 \pm 0.75$ , respectively. The mean serum glutamic-pyruvic transaminase levels were  $155.07 \pm 192$  in HBV,  $103.71 \pm 178.58$  in HCV, and  $117.50 \pm 43.60$  in both HBV and HCV. The mean serum glutamic-oxaloacetic transaminase levels of HBV, HCV, and both HBV and HCV were  $332.85 \pm 654.82$ ,  $119.40 \pm 202.48$ , and  $37.50 \pm 49.80$ , respectively. The mean alanine phosphatase and total protein increased levels were found in patients of HBV ( $121.85 \pm 99.72$ ) and both HBV and HCV infection, respectively.

**Conclusion:** In our country, HBV and HCV are the common causes of liver dysfunction. According to our study, HBV is the major causative agent of liver dysfunction, followed by HCV. Therefore, all the patients of hepatitis must undergo screening of liver function tests.

**Key words:** Hepatitis B, Hepatitis C, Liver function tests

## INTRODUCTION

In India, the etiological role of acute Hepatitis B virus (HBV) and Hepatitis C virus (HCV) is endemic,

worldwide chronic liver infection, approximately 300 million cases are infected with HBV and 50-70% of which end up with chronic liver disease.<sup>1</sup> In worldwide, approximately 350 million people are infected with HBV and about 170 million people infected with HCV.<sup>2</sup> The leading cases of hepatocellular carcinoma, liver pathologies, with a very broad clinical spectrum ranging from asymptomatic carrier state to cirrhosis are HBV and HCV.<sup>3</sup>

HBV is a member of Hepadnaviridae family, which is characterized by the presence of partially double-stranded

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DNA and surrounding the lipoprotein and inner core which infects human and certain animal species such as ground squirrel, woodchuck, and duck.<sup>4</sup> A substantial portion of liver disease in world and infected individual can remain asymptomatic for decades are HBV and HCV. However, 20-30 year later it increased risk of liver cirrhosis, liver failure, and liver cancer become chronic cirrhosis more than 80% of them.<sup>5</sup>

Liver function tests (LFTs) reflect the various functions of the liver. They usually include bilirubin, total protein, alkaline phosphatase (ALP), gamma glutamyl, serum glutamic-oxaloacetic transaminase (SGOT), and serum glutamic-pyruvic transaminase (SGPT). Any abnormality in LFTs gives an idea for the function of liver and enzymes are usually raised in hepatic abnormality with alanine aminotransferase more specific to liver.<sup>6</sup>

Liver disease constitutes a significant health burden. They are from infectious disease to metabolic ones. Viral infections are responsible for significant numbers of liver diseases. Most common of these are HBV and HCV infection.<sup>7</sup> For non-specific symptoms or screening purposes, usually LFT is performed.<sup>8</sup>

The clinical illnesses characterized by nausea, fever, lack of appetite, abdominal pain, acute Hepatitis, and yellowing of the skin can be severe with symptomatic feature lasting for many weeks or month and it can no longer liver function in which the liver is so badly damage and is much less commonly life-threatening or fulminate by infection with HBV.<sup>9</sup>

Lymphoid follicles and aggregates, bile duct injury, and fibrosis are included in the histological features of chronic Hepatitis C have been well documented.<sup>10-12</sup> About two million deaths annually are commonly caused by liver cirrhosis, liver cancer, as well as liver failure.<sup>13</sup> Inflammation of liver has many reasons such as toxin, metabolic, viral, pharmacology, or immune-mediate attack on the liver.<sup>14</sup>

In our country, a major cause of the chronic liver disease is HCV. Body piercing including acupuncture and tattooing, unsafe injection, blood products, and improperly screened blood are the source of spread.<sup>15</sup> Regarding the seroprevalence, there are a number of studies of HBV and HCV among the various population groups including healthy blood donors, general public, and hospitalized patients, but out of them Pakistani population is most commonly affected.<sup>16</sup> The aim of our study was to determine the HBV and HCV infected cases and their correlation with liver function test.

## MATERIALS AND METHODS

It is a type of prospective study, and it was conducted in the Department of Microbiology, in the patients infected with HBV and HCV who visited Teerthanker Mahaveer Medical College and Hospital, Moradabad, from March 2015 to January 2016 after obtaining written and informed consent from each patient.

### Collection of Blood (Serum) Sample

Verbal consent was taken from the patient before the collection of blood sample. 5 ml of blood was collected in 2 ml ethylenediaminetetraacetic acid - vial and 3 ml in plain vial. All age group patients were included. The sample was taken from 250 patients.

Microbiological tests: The following investigations were carried out in each to confirm the diagnosis. Rapid card tests were used for the diagnosis of Hepatitis B and Hepatitis C. Rapid card test for Hepatitis B surface antigen (HBsAg) was used for Hepatitis B and Tri-Dot Rapid card test used for Hepatitis C.

LFTs were checked for all patients included in the study. LFTs included total bilirubin, SGPT, SGOT, ALP, and total protein. LFTs were performed using automatic blood chemistry analyzer (Hitachi 902, Roche Diagnostics, Germany). 5 ml of blood was taken under strict aseptic conditions. HBsAg and anti-HCV antibodies were checked using rapid diagnostic kits (Standard Diagnostics Inc. Korea). For Hepatitis B, about 100  $\mu$ L blood was placed on test chamber using micropipette. The result was recorded after 20 min. The presence of two bands means a positive result. The presence of only one band signified negative result. For Hepatitis C, about 10  $\mu$ L blood was placed on test chamber using micropipette. Four drops of assay diluent were placed in the designated chamber by keeping the diluents bottle at 90°C. The result was recorded after 5-20 min. The presence of two bands means a positive result. These were disposable kits; therefore, each kit was used only once and discarded properly after use.

### Statistical Analysis

The proportion of the positive individuals is expressed in percentage in the total population and determined the prevalence of each viral infection (HBV and HCV). To determine the relationship between age and presence of HBV and Hepatitis C infection risk factor at  $P < 0.05$  was employed by Chi-square test.

## RESULT

Total 250 cases of Hepatitis B and Hepatitis C were included in this study. There were 134 (53.60%) male

and 116 (46.40%) female, with male to female ratio of 2.09:1.80 as shown in (Table 1). In our study, from the total number of cases of Hepatitis B and Hepatitis C, the number of positive cases was 172 and negative cases was 78 (Table 1 and Figure 1).

In this study, out of 172 (68.80%) positive cases, the cases of HBV were 76, HCV 88, and both Hepatitis B and C were 8 (Table 2). Among HBV, males were 38 (38.78%) and females were also 38 (51.35%). Out of 88 HCV cases, 56 (57.14%) were males and 32 (43.25%) were females; and out of 8 (both HBV and HCV), 4 (4.08%) were males and 4 (5.40%) were female (Table 2 and Figure 2).

Showing the percentage of male and female patients with HBV, HCV, and both HBV and HCV infection. There were no significant differences among them (Table 3).

Stratifying according to the age group among males, the majority of positive cases among HBV was in the age group of 51-60 years was 12 (30%), and among HCV and both HBV and HCV also in the same group, i.e., 51-60 years 22 (39.28%) and 1 (25%), respectively, followed by the other age groups (Table 4 and Figure 3).

**Table 1: Hepatitis positive and hepatitis negative cases with percentage (n=250)**

Test name	Number of patient (%)
Hepatitis positive	172 (68.80)
Hepatitis negative	78 (31.20)
Total	250 (100)

**Table 2: Hepatitis (n=172) positive cases are distributed in male and female with percentage**

Test name	No. of cases (%)	
	Male	Female
HBV	40 (40.82)	36 (48.65)
HCV	56 (57.14)	32 (43.24)
Both HBV and HCV	2 (2.04)	6 (8.11)
Total	98 (100)	74 (100)

HCV: Hepatitis C virus, HBV: Hepatitis B virus

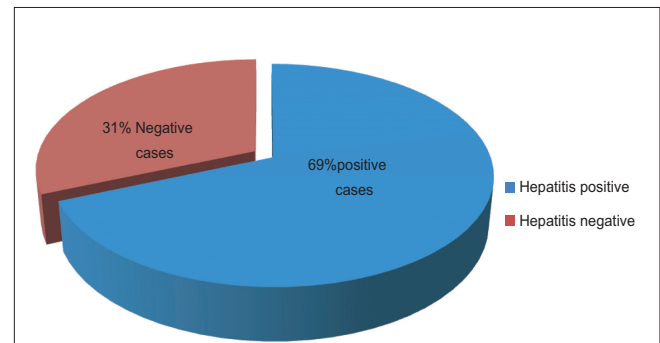
**Table 3: Hepatitis (n=172) positive cases are distributed in male and female with percentage and Chi-square value and p-value**

Test name	No. of cases (%)		$\chi^2$ value	P value
	Male	Female		
HBV	40 (40.82)	36 (48.65)	0.755	0.36
HCV	56 (57.14)	32 (43.24)	2.728	0.0986
Both HBV and HCV	2 (2.04)	6 (8.11)	2.265	0.1323
Total	98 (100)	74 (100)		

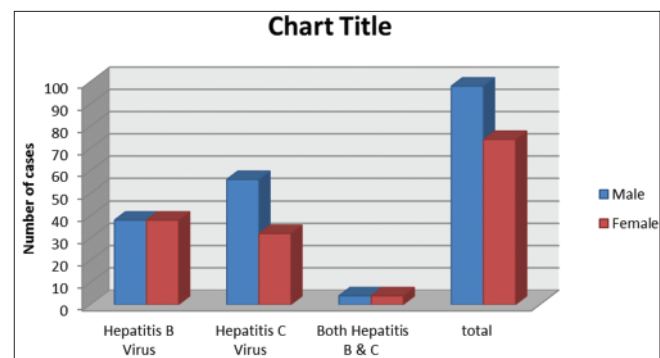
HCV: Hepatitis C virus, HBV: Hepatitis B virus

The major age group among females that was affected is 51-60 years by HBV were 12 (31.57%) and HCV were 10 (31.25%) and there were no cases of both HBV and HCV. The major age group that was affected by both the HBV and HCV was 21-30 year and 41-50 year 2 (33.33%) each (Table 5 and Figure 4).

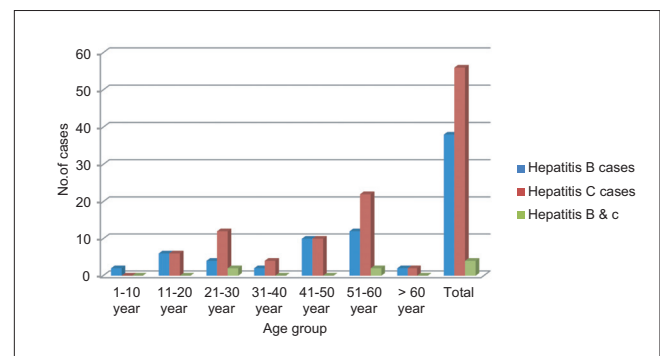
According to study, the mean total bilirubin levels of HBV, HCV, and both HBV and HCV were  $3.50 \pm 5.78$ ,  $3.32 \pm 13.76$ , and  $1.35 \pm 0.75$ , respectively. The mean SGPT levels were  $155.07 \pm 192$  in HBV,  $103.71 \pm 178.58$  in HCV, and  $117.50 \pm 43.60$  in both HBV and HCV. The mean SGOT levels of HBV, HCV, and both HBV and HCV were  $332.85 \pm 654.82$ ,  $119.40 \pm 202.48$ , and  $37.50 \pm 49.80$ , respectively.



**Figure 1: Hepatitis positive and negative cases (n = 250)**



**Figure 2: The distribution of male and female (n = 172)**



**Figure 3: Age-wise distribution of Hepatitis B virus, Hepatitis C virus, and both Hepatitis B and C in male (n = 98)**

**Table 4: Age-wise distributions of Hepatitis B and C in male with percentage (n=98)**

Age of patients	HBV (%)	HCV (%)	Both HBV and HCV (%)	Total
1-10	4 (10)	0 (0)	0 (0)	4
11-20	6 (15)	6 (10.71)	0 (0)	12
21-30	4 (10)	12 (21.42)	1 (25)	17
31-40	2 (5)	4 (7.14)	0 (0)	6
41-50	10 (25)	10 (17.85)	0 (0)	20
51-60	12 (30)	22 (39.28)	1 (25)	35
>60	2 (5)	2 (3.57)	0 (0)	4
Total	40	56	2	98

HCV: Hepatitis C virus, HBV: Hepatitis B virus

**Table 5: Age-wise distributions of HBV, HCV, and both HBV and HCV in female (n=74 cases) with percentage**

Age of patients	HBV (%)	HCV (%)	Both HBV and HCV (%)	Total
1-10	1 (2.63)	0 (0)	0 (0)	1
11-20	5 (15.79)	4 (12.5)	0 (0)	9
21-30	7 (21.05)	8 (25)	2 (33.33)	17
31-40	4 (10.53)	2 (6.25)	0 (0)	6
41-50	5 (13.15)	6 (18.75)	2 (33.33)	13
51-60	12 (31.57)	10 (31.25)	2 (33.33)	24
+61	2 (5.26)	2 (6.25)	0 (0)	4
Total	36	32	6	74

HCV: Hepatitis C virus, HBV: Hepatitis B virus

**Table 6: The mean value of biochemical parameter hepatitis correlation with liver function test (n=172)**

Parameters	Group of hepatitis positive patients			Normal value
	Hepatitis B (n=40)	Hepatitis C (n=56)	Both B and C (n=2)	
Total bilirubin	3.50	3.32	1.35	0.2-1.0 mg/dl
SGPT	155.07	103.71	117.50	5-45 g/dl
SGOT	332.85	119.40	37.50	5-40 g/dl
ALP	121.85	116.42	83.0	20-140 IU/l
Total protein	12.38	9.93	36.25	6.0-8.3 g/dl

ALP: Alkaline phosphatase, SGOT: Serum glutamic-oxaloacetic transaminase, SGPT: Serum glutamic-pyruvic transaminase

The mean ALP and total protein increased levels were found in patients with HBV (121.85 ± 99.72) and both HBV and HCV infection, respectively (Table 6; Figure 5).

The values of LFTs in Hepatitis B, Hepatitis C, and both Hepatitis B and C, male and female patients were given in Tables 7 and 8, respectively. The Tables 8 and 9 present the mean value of the given test in Hepatitis B and Hepatitis C patients.

## DISCUSSION

In this study, HCV-infected male was more than the female patient. Our study is similar to the study of Adoga *et al.*<sup>17</sup> Many diseases are caused by liver dysfunction, mostly HBV

**Table 7: The mean value of biochemical parameter in male's Hepatitis B and Hepatitis C patient (n=98)**

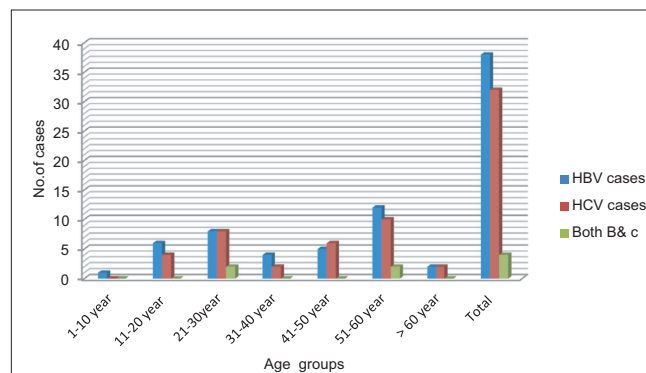
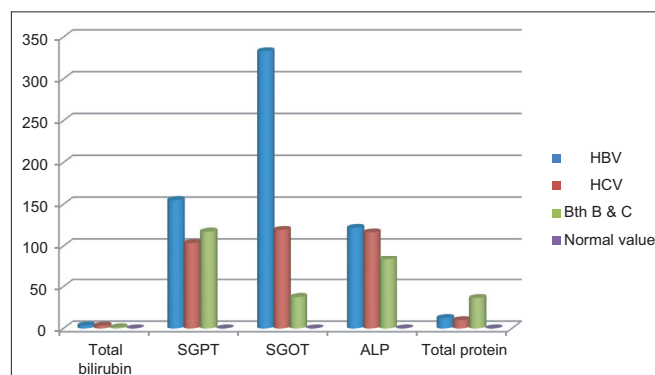
Parameters	Group hepatitis patients			Normal value
	Hepatitis B (n=40)	Hepatitis C (n=56)	Both B and C (n=2)	
Total bilirubin	3.50	3.32	1.35	0.2-1.0 mg/dl
SGPT	155.07	103.71	117.5	5-45 mg/dl
SGOT	332.85	119.40	37.50	5-40 mg/dl
ALP	121.85	116.42	83.0	20-140 IU/l
Total protein	12.38	9.93	36.25	6.0-8.3 mg/dl

ALP: Alkaline phosphatase, SGOT: Serum glutamic-oxaloacetic transaminase, SGPT: Serum glutamic-pyruvic transaminase

**Table 8: The mean value of biochemical parameter in females Hepatitis B and Hepatitis C patients (n=74)**

Parameter	Group hepatitis patients			Normal value
	Hepatitis B (n=36)	Hepatitis C (n=32)	Both B and C (n=6)	
Total bilirubin	2.05	2.39	1.11	0.2-1.0 mg/dl
SGPT	112.92	116.13	63.33	5-45 g/dl
SGOT	126.42	122.45	68.35	5-40 mg/dl
ALP	135.14	111.0	101.67	20-140 IU/L
Total protein	6.26	9.11	8.88	6.0-8.3 g/dl

ALP: Alkaline phosphatase, SGOT: Serum glutamic-oxaloacetic transaminase, SGPT: Serum glutamic-pyruvic transaminase

**Figure 4: Age-wise distribution of Hepatitis B virus, Hepatitis C virus, and Both Hepatitis B and C virus in female (n = 74)****Figure 5: Biochemical parameters mean value correlation with liver function test of infected Hepatitis positive patients (n = 172)**

and HCV are the viruses that cause viral infection in the liver. HBV and HCV are the viruses among hepatitis viruses causes viral infection of the liver, it accounts for significant amount of liver disease especially in South Asia.<sup>2</sup>

Hepatitis B and C infections are prevalent in different parts of the world from region to region and from one population to another in a country or region (Zali *et al.*, 1996).<sup>18</sup> According to our study, the prevalence among the patients HBV, HCV, and both HBV and HCV were 76 (41.18%), 88 (57.16%), and 8 (4.65%), respectively. Our study is comparable with the study of the Khan *et al.*<sup>19</sup> According to that study, HBV, HCV, and both HBV and HCV were 75%, 23%, and 2%, respectively.

According to the gender, our study shows that among HBV, males were 38% and females were 51.35%, among HCV males were 57.14% and females were 43.25% while among both HBV and HCV males and females were 4.08% and 5.04%, respectively, which is comparable to the study of Tungtrongchitr *et al.*<sup>20</sup> The major age group among male and female which caused by HBV, HCV, and both HBV and HCV were same that is 51-60 year and our study is comparable with the study of Zainal *et al.*<sup>21</sup>

In our study, all the biochemical parameters are highest among the HBV except total protein that is highest among both HBV and HCV patients, which is comparable with the study of Anjum *et al.*<sup>6</sup>

## CONCLUSION

In our country, HBV and HCV are a common causative agent of dysfunction of liver. According to our study, HBV is the major causative agent of liver dysfunction, followed by HCV. Among Hepatitis patients, SGPT and SGOT are the LFTs, which are raised. Therefore, all the patients of Hepatitis must undergo screening of LFTs.

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# Correlation between Deviated Nasal Septum and Sinusitis: A Clinical and Histopathological Study

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## Abstract

**Introduction:** Deviated nasal septum is a frequently occurring condition which alters the normal air flow pattern making it turbulent, producing a nasal obstruction in an individual. It may result in permanent changes in the nasal and sinus mucosa. This study makes an attempt to evaluate the deviated nasal septum and associated sinus pathology.

**Materials and Methods:** Study was done in 30 patients of rhino-sinusitis, divided into 2 groups - control and study group of 15 each. Patients were then assessed clinically by using various parameters such as Patency test, Rhinoscopy, Nasal diagnostic endoscopy, X-ray peripheral nervous system, and computed tomography scan. Histopathological examination of mucosal biopsies from maxillary sinus of patients was also done.

**Results:** Incidences of symptoms and signs of acute and chronic inflammation of nasal and sinus mucosa were high in the study group.

**Conclusion:** Our study shows that most common anatomical variant associated with chronic inflammation of sinuses is deviated nasal septum.

**Key words:** Deviated nasal septum, Maxillary sinus, Sinusitis

## INTRODUCTION

The nasal septum divides nasal cavity into the left and right halves both anatomically and physiologically. It is an accepted fact that some amount of deviation of nasal septum is common and having a perfectly straight septum is a rarity.<sup>1</sup> Various reasons have been attributed to the occurrence of deviated nasal septum including racial factors, birth molding of septum during parturition trauma and developmental deformities of septum.<sup>2</sup> Deviated nasal septum may cause nasal obstruction and symptoms of rhinosinusitis. Normally paranasal air sinuses drain the mucous and fluid into the nose through various openings.

Severe obstruction may block these openings triggering chronic sinusitis. Tocik<sup>3</sup> evaluated the relationship between deviation of the nasal septum and diseases of the paranasal sinuses. Aust *et al.*<sup>4</sup> stated that if ostium size is <2.5 mm, it predisposes to the development of disease. Smith and Cable<sup>5</sup> assessed maxillary antral mucosa in chronic sinusitis patients.

In our present study, we tried to analyze the role of deviated nasal septum in sinus pathology in patients.

## MATERIALS AND METHODS

The present study was conducted in the Departments of Anatomy and E.N.T. at Himalayan Institute of Medical Sciences Dehradun and Shri Guru Ram Rai Institute of Medical and Health Sciences Dehradun. The study was divided into two groups (15 each).

Group - A (Control): It comprised of 15 patients with a midline nasal septum, with symptoms of rhinosinusitis.

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Group - B (Study): It comprised of 15 patients with a deviated nasal septum, taken up for septal surgery.

Total we have taken 30 patients with symptoms of rhinosinusitis.

Chronic sinusitis in our patients was defined as inflammation of the nasal and paranasal mucosa, with persistent mucoid or mucopurulent discharge for longer than 3 months that was resistant to repeated antimicrobial therapy and antral irrigation.

Patients with allergic rhinitis, polyps, or abnormal mass in nasal cavity and grossly deformed nose due to pathological condition were excluded from the study.

After examining ears, throat, mouth, larynx, a detailed examinations of the nose and paranasal sinuses was done.

Maxillary sinuses are most commonly involved in chronic sinusitis as drainage is against gravity because of higher position of its Ostia. Therefore, in this study, only maxillary sinus was taken into account.

We observed following parameters:

#### I. Clinical examination:

1. A detailed examination of nose and paranasal sinuses was done through various methods as:
  - Rhinoscopy
  - Patency test
  - Antral puncture (proof puncture) - Only in selected cases with the help of antral trocar and cannula
  - Nasal diagnostic endoscopy - Wherever necessary.
2. X-ray of nasal cavity and paranasal sinuses (Occipitomental [Water's] view) was done in all patients.
3. Computed tomography CT-scan - Was done in some patients, wherever required.

The results were compared between the two groups.

#### II. Histopathological examination:

Mucosal biopsies from maxillary sinus were taken from patients who underwent septal surgery to yield diagnostic information to guide post-operative treatment for optimal long-term results. These were fixed in 10% formalin and further processed for paraffin sections and were stained by Hematoxylin and Eosin method.

## RESULTS

#### I. Clinical examination:

1. All incidences of symptoms and signs seen by rhinoscopy and patency test were high in Group B (Tables 1 and 2).

The incidence of findings seen by nasal diagnostic endoscopy was found to be high in Group B except concha, bullosa, mucoid discharge, and accessory Ostia (Table 3).

Group A - Done on 5 patients

Group B - Done on 10 patients.

2. X-ray nose and PNS - Incidences of all findings were found to be high in Group B (Table 4, Figures 1 and 2).
3. CT-scan nose and PNS.

Incidences of most of the findings were found to be high in Group B (Table 5 and Figure 3).

**Table 1: Incidence of symptoms and signs by rhinoscopy**

Symptoms/ signs	Group A		Group B	
	Number of cases	Percent cases	Number of cases	Percent cases
Inferior turbinate hypertrophy	2	13.3	12	80
Middle turbinate hypertrophy	1	6.6	2	13.3
Nasal discharge	5	33.3	12	80
Congested nasal mucosa	7	46.6	10	66.6

**Table 2: Incidence of positive cases (patency test)**

Side	Group A		Group B	
	Number of cases	Percent cases	Number of cases	Percent cases
Right side	5	33.3	5	33.3
Left side	7	46.6	4	26.6
Both side	3	20	1	6.66

**Table 3: Incidence of findings by endoscopy**

Signs	Group A		Group B	
	Number of cases	Percent cases	Number of cases	Percent cases
Inferior turbinate hypertrophy	2	40	10	100
Middle turbinate hypertrophy	1	20	4	40
Spur	0	0	2	20
Concha bullosa	2	40	1	10
Paradoxical middle turbinate	1	20	2	20
Accessory ostia	2	40	1	10
Mucoid discharge	3	60	2	20
Mucopurulent discharge	2	40	6	60

**Table 4: Incidence of cases by X-ray**

Findings	Group A		Group B	
	Number of cases	Percent cases	Number of cases	Percent cases
Mucosal thickening	6	40	15	100
Inferior turbinate hypertrophy	2	13.33	12	80
Air-fluid level	0	0	4	26.67

Group A - Done on 2 patients

Group B - Done on 7 patients.

## II. Histopathological examination:

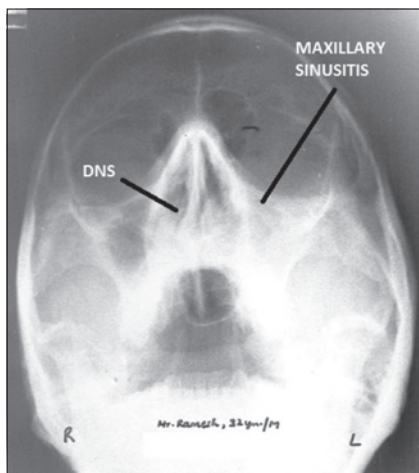
On microscopic examination of mucosa, it was observed that Findings suggestive of acute as well as chronic inflammation were seen.

- Acute inflammation - There was hemorrhage in lamina propria and submucosa with infiltration of polymorphs (Figure 4)

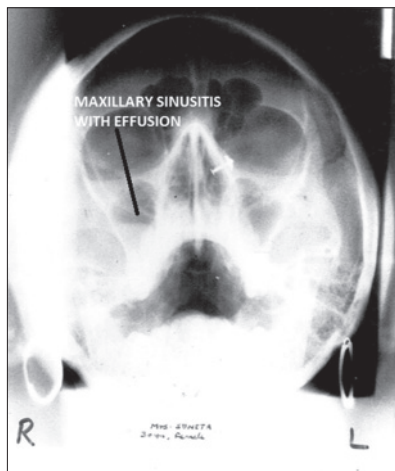
**Table 5: Incidence of cases by CT-scan**

Findings	Group A		Group B	
	Number of cases	Percent cases	Number of cases	Percent cases
Mucosal thickening	1	50	7	100
Air-fluid level	1	50	4	57.14
Inferior turbinate hypertrophy	1	50	3	42.85

CT: Computed tomography



**Figure 1: X-ray of patient having deviated septum showing mucosal thickening in maxillary sinus**



**Figure 2: X-ray of patient having deviated septum showing air-fluid level in maxillary sinus**

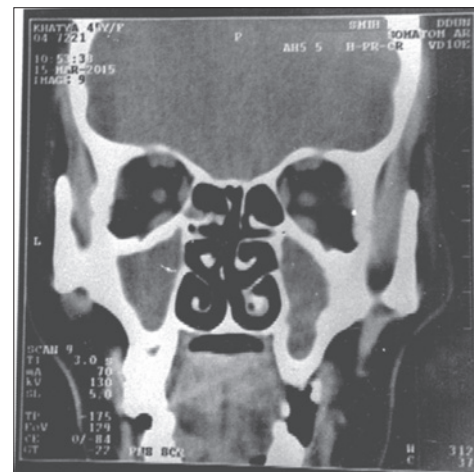
- Chronic inflammation - Epithelial erosion was seen along with edema in submucosa. Glands were exceedingly numerous and hyperplastic (Figure 5).

## DISCUSSION

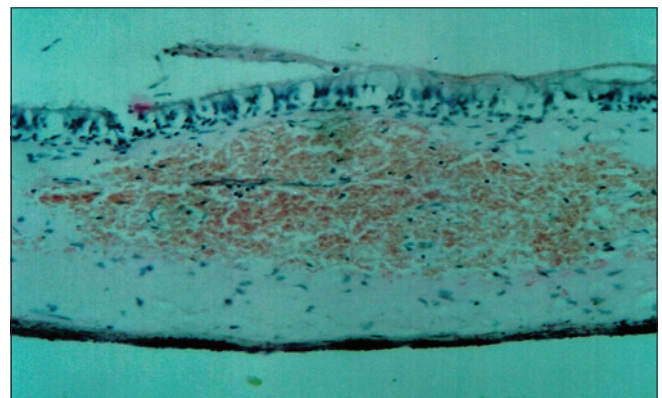
In the present study, we observed nasal septal deviation as one of the prime cause of chronic sinusitis.

In clinical study, incidence of all findings in patients related with sinus disease was high in Group B in comparison to Group A. In patients with midline septum, few cases of chronic sinusitis were confirmed with other pathological abnormalities in ostiomeatal area. To confirm this and differentiate the pathogenesis of chronic sinusitis in both groups (Groups A and B), CT-scan was performed in few patients of both groups.

Histological findings from mucosal biopsies correlated well with clinical findings. There were marked changes in mucosa of maxillary sinus like acute as well as chronic inflammation.

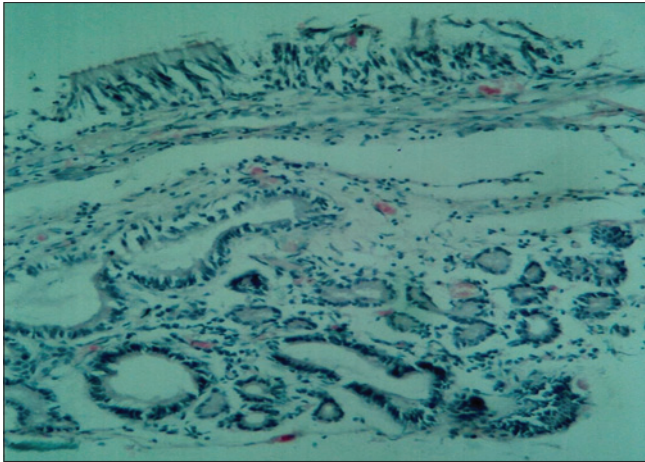


**Figure 3: Coronal computed tomography-scan of a patient having deviated nasal septum showing bilateral hyper density in maxillary sinuses**



**Figure 4: Sinus mucosa of patient having deviated septum showing acute inflammation. Hemorrhage in lamina propria and submucosa is seen with infiltration of polymorphs (H&E, x200)**





**Figure 5: Sinus mucosa of patient having deviated septum showing chronic inflammation. Epithelial erosion along with oedema in submucosa is seen. Glands are exceedingly numerous and hyperplastic (H&E,  $\times 200$ )**

In previous studies, Inagi<sup>6</sup> investigated the histological changes in mucous membrane of human nasal septum in relation to the deviation of septum. Schall<sup>7</sup> studied the histology of mucosa of maxillary sinuses in humans in detail.

Collet *et al.*<sup>8</sup> evaluated the role of septal deviation in adults in pathogenesis of chronic sinusitis. Arslan *et al.*<sup>9</sup> did CT study and found most common anatomical variant was septal deviation in 36%.

## CONCLUSION

In the present study, detailed clinical and radiological examination of patients was done along with

histo-pathological examination of maxillary sinus mucosa, which proves that all cases of chronic maxillary sinusitis were associated with anatomical variations and most common was deviated nasal septum. Therefore, it is recommended that management of chronic maxillary sinusitis should include simultaneous treatment of any anatomical variation. For treating chronic sinusitis along with deviated nasal septum, nowadays treatment of choice is Septoplasty along with Functional Endoscopic Sinus Surgery (FESS). FESS technique is used for managing sinus infection and ostial obstruction.

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# Magnetic Resonance Imaging Lumbo Sacral Spine in Assessment of Low Back Pain in Young Adults

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## Abstract

**Introduction:** Low back pain (LBP) is a common health problem in population worldwide leading to concomitant disability which has assumed a public health importance in our setting. While it is relatively common in elderly, the incidence of LBP in young adults was alarmingly increasing.

**Purpose:** To find etiology of LBP in symptomatic young adults (10-35 years). Identification of associated modifiable risk factors of LBP in young adults and accordingly enable successful implementation of prevention strategies.

**Materials and Methods:** This was a prospective study of 100 respondents. A questionnaire was used to obtain information on clinical symptoms, socio-demography, lifestyle, occupation, and other risk factors associated with LBP amongst clinically symptomatic young cases below 35 years attending magnetic resonance imaging (MRI) department in Government Medical College, Aurangabad.

**Results:** Of 100 cases, 54 were females and 46 males, 30 (65.21%) males and 35 (64.81%) females had abnormal MRI findings. Most common etiology of LBP found was degenerative disc disease (76.92%) followed by trauma (7.69%), tumors (4.61%) and infective (4.61%), inflammatory (3.07%) and least common etiologies being metabolic (1.53%) and developmental - Scheuermann's disease (1.53%). Among 50 cases showing positive disc degeneration findings, 27 (54%) were involved in heavy physical activity, 21 (42%) in prolonged hours of sitting (>8 h), and rest 2 were involved in prolonged standing. Hence, we found that LBP incidence was associated with increased hours of heavy physical activity and prolonged hours of sitting.

**Conclusion:** The prevalence of LBP among young adult cases in our setting is high, with preventable and treatable predisposing factors. Cases should improve their physical fitness, practice frequent breaks, and stretching during sitting. Public health efforts should be directed at educating people on occupational and lifestyle habits.

**Key words:** Astrocytoma, Discogenic, Hemangioma, Sacroiliitis, Scheuermann

## INTRODUCTION

Low back pain (LBP) or lumbago is one of the most common patient complaints encountered in clinical practice, having significant economic consequences to the affected patient, especially young employed individuals thereby leading to loss of national economy by loss of

labor working days. About 40% of sick absences from work is because of LBP - making it the second most common cause of workplace absenteeism after the common cold.<sup>1</sup>

Occupation related factors are the most important risks associated with LBP.<sup>2</sup> Modifiable factors are poor posturing, prolonged sitting, twisting, bending, stooping, and lifting of heavy loads.<sup>3</sup>

### Need for the Study

The association of lumbar disc disease with advancing age is well known and documented.<sup>4,5</sup> However, an increasing incidence of lumbar disc disease in young adults and adolescents has also been reported by studies done in various populations world over.<sup>6-8</sup>

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We noticed an alarming increase in number of young population between 15 and 35 years complaining of LBP, who were referred to The Department of Radiodiagnosis, Government Medical College Aurangabad for MRI Lumbosacral spine. Associated modifiable risk factors were faulty posturing, general health status, hours of physical activity, prolonged hours of sitting, computer usage.

Lumbar disc disease is an important cause of low back ache and describes L4-L5 as the most common site for degenerative disc disease.<sup>9</sup>

Variety of factors contributing to this degeneration are aging, axial loading of disc, abnormal posturing, vascular in growth, and abnormalities in collagen and proteoglycan all contribute to disc degeneration. Disc herniation with radiculopathy and chronic discogenic LBP are the result of this degenerative process.<sup>10</sup>

MRI has become the initial imaging technique of choice in evaluation of cases having lower back pain or radicular pain for demonstration of objective evidence of pathology in a location consistent with clinical findings.<sup>11</sup>

MRI demonstrates the lumbar spine in multiple planes and extradural soft tissues (including intervertebral discs), paravertebral musculature, the exiting nerve roots and intradural structures (spinal cord, conus medullaris, and intrathecal roots).

The causes of LBP include:

1. Degenerative: Intervertebral disc abnormalities, lumbar canal stenosis associated nerve compression, spondylolisthesis, facet arthropathy, Schmorl's nodes
2. Infections: Tuberculosis (TB)
3. Inflammation: Sacroilitis (young females)
4. Developmental and congenital abnormalities: Transition vertebra, scoliosis, Scheuermann's disease<sup>12</sup>
5. Neoplastic: Primary/metastatic bone disease
6. Lumbosacral muscle and soft tissue related disorders: Muscle sprain and strains
7. Miscellaneous: Osteopenia/Osteomalacia/Osteoporosis and non-spinal causes such as renal calculi, pancreatitis, abdominal aortic aneurysm, and gynecological disorders like endometriosis.

## MATERIALS AND METHODS

MRI machine PHILIPS 1.5 Tesla, in Department of Radiodiagnosis, Government Medical College and hospital, Aurangabad was used for MRI scanning of lumbosacral spine.

MRI lumbosacral spine was done in all patients as described below:

The details of the procedure were explained to the patient and relatives. A written, informed, valid consent was taken from patient and relatives. Prior to scan detailed history of operations, pacemaker surgery, aneurysmal clip, otology implants, etc., was taken. Contrast study was done in very rare cases under anesthesia standby with all emergency drugs ready to manage the sensitivity reactions of contrast media.

### Inclusion Criteria

All cases (15-35 years) of low back ache referred to Government Medical College Aurangabad, Radiology department for MRI imaging, during the study period.

### Exclusion Criteria

Pregnant women, age > 35 years, <15 years, patients with metallic implants (cardiac pacemakers, cochlear implants, ocular prostheses, dental implants, and implantable cardiac defibrillators).

## OBSERVATION AND RESULTS

MRI of the lumbosacral spine was performed on 100 cases in the age group of 10-35 years. There were 46 males and 54 females.

Among 46 males presenting with back pain 30 cases (65.21%) had abnormal MRI findings and among 54 females presenting with back pain 35 (64.81%) had abnormal MRI findings (Table 1).

35 of the 100 cases in the study group had no abnormal MRI findings (Table 1).

Most common etiology of LBP found in young adults was degenerative disc disease (76.92%) (Table 2).

Maximum number of cases affected by degenerative disc disease was noted in age group of 31-35 years (52%) (Table 3).

Out of total 50 cases showing disc degeneration, 84% patients showed the involvement of L4-L5 intervertebral disc level, followed by L5-S1 (44%) and L1-L2 (10%) was least commonly affected (Table 4).

27 (54%) were involved in heavy physical activity, and out of these, 12 were homemakers (Table 5).

21 (42%) cases were involved in prolonged hours of sitting, and out of these, 12 were involved in clerical jobs like bank employees, typist, young call center employees (Table 5).

**Table 1: Gender wise incidence of normal and abnormal MRI**

MRI Findings	Males	Females	Total
Abnormal MRI	30	35	65
Normal MRI	16	19	35
Total	46	54	100

MRI: Magnetic resonance imaging

**Table 2: Sex wise distribution of etiologies of low back pain**

Etiologies	Males	Females	Total
Degenerative	21	29	50
Trauma	4	1	5
Tumor	1	2	3
Infection	2	1	3
Inflammation	0	2	2
Metabolic	1	0	1
Developmental disorder-Scheuermann's disease	1	0	1
Total	30	35	65

Total MRI positive cases 65, MRI: Magnetic resonance imaging

**Table 3: Age and sex wise distribution of degenerative disc disease**

Age	Males	Females	Total
10-15	0	0	0
16-20	1	0	1
21-25	2	2	4
26-30	7	12	19
31-35	11	15	26
Total	21	29	50

Total cases showing disc degeneration - 50

Thus, excluding the positive cases of trauma (5), tumor (3), infection (3), inflammatory (2), metabolic (1), and Scheuermann's disease (1), out of the rest 85 symptomatic cases, 44 (51%) were involved in heavy physical activity of which 17 (38.6%) had normal MRI findings, second 36 (42.35%) were involved in prolonged sitting, of which 15 (41.67%) patients were normal (Table 6).

On follow-up, we noticed that most of these cases were subjected to back exercises and stretching which helped them become symptom-free.

- After degenerative disc disease being the most common cause of LBP, we had 5 patients of traumatic backache
- We saw 3 cases of Infective etiology; all three were below 30 years of age
- 3 patients had findings of spinal tumors one each of spinal astrocytoma, osteoblastoma and spinal dermoid
- Inflammation was seen in 2 cases, both of them were females below 30 years and known cases of ankylosing spondylitis with raised HLA B27 levels
- Rare causes included one patient of thalassemia and another of Scheuermann's disease.

**Table 4: Level wise distribution of disc involvement**

Level of affected disc	Males	Females	Total
L1-L2	1	4	5
L2-L3	3	4	7
L3-L4	4	12	16
L4-L5	18	24	42
L5-S1	11	11	22

**Table 5: Occupation wise distribution of degenerative disc disease**

Age in years	Heavy physical activity		Prolonged sitting		Prolonged standing	
	Males	Females	Males	Females	Males	Females
10-15	0	0	1	0	0	0
16-20	0	0	1	0	0	0
21-25	2	1	0	1	0	0
26-30	1	7	6	4	0	1
31-35	5	11	7	2	0	1
Total M/F	8	19	14	7	0	2
Total M+F	27		21		2	

Total degenerative cases - 50, M: Males, F: Female

**Table 6: Occupational factors responsible for signs and symptoms**

Occupational factors	Abnormal MRI	Normal MRI	Total
Heavy physical activity	27	17	44
Prolonged sitting	21	15	36
Prolonged standing	2	3	5

## DISCUSSION

Lumbar disc degeneration was the most common cause of LBP around world and the majority is due to disc herniation. Due to development of MRI, non-invasive and excellent imaging of spine is possible.

In our study, there were more females (54%) as compared to male cases (46%).

Among 46 males presenting with back pain 30 cases (65.21%) had abnormal MRI findings. Among 54 females presenting with back pain 35 (64.81%) had abnormal MRI findings. Hence, in our study, males showed a slightly higher affection than females.

Men are more commonly affected to disc degeneration than women. It is most likely due to increased mechanical stress and injury.<sup>13</sup> In a review by Punnett, the attributable factor for LBP was also higher among men (41%) than women (32%).<sup>14</sup> The reason proffered was that men usually engage in occupations associated with heavy physical workload and whole-body-vibration compared with women.<sup>14</sup>



Females had a higher prevalence of LBP as compared to males (Schneider *et al.* 2006 total sample of 5315 persons, Wijnhoven *et al.* 2006).<sup>15,16</sup> It has been associated with hormonal changes, irregular or prolonged menstrual cycle, different pain perception and recall of symptoms.<sup>16,17</sup> In another study, female rice farmers in Thailand were more likely to develop LBP than males.<sup>18</sup> Another study among staff in a rural hospital also found that female workers had a greater prevalence of LBP.<sup>19</sup>

### Degenerative Disc Disease

The most common abnormality noted in our study was degenerative disc disease (76.92%). Most cases of disc degeneration were observed in age group of 31-35 years in our study.

Disc dessication is a common degenerative change of intervertebral discs. It results from replacement of the glycosaminoglycans within the nucleus pulposus with fibrocartilage which leads to reduced disc height due to reduction in nucleus pulposus volume.<sup>20</sup>

In study by Takatalo *et al.* (2011). Intervertebral disc degeneration was associated with low back symptom severity among young adults suggesting that the symptoms may have a discogenic origin at this age.<sup>21</sup>

In our study, we have found the majority of the disc lesions were at L4-5 (84%) followed by at the level L5-S1 (44%), least being at the level of L1-L2 (10%) which were consistent with findings of other studies. Similar findings were seen in a study conducted by Saleem *et al.* (2013) out of 163 cases; disc degeneration was most commonly present at the level of L4-L5 105 (64.4%).<sup>22</sup>

In our study, among 50 cases showing positive disc degeneration MRI findings, 27 cases (54%) were involved in heavy physical activity. In the world, 37% of LBP are attributed to occupation.<sup>23</sup> Professionals who are exposed to vibrations or long-standing positions such as health-care workers, occupational drivers and construction workers are more prone to LBP. LBP is associated with working postures which included vigorous bending, bending and twisting simultaneously, a bent and twisted posture for long periods, and making repetitive movements with the trunk. This finding was consistent with other studies.<sup>14,24-27</sup>

In our study, 21 cases (42%) were involved in prolonged hours of sitting (> 8 h), of which 10 cases were involved in clerical jobs such as bank employees, typist, young call center employees and 2 cases (4%) were involved in jobs requiring prolonged standing hours such as teacher and salon worker.

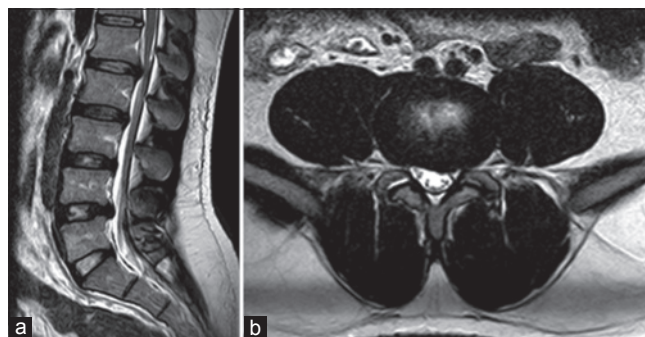
Our findings were comparable to many other previous studies, In 2007, Lis *et al.* concluded, that in working adults, prolonged sitting has been identified as a risk factor for LBP.<sup>28</sup> According to a study done by Callaghan and McGill in 2001, the reported consequences of prolonged sitting are increased spinal compression load<sup>29</sup> and increased activity of paraspinal muscles.<sup>30</sup> As a result, LBP can occur due to tissue microdamage and paraspinal muscle dysfunction.<sup>31</sup>

A total of 50 cases had degenerative disc degeneration findings in lumbosacral spine of which 18 cases had affection at multiple contiguous sites, and 5 cases showed the involvement of multiple non-contiguous sites (Figure 1a and b) and rest 27 had affection of single intervertebral disc level (Figure 2a and b).

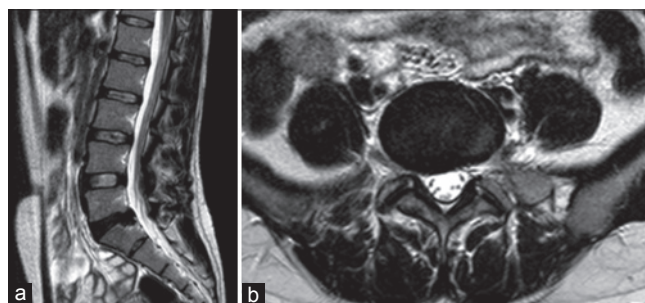
Other associated findings were Schmorl's nodes in 5 (10%) patients and endplate changes in 7 (14%) patients.

### Sacroiliitis

Two (3.07%) cases in our study showed evidence of sacroiliitis, and both were females. These were known cases of ankylosing spondylosis with raised HLA B27 levels, one



**Figure 1: (a) Typical imaging findings in degenerative disc disease - T2W sagittal image showing affection at multiple contiguous intervertebral disc levels L1-2, L2-3, L4-5, (b) T2W axial image at the level of L4-5 intervertebral disc showing postero and bilateral paracentral disc protrusion compressing traversing and bilateral exiting nerve roots**



**Figure 2: (a) Typical imaging findings in degenerative disc disease. T2W sagittal image showing affection at single L5-S1 disc level, (b) T2W axial image at the level of L5-S1 intervertebral disc showing right paracentral disc protrusion compressing right exiting nerve root**



of them revealed short tau inversion recovery hyperintense signal intensity in articular surface of sacrum on the left side (Figure 3). Another patient showed altered signal intensity in bilateral iliac blades.

Sacroiliitis is a noninfectious inflammatory process involving the sacroiliac joint and is a diagnostic criterion for seronegative spondyloarthropathies. Imaging methods are of great value for confirming the diagnosis of this condition.<sup>32</sup> Cases typically have an insidious onset pain, which is relieved with physical activity and worsens during late night time. Sciatica may be the result of referred pain or the inflammatory changes in the immediate vicinity of the sacroiliac joint directly affecting the nerve.<sup>33</sup> MRI can provide information about the activity of the disease and for making an early diagnosis of sacroiliitis.<sup>34</sup>

Shankar *et al.* (2009) showed that MRI abnormality was present in 29 cases (50 joints, bilateral in 21 and unilateral in 8) and in none of the controls. This accounts for a sensitivity of 87.9% and a specificity of 100%.<sup>35</sup>

### Tubercular Spondylitis

3 (4.61%) cases in our study were diagnosed as tubercular spondylodiscitis, 2 of these cases had hyperintense signal on T2W images involving L3-L4 intervertebral disc and adjoining superior and inferior end plates of vertebral bodies. Another patient revealed infective etiology at D12 vertebra, with anterior epidural extension of the associated soft tissue compressing spinal cord.

TB spondylitis can occur at any age. Middle-aged adults are the most frequently affected by TB spinal infection.

In a study of 42 cases by Khalequzzaman and Hoque (2012). The peak incidence was found to be in a 3<sup>rd</sup> decade

(48.43%) with male predominance, 2.5 times more than females. Destruction and collapse of vertebrae (88.1%) with posterior element involvement (54.76%). Paraspinal soft tissue involvement was seen in most of the cases (80.95%). MRI was found sensitive and accurate modality for diagnosis of TB spondylitis.<sup>36</sup>

### Trauma

5 (6.15%) cases in our study had traumatic LBP, two of the cases showed compression fracture of L1 vertebral body, two cases had anterior wedge compression fracture of L2 vertebral body one of them with accompanying diffuse marrow edema, and last one revealed a fracture of L3 vertebral body.

### Tumor

3 (4.61%) cases of our study group had spinal tumors. One patient revealed Grade I osteoblastoma involving posterior part of L2 vertebral body on the right side, right pedicle, and right transverse process extending into the spinal canal and causing nerve compression. Other patient had heterogeneously enhancing elongated intradural intramedullary lobulated lesion, extending from vertebral levels L1-L2 vertebrae causing spinal canal expansion at this level (Figure 4a and b) Findings of spinal astrocytoma were confirmed postoperatively. The third patient was a case of recurrent spinal dermoid.

### Bone Hemangiomas

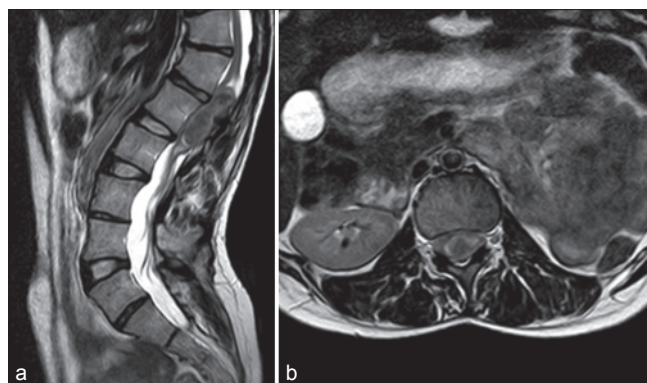
In our study, hemangiomas were noted incidentally in 11 cases mostly in L3 and L4 vertebral bodies along with associated other degenerative disc disease findings. This appeared to be incidental finding with no correlation with symptomatology.

### Metabolic

We had one patient who was a known case of thalassemia major suffering from LBP; his spine revealed diffusely



**Figure 3: Ankylosing spondylitis, showing short tau inversion recovery hyperintensity in articular surface of sacrum on left side**



**Figure 4: T2W sagittal (a) and axial (b) image shows elongated intradural intramedullary lobulated lesion, extending from vertebral levels L1-L2 vertebrae causing spinal canal expansion at this level, findings of spinal astrocytoma were confirmed**



**Figure 5: Scheuermann's disease revealed multiple Schmorl's nodes at superior endplate of D7, L2, L3, L4 and inferior endplates of D5 vertebral body with narrowed L4-5 disc space. Partial fusion of D1, D2, D3, D4-D5 and D7-D8 vertebral bodies**

decreased signal intensity (hypointense on all sequences) involving all vertebrae and their posterior elements, visualized calvaria and base of skull, s/o Hematopoietic marrow-marrow reconversion.

### Scheuermann's Disease

We had one patient of Scheuermann's disease which revealed Schmorl's nodes at superior end plate of D7, L2, L3, L4 vertebral bodies and inferior endplate of D5 vertebrae, with relatively narrowed L4-L5 intervertebral disc. Partial anterior fusion of D1, D2, D3, and D4-D5 and D7-D8 vertebral bodies was also seen (Figure 5).

Scheuermann Disease is a spinal disorder named after Dr. Holger Werfel Scheuermann who in 1921, first described a structural thoracic kyphosis mainly affecting adolescents.<sup>37</sup> Its classic diagnostic criterion was "3 or more consecutive wedged thoracic vertebrae," proposed by Sorenson in 1964.<sup>38</sup> However, this disease included pathological changes also like disc and endplate lesions, primarily Schmorl's node, and irregular vertebral endplate.<sup>37,38</sup> Therefore, the diagnosis of "atypical" Scheuermann disease was proposed for cases with only one or 2 wedged vertebrae and no notable kyphosis, but characteristic disc/endplate lesions including Schmorl's node and endplate irregularity.<sup>39-42</sup>

### CONCLUSION

MRI is the most comprehensive, non-invasive and safe imaging modality for diagnosis of LBP. The incidence of LBP is considerably high in young adults and more frequent in age group of 31-35 years. Most common etiology of LBP found in young adults is degenerative disc disease (76.92%) and the most commonly affected intervertebral

disc level is L4-L5 (84%), followed by L5-S1 (44%). Heavy physical activity (61.36%) is the most common occupational factor responsible for degenerative disc disease, followed by prolonged sitting (42%). Among symptomatic patients involved in prolonged sitting, 41.67% revealed no signs on MRI indicating the modifiable nature of degenerative disc disease in that group.

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# Perforated Appendix - Delay in Presentation Rather than Delay in the Surgical Intervention: Retrospective Database Analysis of 2573 Saudi Arabian Patients in 10 Years

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## Abstract

**Background:** Perforated appendicitis is the result of a delay in treating acute appendicitis either due to patient's related factors, or misdiagnosis and delay of treatment.

**Aim:** The aim of this study to evaluate the effect of time on perforated appendicitis cases to determine whether the delay in presentation or the delay in treatment have a role in the progressing of acute appendicitis to perforation of the appendix.

**Materials and Methods:** A retrospective database analysis of 2573 Saudi Arabian patients treated surgically for acute appendicitis between January 2006 and December 2015 in a public health general hospital in Medina, Saudi Arabia was done. The inclusion criteria included adult patients, diagnosed initially as acute appendicitis, and proven to have had perforated appendix. Diagnostic temperature, complete blood count, ultrasound, operative diagnosis, duration of symptoms, duration of hospitalization, and complications were analyzed.

**Results:** A total of 363 patients (145 females and 218 males) were proven to have had a perforated appendix. The number was higher in males compared to females, and the difference was statistically significant ( $P = 0.033$ ). The mean age of the patients was 29.99 (median 26, range: 14-79). The duration of symptoms was significantly longer ( $68.80 \pm 12.40$  h and  $P < 0.001$ ), and it was statistically significant for both males ( $P = 0.004$ ) and females ( $P = 0.001$ ).

**Conclusion:** To conclude that in our local community, the majority of perforated appendix cases were found to be associated with the delay in presentation rather than the delay in management.

**Key words:** Appendicitis, Complications, Perforated appendix, Peritonitis, Surgery

## INTRODUCTION

Acute appendicitis is the most common acute surgical abdominal emergency occurrence worldwide. It is most common between the ages of 10 and 20 years, but can affect any age. The male to female ratio is 1.4:1, and the lifetime risk is 8.6% for males and 6.7% for females.<sup>1</sup>

A perforated appendix is a complication of untreated or delayed acute appendicitis. Ischemic necrosis of a portion of the appendiceal wall will lead to the perforation. Fecolith was found to be responsible for the perforation in about 90% of cases causing obstruction, increased pressure, and leading to ischemic necrosis. Other causes of luminal obstruction have also been reported such as fruit seeds and vegetables, lymphoid hyperplasia, intestinal worms (*Ascaris*), malignant tissues, and foreign bodies.<sup>2</sup>

Perforation of the appendix is reported to be more common in the elderly patients as a result of the late and atypical presentation, delay in the diagnosis, delay in the decision for surgery, and to the age acquired physiological changes. The mortality and morbidity rates had increased

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because the perforation could lead to prolonged and difficult treatment, convalescence, and could lead to death.<sup>3</sup>

The most recognized contributing factor in perforation of the appendix is the time factor in which the late presentation of the patients was reported to be a major cause, because when the delay in time between the onset of symptoms and the delivery of treatment increases, the probability of complications increase.<sup>4</sup> The age was proven to be a substantial contributing risk factor, patients under 10 years and more than 40 years are at a significant risk of increased morbidity and mortality.<sup>5</sup> Co-morbid conditions, mainly diabetes mellitus were found to increase the mortality and morbidity in perforated appendix patients. The co-existence of pregnancy and acute appendicitis is reported to increase the morbidity and mortality in both the mother and fetus.<sup>6</sup>

The clinical presentation of appendicitis is influenced by various symptoms and signs with reported variations in about 20-30% of the patients who present with atypical symptoms, signs, or laboratory findings. The patient-related factors are reported in many clinical studies to constitute the main reason for delays although physician-related diagnostic, and management delays have been also reported.<sup>7</sup>

Some clinical studies suggested a close relation between the level of inflammation or perforation and duration of inflammation;<sup>8</sup> however, there have been a lack of evidence-based data on the progress of appendicitis in time, and it is not proven scientifically if the risk of perforation is related to the duration of inflammation or it is because of the patient-related factors.<sup>9</sup>

Clinical studies had demonstrated that computed tomography provides a high degree of sensitivity (95%) and specificity (95%) for diagnosing perforation. The reported specific findings on a computed tomography (CT) scan that can lead to identifying a perforated appendix are: The presence of a localized the right iliac fossa abscess or phlegmon, a clear demonstrable defect in the appendiceal wall, an extra luminal air locules or free intraperitoneal air, the presence of appendicolith outside the appendix or within the right iliac fossa abscess, an intraperitoneal leak of rectal contrast, and the presence of multiple appendicoliths in association with thickened appendix, or peri-appendiceal inflammation. Ultrasound is reported to be less reliable than a contrast enhanced CT.<sup>10</sup>

The management of perforated appendicitis is different than that of acute non-perforated disease. The patients who progress to perforated appendicitis will have a longer duration of symptoms, high fever, and a higher white

blood count (WBC). Most of these patients have an established peritonitis and should receive a broad-spectrum intravenous antibiotic therapy, which should start as soon as the diagnosis is established.<sup>11</sup>

Surgical management is through two possible approaches: An open laparotomy or laparoscopy, but controversy regarding the use of laparoscopy in patients with an advanced disease does exist because of the high incidence of postoperative intra-abdominal abscess formation.<sup>12</sup>

We aim in this study to evaluate the effect of time on perforated appendicitis cases to determine whether the delay in presentation or the delay in treatment have a role in the progressing of acute appendicitis to perforation of the appendix.

## MATERIALS AND METHODS

A retrospective database analysis of the treatment outcome of 2573 Saudi Arabian patients treated surgically for acute appendicitis between January 2006 and December 2015 in a public health general hospital in Medina; Saudi Arabia was done.

The inclusion criteria included all adult patients age 12 years and above (according to the age classifications in hospitals of the Saudi Arabian ministry of health), all patients under 12-year-old were excluded due to unavailability of pediatric surgery unit in the hospital.

All patients who were diagnosed initially as acute appendicitis and proven to have had perforated appendix were selected, and random selection in regard to age, gender, and co-morbid conditions was done. All patients had the same diagnostic investigations (complete blood count, blood chemistry, chest X-ray, ultrasound abdomen, and electrocardiogram).

The diagnosis was made by the surgeon, who was on duty in the emergency surgery department, on the basis of the patient's history, clinical findings, laboratory, and radiology investigations. All appendectomy operations were performed as an emergency open procedure. All appendectomy samples were histologically evaluated.

Preoperative WBC count, body temperature, the ultrasound findings, and the diagnosis of a perforated appendix (preoperatively or intraoperatively) were analyzed for characteristics of the diagnosis. Age, gender, duration of symptoms before admission, duration of hospitalization, and mode of patient's referral from other health facilities were recorded and analyzed.



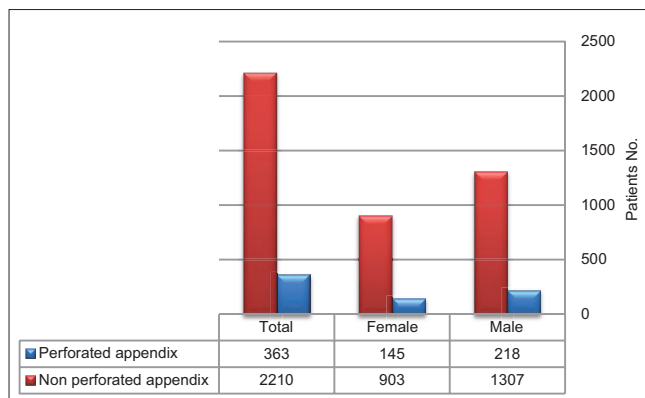
## RESULTS

A total of 2573 Saudi Arabian patients who were treated surgically for acute appendicitis between January 2003 and December 2012 were included, among them, 363 (14.11%) patients were proven to have had perforated appendix, of which 145 (39.9%) were females and 218 (60.1%) were males, male to female ratio of 1.5:1. The incidence rate of the perforated appendix in our study is 14.1%. The number of perforated cases was higher in males compared with females, and the difference was found to be statistically significant ( $P = 0.033$ ). The mean age of the patients was 35.76 years, (median 36.5, range: 14 - 61) (Table 1 and Figure 1).

The duration of symptoms in patients with perforated appendicitis was significantly longer ( $68.80 \pm 12.40$  h and  $P < 0.001$ ). This was found to be statistically significant for both males ( $P = 0.004$ ) and females ( $P = 0.001$ ). Analysis of the data in perforated patients, based on the age and sex, showed that the duration of pre-operative symptoms was very long in females, compared with males. However, this is not statistically significant ( $P = 0.486$  and  $P > 0.05$ ) (Table 2).

Body temperature as part of the vital signs did not show a statistical difference in perforated and non-perforated cases. In the comparison of white blood cells levels of the groups, high levels of WBC levels in patients with appendix perforation were statistically significant ( $P < 0.05$ ) (Table 3 and Figure 2).

It was statistically significant that the time of hospitalization was increasing in accordance with the complicated acute appendicitis (perforated appendix). Comparison of the preoperative ultrasound findings did not reveal a statistically significant difference between the rates of consistency of ultrasound with pathology ( $P > 0.05$ ). However, the highest rate of consistency between ultrasound and pathology was identified in the perforated group (Tables 4 and 5).



**Figure 1: Patients gender of perforated and non-perforated appendix**

The mortality rate was (0%) in all acute appendicitis patients including perforated and non-perforated appendix. The rates of postoperative morbidities were found as 2.5% in total of the non-perforated group (56 patients of 2210), and 17% in the perforated group (62 patients of 363) (Table 6).

**Table 1: Demographic characteristics of the patients with perforated appendix**

Age group (years)	Male (%)	Female (%)	Total (%)
12-19	51 (63.0)	30 (37.0)	81 (100.0)
20-49	143 (58.1)	103 (41.9)	246 (100.0)
≥ 50	24 (66.7)	12 (33.3)	36 (100.0)
Total	218 (60.1)	145 (39.9)	363 (100.0)

**Table 2: Distribution of age, gender-stratified mean, duration of pre-admission symptom according to level of inflammation (perforated/non-perforated)**

Age group (years)	Non-perforated appendix		Perforated appendix	
	Male (h)	Female (h)	Male (h)	Female (h)
12-19	32.0 (12)	35.2 (15)	160.0 (3)	74.6 (9)
20-49	32.8 (46)	39.5 (48)	87.0 (8)	46.6 (18)
≥ 50	36.0 (6)	33.6 (5)	56.0 (3)	60.0 (4)
Total	33.0 (64)	38.1 (68)	56.5 (31)	96.0 (14)

**Table 3: WBC count in perforated and non-perforated appendix**

WBC	Non-perforated (%)	Perforated (%)
10-15	899 (40.7)	0 (0)
15-20	847 (38.3)	85 (23.4)
20-25	437 (19.8)	185 (50.9)
25-30	27 (1.2)	93 (25.6)
WBC (±SD) $P < 0.05$	11.54 (±3.28)	15.49 (±3.75)

WBC: White blood cells, SD: Standard deviation

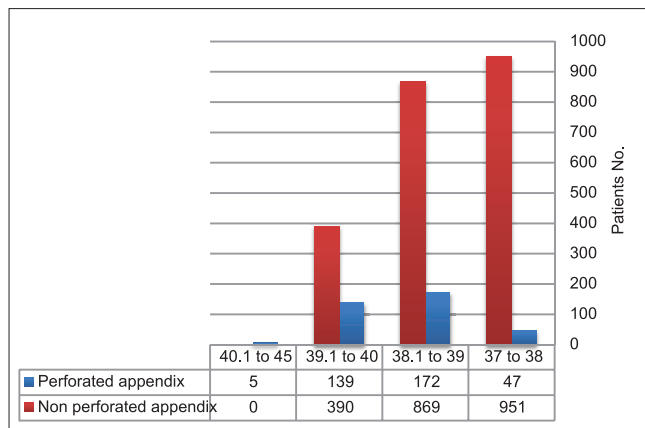
**Table 4: Distribution of mean duration of hospitalization according to the perforated and non-perforated**

Appendicitis	Average±SD
Non-perforated	1.85±1.03
Perforated	4.24±2.39

SD: Standard deviation

**Table 5: Distribution of pathology and ultrasound findings in perforated and non-perforated appendix**

Ultrasound finding	Non-perforated (%)	Perforated (%)
Appendicitis (+)	44.7	57.8
Appendicitis (-)	55.3	42.2
P value	0.715	



**Figure 2: Body temperature in perforated and non-perforated**

**Table 6: Postoperative complications in perforated and non-perforated appendicitis patients**

Data	Non-perforated appendix group	Perforated appendix group
Complications patients no	56	62
Total no of patients	2210	363
Paralytic ileus	17	30
Urinary tract infection	12	13
Wound infection	3	6
Fever (atelectasis)	16	10
Chest infection	9	3

## DISCUSSION

The delay in the diagnosis and management of acute appendicitis is proved to occur in a group of patients who present with the atypical clinical picture including those who had received narcotics or other strong analgesic medications. The fact that despite recent advances in laboratory and radiographic diagnostic tools, a high rate of complicated, gangrenous, or perforated appendicitis is still encountered necessitated the review of cases of appendicitis in regard to the time events starting from the initial presentation to the definitive treatment. Several clinical studies proved that the high rate of complicated acute appendicitis and the increased morbidity and mortality rates were primarily the direct results of the patient delay.<sup>13-15</sup>

Several clinical studies pointed to the preadmission delay on the part of the patient and the post admission delay on the part of the surgeon.<sup>15-17</sup> The major finding of our study was that the time between the onset of symptoms and the presentation to the emergency department was significantly longer in patients with a perforated appendix in comparison to patients with non-perforated acute appendicitis. Perforation of the appendix was proven in some clinical studies to increase the risk of complications up to 39%, and if there is no perforation

during the operation, this rate is about 8%.<sup>12,18</sup> That was in accordance with our study results where the complication rates were 17% and 2.5% in the groups with and without perforation, respectively. The duration of postoperative hospitalization in patients who had perforated appendix was significantly higher compared with the non-perforated.

In the last years, there have been ongoing debates on whether the delay of diagnosis is patient-related or surgeon-related factors. Our findings were consistent with the results of many studies which concluded that perforation of the appendix has mainly depended on the duration of the preadmission factors.<sup>10,19-21</sup> On the other hand, some studies had emphasized the role of the surgeon-related delay of diagnosis and treatment as a cause of complicated appendicitis.<sup>8</sup> The main factor was the diagnostic uncertainty for doubtful presentations of appendicitis patients. To overcome this dilemma, many surgeons adopted the policy that it is possible to avoid perforation by an earlier operation.<sup>20,21</sup>

Many clinical studies outlined the role of preoperative radiological investigations in confirming the diagnosis either by ultrasound or CT.<sup>22,23</sup> In our study, the results of ultrasound investigations showed that the association between the ultrasound findings and the pathology was highest in the perforated appendix group, but statistically no significant difference was found. We interpreted this finding to the usefulness of ultrasound as the second important preoperative factor to the clinical examination, which we believe is the first.

An article published in 2003, a prospective randomized clinical study compared the value of the clinical examination compared to CT scan in the diagnosis of acute appendicitis concluded that CT scan did not increase the accuracy of the diagnosis.<sup>24</sup> In our study, we did not rely on the CT scan method because most of the cases with perforation presented in the preadmission period, and the clinical diagnosis was most important factor in the decision-making to admit and operate.

Some clinical studies<sup>10,25-27</sup> reported that perforated appendicitis presented with high incidence in patients over 50 years of age, but in our study, the duration of appendicitis before presentation in comparison to the age factor was not found to cause a delay in admission, and no statistically significant difference was found in the mean duration of pain before the presentation when we compared the patients under and over 50-year-old. The duration of symptoms was relatively long in female patients who had perforated appendix compared to male patients, but it was not found to be statistically significant.

According to our results, the delay of presentation is the major factor leading to acute appendicitis complications in general and perforation in particular. The clinical picture of appendix perforation is not affected by age or gender in our local society. One of the limitations of this study was the exclusion of patients under the age of 12 years as they could not be operated due to the absence of pediatric surgery in the hospital where the study was conducted. Another limitation was the referral system between hospitals at night hours with all possible causes of delay in transferring the patients for available surgical service.

Diagnosis of perforated appendicitis may be a difficult task and remains a clinical challenge in the emergency departments. Despite technologic advances, the diagnosis is still based primarily on the patient's history and the physical examination, thus, on the surgeon's clinical judgment. Careful attention to the patient's history, a thorough physical examination, and early clinical review will minimize the possibility of a delay in diagnosis of acute appendicitis and its complications including perforation.

The observation of the late presentation due to the limitations of the referral system should be strongly addressed as it had affected the progression of acute appendicitis to a perforated appendix, especially in patients referred from other faraway medical centers.

## CONCLUSIONS

We conclude that in our local community, the majority of perforated appendix cases were found to be associated with the delay in presentation rather than the delay in management.

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# Gingival Enlargement and Seizure-related Oro-dental Injuries in Patients with Epilepsy

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## Abstract

**Background:** Patients living with epilepsy suffer from the adverse effects of antiepileptic medication such as gingival enlargement and traumatic injuries of the oral cavity related to the epileptic seizures. This study aimed to assess the prevalence of gingival enlargement and seizure-related oro-dental injuries among patients with epilepsy.

**Materials and Methods:** This descriptive cross-sectional study included 500 consecutive patients with epilepsy attending the Outpatient Department of Neurology at a tertiary care hospital in Bengaluru, India. Patients were categorized into four groups according to the dental risk factors and manageability.

**Results:** Gingival enlargement was observed in 59% of patients on phenytoin (PHT) therapy. Among them, 33% of patients were on PHT monotherapy and 67% were on PHT polytherapy. Of the 120 subjects with gingival enlargement, 49% had moderate enlargement while 10% had a severe enlargement. Oro-mucosal injuries were significantly more in the study population as compared to injuries of the teeth and jaws. This comparison across the groups was statistically significant ( $P < 0.03$ ). Trauma to the tongue, cheek biting, lip injury, fracture and loss of teeth, and jaw fractures were seen only in patients with generalized tonic-clonic seizures (Groups II, III, and IV). Lip injury, cheek biting, trauma to tongue, loss of teeth, and jaw fracture were all significantly associated ( $P < 0.05$ ) with seizures occurring more than once a year.

**Conclusions:** The prevalence of gingival enlargement and seizure-related hard and soft tissue injuries of the oral cavity in patients with epilepsy supported the need for an interdisciplinary approach and targeted oral health promotion to ameliorate the oral health of these patients with epilepsy.

**Key words:** Antiepileptic drugs, Dental injury, Epilepsy, Fracture, Gingival enlargement, Seizure

## INTRODUCTION

Gingival overgrowth (GO) or gingival enlargement is one of the most frequent and troublesome adverse effects associated with the administration of the anticonvulsant drug phenytoin (PHT), calcium channel blockers such as nifedipine, and the immunosuppressant cyclosporine.<sup>1</sup> It has been reported to occur in 16-94% of patients treated

with PHT.<sup>2</sup> Gingival enlargement is also a side effect of other antiepileptic drugs (AEDs) such as barbiturate, sodium valproate, carbamazepine, and vigabatrin therapy. Clinical manifestation of gingival enlargement frequently appears within 1-3 months after initiation of treatment with the associated medications. GO normally begins at the interdental papillae and is more frequently found in the anterior segment of the labial surfaces. Gradually, gingival lobulations are formed that may appear inflamed or more fibrotic in nature, depending on the degree of local factor-induced inflammation.<sup>3</sup> The fibrotic enlargement normally is confined to the attached gingiva but may extend coronally and interfere with esthetics, mastication, or speech. Disfiguring GO triggered by these medications is not only displeasing but often impairs nutrition and access for oral hygiene, resulting in retention of food

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and debris, halitosis, an increased susceptibility to oral infections, caries, and periodontal diseases.<sup>3</sup> The gingival tissue overgrowth may also lead to delayed eruption of the teeth and sometimes malalignment of teeth.<sup>4</sup>

Patients with epilepsy have increased the risk of dental and maxillofacial trauma. Falls during seizures can cause soft tissue lacerations, facial fractures, temporomandibular joint subluxation, and devitalization, fractures, and subluxation or avulsion of teeth.<sup>5</sup> In a report, the proportion of people who sustained various injuries during a seizure and had at least one seizure during the previous year was: 24% sustained at least one head injury, 16% sustained a burn or scald, 10% a dental injury, and 6% some other fracture.<sup>6</sup> Studies have shown an increased prevalence of traumatic anterior dental injuries in patients with epilepsy as compared with the prevalence reported for those without epilepsy.<sup>7</sup> In patients with epilepsy and AEDs, the incidence of fractures is 2-6 times higher compared to the general population.<sup>8</sup> Relatively, little has been reported in the literature about the incidence and nature of non-fatal seizure-related injuries of the craniofacial complex, especially the oro-dental injuries among the patients living with epilepsy in India.

This study was carried out to assess the oral health status and dental treatment needs and also the seizure-related injuries of the oral cavity, among patients living with epilepsy, who attended the Outpatient Department of Neurology at a tertiary care government teaching hospital in Bengaluru, Karnataka, India. The prevalence of gingival enlargement and seizure-related oro-dental injuries is reported in this paper; the oral health status and dental treatment needs will be described in a subsequent publication.

## MATERIALS AND METHODS

This descriptive cross-sectional study was carried out on 500 consecutive epileptic patients visiting the Outpatient Department (OPD) of the Department of Neurology of a tertiary care Government teaching hospital in Bengaluru city, during 2008-2009. Patients fulfilling the following eligibility criteria were included in the study: Persons aged above 5 years, diagnosed with epilepsy as per the case definition of epilepsy given by the Commission on Epidemiology and Prognosis, International League Against Epilepsy,<sup>9</sup> who had been under treatment for at least six months duration (as per the patients' case records) before the day of dental examination. Individuals who had only febrile seizures or only neonatal seizures, and those who were concurrently on other medications known to cause gingival enlargement and were not included in the study. Informed consent and ethical clearance were obtained.

The clinical and diagnostic features of the patient's epilepsy were sought from the case records and from interviewing the patients if required. A specially designed proforma in a structured questionnaire format was used to collect information on patients' demographic details, oral hygiene practices, epileptic history (age of onset, most recent occurrence of seizure, type and frequency of seizure, time of attacks, aura, involvement of masticatory system, AED therapy), including details of seizure-related injuries to the oral cavity, visits to dentist, and categorize patients into 4 groups according to the dental risk factors and manageability. Epileptic patients were categorized, with the help of the neurologist, into dental subgroups, as given in the classification by Károlyházy *et al.*<sup>10</sup>

The oral examination of all patients was carried out in the Outpatient Department of the Department of Neurology, Victoria hospital, by a single investigator (S.S.Y) after calibration to limit intra-examiner variability. Information on gingival enlargement was recorded on the WHO oral health assessment form (1997),<sup>11</sup> and the grading for gingival enlargement was done as follows: The dentition was divided into six sextants as used for the Community Periodontal index (CPI index).<sup>11</sup> Probing depth (PD) measured by a CPI probe (Hu-Friedy) was used as a marker of the development and progression of gingival enlargement (none: PD ≤ 3 mm, moderate: PD 3-5 mm, and severe: >5 mm). The tooth with the most serious gingival condition in each sextant was selected as representative.<sup>1</sup>

The data were analyzed using SPSS 15.0 software package. Univariate and Bivariate frequency tables were generated with percentages for comparison of various categories between groups. Descriptive statistics were computed for continuous variables studied. Association for some key variables and groups were studied using Chi-square test statistic with appropriate degrees of freedom. Z-test for proportion based on binomial distribution has been used to find the significance of association of seizure-related injuries with the study characteristics. Any  $P < 0.05$  was considered to be statistically significant.

## RESULTS

A total of 500 patients with epilepsy, in the age range of 5-85 years, were examined, out of which 302 (60.4%) were males (mean age  $30.80 \pm 14.18$  years) and 198 (39.6%) were females (mean age  $28.48 \pm 11.57$  years). As per the classification of patients based on dental risk factors and manageability, the study subjects belonged to one of the 4 groups as follows: 8% ( $n = 40$ ) were in Group I, 68.2% ( $n = 341$ ) in Group II, 20.4% ( $n = 102$ ) in Group III, and 3.4% ( $n = 17$ ) in Group IV.



## Gingival Enlargement

Gingival enlargement was observed in 120 (59%) of the 203 patients on PHT therapy. Based on the severity of gingival enlargement, none or no enlargement was present in 83 patients (41%); moderate gingival enlargement was seen in 99 subjects (49%), and severe enlargement of the gingiva was noted in 21 (10%) of the 203 study subjects all of whom were on treatment with PHT therapy. Of the 120 patients who presented with gingival enlargement, 33% were on PHT monotherapy, and the rest (67%) were on PHT polytherapy/multi-drug therapy, i.e., in combination with phenobarbitone (PB) in most cases, or a combination of PHT, PB, and carbamazepine in a few cases.

## Seizure-related Injuries of the Oral Cavity

The prevalence of seizure-related injuries of oral cavity and jaw bones showed that 46.8% had no injury, 14% had cheek biting, 46% had tongue bite, 5.2% had lip injury, 7.2% had fractured teeth, 6.8% had loss of teeth, and 1% had jaw fracture. The percentages do not add up to 100 as some subjects had more than one type of injury. Group I patients did not experience any injuries. The distribution of the number of subjects by seizure-related injuries of the oral cavity, across the four subgroups, is shown in Table 1.

Cheek biting had been experienced by more number of subjects from Group II. Trauma to tongue during seizures was the most common injury among the study population and had occurred in 230 (46%) subjects. Lip injury had occurred in more number of subjects in Group III and Group II (Table 1).

Fracture of teeth due to seizure-related injury had occurred in a greater number of patients from Group II, whereas loss of teeth as a consequence of seizures had occurred in an equal number of subjects in Groups II and III. Fracture of teeth involved the anterior teeth in all cases except three subjects: Two subjects with molar fractures and one with premolar fracture; loss of teeth also involved the anterior teeth in all cases, except four cases which also involved loss of posterior teeth (loss of premolars in two subjects and loss of first molar teeth in two subjects).

Fracture of the jaws due to seizure-related injury had been recorded in five patients, out of whom one belonged to Group II and four belonged to Group III (Table 1).

The association, if any, between age, gender, duration of seizure, frequency of seizures, and time of attacks with the various seizure-related injuries was explored. A significant association was seen between the age groups of 31-40 years and seizure-related injury ( $P < 0.05$ ), particularly, cheek biting ( $P < 0.05$ ) and trauma to tongue ( $P \leq 0.01$ ). The association between fracture of teeth and ages 51-60 years was significant ( $P < 0.05$ ) while that between gender and the seizure-related injury was not significant. The associations between fractures of the jaw and ages 51-60 years and duration of seizure and trauma to tongue and fracture of teeth were suggestive of statistical significance. The frequency of seizures of more than once a year ( $P \leq 0.01$ ) and one or more seizures a month ( $P < 0.05$ ) was related to seizure-related injuries (Table 2). The association of lip injury to a seizure frequency of more than once a year was highly significantly ( $P \leq 0.01$ ). Cheek biting, trauma to tongue, loss of teeth, and jaw fracture were all significantly related ( $P < 0.05$ ) to seizures occurring more than once a year. Frequent seizures of one or more a month were significantly associated ( $P < 0.05$ ), with seizure-related injury and loss of teeth in particular.

The association between time of attack and seizure-related injury is shown in Table 3. Statistical significance ( $P < 0.05$ ) was noted only in case of seizure-related injury, especially trauma to the tongue and nocturnal attacks. Both diurnal and nocturnal attacks were significantly related to cheek biting and statistical significance was suggested in case of the association between fracture of teeth and such unpredictability of time of attack.

## DISCUSSION

The severity of gingival enlargement noted in the present study is comparable to that described by Akiyama *et al.*<sup>1</sup> However, of the 120 patients who presented with gingival enlargement, 33% were on PHT monotherapy, akin to the results of a Nigerian study;<sup>7</sup> and the rest (67%) were on PHT multi-drug therapy, i.e., in combination with PB in most cases, or a combination of PHT, PB, and carbamazepine in a few cases.

Numerous reports suggest that young age is an important risk factor in PHT-induced gingival enlargement.<sup>12</sup> Since

**Table 1: Distribution of subjects by seizure-related injuries of the oral cavity**

Injuries	None	Cheek biting	Trauma to tongue	Lip injury	Teeth fracture	Loss of teeth	Jaw fracture
Group I (n=40)	No.	40	0	0	0	0	0
Group II (n=341)	No.	162	42	152	10	25	14
Group III (n=102)	No.	25	24	68	12	10	14
Group IV (n=17)	No.	7	4	10	4	1	0
Total	No.	234	70	230	26	36	29

Numbers do not add up to 500 as some subjects had more than one condition

**Table 2: Association of frequency of seizure and related injury**

Frequency of seizure	Total number of patients	No injury	Injury	Cheek biting	Trauma to tongue	Lip injury	Fracture of teeth	Loss of teeth	Jaw fracture
None in past year	3	2 (66.7)	1 (33.3)	0	1 (33.3)	0	0	0	0
Less than once a year	362	189 (52.2)	173 (47.8)	43 (11.8)	147 (40.6)	11 (3.1)	25 (6.9)	15 (4.1)	1 (0.3)
More than once a year	98	33 (33.7)	65** (66.3)	21* (21.4)	57* (58.2)	11** (11.2)	8 (8.2)	13* (13.3)	3* (3.1)
One or more a month	37	10 (27.1)	27* (72.9)	6 (16.2)	25 (67.6)	4 (10.8)	3 (8.1)	6* (16.2)	1 (2.7)
Total	500	234 (46.8)	266 (53.2)	70 (14.0)	230 (46.0)	26 (5.2)	36 (7.2)	34 (6.8)	5 (1.0)

\* $P < 0.05$ , \*\* $P < 0.01$ ; Figures in parenthesis indicate percentages

**Table 3: Association of time of epileptic attack and related injury**

Time of attack	Total number of patients	No injury	Injury	Cheek biting	Trauma to tongue	Lip injury	Fracture of teeth	Loss of teeth	Jaw fracture
Diurnal	230	130 (56.5)	100 (43.5)	19 (8.3)	85 (36.9)	10 (4.3)	17 (7.4)	17 (7.4)	2 (0.9)
Nocturnal	149	57 (38.3)	92* (61.7)	26 (17.4)	83* (55.7)	7 (4.7)	5 (3.4)	8 (5.4)	1 (0.7)
Both diurnal and nocturnal	121	47 (38.8)	74 (61.2)	25* (20.7)	62 (51.2)	9 (7.4)	14 (11.6)	9 (7.4)	2 (1.7)
Total	500	234 (46.8)	266 (53.2)	70 (14.0)	230 (46.0)	26 (5.2)	36 (7.2)	34 (6.8)	5 (1.0)

\* $P < 0.05$ , Figures in parenthesis indicate percentages

58% of the study population was below the age of 30 years (the mean age of the total population was 29.49 [ $\pm 13.25$ ] years), it is a likely explanation for the prevalence of gingival enlargement seen in patients on PHT therapy in the present study. However, this relation between age and gingival enlargement was not statistically analyzed as it was not one of the objectives of the study. Similar findings as in the present study were observed by Majola *et al.*<sup>12</sup> in the South African outpatient population (62% prevalence, mean age of population was 33.6 years and statistically significant relation to age was seen) and also among Indian children (57% prevalence, age range 8-13 years) with epileptic disorders and receiving monodrug therapy with PHT, at Post Graduate Institute of Medical Education and Research, Chandigarh (PGIMER).<sup>13</sup>

Firm evidence of the involvement of PHT as the principal iatrogenic factor in the development of gingival enlargement has been presented in the literature. Similar to the Nigerian study,<sup>7</sup> none of the patients receiving PB as monotherapy manifested the disorder. Therefore, PB appears to potentiate the effect of PHT in causing gingival enlargement. Contrastingly, in the Yelandur study gingival enlargement was noted in 4% of patients on phenobarbital and 43% of those on PHT.<sup>14</sup> These differences may be due, at least in part, to the assessment of enlargement by medical (i.e., non-dental) personnel, differing indices of overgrowth and a community-based study population. The exact role of PB alone and in combination with other anticonvulsants in causing enlargement of gingival tissues needs to be elucidated, especially in the local epileptic population, since the drug is widely used here. PB was observed to be the most commonly used the antiepileptic drug in the present study. Good plaque control, removal of plaque retentive factors and treatment of any underlying

periodontal condition will reduce gingival inflammation and hence the severity of any drug-induced GO.<sup>15</sup> A 3-month interval for periodontal maintenance therapy has been recommended for patients taking drugs associated with gingival enlargement.<sup>16</sup>

The assessment of seizure-related injuries ever experienced by the study population showed that many ( $n = 234$ ) of the subjects had not experienced any seizure-related injuries of the oral cavity and especially those from Group I were free of such injuries. This could be because subjects from Group I had seizures without falls and effect on the teeth (masticatory system). Oro-mucosal injuries were significantly more in the study population as compared to injuries of the teeth and jaws, and this comparison across the groups was also statistically significant ( $P < 0.03$ ). Trauma to tongue during seizures was the most common injury among the study population and had occurred in 230 subjects. This is similar to the study of Roberge and Maceira-Rodriguez where the tongue was the most common site of injury among those with generalized seizures and 48 of 52 seizure-related oral lacerations involved the tongue.<sup>17</sup> In the present study, trauma to tongue, cheek biting, and lip injury was reported by patients with grand mal convulsions and hence seen only among subjects from Groups II, III, and IV. Fracture and loss of teeth and jaw fractures were also seen only in patients with generalized tonic-clonic seizures (Groups II, III, and IV). This is in accordance with previous observations that generalized tonic-clonic seizures very often cause minor oral cavity injuries, such as biting of the tongue or other areas of the oral mucosa, but frequently lead to injuries of the teeth and sometimes also cause fractures of jaws and other extremities.<sup>17</sup> The finding that fracture and loss of teeth predominantly

affected the anterior teeth in the present study is similar to that reported in the Nigerian study.<sup>7</sup> In the study by Buck *et al.*, 28 of 344 epilepsy patients had seizure-related tooth injuries within 1 year.<sup>6</sup> These might occur as a result of the fall or of the forceful contraction of the masticatory muscles during both the tonic and clonic phases. Thus, the exertion and risk of injury of the teeth of patients with frequent generalized tonic-clonic seizures (Group III) are very much increased, contributing to the compromised dental health status.<sup>10</sup>

The association, if any, between age, gender, duration of seizure, frequency of seizures, and time of attacks with the various seizure-related injuries was explored. The association between fracture of teeth and ages 51-60 years was significant ( $P < 0.05$ ), whereas that between gender and the seizure-related injury was not significant, which is in accordance with the study of Tiamkao and Shorvon.<sup>18</sup> The frequency of seizures of more than once a year ( $P \leq 0.01$ ) and one or more seizures a month ( $P < 0.05$ ) was definitely related to seizure-related injuries, and this finding is supported by other studies; the study by Buck *et al.* showed that seizure severity, type, and frequency were the best predictors of all types of injury (head injury, burns/scalds, dental injury including loss of teeth, jaw fracture, admission to hospital and major dental surgery, other fractures, and seizures while bathing/swimming) and having tonic-clonic seizures or the combination of tonic-clonic and other seizures and at least three drug-related adverse effects significantly increased the chances of sustaining dental trauma.<sup>6</sup> Lip injury, cheek biting, trauma to tongue, loss of teeth, and jaw fracture were all significantly associated ( $P < 0.05$ ) with seizures occurring more than once a year. Frequent seizures of one or more a month were significantly associated ( $P < 0.05$ ) with seizure-related injury and loss of teeth in particular. The study by Tiamkao and Shorvon also reported that significant risk factors for injury were generalized tonic-clonic seizures, high frequency of seizures, and seizures with a fall.<sup>18</sup>

Thus, the classification of epileptic patients<sup>10</sup> used in the present study makes it useful for the study of seizure-related injuries of the oral cavity. However, a prospective study, wherein patients or care givers could maintain a diary recording the occurrence of seizures, and seizure-related injuries would reduce recall error, problems of inadequate medical documentation, especially of minor injuries and be better suited to elicit valid and reliable data on the seizure-related injuries of the oral cavity. The present study, being restricted to the hospital outpatients only, may not be adequately representative of all epileptic patients in the community. This limits the generalizability of the findings.

This study is a foray into an area of oral health research that has barely been investigated in the Indian context. The data on seizure-related injuries of the oral cavity add to the sparse literature<sup>19</sup> available in this regard.

## CONCLUSION

Interdisciplinary collaboration, referral by the neurologist for preventive dental care including adequate dental plaque control measures as well as thorough examination of the injuries to the oral cavity to rule out occult maxillofacial trauma can help improve the overall health and quality of life of patients with epilepsy.

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# Comparison of Clonidine and Dexmedetomidine on Cardiovascular Stability in Laparoscopic Cholecystectomy

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## Abstract

**Introduction:** Laparoscopic cholecystectomy has revolutionized gall bladder surgeries and it has now become the gold standard for the treatment of cholelithiasis. Despite multiple benefits, all laparoscopic surgeries are challenging from an anesthesia point of view, mainly due to significant alteration of hemodynamics. Numerous agents and combination of agents have been used in an effort to minimize the hemodynamic instability during this period, but search for an ideal agent to control this instability in hemodynamics is still on. In this study, it has been attempted to compare the beneficial effect of the two  $\alpha_2$  agonists, clonidine and dexmedetomidine, in maintaining perioperative parameters like mean arterial pressure (MAP) and heart rate (HR).

**Purpose:** To assess the efficacies of clonidine and dexmedetomidine in maintaining hemodynamic stability during laparoscopic cholecystectomy.

**Materials and Methods:** Patients were randomly divided into three groups, who received 0.9% normal saline infusion, 3 mcg/kg/h of clonidine infusion, and 0.2 mcg/kg/h of dexmedetomidine infusion, intravenously. Intraoperative hemodynamic stability was assessed by monitoring HR, MAP and requirement of isoflurane in the three groups.

**Results:** Clonidine and dexmedetomidine caused significant reductions in intraoperative HR, MAP and requirement of isoflurane when compared to the control (normal saline) group. Clonidine caused a significant reduction in HR when compared to dexmedetomidine. No significant differences were observed in MAP and requirement of isoflurane between the two drugs.

**Conclusion:** Both clonidine and dexmedetomidine favorably alter the intraoperative hemodynamics during laparoscopic cholecystectomy. Clonidine decreased intraoperative HR more than dexmedetomidine.

**Key words:** Clonidine, Dexmedetomidine, Hemodynamic stability, Inhalational agent sparing effect, Laparoscopic cholecystectomy

## INTRODUCTION

Laparoscopic surgery is a modern surgical technique involving insufflation of gas (usually CO<sub>2</sub>) into the peritoneal cavity, under pressure, to separate the organs from the abdominal cavity.<sup>1</sup> Laparoscopic cholecystectomy has revolutionized gall bladder surgeries and it has now become

the gold standard for the treatment of cholelithiasis. Since the introduction of diagnostic laparoscopic procedures in early 1970's and the first laparoscopic cholecystectomy procedures in late 1980's, laparoscopy has expanded impressively both in scope and volume. Increasing the success of laparoscopic surgery can be attributed to the fact that it results in multiple benefits compared with open procedures such as reduced trauma to the patient, disturbance of homeostasis, morbidity, mortality, recovery time, and hospital stay with a consequent reduction in healthcare costs.

Despite multiple benefits, all laparoscopic surgeries are challenging from an anesthesia point of view, mainly due to significant alteration of hemodynamics, resulting

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from the combined effects of pneumoperitoneum, patient position, and hypercapnia from the absorbed CO<sub>2</sub>. Pneumoperitoneum creation raises the intra-abdominal pressure (IAP) and is immediately followed by an increased plasma renin activity and increase in plasma norepinephrine and epinephrine levels. There is also an increase in the circulating blood volume, which is due to the shifting of blood from the splanchnic capacitance blood vessels to the systemic circulation. All these changes collectively lead to an elevated arterial pressure, increased systemic and pulmonary vascular resistance, and decreased cardiac output. These hemodynamic responses are well tolerated in otherwise healthy individuals, but in patients with hypertension, coronary heart disease, cerebrovascular disease, and intracranial aneurysm; these transient changes can result in potentially deleterious effects such as left ventricular failure, pulmonary edema, myocardial ischemia, ventricular dysrhythmias, and cerebral hemorrhage.<sup>2,3</sup>

Numerous agents and combination of agents have been used in an effort to minimize the hemodynamic instability during this period. Volatile agents such as isoflurane and sevoflurane<sup>3</sup> have been used with limited success in maintaining hemodynamic stability as volatile agents decrease surgical stimulus induced catecholamine secretion. Opioids have traditionally been used for blunting the perioperative stress response during general anesthesia. General anesthesia has been supplemented on occasions with intraoperative infusions of propofol, due to its intrinsic ability to inhibit catecholamine secretion, and infusions of nitroglycerine or beta blockers, to control perioperative stress. Combined general with epidural anesthesia<sup>4</sup> is yet another strategy employed by anesthesiologists to control perioperative hemodynamic instability with limited success. But search for an ideal agent to control this instability in hemodynamics is still on.

$\alpha_2$  agonists produce diverse responses, including analgesia, anxiolysis, sedation, and sympatholysis, each of which has been reported to be useful in the treatment of patients with surgical and chronic pain. The Food and Drug Administration has approved two novel  $\alpha_2$  adrenergic agonists, clonidine and dexmedetomidine, for intravenous administration.<sup>5</sup>

Clonidine, with elimination half-life of 6-10 h, is a centrally acting selective partial  $\alpha_2$  agonist (220:1  $\alpha_2$  to  $\alpha_1$ ). It is known to induce sedation, decrease anesthetic drug requirement and improve perioperative hemodynamics by attenuating blood pressure and heart rate (HR) responses to surgical stimulation, and protect against perioperative myocardial ischemia. It provides sympathoadrenal stability and suppresses renin-angiotensin activity. There are studies

indicating benefits of using clonidine for maintenance of hemodynamic stability in laparoscopic cholecystectomy.

Dexmedetomidine, with elimination half-life of 2-3 h, is a highly selective and potent  $\alpha_2$  agonist (1620:1  $\alpha_2$  to  $\alpha_1$ ), and is seven to ten times more selective for  $\alpha_2$  receptors compared to clonidine, and has a shorter duration of action. Dexmedetomidine is considered full agonist at  $\alpha_2$  receptors as compared to clonidine, which is considered a partial agonist. Similar to clonidine, dexmedetomidine, also attenuates the hemodynamic response to tracheal intubation, decreases plasma catecholamine concentration during anesthesia and decreases perioperative requirements of inhaled anesthetics.<sup>6</sup>

Laparoscopic cholecystectomy is a routinely performed surgery and it is desirable to have a stable intraoperative hemodynamic status. Hence, in this study, it has been attempted to compare the beneficial effect of the two  $\alpha_2$  agonists, clonidine and dexmedetomidine, in maintaining perioperative parameters like mean arterial pressure (MAP) and HR.

## MATERIALS AND METHODS

The study entitled "Comparison of clonidine and dexmedetomidine on cardiovascular stability in laparoscopic cholecystectomy" was carried on 120 American Society of Anesthesiologists (ASA) Grades I and II patients of either sex with comparable characteristics in the Department of Anaesthesiology, Critical Care and Pain Management, Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, Uttar Pradesh, India.

The study was conducted after obtaining approval from the ethical, academic committee and a written, informed consent from the patients.

The study was conducted in three groups comprising 40 patients each.

1. Group 1 (control group): Received 0.9% normal saline infusion
2. Group 2 (clonidine group): Received 3 mcg/kg/h of clonidine in 0.9% normal saline
3. Group 3 (dexmedetomidine group): Received 0.2 mcg/kg/h of dexmedetomidine in 0.9% normal saline.

### Exclusion Criteria

1. Patient refusal
2. Patients with known hypersensitivity to the drugs used in the study
3. Patients less than 18 years or more than 60 years of age

4. ASA Grades III and IV patients
5. Patients with cardiac disorders
6. Patients with hepatic dysfunction
7. Patients with renal dysfunction
8. Hypertensive patients
9. Patients with basal HR less than 55 bpm
10. Pregnant and lactating patients.

Furthermore, surgeries lasting for more than 120 min were not considered in the study.

The study drug was provided as prefilled and coded identical 20 mL syringes containing study drugs, as per the randomization protocol, in dilutions of:

1. Normal saline 0.9% - 20 ml
2. Clonidine - 20 ml (30 mcg/mL)
3. Dexmedetomidine - 20 ml (2 mcg/mL).

The investigators involved in the study did not know about the content of the drug infusion syringes. Patients were explained about the study but did not know which drug was used. The study drug prefilled and coded syringes were obtained on the day of the surgery from a third person not directly involved in the study. Randomization was ensured by picking up a chit from a pool of 120 chits to decide which drug to administer to a particular patient.

Preanesthetic check-up, comprising detailed history and thorough physical examination, of all the patients was done 1 day before the surgery. The following investigations were performed:

- Hemoglobin, packed cell volume
- Total leukocyte count, differential leukocyte count, Erythrocyte sedimentation rate
- Platelet count
- Prothrombin time, partial thromboplastin time
- Random blood sugar
- Kidney function test
- Liver function test
- Serum electrolytes
- Electrocardiogram (ECG)
- Chest X-ray (posterioranterior view).

Two intravenous lines of 18 G and 20 G were secured on any two convenient veins on the left and the right hand, respectively. The 20 G line was used to administer the infusion of drugs under study, while the 18 G line was used to administer intravenous (IV) fluids and all the other drugs.

The monitoring of the patient was started 15 min before the induction and was continued into the post-operative room until 15 min after the extubation. It comprised monitoring the HR, systolic and diastolic blood pressures, MAP, ECG, oxygen saturation and capnography.

After shifting to the operation theatre and attaching all the monitors, the patient was pre-medicated using injection ondansetron 0.08 mg/kg IV, injection glycopyrrolate 4 mcg/kg IV and injection fentanyl 1.5 mcg/kg IV. The anesthesia was induced using injection propofol 2 mg/kg IV. The trachea was then intubated using the appropriate sized cuffed oral endotracheal tube, facilitated with the help of injection vecuronium 0.08 mg/kg IV. The anesthesia was maintained on O<sub>2</sub>:N<sub>2</sub>O (50%:50%) and variable rate of isoflurane 0.2-0.4% v/v. Incremental dosage of injection vecuronium was used for muscle relaxation, as and when required. End-tidal carbon dioxide was monitored intraoperatively and kept between 25 and 30 mm of Hg.

The study drug infusion, in prefilled coded 20 ml syringe, was started 10 min before creation of pneumoperitoneum, using infusion pump, at the rate of 0.1 mL/kg body weight/hour, and the code number of the study drug syringe was noted down in the proforma. The IAP was maintained at 14 mmHg. The drug infusion was stopped when the pneumoperitoneum was resolved back to the status quo ante.

Throughout the procedure, any change in the MAP of over 20% of the basal value was countered by varying the rate of isoflurane. HR less than 50 beats per minute was treated by administering Injection Atropine 0.6 mg.

After the surgery, the residual neuromuscular blockade was reversed using injection neostigmine 0.05 mg/kg IV and injection glycopyrrolate 0.01 mg/kg IV. The trachea was extubated and patient shifted to the post-operative recovery room.

### Assessment

The following parameters were assessed in the case studies:

- HR
- MAP
- ECG changes.

Additional parameters included:

- Requirement of isoflurane
- Requirement of atropine
- Total surgery time
- Total anesthesia time.

The MAP and HR were monitored at the following junctures:

1. In the pre-operative room
2. 5 min before induction
3. Start of drug infusion
4. Creation of pneumoperitoneum
5. Thereafter every 5 min till the pneumoperitoneum is resolved
6. After reversal
7. In the post-operative room.

### Statistical Analysis

Statistical analysis was performed using the SPSS statistical package (version 17.0; SPSS). Continuous variables, including hemodynamic over time within the groups, were analyzed using repeated measures analysis of variance (ANOVA) followed by Bonferroni's *post hoc* testing. Statistical comparisons among the groups were performed using ANOVA. If the *F* value was significant and variance was homogeneous, Tukey's multiple comparison test was used to assess the differences between the individual groups; otherwise, Tamhane's T2 test was used. Nominal or categorical data between the three groups were analyzed and compared using the Chi-square test.  $P < 0.05$  was considered statistically significant.

## RESULTS

There was no statistically significant difference between the groups with regard to age distribution, weight distribution (Table 1), sex distribution (Table 2), surgery time, and anesthesia time (Table 3) with  $P > 0.05$  among the groups.

### HR (Table 4)

#### Group 1 (control) versus Group 2 (clonidine)

HR in Group 1 increased significantly, compared to Group 2 at 5, 10, 15, 20, 25, 30, 35, and 40 min after the creation of pneumoperitoneum; at the end of pneumoperitoneum; after reversal; and postoperatively ( $P < 0.05$ ).

#### Group 1 (control) versus Group 3 (dexmedetomidine)

HR in Group 1 increased significantly compared to Group 3 at 5, 10, 15, 20, 25, 30, 35 and 40 min after the creation of pneumoperitoneum; at the end of pneumoperitoneum; after reversal; and postoperatively ( $P < 0.05$ ).

#### Group 2 (clonidine) versus Group 3 (dexmedetomidine)

The decrease in HR appeared more in Group 2 at all intervals, compared to Group 3, but the decrease was found to be statistically significant only at 25, 30 and 35 min after creation of pneumoperitoneum; and postoperatively ( $P < 0.05$ ), when HR was found to be more in Group 3.

### MAP (Table 5)

#### Group 1 (control) versus Group 2 (clonidine)

MAP in Group 1 increased significantly when compared to Group 2 at 5, 10, 15, 20, 25, 30, 35, 40 and 45 min after the creation of pneumoperitoneum; at the end of pneumoperitoneum; after reversal; and postoperatively ( $P < 0.05$ ).

#### Group 1 (control) versus Group 3 (dexmedetomidine)

MAP in Group 1 was significantly higher, compared to Group 3 after creation of pneumoperitoneum; 5, 10, 15, 20, 25, 30, 35, 40 and 45 min after the creation of

**Table 1: Age and weight distribution**

Age and weight	Mean±SD			P value		
	Group 1	Group 2	Group 3	Group 1 versus Group 2	Group 1 versus Group 3	Group 2 versus Group 3
Age (years)	38.15±12.16	40.13±12.79	41.70±11.01	0.743	0.386	0.828
Weight (kg)	58.73±6.62	55.60±8.96	56.10±5.34	0.127	0.231	0.947

SD: Standard deviation

**Table 2: Sex distribution**

Sex	Frequency (%)			P value		
	Group 1	Group 2	Group 3	Group 1 versus Group 2	Group 1 versus Group 3	Group 2 versus Group 3
Female	30 (75)	33 (82.5)	33 (82.5)	0.412	0.412	1.000
Male	10 (25)	7 (17.5)	7 (17.5)			
Total	40 (100)	40 (100)	40 (100)			

SD: Standard deviation

**Table 3: Duration of surgery and duration of anesthesia**

Duration	Mean±SD			Group 1 versus Group 2	Group 1 versus Group 3	Group 2 versus Group 3
	Group 1	Group 2	Group 3			
Duration of surgery (min)	49.25±4.74	50.13±6.25	51.75±5.72	0.765	0.118	0.400
Duration of anesthesia (min)	70.13±5.13	71.25±5.75	72.00±5.97	0.645	0.299	0.822

SD: Standard deviation

pneumoperitoneum; at the end of pneumoperitoneum; after reversal; and postoperatively ( $P < 0.05$ ).

#### Group 2 (clonidine) versus Group 3 (dexmedetomidine)

There was no statistically significant difference in MAP between the two groups. MAP between the two groups was found to be comparable.

#### Requirement of Isoflurane (Table 6)

All the patients in Group 1 (100%); 3 patients in Group 2 (7.5%); and 4 patients in Group 3 (10%) required isoflurane concentration of more than 1%, during the intraoperative period. Patients in Group 1 had significantly

increased requirements, compared to Group 2 and Group 3 ( $P < 0.05$ ).

#### Requirement of Atropine (Table 7)

None of the patients in Group 1 (0%); 5 patients in Group 2 (12.5%); and 3 patients in Group 3 (7.5%) required intraoperative Atropine for the treatment of Bradycardia. There was no statistically significant difference in the requirement of Atropine among the three groups ( $P > 0.05$ ).

#### Perioperative ECG Changes

No perioperative ECG changes were seen in any of the patients included the study.

**Table 4: HR**

HR	Mean $\pm$ SD			P value		
	Group 1	Group 2	Group 3	Group 1 versus Group 2	Group 1 versus Group 3	Group 2 versus Group 3
Baseline	87.80 $\pm$ 8.57	86.80 $\pm$ 8.31	87.33 $\pm$ 10.01	0.873	0.970	0.963
5 min before induction	90.18 $\pm$ 8.82	89.03 $\pm$ 7.97	89.35 $\pm$ 9.37	0.827	0.907	0.985
Start of drug infusion	91.03 $\pm$ 8.95	91.10 $\pm$ 8.04	87.53 $\pm$ 10.25	0.999	0.204	0.191
Pneumoperitoneum	90.90 $\pm$ 8.70	89.13 $\pm$ 8.37	88.53 $\pm$ 10.77	0.673	0.493	0.956
5 min	95.20 $\pm$ 9.48	85.88 $\pm$ 8.06	89.10 $\pm$ 10.44	<0.001	0.012	0.277
10 min	99.88 $\pm$ 10.45	81.35 $\pm$ 8.03	83.15 $\pm$ 9.90	<0.001	<0.001	0.675
15 min	100.03 $\pm$ 9.66	76.75 $\pm$ 7.28	80.15 $\pm$ 10.10	<0.001	<0.001	0.221
20 min	98.25 $\pm$ 9.24	75.23 $\pm$ 8.35	79.18 $\pm$ 11.07	<0.001	<0.001	0.162
25 min	97.45 $\pm$ 9.15	73.83 $\pm$ 8.95	79.98 $\pm$ 11.25	<0.001	<0.001	0.017
30 min	96.63 $\pm$ 9.35	72.06 $\pm$ 9.86	79.75 $\pm$ 11.67	<0.001	<0.001	0.007
35 min	99.22 $\pm$ 9.05	71.36 $\pm$ 11.66	81 $\pm$ 11.93	<0.001	<0.001	0.010
40 min	98.78 $\pm$ 10.39	73.00 $\pm$ 9.85	82.67 $\pm$ 10.50	<0.001	0.002	0.060
45 min	103.50 $\pm$ 6.36	80 $\pm$ 11.04	83.50 $\pm$ 11.57	0.067	0.113	0.860
50 min		86.50 $\pm$ 20.21	68.00 $\pm$ 0			
End of pneumoperitoneum	92.90 $\pm$ 9.07	78.38 $\pm$ 10.75	81.73 $\pm$ 9.14	<0.001	<0.001	0.273
Reversal	98.68 $\pm$ 9.23	92.83 $\pm$ 9.29	93.18 $\pm$ 9.57	0.017	0.026	0.985
Post-operative	88.58 $\pm$ 7.89	78.60 $\pm$ 7.78	83.28 $\pm$ 8.34	<0.001	0.010	0.027

SD: Standard deviation, HR: Heart rate

**Table 5: MAP**

MAP	Mean $\pm$ SD			P value		
	Group 1	Group 2	Group 3	Group 1 versus Group 2	Group 1 versus Group 3	Group 2 versus Group 3
Baseline	73.73 $\pm$ 5.15	94.08 $\pm$ 5.68	93.80 $\pm$ 6.05	0.958	0.998	0.974
5 min before induction	97.05 $\pm$ 4.74	96.25 $\pm$ 4.81	96.68 $\pm$ 5.70	0.764	0.942	0.927
Start of drug infusion	96.86 $\pm$ 4.54	94.50 $\pm$ 5.19	94.60 $\pm$ 6.03	0.117	0.138	0.996
Pneumoperitoneum	99.80 $\pm$ 4.92	97.38 $\pm$ 5.20	96.93 $\pm$ 5.69	0.104	0.043	0.923
5 min	104.55 $\pm$ 4.63	96.83 $\pm$ 6.18	96.40 $\pm$ 7.17	<0.001	<0.001	0.978
10 min	110.50 $\pm$ 5.43	91.90 $\pm$ 9.00	92.98 $\pm$ 9.19	<0.001	<0.001	0.822
15 min	116.65 $\pm$ 5.35	87.43 $\pm$ 10.82	89.80 $\pm$ 10.13	<0.001	<0.001	0.475
20 min	113.28 $\pm$ 5.17	88 $\pm$ 11.49	90.53 $\pm$ 10.62	<0.001	<0.001	0.463
25 min	110.65 $\pm$ 5.49	87.45 $\pm$ 11.46	89.90 $\pm$ 10.17	<0.001	<0.001	0.476
30 min	107.91 $\pm$ 5.77	85.59 $\pm$ 10.17	88.53 $\pm$ 9.01	<0.001	<0.001	0.322
35 min	106.83 $\pm$ 5.35	85 $\pm$ 10.51	87.42 $\pm$ 7.97	<0.001	<0.001	0.564
40 min	106.11 $\pm$ 5.37	83.55 $\pm$ 7.62	84.40 $\pm$ 14.63	<0.001	<0.001	0.979
45 min	110 $\pm$ 1.41	82.60 $\pm$ 5.22	87.83 $\pm$ 4.07	0.003	0.001	0.172
50 min	0 $\pm$ 0	86.50 $\pm$ 0.71	91 $\pm$ 0			
End of pneumoperitoneum	103.55 $\pm$ 5.59	86.00 $\pm$ 9.56	87.58 $\pm$ 7.82	<0.001	<0.001	0.642
Reversal	108.45 $\pm$ 5.88	97.65 $\pm$ 6.39	98.55 $\pm$ 7.35	<0.001	<0.001	0.814
Post-operative	93.93 $\pm$ 5.34	89.71 $\pm$ 5.15	91.22 $\pm$ 5.88	0.002	0.042	0.438

SD: Standard deviation, MAP: Mean arterial pressure

**Table 6: Requirement of isoflurane**

Requirement of isoflurane	Frequency (%)			P value		
	Group 1	Group 2	Group 3	Group 1 versus Group 2	Group 1 versus Group 3	Group 2 versus Group 3
No	0 (0)	37 (92.5)	36 (90)	<0.001	<0.001	1.000
Yes	40 (100)	3 (7.5)	4 (10)			
Total	40 (100)	40 (100)	40 (100)			

**Table 7: Requirement of atropine**

Requirement of atropine	Frequency (%)			(P value)		
	Group 1	Group 2	Group 3	Group 1 versus Group 2	Group 1 versus Group 3	Group 2 versus Group 3
No	40 (100)	35 (87.5)	37 (92.5)	0.055	0.241	0.712
Yes	0 (0)	5 (12.5)	3 (7.5)			
Total	40 (100)	40 (100)	40 (100)			

## DISCUSSION

### Baseline Comparison

Baseline comparison between the three study groups revealed that the groups were comparable with respect to age, sex, weight, total surgery time, and total anesthesia time. There was no statistically significant variation in these baseline characteristics among the three groups.

### Clonidine versus Control

Statistically significant differences were observed in the HR, MAP and requirement of isoflurane between control (Group 1) and clonidine (Group 2) groups. The HR and MAP were found to be lower in Group 2, and the patients in Group 2 required lesser isoflurane.

No statistically significant difference was observed in the requirement of atropine between the two groups.

### Dexmedetomidine versus Control

Statistically significant differences were observed in the HR, MAP and requirement of isoflurane between control (Group 1) and dexmedetomidine (Group 3) groups. The HR and MAP were found to be lower in Group 3, and the patients in Group 3 required lesser isoflurane.

No statistically significant difference was observed in the requirement of atropine between the two groups.

### Clonidine versus Dexmedetomidine

Although decrease in HR appeared more in clonidine group (Group 2), compared to dexmedetomidine group (Group 3), at all the intervals, but the difference was found to be statistically significant only at 25, 30, and 35 min after creation of pneumoperitoneum; and postoperatively ( $P < 0.05$ ).

No statistically significant difference was found in MAP, requirement of isoflurane and requirement of atropine between the two groups.

Ghignone *et al.*<sup>7</sup> reported less than 20% intraoperative fluctuation in both HR and blood pressure of the preinduction values; and blunting of the cardiovascular response to intubation effectively, in patients receiving clonidine 5 mcg/kg orally, 90 min before induction. They found consistently lower HR; and mean, systolic, and diastolic blood pressures in the clonidine group ( $n = 12$ ) when compared to the control group ( $n = 12$ ), during the intraoperative period. These results are in agreement with that of the present study. The blunting of the cardiovascular response to intubation was not seen in the current study as the study drug infusion was started after intubation and induction of anesthesia.

Hall *et al.*<sup>8</sup> compared the dose-response relationship of 1 h infusions of clonidine 1, 2, and 4 mcg/kg/h; and placebo in 8 healthy individuals. MAP decreased by 13% of the baseline value in clonidine 4 mcg/kg/h group, 1 h after starting the infusion. In the current study, MAP decreased by 12.20%, 50 min after starting the clonidine infusion.

The effect of 150 mcg of oral clonidine, 90 min before induction, was studied by Singh and Arora<sup>9</sup> in 50 patients undergoing laparoscopic cholecystectomy. It was found that the perioperative mean arterial blood pressure and HR were significantly lower in clonidine group at all time points. The study also demonstrated a significant decrease in the requirement of isoflurane in the clonidine group. Results of the present study are similar except for the fact that significant lowering of MAP and HR were not seen at all time points, but only after creation of the pneumoperitoneum. This could be attributed to the fact



that clonidine was administered 90 min before induction in the said study, while it was administered after induction in the present study. Isoflurane sparing effect of clonidine was also observed in the present study.

Aantaa *et al.*<sup>10</sup> conducted a study, to define the interaction between intravenous infusion of dexmedetomidine and isoflurane in 49 women undergoing abdominal hysterectomy using minimum alveolar concentration (MAC) of isoflurane as the measure of anesthetic potency. The study included 49 women, randomly allocated to receive either a placebo infusion ( $n = 16$ ) or a two staged infusion of dexmedetomidine with target plasma concentration of 0.3 ng/mL ( $n = 17$ ) or 0.6 ng/mL ( $n = 16$ ). It was found that the MAC of isoflurane was 0.85% end tidal in the control group, 0.55% end tidal with the low-dose dexmedetomidine and 0.45% end tidal with high-dose dexmedetomidine. Similar results were observed regarding the isoflurane-sparing effect of dexmedetomidine in the current study.

Bhattacharjee *et al.*<sup>11</sup> studied the effects of dexmedetomidine infusion (0.2 mcg/kg/h) for hemodynamic stability in 60 patients undergoing laparoscopic cholecystectomy and found that MAP and HR in dexmedetomidine group were significantly less after intubation and throughout the period of pneumoperitoneum. Similar results were obtained in the present study.

Taittonen *et al.*<sup>12</sup> administered clonidine 4 mcg/kg and dexmedetomidine 2.5 mcg/kg 40-50 min before the anticipated induction of anesthesia in 30 ASA I patients and observed that HR and MAP were lower in clonidine and dexmedetomidine groups when compared to placebo group. These results are comparable to those obtained in the current study.

## CONCLUSION

Laparoscopic cholecystectomy is a routinely performed surgery and it is desirable to have a stable intraoperative hemodynamic status by avoiding hypertension, hypotension, or tachycardia. Opioids; volatile agents such as isoflurane and sevoflurane; nitroglycerine; beta blockers; etc., have been used to control perioperative stress during laparoscopy. However, the search for an ideal agent is still on. Of late,  $\alpha_2$  adrenergic agonists have generated interest in this regard. Hence, the present study was conducted to establish and compare the beneficial effect of two  $\alpha_2$  agonists, clonidine and dexmedetomidine, in maintaining perioperative cardiovascular stability during laparoscopic cholecystectomy.

On the basis of observations made during study, following conclusions were drawn:

1. Intraoperative HR was significantly lower in clonidine and dexmedetomidine groups, compared to the control group.
2. Intraoperative HR was significantly lower in clonidine group, compared to dexmedetomidine group.
3. There was no statistically significant difference in the requirement of atropine among the three groups, indicating that there was no significant rise in the episodes of bradycardia associated with the use of either clonidine or dexmedetomidine.
4. Intraoperative blood pressure (MAP) was significantly lower in clonidine and dexmedetomidine groups, compared to the control group.
5. There was no statistically significant difference in intraoperative blood pressure (MAP) between clonidine and dexmedetomidine groups.
6. Requirement of isoflurane was significantly lower in clonidine and dexmedetomidine groups, compared to the control group, indicating the inhalational agent sparing effects of the two drugs.
7. There was no statistically significant difference in the requirement of isoflurane between clonidine and dexmedetomidine groups.
8. There were no ECG changes associated with the use of the two study drugs.
9. Thus, both clonidine and dexmedetomidine favorably alter the intraoperative hemodynamics and maintain cardiovascular stability during laparoscopic cholecystectomy. In the doses used in the current study, clonidine decreased intraoperative HR more than dexmedetomidine.

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# Knowledge and Awareness Regarding Traumatic Dental Injuries in School Children among Physical Education Teachers in Patna: A Cross-Sectional Study

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## Abstract

**Introduction:** A major cause of morbidity in both developed and developing countries around the world is orofacial injuries. Traumatic dental injuries are caused by a complex array of social and environmental factors.

**Aim:** The aim of this study was to evaluate physical education teacher's knowledge and awareness in Patna regarding traumatic dental injuries among school children.

**Materials and Methods:** The study was conducted among 60 physical education teachers from randomly selected schools in Patna using modified questionnaire that was used in the study done by Randhawa *et al.*

**Results:** The study results showed that physical education teachers had completely inadequate knowledge regarding management of traumatic dental injuries among school children.

**Conclusion:** For the physical education teachers having a lack of knowledge regarding management of dental injuries, educational and motivational programs are necessary to improve their level of knowledge.

**Key words:** Dental injuries, Knowledge, Physical education

## INTRODUCTION

Traumatic dental injury (TDI) is a developing and challenging public health problem to dental health professionals, nowadays, and it has been seriously neglected worldwide.<sup>1</sup> Dental trauma refers to trauma (injury) to the teeth and/or periodontium (gums, periodontal ligament, and alveolar bone), and nearby soft tissues such as the lips and tongue and more than 20% of school-aged children reported to have been affected. Dental trauma mainly

affects the upper anterior which leads to the development of negative quality of life due to loss of function, psychological and social discomfort, lowered self-esteem and financial burden over the parents.

Dental traumatic injuries can vary from simple concussions to extensive maxillofacial damage which involves periodontal structures and displacement or avulsion of teeth. The most frequent type of injury is crown fracture, comprising 26-76% of injuries to the permanent dentition. Luxation injuries comprise 30-44% of all the dental injuries. The complete detachment of tooth from the socket is known as avulsion, which is the most complicated and serious problems comprising 1-16% of dental injuries with peak incidence record in the 7-11 years old age group and the maxillary central incisors being the most affected. It was 75% more frequent in children under the age of 15.<sup>2</sup>

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Schools are places where one can find a noticeable risk of traumatic dental injuries during playing activity. Knowledge and awareness of physical education teacher regarding emergency management of dental trauma is decisive for better prognosis. Many literatures around the world indicated the lack of knowledge of physical education teachers with regard to emergency management of traumatic dental injuries. However, no such studies related to knowledge and awareness of physical education teachers on dental trauma management have been done in Patna. The purpose of this study was to evaluate physical education teacher's knowledge and awareness in Patna regarding traumatic dental injuries among school children.

## MATERIALS AND METHODS

A modified questionnaire that was used in the study done by Randhawa *et al.* which comprises demographic information including gender, age, teaching experience, first aid training, dental trauma experience and multiple choice questions on subjective self-assessment of attitude and source of knowledge regarding management of traumatic dental injuries was used in the present study.

A total of 60 physical education teachers were enrolled in the study and it was conducted in 60 different schools of Patna over a period of 2-month from October to November 2015. The permission for the study was taken from the concerned authorities in the participating schools, and ethical clearance was obtained from institutional ethical clearance committee of Buddha Institute of Dental Sciences and Hospital, Patna. Questionnaires were personally handed over to all physical education teachers at school counters and collected after 2 days (Table 1).

## RESULTS

A total of 60 physical education teachers completed the questionnaires provided to them and participated in the study. The respondents consisted of 30% were males and 70% were females. With the exception of 55 (91.6%), only 5 (8.3%) of them had received training regarding the first aid. When they were asked regarding who all had come across dental trauma, only 16 (26.6%) had a positive response, 6 (10%) had come across broken tooth with bleeding, and 10 (16.6%) found tooth that had fallen off, whereas 2 (3.3%) had come across soft tissue injuries. When asked about the first reaction on seeing the child with trauma, only 30 (50%) replied that they would contact parents and carry the child to the dentist nearby the school, while 20 (33.3%) replied that they would give child warm drink and call parents. When asked regarding the kind of first aid they would provide to the students in the case of

**Table 1: Knowledge, attitude and practice of physical education teachers regarding the traumatic tooth injuries in school children**

Questions	N (%)
Do you have any formal training of first aid?	
Yes	5 (8.3)
No	55 (91.6)
Have you ever come across dental trauma in your school?	
Yes	16 (26.6)
No	40 (66.6)
-	4 (6.6)
What kind of trauma it was?	
Broken tooth without bleeding	5 (8.3)
Broken tooth with bleeding	6 (10)
Tooth that had fallen off	10 (16.6)
Displaced tooth	2 (3.3)
Soft tissue injuries	2 (3.3)
Others	35 (58.3)
What would be your first reaction when you see some child with trauma	
Immediately contact the parents and call them for further action	5 (8.3)
Give child warm drink and call parents	20 (33.3)
Contact parents and immediately carry child to the nearest dentist	30 (50)
None of the above	5 (8.3)
What kind of first aid would you give to your students in case of trauma?	
Sideline injured subject and ask to bite on handkerchief	10 (16.6)
Wash the affected traumatic area and look for broken toothpiece if any and seek dentist opinion	30 (50)
None of the above	20 (33.3)
Can a broken toothpiece be reattached?	
Yes	10 (16.6)
No	30 (50)
Don't know	20 (33.3)
Can a completely fallen off tooth be replanted back?	
Yes	15 (25)
No	30 (50)
Don't know	15 (25)
What would you do if you see completely avulsed or fallen off tooth or piece of tooth	
Wrap it in a clean cloth and carry to the dentist	5 (8.3)
Wash under running tap water and wrap in a clean cloth and carry to the dentist	20 (33.3)
Wash under running tap water and carry in a milk container to the dentist	7 (11.6)
Wash under running tap water and ask child to keep in the mouth and carry to the dentist	10 (16.6)
Wash under running tap water and try to replant back in the socket and carry to the dentist	1 (1.6)
Don't know	9 (15)
Others	8 (13.3)

injury, 10 (16.6%) sideline injured subject and ask them to bite on the handkerchief. Whereas 30 (50%) participants responded that they would wash affected the traumatic area and look for broken tooth piece if any and seek dentist opinion. Regarding the knowledge about management of broken tooth piece 30 (50%) responded that broken tooth piece cannot be reattached. Moreover, regarding

the replantation of completely fallen off tooth, 30 (50%) replied that it is not possible to replant the tooth back into the socket once it has completely fallen off. Regarding the immediate management of completely fallen off tooth, 20 (33.3%) answered that they would wash it under running tap water, and wrap it in a clean cloth and carry to the dentist, whereas 8 (13.3%) had belief that once a tooth is completely fallen off, it is of no use, it should be dumped in the ground or thrown in the running Ganga water.

## DISCUSSION

A major cause of morbidity in both developed and developing countries around the world is orofacial injuries. Traumatic dental injuries are caused by a complex array of social and environmental factors. Contact sports, violence, falls, traffic accidents, and poor environments have all been implicated in injuries. Traumatic dental injuries are serious dental public health problem among children and adolescents causing both functional and esthetic problems, with possible impacts on the patient's quality of life.<sup>1</sup>

Fractured teeth or its loss as a result of trauma may cause a negative impact on the physical appearance of individuals and society. According to American organization for the prevention of sports-related trauma, there are 10% chances of suffering an orofacial injury and 18.9% of 12-year-old children have suffered TDI during leisure and sports activities. Traebert *et al.* reported that majority of the accidents occurred at home (60.4%) followed by school (18.6%) and outside in street (16%).<sup>3</sup>

The future course of an injured tooth will extremely rely on a sufficient urgent administration of treatment. Physical education teachers were selected as the study group because a great deal of dental trauma may occur during sports activities in school premises. Among the 60 participants, only 5 (8.3%) respondents underwent first aid training during the course. In the study conducted by Randhawa *et al.*,<sup>4</sup> this percentage was almost same as in the present study.

When a question was asked regarding the action to be taken on seeing a child with dental trauma, only 5 (8.3%) replied that they would contact parents and ask them to take further action, which was found to be slightly higher than reported by Randhawa *et al.*

Regarding the management of broken tooth piece or completely fallen off tooth, 30 (50%) replied that broken tooth piece cannot be reattached and 50% replied that completely avulsed tooth cannot be replanted back. This strongly reflects the lack of knowledge about emergency

management of avulsed teeth among physical education teachers could be due to their lack of prior experience or information from other sources.

In response to the question, regarding, immediate management of completely fallen off tooth, the ideal treatment would be, to wash under running tap water and try to replant back in socket and carry to the dentist, but this study, only 20 (33.3%) participants opted for this option which was found to be higher than as reported by Randhawa *et al.* This could be explained by the abundant availability of private dental facilities and their idea that dental profession has a comparatively well knowledge of correct activities taken in case of tooth separation than the medical profession.

Based on this, it is of prime importance to introduce dental trauma management in physical education trainees' curriculum, which is in agreement with Chan *et al.*<sup>5</sup> The cooperative actions between dental and physical education teachers are needed to develop continued education programs, since physical education teachers are not adequately prepared to provide emergency care to dental trauma victims. From here to abstain this, it is inevitable to invest on preventive educational strategies to promote oral health, aiming to qualify these future professionals so that they are aware of their leading role when dealing with dental trauma. The results suggest that almost all of the physical education colleges have no contents regarding dental trauma in their curriculum, as is evident from their inadequate knowledge and awareness toward the matter which coincides with the results of the study conducted by Alencar *et al.*<sup>6</sup>

## CONCLUSION

The study gave a clear picture that there were insufficient knowledge and awareness of physical education teachers in Patna in the management of traumatic dental injuries. Various protocols may be used to improve the knowledge of physical education teachers including educational and motivational programs, lectures, seminars and regular visit to the school dentist.

## ACKNOWLEDGMENT

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# Evaluation of the Post-operative Analgesia in Supraclavicular Brachial Plexus Block with 0.375% Plain Bupivacaine + 0.2 mmol Potassium Chloride (0.1 ml) as an Adjuvant

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## Abstract

**Introduction:** The techniques of peripheral neural blockade were developed early in the history of anesthesia. It is approximately 130 years that brachial plexus block was first attempted that is, in 1884, Halstead injected the roots of the brachial plexus under vision, less than a year after Koller demonstrated the anesthetic properties of cocaine.

**Materials and Methods:** Patients were assigned into two groups. Group I ( $n = 50$ ) received 30 ml 0.375% bupivacaine + 0.2 mmol potassium chloride (0.1 ml) and Group II ( $n = 50$ ) received 30 ml 0.375% bupivacaine + 0.1 ml normal saline.

**Results:** This observation shows that the duration of the requirement of post-operative analgesia is significantly increased by the addition of 0.2 mmol of potassium chloride to 0.375% bupivacaine hydrochloride.

**Conclusion:** We conclude that potassium chloride when added to 0.375% bupivacaine for supraclavicular brachial plexus block increased the duration of post-operative analgesia.

**Key words:** Bupivacaine, Potassium chloride, Supraclavicular

## INTRODUCTION

The international association for the study of pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”<sup>1,2</sup>

It is always a subjective experience. Pain has been a major concern of humankind, and it has been the object of ubiquitous efforts to understand and to control it. Peripheral nerve block provides longer and more localized

pain relief than neuraxial technique while also avoiding the side effects of systemic medications. Regional anesthesia of the extremities and the abdomen is a useful alternative to general anesthesia in many situations.<sup>3</sup>

Since the discovery of local anesthetic drugs, the anesthesiologists have become increasingly involved in the provision of post-operative analgesia; the need of pain relief during surgery without loss of consciousness which is appreciated more, both by anesthesiologists and surgeons.<sup>4,5</sup>

In the past two decades, two factors have brought about a reappraisal of regional techniques. First, a local block in combination with controllable sedation so that the patient stay awake during surgery, and second, realization has grown that excellent post-operative pain relief can be provided easily and in no time to the patient with an appropriate regional blockade.<sup>6</sup>

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The techniques of peripheral neural blockade were developed early in the history of anesthesia. It is approximately 130 years that brachial plexus block was first attempted that is, in 1884, Halstead injected the roots of the brachial plexus under vision, less than a year after Koller demonstrated the anesthetic properties of cocaine. Later, studies revealed that the nerves supplying the arm and the forearm are geographically grouped closely together in the brachial plexus, and a single injection could provide analgesia for the whole limb.<sup>7-9</sup>

D. Kulenkampff introduced the technique of supraclavicular brachial plexus block a few months after Hirschel described the axillary approach.<sup>10</sup> Early reports indicated a frequent incidence of success with this block, but other practitioners soon reported complications such as pneumothorax and mediastinal emphysema. Several modifications of the supraclavicular block have emerged in an effort to avoid pneumothorax.<sup>6</sup>

Regional techniques have become the preferred choice of anesthesiologists whenever possible, reasons being:<sup>7</sup>

- Less interference with general body physiology. Stress-induced changes in body metabolism and hormonal milieu is minimal
- Relatively simple to administer and preserves consciousness and protective reflexes
- Reduced post-operative nursing care
- Mental function is preserved in an elderly patient
- Lesser quantity of drugs used as compared to general anesthesia, so fewer drug interactions and side effects
- Prolonged post-operative analgesia
- No risk of operation theater pollution as noted with inhalational agents.

Now a days, the neural blockade has become widely accepted and reliable technique to achieve analgesia and anesthesia in the area supplied by brachial plexus. Different local anesthetics are used for this purpose. Most widely used and easily available among which is bupivacaine. Due to its wide use and easy availability, this drug naturally lends itself as the first choice for study.<sup>11</sup>

Numerous routes to perform brachial plexus block have been described. They are:

- Supraclavicular
- Interscalene
- Infraclavicular
- Axillary.

The supraclavicular route was used in this study.<sup>12-14</sup>

The technique, however, is not without complications.

The limitations of local anesthetics are:

- Slower onset of action
- Shorter duration of action
- Reduced motor and sensory blockade.

Therefore, different adjuncts have been tried to fill the lacunae created by the local anesthetics. Various workers have investigated adjuvants including opioids, clonidine, neostigmine, hyaluronidase, dexamethasone, and bicarbonate.<sup>15-19</sup>

Alpha 2-adrenoreceptor agonists have been used a number of times for their sedative, analgesic, perioperative sympatholytic, and cardiovascular stabilizing effects.<sup>20</sup>

Subsequently, Aldrete *et al.*, in 1969, and Parris and Chambers, in 1986, also found some encouraging results using potassium with local anesthetics such as lignocaine and bupivacaine.<sup>21</sup>

Thus, we thought it worthwhile to try 0.2 mmol potassium chloride (0.1 ml) as an adjuvant with 0.375% bupivacaine (Group I) and its comparison with 0.375% bupivacaine (Group II) in supraclavicular brachial plexus block.

## MATERIALS AND METHODS

- The study was conducted after obtaining approval from ethical, academic committee and a written informed consent from the patient.

The study will be conducted in two groups comprising of 50 patients in each group.

- Group I: 0.375% plain bupivacaine (30 ml) + 0.2 mmol potassium chloride (0.1 ml)
- Group II: 0.375% plain bupivacaine (30 ml) + 0.9% normal saline (0.1 ml).

The following group of patient will be excluded from the study:

- Patient not willing to get enrolled, in the study
- Age below 18 years or above 60 years
- Infection at block site
- Patient with clavicle fracture, bleeding disorder
- Patient with torticollis, pre-existing peripheral neuropathy
- Patient with systemic diseases such as diabetes mellitus and hypertension
- Patient with hyperkalemia
- Surgery duration >4-5 h.

## Pre-operative Preparation

All the patients were visited and evaluated thoroughly on the day before the surgery. During the pre-anesthetic

evaluation, a thorough examination of all the systems was done; including the surface anatomy where the block was given. A meticulous airway assessment was carried out. The anesthetic procedure to be undertaken including the development of paresthesia was explained to the patients, and an attempt was made to alleviate the anxiety of patient. A written informed consent was taken. Pre-anesthetic preparation of a patient included a period of overnight fasting. Sedative and hypnotic were avoided as premedication, as well as in the intraoperative period routine investigations such as complete blood count, urine examination (routine and microscopy), bleeding time and clotting time, blood sugar level, blood urea level, serum creatinine, Chest X-ray, ECG, HIV, and HbsAg were done.

Brachial plexus block was given by supraclavicular approach. Neural localization was achieved by a nerve stimulator (Fisher and Paykel, New Zealand), connected to 22 G, 50 mm long stimulating needle. After negative aspiration, 30 cc of solution with and without adjuvants was given. A 3 min massage was given for even distribution of drug over brachial plexus.

### Assessment

#### Sensory block

Sensory block was assessed by pinprick method in all dermatomal areas corresponding to radial, ulnar, median, and musculocutaneous nerves, every minute till complete sensory block.

#### Grading

1. Grade 0: Sharp pin felt
2. Grade 1: Analgesia, dull sensation felt
3. Grade 2: Anesthesia, no sensation felt.

#### Motor block

Motor block will be assessed on modified Bromage scale for upper extremity on a three-point scale.

#### Grading

1. Grade 0: Normal motor function with full extension of elbow, wrist, and fingers
2. Grade 1: Decreased motor strength with ability to move the fingers only
3. Grade 2: Complete motor block with inability to move fingers.

#### Operative quality

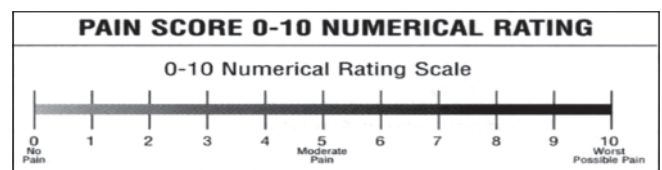
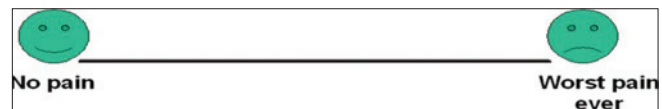
Operative quality will be assessed on the following numeric scale.

- Grade 4 (excellent): No complaint from patient.
- Grade 3 (good): Minor complaint with no need for supplemental analgesia.
- Grade 2 (moderate): Complaint that required

supplemental analgesia.

- Grade 1 (unsuccessful): Patient given general anesthesia.
- Post-operative analgesia will assessed on VAS (visual analog score) from 0 to 10.
- Patient will not be shown the numbered scale.

## OBSERVATION AND RESULTS



Numerical rating scale

## RESULT

- In the present study, 100 ASA I and II patients of both sexes and different age group between 18 and 60 years were studied. All of them underwent upper extremity surgeries. The study included only those patients who had successful surgical anesthesia from the supraclavicular brachial plexus block alone. Patients who required general or local anesthesia supplementation or IV opioids or analgesics were excluded from the study.
- The study will be conducted in two groups comprising of 50 patients in each group.
- Group I ( $n = 50$ ) received 30 ml 0.375% bupivacaine + 0.2 mmol potassium chloride (0.1 ml).
- Group II ( $n = 50$ ) received 30 ml 0.375% bupivacaine + 0.1 ml normal saline.
- The mean age of Group I was 35.88 and in Group II was 39.52, respectively. Statistical analysis when compared between two groups for age was found to be insignificant ( $P > 0.5$ ) (Table 1 and Graph 1).
- The mean height of Group I was 165.64 cm and in Group II was 165.84 cm, respectively. Statistical analysis when compared between two groups for height was found to be insignificant ( $P > 0.5$ ) (Table 1 and Graph 1).
- The mean weight of Group I was 66.60 and in Group II was 67.64, respectively. Statistical analysis when

compared between two groups for weight was found to be insignificant ( $P > 0.5$ ) (Table 1 and Graph 1).

- There were 9 female patients in Group I as compared to 11 female patients in Group II, and there were 41 male patients in Group I as compared to 39 female patients in Group II. Statistical analysis when compared between two groups for sex was found to be insignificant ( $P > 0.05$ ).
- The mean heart rate of Group I was 78.32 and in Group II was 78.36, respectively. Statistical analysis when compared between two groups for age was found to be insignificant ( $P > 0.5$ ).
- The mean systolic blood pressure of Group I was 126.70 and in Group II was 128.72, respectively. Statistical analysis when compared between two groups for systolic blood pressure was found to be insignificant ( $P > 0.5$ ).
- The mean diastolic blood pressure of Group I was 72 and in Group II was 75.32, respectively. Statistical analysis when compared between two groups for diastolic blood pressure was found to be insignificant ( $P > 0.5$ ).
- The time of requirement of post-operative analgesia in Group I was  $512.04 \pm 28.80$  as compared to in Group II was  $240.90 \pm 19.42$  (Table 2 and Graph 2).
- Statistical analysis when compared between two groups for the post of analgesia was found to be significant ( $P < 0.001$ ).

## DISCUSSION

The present study entitled to evaluate the post-operative analgesia in supraclavicular brachial plexus block with 0.375% plain bupivacaine + 0.2 mmol potassium chloride (0.1 ml) as an adjuvant was undertaken on 100 patients of upper limb surgery to clinically assess the effects of adding small amounts (0.2 mmol) of potassium chloride to 0.375% bupivacaine hydrochloride on the onset, duration, and quality of supraclavicular brachial plexus block. Supraclavicular brachial plexus block was chosen because of its relative easiness and low incidence of serious complications.

Brachial plexus blockade provides ideal operating conditions for the surgeon with good analgesia and complete muscular relaxation and sympathetic block which reduces post-operative vasospasm, pain, and edema. Although bupivacaine has prolonged the duration of action its long latency makes it unsuitable for routine use in a busy clinical environment for giving brachial plexus block.

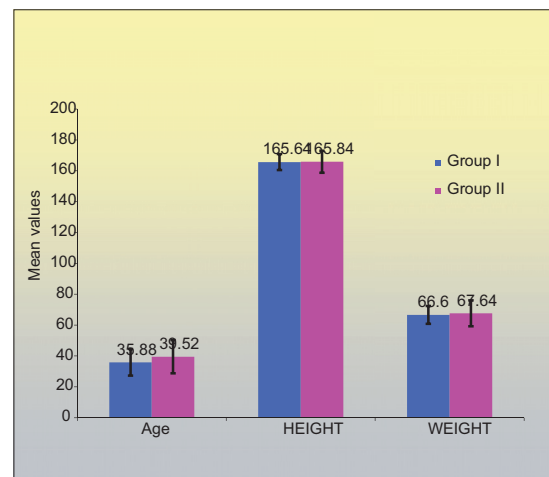
Potassium salts, as an adjuvant to local anesthetic, have been used with varying success for many years.<sup>22,23</sup> Since then, many authors have studied their effects on the local

**Table 1: Age, height, and weight distribution in two groups**

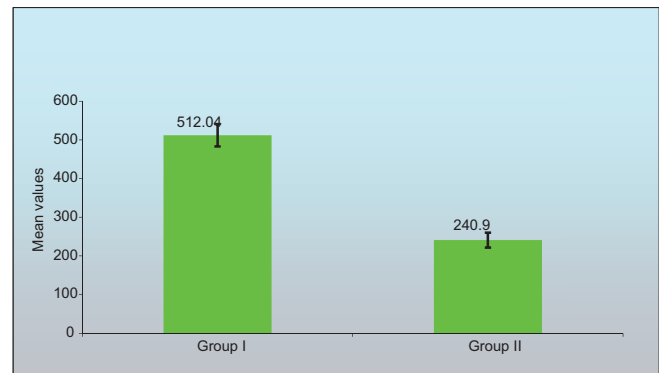
Variables	Mean $\pm$ SD		P value
	Group I (n=50)	Group II (n=50)	
Age (years)	35.88 $\pm$ 8.63	39.52 $\pm$ 10.73	0.065
Height (cm)	165.64 $\pm$ 5.20	165.84 $\pm$ 7.10	0.873
Weight (kg)	66.60 $\pm$ 5.79	67.64 $\pm$ 8.39	0.473

**Table 2: Requirement of post-operative analgesia**

Variables	Mean $\pm$ SD		P value
	Group I (n=50)	Group II (n=50)	
Post-operative analgesia (min)	512.04 $\pm$ 28.80	240.90 $\pm$ 19.42	<0.001



**Graph 1: Comparison of Demographic profile of patients between Group I and Group II**



**Graph 2: Comparison of post-operative analgesia between Group I and Group II**

anesthetic and reported some encouraging results. In their study on the extradural blockade, Bramage and Michael<sup>24</sup> observed a shortened latency of spread, more intense quality of sensory block and increased the duration of block when 1% potassium chloride was added to 2% lignocaine. Parris and Chambers<sup>25</sup> and Khosa *et al.*<sup>26</sup> in



their study on axillary and supraclavicular brachial plexus block, respectively, and also reported better results by the addition of potassium chloride to bupivacaine solutions.

### Distribution of Patient According to Age, Sex, and Weight

In the present study, age, sex, and weight of the patients were comparable in both the groups. Statistical analysis of age, sex, and weight when compared between two groups was not significant ( $P > 0.05$ ).

### Volume, Strength, and Dose of Bupivacaine Used

Mean volume of bupivacaine hydrochloride injected was 30.1 ml in Group II as compared to 30.1 ml in Group I for supraclavicular brachial plexus block. In Group I, 0.2 mmol of potassium chloride (0.1 ml) was added to bupivacaine hydrochloride before making the block. In the present study, bupivacaine hydrochloride was used in the strength of 0.375% in both the groups.

Parris and Chambers<sup>25</sup> used 40 ml of 0.25% bupivacaine solution irrespective of the weight of the patients with or without the addition of potassium chloride 0.2 mmol in their study on axillary brachial plexus block, whereas 30 ml of 0.37% bupivacaine irrespective of the weight of the patients with or without the addition of potassium chloride 0.2 mmol was used by Khosa *et al.*<sup>26</sup> in supraclavicular brachial plexus block.

### Duration of Post-operative Analgesia

In the present study, mean duration for post-operative analgesia was  $512.04 \pm 28.80$  min in Group I as compared to  $240.90 \pm 19.42$  min in Group II. On comparing the results between two groups, they found to be significant statistically ( $P < 0$ ).

This observation shows that the duration for post-operative analgesia is significantly increased by the addition of 0.2 mmol of potassium chloride to 0.375% bupivacaine hydrochloride.

Our results are comparable with those of Swetha,<sup>27</sup> who also reported an increase in duration of post-operative analgesia when 0.2 mmol potassium chloride was added to 0.375% bupivacaine for supraclavicular brachial plexus block.

Agarwal *et al.*<sup>28</sup> had reported the duration of post-operative analgesia to be  $241 \pm 51.2$  min with 0.325% bupivacaine.

Above observation suggests that the addition of potassium chloride to bupivacaine prolongs the post-operative analgesia requirement. Aldrete *et al.*<sup>21</sup> attributed this delay in terms of the difference of potassium concentration, thus slowing the recovery of the resting potential. The local anesthetic

deposited prevents its depolarization rendering it impermeable to Na ions, but K ions are allowed to migrate, due to different gradient existing on both sides of the membrane. Exogenous potassium outside the nerve will prevent such movement which causes delay in the repolarization, and thus the duration of anesthesia is prolonged.

### Cardiorespiratory Changes

In the present study, cardiorespiratory changes were found to be minimal in most of the cases of both the groups. On statistical analysis, cardiorespiratory changes were found to be insignificant when compared between two groups.

No irregularities in pulse or blood pressure were recorded in any of the groups.

These observations suggest that the addition of small amounts of (0.2 mmol) of potassium chloride to 0.375% bupivacaine did not produce any significant cardiorespiratory changes. Other workers did not report any cardiorespiratory changes on brachial plexus block with the use of bupivacaine either alone or with potassium chloride.

### Complications

No complications were reported in both the groups. Addition of potassium chloride to bupivacaine also did not produce any complications.

Bramage and Michael reported a case of convulsions following inadvertent perforation of spinal dura while performing extradural blockade and thereby injecting large concentrations of potassium into the subarachnoid space.

In our study, we have given the fixed dose of the study drugs irrespective of the patient's age, weight, or body surface area.

## CONCLUSION

- Supraclavicular brachial plexus block is a useful method of providing anesthesia for surgery of upper limb.
- The method of blocking the brachial plexus by injecting at the highest point and applying digital pressure for 10 min immediately after giving the block, results in high success rate and low incidence of inadequate block.
- Bupivacaine hydrochloride provides long duration of action, but the latency of blockade is also prolonged.
- The duration of post-operative analgesia requirement of bupivacaine hydrochloride is significantly prolonged by the addition of 0.2 mmol of potassium chloride.
- Addition of 0.2 mmol of potassium chloride to 0.375%

bupivacaine hydrochloride does not have any effect on the quality of block.

- Cardiorespiratory changes are almost negligible with the use to 0.2 mmol of potassium chloride with bupivacaine hydrochloride.

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# Common Etiology of Acute Fever with Thrombocytopenia in a Tertiary Care Hospital, Mysuru

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## Abstract

**Background:** Acute fever with thrombocytopenia is a common problem with increased mortality and morbidity if not diagnosed and treated properly in time. So, in addition to common causes such as dengue, malaria, chikungunya, enteric fever, and sepsis, it is wise to suspect rickettsial in patients with rash and multiorgan dysfunction syndrome (MODS) also as therapy is simple and results rewarding.

**Materials and Methods:** A total of 150 patients who were admitted to Krishna Rajendra Hospital, Mysuru, Karnataka, India during June 2014 to November 2015 were retrospectively studied.

**Results:** Most common cause was dengue and unspecified fevers followed by sepsis. 6.6% cases had fever and rash and MODS raising a high degree of suspicion for rickettsial, and they responded well to Doxy. Only 6 patients had bleeding and it occurred only in patients with platelet count <20,000. In our study, mortality occurred in total 7 cases.

**Conclusion:** Fever with thrombocytopenia is a very common problem. Unspecified fevers were the most common followed by dengue and sepsis and next most probably rickettsial. So, it is necessary to also keep rickettsial diagnosis in mind as we can reduce mortality and morbidity can be reduced with simple DOXY therapy. Further prospective studies are needed to uphold this.

**Key words:** Fever with thrombocytopenia, Multiorgan dysfunction syndrome, Rash, Rickettsial

## INTRODUCTION

Acute fever with thrombocytopenia (platelet count less than 150,000) is a common clinical problem in our medical wards. Common causes include dengue, malaria, leptospirosis, chikungunya, enteric fever, rickettsial fever, and Japanese encephalitis.<sup>1,2</sup>

Fever with thrombocytopenia patients having multiorgan dysfunction is better evaluated for scrub typhus as the treatment is so simple with doxycycline and rewarding. Otherwise, they go for mortality and morbidity.

Scrub typhus could be one of the important causes of acute febrile illness with multiorgan involvement. Many of the cases remain undiagnosed and therefore not treated resulting in high mortality.

Scrub typhus is grossly under-diagnosed in India due to its non-specific clinical presentation, limited awareness and low index of suspicion among clinicians, and lack of diagnostic facilities.<sup>3-5</sup>

The World Health Organization identifies scrub typhus as a re-emerging disease in South-East Asia and the South-Western Pacific region with a case fatality rate of up to 30% in untreated cases and stresses the need for its surveillance.

Rickettsial diseases in India: Not as uncommon as believed. Even scrub typhus is common in the month of July to November when dengue, chikungunya, leptospira, malaria, etc., are also more in the same months.

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Scrub typhus is under-reported in our area, and it should be considered as an important differential diagnosis in febrile patients with thrombocytopenia, especially with multiorgan dysfunction syndrome (MODS).<sup>6-10</sup>

Early diagnosis and appropriate treatment is rewarding and prevents morbidity and mortality in rickettsial disease.

So, this study is intended to find out the various causes of acute fever with thrombocytopenia in our patients and with special reference to rickettsial illness. Moreover to assess outcome associated with various etiology and to correlate the clinical features and other laboratory parameters.

### Objectives of the Study

1. To identify the various causes of fever with thrombocytopenia with special reference to scrub typhus
2. To correlate clinical features and laboratory parameters
3. To assess the complications associated with fever and thrombocytopenia
4. To assess the prognosis of the disease condition.

## MATERIALS AND METHODS

The study was conducted on 150 subjects who were admitted to Krishna Rajendra Hospital, Mysuru during June 2014 to Nov 2015. Selection of patients done according to inclusion and exclusion criteria. Details will be entered according to prestructured proforma.

### Inclusion Criteria

All patients who were diagnosed with fever with thrombocytopenia, i.e., platelet count less than 1.5 laks at KRH between June 2014 and November 2015 were eligible for inclusion in this study.

### Exclusion Criteria

1. Patients with fever with thrombocytopenia other than infective etiology like immune thrombocytopenia, drug-induced thrombocytopenia, hemolysis, elevated liver enzymes and low platelets, myeloproliferative diseases, disseminated intravascular coagulation of non-infective etiology (abruptio placentae, snake bite)
2. Patients with chronic liver disease
3. Patients with autoimmune diseases.

This was a retrospective study analyzing the case sheet records to know various causes of acute fever with thrombocytopenia and how many had complications such as bleeding and multiorgan dysfunction.

### Study Design

Retrospective study.

### Statistical Methods

Data collected will be analyzed by frequency, percentage, mean, standard deviation, and Chi-square test.

## RESULTS

In our study, 150 patients were admitted with acute fever with thrombocytopenia due to various causes. 90 were males and 60 females (Figure 1).

Maximum number of patients were in the age group of 18-24 years followed by 25-34 years group (Figure 2).

Among cases of acute fever, majority were unspecified fever who responded to our clinical judgment and empirical treatment even though they could not be evaluated for confirmation of the diagnosis. Next, it was followed by dengue fever (20 cases NS 1 positive, 5 cases immunoglobulin M [IgM] positive, and 5 cases IgG positive). Moreover, 10 cases with MODS responded well to Doxy therapy. 12 cases of sepsis were having a focus of sepsis and high temperature and high leukocyte count and SIRS features. Among 3 cases of Malaria, 1 was *Plasmodium*

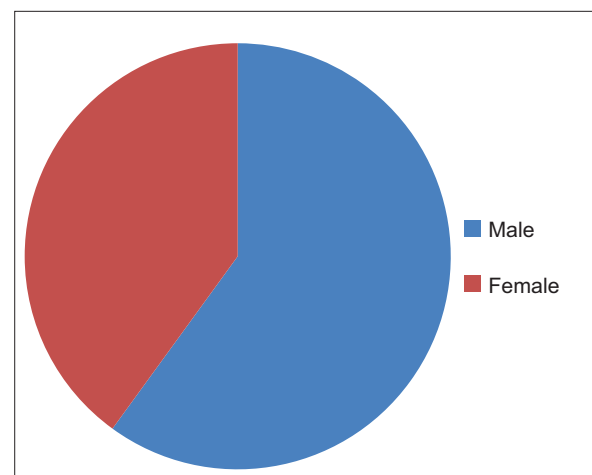


Figure 1: Sex wise distribution

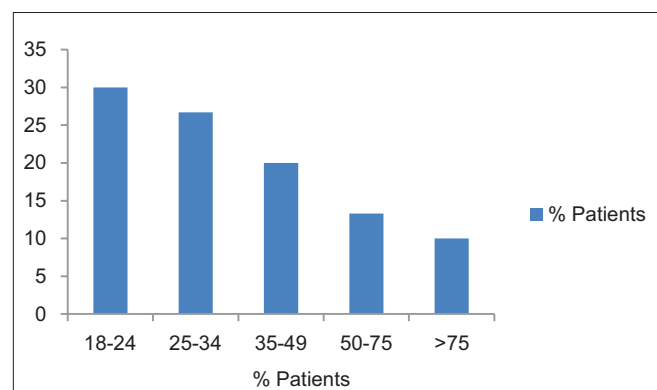


Figure 2: Age wise distribution of patients

*vivax* positive and 2 others even though smear negative responded to antimalarial therapy (Table 1).

Maximum number of patients had platelet count between 50,000-100,000 (Table 2).

In our study, only 6 patients had bleeding and it occurred only in patients with platelet count <20,000. All were managed successfully with platelet transfusion and other therapy (Table 3).

In our study, mortality occurred in total 7 cases. Out of that three cases with sepsis went into multiorgan dysfunction including acute respiratory distress syndrome, and acute kidney injury. In unspecified fever group, 4 cases who were suspected of having? *Leptospira* succumbed with MODS (Table 4).

## DISCUSSION

Acute fever with thrombocytopenia is a very common problem faced by all physicians day to day in medical wards. When diagnosis is made properly and treated, early results are good, and we can prevent mortality and morbidity. Even though the most common causes are dengue, malaria, leptospirosis, chikungunya, enteric fever, rickettsial fever also should be thought in the evaluation.

Rickettsia diseases are not as uncommon as believed in our population. Only, it needs a high degree of suspicion

**Table 1: Causes of acute fever with thrombocytopenia**

Diagnosis	Number of patients (%)
Unspecified fever	92 (61.4)
Dengue	30 (20)
Acute fever with MODS who responded to Doxy (?scrub typhus)	10 (6.6)
Sepsis	12 (8)
Malaria	3 (2)
Typhoid	3 (2)

MODS: Multiorgan dysfunction syndrome

**Table 2: Number of patients with various levels of thrombocytopenia**

Platelet count	Number of cases (%)
<10,000	1 (1.5)
10,000-20,000	16 (24)
20,000-30,000	10 (15)
30,000-50,000	30 (45)
50,000-75,000	40 (60)
75,000-1,00,000	30 (45)
>1,00,000	23 (34.5)
Total	150

that too a febrile patient having a rash, thrombocytopenia, and not responding to routine treatment and progressing to MODS. We should evaluate for scrub typhus and treat.

In our study, the majority had unspecified (?viral) fevers (61.4%). The reason for this may be most of our patients are from poor background, and they could not get serology for dengue, chikungunya, leptospira, scrub typhus done from outside laboratory due to financial constraints. However, in this group also 35-40 cases were clinically looking like dengue. Other 20 cases had features suggestive of chikungunya, 10 cases we suspected leptospira (combination of raised bilirubin and raised creatinine), 10 cases malaria (spikes of high fever with chills and rigors), and 6 cases had rash and fever and responded to Doxy so mostly rickettsial.

Remaining cases looked like sepsis with high total leukocyte count but no demonstrable focus of sepsis.

In our study, dengue was the most common as we included IgM, IgG, and NS1 positive cases and those cases in the unspecified group having dengue-like features (Table 5).

**Table 3: Patients showing different type of bleeding manifestations**

Type of bleeding	Number of cases	Platelet count
Gum bleeding	1	<10,000
Petechiae	2	10,000-20,000
Hematuria	1	10,000-20,000
Menorrhagia	1	10,000-20,000
Bleeding PR	1	10,000-20,000

**Table 4: Outcome**

Diagnosis	Total number of cases	Good recovery	Mortality
Unspecified fevers	92	88	4
Dengue	30	30	0
Acute fever with MODS who responded to Doxy (?scrub typhus)	10	10	0
Septicemia	12	9	3
Malaria and typhoid	3	3	0
	3	3	0

MODS: Multiorgan dysfunction syndrome

**Table 5: Comparison of causes of fever with thrombocytopenia**

Disease	Present study (%)	Nair <i>et al.</i> (%)	Patil <i>et al.</i> (%)	Dash <i>et al.</i> (%)
Dengue	46.6	13.8	15	20
Malaria	8.6	9.2	54	45
Enteric fever	2	14.7	6	10
Others	42.8	62.3	25	25



Comparatively, enteric fevers were less in our study.

As we do not have facility of doing Weil–Felix test, we could not confirm the diagnosis of scrub typhus. However, patients with fever rash thrombocytopenia with MODS, we empirically started Doxy after they failed to other therapy and they responded well. Hence, this group could be rickettsial?

## CONCLUSION

Fever with thrombocytopenia is a very common problem. Unspecified fevers were the most common followed by dengue and sepsis and next most probably rickettsial. So, it is necessary to also keep rickettsial diagnosis in mind as we can reduce mortality and morbidity can be reduced with simple DOXY therapy. Further prospective studies are needed to uphold this.

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# Systemic Complication of Falciparum Malaria in Tertiary Care Hospital at Mysore: A Clinical Study

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## Abstract

**Introduction:** Malaria is the most important parasitic disease of man. The human disease is a protozoan infection of red blood cells transmitted by the bite of a blood-feeding female anopheles mosquito. Malaria is one of the leading causes of morbidity and mortality worldwide, with over 100 million cases and at least a million deaths a year. It is estimated that over 40% of all deaths from malaria in the country are due to *Plasmodium falciparum* infection.

**Materials and Methods:** It is a retrospective study conducted on patients admitted to K R Hospital, Mysore, was conducted in January 2013 to January 2015, a total of 50 patients were admitted during this period. As per inclusion criteria and exclusion criteria, cases are included and excluded and a pre-structured proforma was used and data were entered. The study is approved by the Institutional Ethical Committee.

**Results:** Most of the cases are young, males are more than female (2:1), and most cases were referred from endemic areas. Total case fatality rate is 14%. Cerebral malaria is the most common cause of death. Early diagnosis and prompt treatment will reduce the morbidity and mortality associated with falciparum malaria.

**Conclusion:** Community participation is the key for the success of any health program. It is necessary to involve the community at large and create awareness about the problems of falciparum malaria.

**Key words:** Cerebral malaria, Community participation, Health program, Falciparum malaria

## INTRODUCTION

Malaria is the most important parasitic disease of man. The human disease is a protozoan infection of red blood cells transmitted by the bite of a blood-feeding female anopheles mosquito. Malaria is one of the leading causes of morbidity and mortality worldwide, with over 100 million cases and at least a million deaths a year.<sup>1,2</sup> Most of these deaths are in the poorest regions of the world. Because malaria is a highly complex disease caused by plasmodium species, the diversity of research to prevent and treat it is probably greater than for any other disease.<sup>3</sup>

At present, about 100 countries in the world are considered endemic, almost half of which are in Sub-Saharan Africa. More than 2.4 million of world's population is still at risk. Malaria is thought to kill between 1.1 and 7 million people worldwide each year. However, the problem is even more in rural and remote areas, where patients have restricted access to adequate treatment.<sup>4,5</sup>

In India, about 70% of the infections are reported to be due to *Plasmodium vivax*; 21-30% due to *Plasmodium falciparum* and 4-8% due to mixed infection. *Plasmodium malariae* infections are <1% and are reported from Tumkur and Hassan districts of Karnataka.<sup>6</sup>

## Epidemiology

The transmission of malaria requires interaction of epidemiological factors:

1. The human host (intermediate host)
2. Malarial parasite (agent)
3. The anopheles mosquito (vector)
4. Environment (physical, biological, and socioeconomic).

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### Life Cycle

The malaria parasite undergoes 2 cycles of development.

1. The human or asexual cycle (endogenous/schizogony)
  - a. Exoerythrocytic or hepatic phase
  - b. Erythrocytic phase.
2. The mosquito or sexual cycle (exogenous/sporogony).  
Man is the intermediate host, and mosquito is the definitive host.

### Clinical Features

It varies from asymptomatic parasitemia to fulminant lethal malaria. The first symptoms of malaria are non-specific and start with a headache, muscular ache, vague abdominal discomfort, lethargy, lassitude, and dysphoria often precede fever by up to 2 days. It is followed by chills, rigors, arthralgia, pain abdomen, diarrhea, cough, and cold in some cases. Other clinical features are jaundice, hepatomegaly, splenomegaly, and anemia.

The typical attack comprises of three stages:

Cold stage, hot stage, sweating stage.

The febrile paroxysm synchronizes with erythrocytic schizogony of the malarial parasite.

## MATERIALS AND METHODS

All the cases of *P. falciparum* malaria, diagnosed either by peripheral smear or by quantitative buffy coat method, admitted to K R Hospital during the study period were screened thoroughly. Among them, 50 cases with systemic complications proposed by the WHO were taken for the study. Cases were selected on the basis of the simple random sampling method. A detailed history and thorough clinical examination was done as per the proforma and were investigated further.

### Inclusion Criteria

All cases of *P. falciparum* malaria, with following systemic complications as per WHO, were included in the study.

1. Cerebral malaria
2. Generalized convulsions
3. Severe anemia
4. Hypoglycemia
5. Fluid and electrolyte disturbances
6. Metabolic acidosis
7. Jaundice
8. Algid malaria
9. Hemoglobinuria
10. Acute respiratory distress syndrome
11. Acute renal failure
12. Abnormal spontaneous bleeding
13. Hyperpyrexia.

### Exclusion Criteria

Patients below 12 years of age were excluded.

## RESULTS

In the present study total case fatality rate is 14%. The case fatality rate is highest in hemoglobinuria (100%) followed by 33.3% in algid malaria, 27.7% in cerebral malaria and 16.6% in jaundice. The majority of the deaths are males (71.4%) and between the age group of 31-40 years (42.8%).

The present study include more number of male subjects and are age between 21 and 40 years as shown in Table 1, and most cases between July to December as shown in Table 2. In present study majority of subjects are presented to us with anemia, jaundice and cerebral malaria as shown in Table 3, all these are statistically significant.

In present study showed case fatality is more for hemoglobinuria (100%) but most subjects presented with cerebral malaria having case fatality rate of 27.7% as shown in Table 4.

In present study majority subjects are between 21 and 40 year but case fatality is more for older (>50) year and younger (<20 year) subjects and also those with cerebral malaria has more chances of mortality. Mortality is more in male subjects and mortality increases as the length of hospital stay increase as shown in Table 5.

## DISCUSSION

Malaria still continues to be a major health problem in this part of the state. Although there has been a decline in the

**Table 1: The age and sex distribution of the cases**

Age group (years)	Male (%)	Female (%)	Total (%)
13-20	3 (9.1)	2 (11.8)	5 (10)
21-30	13 (39.4)	4 (23.5)	17 (34)
31-40	10 (30.3)	6 (35.3)	16 (32)
41-50	4 (12.1)	2 (11.8)	6 (12)
51-60	2 (6.1)	2 (11.8)	4 (8)
>60	1 (3.0)	1 (5.8)	2 (4)
Total	33 (100)	17 (100)	50 (100)

Mean age=34.4 years; SD= ±13 years. SD: Standard deviation

**Table 2: The seasonal occurrence of the cases**

Month	Number (%)
January-March (I)	8 (16)
April-June (II)	10 (20)
July-September (III)	18 (36)
October-December (IV)	14 (28)
Total	50 (100)

**Table 3: Various complications**

Complications	Male (%)	Female (%)	Total (%)	P value	Inference
Jaundice	13 (54.1)	11 (45.9)	24 (48)	<0.05	S
Severe anemia	15 (68.1)	7 (31.9)	22 (44)	<0.05	S
Cerebral malaria	12 (66.6)	6 (33.4)	18 (36)	<0.05	S
Algid malaria	2 (66.6)	1 (33.4)	3 (6)	<0.05	S
Renal failure	2 (100)	0 (0)	2 (4)	<0.05	S
Hemoglobinuria	1 (100)	0 (0)	1 (2)	<0.05	S
Hypoglycemia	3 (75)	1 (25)	4 (8)	<0.05	S
Generalized convulsions	3 (100)	0 (0)	3 (6)	<0.05	S

S: Significant

**Table 4: The CFR of various complications**

Complications	Cases	Number of expired*	CFR (%)
Cerebral malaria	18	5	27.7
Algid malaria	3	1	33.3
Hemoglobinuria	1	1	100
Jaundice	24	4	16.6
Severe anemia	22	2	9

\*Intermixed, CFR: Case fatality rates

**Table 5: The case fatality rates and percentage of total expired in various patient parameters**

Parameters	Recovered <i>n</i> <sub>1</sub> =43	Expired (%) <i>n</i> <sub>2</sub> =7	Total <i>n</i> =50	CFR (%)
Age (years)				
13-20	4	1 (14.2)	5	20
21-30	16	1 (14.2)	17	5.8
31-40	13	3 (42.8)	16	18.7
41-50	5	1 (14.2)	6	16.6
51-60	3	1 (14.2)	4	25
>60	2	-	2	-
Sex				
Male	28	5 (71.4)	33	15.1
Female	15	2 (28.5)	17	11.7
Duration of symptoms (days)				
1-5	25	-	25	-
5-10	18	1 (14.3)	19	5.2
10-15	-	6 (85.7)	6	100
Complications*				
Jaundice	20	4 (57.1)	24	16.6
Severe anemia	20	2 (28.5)	22	9
Cerebral malaria	13	5 (71.4)	18	27.7
Algid malaria	2	1 (14.2)	3	33.3
Hemoglobinuria	-	1 (14.2)	1	100
Hyperbilirubinemia				
Conjugated	11	3 (42.8)	14	21.4
Unconjugated	8	2 (28.5)	10	20

\*Intermixed, CFR: Case fatality rates

total number of cases, *P. falciparum* has registered a significant increase. It causes the most severe form of malaria and is known for its protean manifestations, variety of complications and high mortality. Development of complications is more common in patients suffering from *P. falciparum*.

In the present study, 50 cases of falciparum malaria with systemic complications were studied; the following data were compared with standard studies.

**Table 6: The comparison of clinical features in various studies**

Clinical features	Present study (%)	Hazra <i>et al.</i> (%)	Chishti <i>et al.</i> (%)	Murthy <i>et al.</i> (%)
Fever	100	100	100	98.1
Paroxysms	40	40	-	-
Headache	84	100	-	-
Bodyache	76	-	-	-
Nausea/vomiting	52	60	-	-
Pallor	60	80	76.56	-
Jaundice	48	40	29.6	27.21
Hepatomegaly	40	80	37.5	-
Splenomegaly	48	40	37.5	-
Altered sensorium	36	8.33	59.38	48
Abdominal pain	6	10	-	-
Loose stools	2	10	10.9	-
Cough and cold	8	53.33	-	-
Respiratory distress	-	6.6	6.25	-
Convulsions	6	8.33	14.06	-
Spontaneous bleeding	-	3.33	12.5	4.43
Decreased urine output	4	5	26.56	6.96
Edema	-	-	-	-
Black color urine	2	3.33	-	-
Hypotension	6	-	-	18.35

In the present study, age, sex distribution, and seasonal variation are comparable to Harris *et al.*, Shukla *et al.*, Chishti *et al.*, and Murthy *et al.*

### Clinical Features

In the present study, fever was encountered in all the patients (100%). This was also the most common symptom observed in Chishti *et al.* (100%), Hazra *et al.* (100%), and Murthy *et al.* (98%). However, typical paroxysms were observed only in 40% cases, which is a deviation from the frequent description of common classical paroxysms. This finding is consistent with Hazra *et al.* where paroxysms were seen only in 40% of the cases (Table 6).

Jaundice was seen in 48% of the cases in the present study, as compared to 40% in Hazra *et al.*, 29.6% in Chishti *et al.*, and 27.2% in Murthy *et al.*

In the present study, generalized convulsions were seen in 6% of the cases as compared to 8.33% in Hazra *et al.* and 14.06% in Chishti *et al.*

**Table 7: Comparison of complications seen in various studies**

Complications	Present study (2004)	Murthy <i>et al.</i> (2000)	Chishti <i>et al.</i> (2000)	Harris <i>et al.</i> (2001)	Hazra <i>et al.</i> (1998)	Kochar <i>et al.</i> (1997)
Jaundice	48	40.5	29.69	41	40	11.47
Cerebral malaria	36	48	59.38	30	8.33	25.75
Severe anemia	44	74.68	76.56	33	-	5.83
Acute renal failure	4	24.68	26.56	7	5	2.07
Algid malaria	6	18.35	-	-	-	5.26
Bleeding manifestations	-	4.43	12.5	-	3.33	9.58
ARDS	-	11.39	6.25	-	6.6	-
Hypoglycemia	8	8.22	-	-	-	-
Generalized convulsions	6	-	14.06	-	8.33	-
Hemoglobinuria	2	-	-	-	3.33	7.89

ARDS: Acute respiratory distress syndrome

**Table 8: Case fatality rates in various studies**

Study	CFR (%)
Present study	14
Murthy <i>et al.</i>	20.25
Chishti <i>et al.</i>	12.5
Harris <i>et al.</i>	10

CFR: Case fatality rates

Altered sensorium was seen in 36% of the cases in the present study as compared to 8.33% in Hazra *et al.*, 48% in Murthy *et al.*, and 59.38% in Chishti *et al.* All the patients who presented with altered sensorium were found to have cerebral malaria.

In the present study, pallor was seen in 60% of the cases as compared to 76.56% in Chishti *et al.* and 80% in Hazra *et al.*

Hepatomegaly was seen in 40% of cases in the present study as compared to 37.5% in Chishti *et al.* and 80% in Hazra *et al.*

Splenomegaly was seen in only 48% of the cases in the present study in contradiction to the common description of splenomegaly in 85% to 100% of all malaria cases by Marshal *et al.* This finding, in the present study, is consistent with Hazra *et al.* where splenomegaly was found in only 40% of the cases.

### Complications

Intravascular hemolysis of parasitized and non-parasitized red blood cells has been considered as an important factor for the causation of mild to moderate jaundice, which is predominantly unconjugated. Hemolysis alone can never cause severe jaundice or predominantly conjugated hyperbilirubinemia with an increase in liver enzyme levels (Table 7).

### Case Fatality Rate (CFR)

In the present study:

- Total CFR was 14% as compared to 20.25% in Murthy *et al.*, 12.5% in Chishti *et al.*, and 10% in Harris *et al.* (Table 8).

- The CFR was highest in hemoglobinuria (100%) followed by 33.3% in algid malaria, 27.7% in cerebral malaria, and 16.6% in jaundice.
- The majority of the deaths were contributed from males (71.4%) and between the age group of 31-40 years (42.8%).
- The mean duration of illness before admission among those who died was significantly longer than that among who recovered. They constituted 85.7% of total deaths.
- CFR was high (28.5%) in patients with more than one complication, and they contributed to the majority (85.7%) of the deaths. Multiorgan dysfunction is a major cause of mortality in falciparum malaria.
- Conjugated hyperbilirubinemia constituted more (42.8%) for total deaths when compared to unconjugated hyperbilirubinemia (28.5%).
- The level of serum bilirubin, aspartate aminotransferase, alanine transaminase, mean duration of illness was significantly higher in patients who died when compared to patients who recovered. Similar findings were seen with Murthy *et al.* study.
- The level of Glasgow coma scale was significantly lower in patients who died when compared to patients who recovered. Similar findings were seen in Murthy *et al.* study.

### CONCLUSION

Many cases of falciparum malaria were referred from endemic areas with protean manifestations and varied complications. The most common complication observed here was Jaundice, more commonly due to malarial hepatitis than hemolysis. The presence of hepatitis in falciparum malaria indicates more severe illness with a higher incidence of complications and poor prognosis (increased CFR).

Total CFR was 14%. It was directly proportional to the number of complications in a patient and duration of symptoms before admission. Cerebral malaria was



the most common cause of death. Early diagnosis and prompt treatment will reduce the morbidity and mortality associated with falciparum malaria.

There is a need to create more awareness about complications of falciparum malaria among doctors in peripheral health centers to institute prompt and early therapy. Proper preventive measures should be taken to contain the disease, mainly focusing on lower socioeconomic class and people involved with agricultural practices, during monsoon and post-monsoon season. Community participation is the key for the success of any health program. It is necessary to involve the community at large and create awareness about the problems of falciparum malaria.

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# Treatment of Displaced Supracondylar Fracture of Humerus in Children by Lateral Entry Pinning versus Cross Pinning

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## Abstract

**Introduction:** Displaced supracondylar fractures of humerus are one of the most common fractures in pediatric age group with preferred treatment being close reduction with percutaneous K-wire fixation. This study compares whether lateral pin construct alone can provide same stability like cross (medial and lateral) pin fixation, and prevent iatrogenic ulnar nerve injury.

**Materials and Methods:** We evaluated 30 cases of supracondylar fractures of the humerus in children in which 15 were of lateral and 15 of cross pinning group from January 2014 to June 2015 with minimum 4 months follow-up period. Mean age was 7.3 years for both lateral and cross pinning group. We studied the surgical complications in both groups and also compared functional and radiological result of both groups.

**Results:** Patients were assessed by Flynn's criteria. Results were excellent in 66.7% and good in 33.3% of cross pinning group and for lateral pinning group, excellent in 73.3% and good in 26.6% cases which were not statistically significant ( $P = 0.69$ ).

**Conclusion:** With the use of the specific techniques employed in this study, both lateral entry pin fixation and medial and lateral entry pin fixation are effective in the treatment of completely displaced (type III) extension supracondylar fractures of the humerus in children.

**Key words:** Children, Cross pinning, Lateral pinning, Supracondylar fractures humerus

## INTRODUCTION

Supracondylar fractures of the humerus are the most common type of elbow fractures in children, accounting for 50-70% of all fractures about the elbow.

It is estimated that the extension-type represents approximately 96-98% of all pediatric supracondylar fractures of the humerus, whereas the flexion-type represents approximately 2-4%.<sup>1</sup>

Decision to treat operatively depends on the quality of reduction, ability to maintain reduction, the degree of displacement, and fracture stability.

Many methods have been proposed for the treatment of supracondylar fractures of humerus in children:

1. Manipulative reduction and immobilization in a plaster cast with elbow flexed,
2. Axial skeletal traction on the ulna with the elbow flexed,
3. Dunlop's skin traction,
4. Closed reduction and percutaneous pinning and
5. Open reduction and internal fixation.<sup>2</sup>

Immobilization in a cast is generally accepted as the standard treatment for non-displaced fractures, but there is controversy as to the best treatment for displaced fractures.<sup>3</sup> The routine non-operative management of type II and III supracondylar fracture of humerus with plaster cast after

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closed reduction has reportedly been associated with a greater incidence of failure to obtain and maintain the fracture reduction and subsequent complication of malunion which led to the evolution of current techniques of percutaneous pinning.<sup>4</sup>

We conducted a study with the purpose to assess and compare the results of two methods of pinning - crossed pinning and lateral pinning - presently followed in the management of these difficult fractures.

## MATERIALS AND METHODS

This study was conducted in Department of Orthopaedics at Shri Ram Murti Institute of Medical Sciences, Bareilly, Uttar Pradesh, India from January 2014 to June 2015. Institutional board reviews was done and permission obtained.

### Inclusion Criteria

1. Age between 3 and 12 years and presenting within 2 weeks of injury
2. Closed fractures
3. Type II and III supracondylar fracture as per Gartland's Classification.

### Exclusion Criteria

1. Open fractures
2. Floating elbow
3. Previous fracture in the same elbow.

In this study, supracondylar fracture of humerus was classified according to Gartland's classification.<sup>5</sup>

Type I: Undisplaced supracondylar fracture of the humerus

Type II: Displaced supracondylar fracture with intact posterior cortex

Type III: Displaced supracondylar fracture with no cortical contact

- a. Posteromedial
- b. Posterolateral.

A total of 30 patients were included with 15 in lateral pinning group and 15 in cross pinning group in the study. All patients underwent routine pre-operative investigations as required.

### Technique

Immediately after the patient's arrival to the hospital a detailed clinical examination including a thorough neurovascular assessment was carried out. Standard anteroposterior and lateral radiographs of the involved elbow were taken, and the fracture type was noted. The cases were treated on an emergency basis with closed reduction and percutaneous pinning, under the guidance

of C-arm image intensifier.

General anesthesia was employed for all cases. The patient was positioned supine on the operating table with affected limb being placed on a side table or over the sterile draped C-arm image intensifier. Then, a step-wise closed manipulation was performed. Assessment of reduction was done under image intensifier by taking anteroposterior and lateral views; lateral view was taken by external rotation of shoulder. Maintenance of reduction was achieved by passing two crossed K-wires from both the medial and the lateral epicondyles (cross pinning) or by passing two K-wires from the lateral condyle in a divergent fashion (lateral pinning).

When crossed pinning was employed, the lateral pin was inserted first so that the medial pin can be placed with the elbow in less flexion to avoid ulnar nerve injury. Once the pins were in place, the elbow was extended and the adequacy of reduction was assessed with anteroposterior and lateral images. After leaving about 1 cm of the pins outside the skin, pins were bent and cut off and well-padded posterior above elbow slab was applied with elbow flexed to 90° or less as tolerated. Immediately in the post-operative period, the neurovascular status of the limb was assessed.

On 3<sup>rd</sup>/4<sup>th</sup> post-operative day slab was removed. The limb and wound and position of pins were inspected and a new well-fitted splint was reapplied. At 4 weeks, slab and pins were removed, and range of motion exercises were started in consultation with physiotherapist. Thereafter, the patient was regularly followed up at weekly interval of 2 weeks, 4 weeks, 6 weeks, monthly interval of 4 months, 6 months, 8 months, 10 months, and 12 months. At each review, patients were assessed clinically and radiologically. Finally, the functional outcome was assessed by Flynn's criteria (Table 1). The results were graded as excellent, good, fair or poor according to the range of motion and loss of carrying angle.

## OBSERVATIONS AND RESULTS

The average age was 7.3 years (range 3-12 years) with a peak incidence in 5-8 years. Left side involvement was

**Table 1: Flynn's criteria**

Results	Rating	Cosmetic factor: Carrying angle loss (°)	Functional factor: Motion loss (°)
Satisfactory	Excellent	0-5	0-5
	Good	6-10	6-10
	Fair	11-15	11-15
Unsatisfactory	Poor	>15	>15

more as compared to right side. The most common mechanism of injury was fall on outstretched hand (96%). Postero-medial displacement (51.9%) of distal fragment was more common. The average hospital stay for patients was 4.6 days. The average follow-up duration for patients was of 10.5 months.

The average time for radiological union was 7 weeks. The difference of Baumann's angle between affected and unaffected final follow-up X-ray was due to improper reduction as well as secondary displacement. The maximum number of cases with loss of Baumann's angle of  $5^{\circ}$  was 40% in lateral pinning cases and 33% in cross pinning cases. The loss of Baumann's angle is due to secondary displacement with a maximum number of cases with loss of Baumann's angle of  $2^{\circ}$  was 46.7% in lateral pinning and 26.7% in cross pinning cases.

The average loss of carrying angle was  $2.3^{\circ}$  in lateral pinning group and  $1.9^{\circ}$  in cross pinning group which was statistically significant. The significantly higher change in carrying angle in lateral pinning group may be related to comparatively less stable construct with 2 lateral pins compared to 2 cross pins.

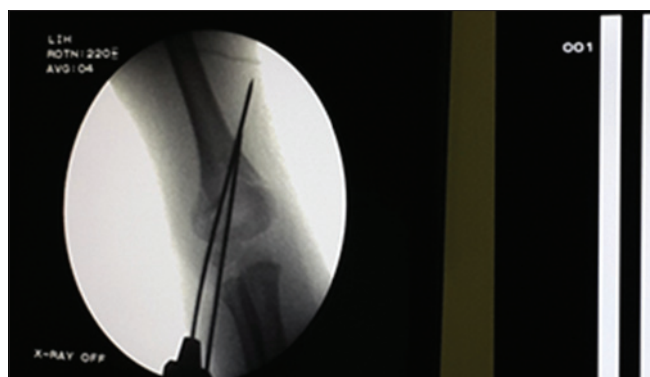


Figure 1: Lateral pinning

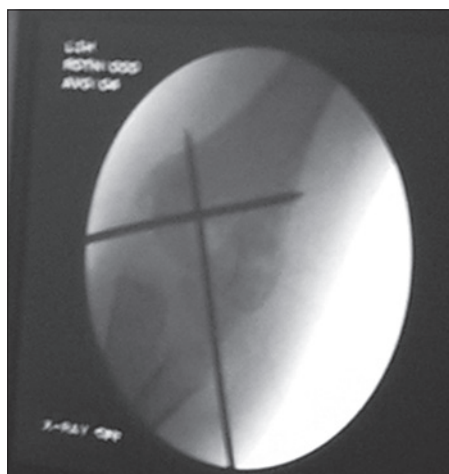


Figure 2: Cross pinning

The average loss of range of motion was  $4.86^{\circ}$  in cross pinning group and  $4.93^{\circ}$  in lateral pinning group which was not statistically significant. Functional outcome in terms of Flynn's criteria was excellent in 66.7% and good in 33.3% of cross pinning group and for lateral pinning group, excellent in 73.3% and good in 26.6% cases which was not statistically significant (0.69), but lateral pinning group definitely had higher number of excellent results (73.3%) as compared to cross pinning group (66.7%).

In terms of complications, pin tract infection was observed in 3 cases (10%). Temporary iatrogenic ulnar nerve injury was seen only in 1 case out of 13 and that too in the cross pinning group (Figures 1-4).

## DISCUSSION

Supracondylar fractures of the humerus are the most common type of elbow fractures in children. It is a fracture that occurs at supracondylar area or metaphysis of distal humerus.<sup>5</sup> Close reduction followed by two percutaneous Kirschner's wire fixation for supracondylar fracture of humerus in children offers simple, safe and affordable treatment option. Two configuration of placement of K-wires exists. One is lateral pinning and the other is cross pinning. Lots of controversies exist in orthopedics literature regarding the best modality of pin configuration.

Keeping these controversies in mind, we conducted a study comparing above two modalities of pin configuration in the management of displaced, closed supracondylar fracture of humerus in children. In this study, 30 children with type II and III supracondylar fractures of humerus who were treated with close reduction and percutaneous pinning (cross or lateral pinning) method were evaluated and compared according to fixed preset criteria.

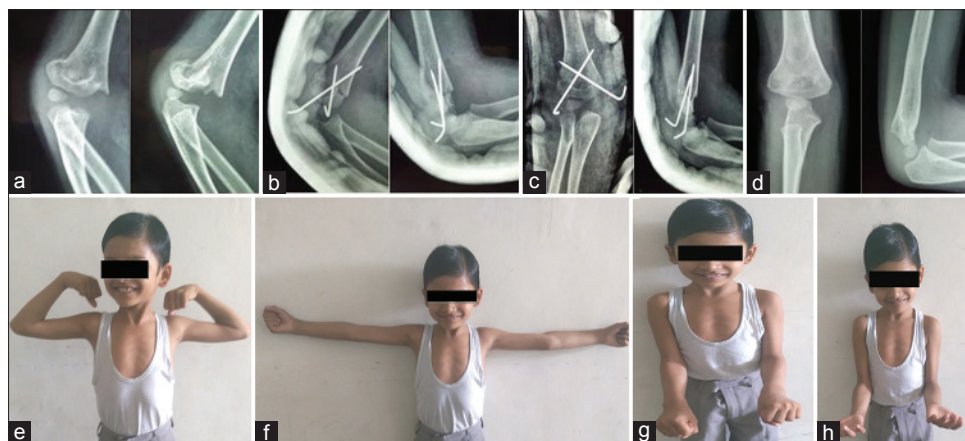
In this study, the average age for supracondylar fracture of the humerus was 7.3 years (range 3-12 years) with a peak incidence in 5-8 years. The average incidence in other series, i.e., 7.0 in Ramsey and Griz,<sup>6</sup> 6.4 in Nacht *et al.*<sup>7</sup> The incidence in male children was 83% and 17% in females. The male predominance was also noted in series of Fowles and Kassab<sup>8</sup> (89%) Nacht *et al.*<sup>7</sup> (50%). Left sided supracondylar fracture of humerus has outnumbered right sided fracture in this study.

Other studies in which left side was commonly involved are Fowles and Kassab<sup>8</sup> (57%), Nacht *et al.*<sup>7</sup> (55%). The common mechanism of injury in our series was fall on an outstretched hand (96%) which is same as that in series by Mostafavi and Spero.<sup>9</sup> and Bhuyan<sup>10</sup> In our series, there was 51.9% incidence of posterior-medial and 48.1% incidence of posterior-lateral displacements. The other series also





**Figure 3: (a) Lateral pinning - pre-operative X-ray. (b) Immediate - post-operative X-ray. (c) At 4 weeks follow-up. (d) Final follow-up. (e) Clinical pictures (lateral pinning) - flexion. (f) Extension. (g) Pronation. (h) Supination**



**Figure 4: (a) Cross pinning - pre-operative X-ray. (b) Immediate - post-operative X-ray. (c) At 4 weeks follow-up. (d) Final follow-up. (e) Clinical pictures (cross pinning) - flexion. (f) Extension. (g) Pronation. (h) Supination**

showed a higher rate of posterior-medial displacement: Aronson and Prager<sup>11</sup> (75%), Pirone *et al.*<sup>12</sup> (81%). The average hospital stay for a patient in our study was 4.6 days (range 2-6 days). The average hospital stay in other series were 3.4 days by Aronson and Prager,<sup>11</sup> 4.2 days by Nacht *et al.*<sup>7</sup>

The follow-up period for cases in our study ranged from 4 to 12 months with an average follow-up duration of 10.5 months. The average follow-up in other series were 8.93 in Foad *et al.*<sup>13</sup> and 7.4 in Zamzam and Bakarman<sup>14</sup> which are comparable and in series by Aronson and Prager.<sup>11</sup> was 17.2 months and Bhuyan<sup>10</sup> was 4.6 years which are at high range and are not comparable.

In our study, the average radiological union was seen in 7 weeks ranging from 6 to 9 weeks. The average radiological union seen in other series were 7.6 weeks by Sudheendra

*et al.*,<sup>15</sup> 6 weeks by Rijal and Pandey<sup>16</sup> which are comparable to our study.

Functional outcome following the two types of pinning was evaluated according to Flynn's criteria. Sudheendra *et al.*<sup>15</sup> in their study noted 82% excellent results and 18% good results in cross pinning case and 71% excellent results and 29% good results in lateral pinning case. Ariño *et al.*<sup>17</sup> in their study noted 69.3% excellent, 15.3% good, 14.8% fair and 0.5% bad results with lateral pinning. Raffic *et al.*<sup>18</sup> in their study found 72% excellent results and 28% good results with lateral pinning.

In our series, the functional outcome following cross pinning was excellent in 66.7% and good in 33.3% of cases, and lateral pinning showed 73.3% excellent and 26.6% good results with no poor results. The difference in functional outcome between the two groups was not



statistically significant (0.69). Pin tract infection occurred in 3 patients in our series (10%). In the series by Mostafavi and Spero,<sup>10</sup> the incidence of pin tract infection was (5%) and (1%) in Pirone *et al.*<sup>12</sup> which was found less compared to our studies.

## CONCLUSION

We conclude that although fixation of supracondylar humerus fracture of Gartland type II and III can be done by both ways either cross or lateral pinning but in view of ulnar nerve injury and extension lag which is more commonly associated with cross pinning, lateral pinning is comparatively safe and reliable for both types of supracondylar fractures of humerus in children. Hence, in our study, we found lateral pinning and cross pinning equally good in terms of safety and efficacy.

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# Protective Effect of Oral N-acetyl Cysteine in Noise-induced Hearing Loss in Factory Workers

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## Abstract

**Introduction:** Noise-induced hearing loss (NIHL) is an important etiological factor for deafness. Occupational exposure to loud sounds has been brought under control through various new factory and labor laws and use of protective devices during work. Still, the incidence of hearing loss in factory workers is on rise.

**Purpose:** The purpose of this study was to evaluate the protective effects of oral N-acetyl cysteine (NAC) in NIHL in factory workers.

**Materials and Methods:** In this study, 60 workers of local factory working with heavy machinery and ambient noise 85-90 dB were selected. All workers were healthy males between the age of 25-35 years with no pre-existing ear pathology.

**Results:** Temporary threshold shift mainly in the three frequencies 2, 3, and 4 kHz. Hearing threshold was normal at 8 kHz which indicated that it's not age related. Temporary threshold shift was similar in both right and left ears. Maximum threshold shift was observed at 4 kHz.

**Conclusion:** NAC use decreased the temporary threshold shifts in workers exposed to loud sounds.

**Key words:** Hearing loss, N-acetyl cysteine, Oxidative damage

## INTRODUCTION

In modern times, noise-induced hearing loss (NIHL) has been seen in two settings. First, the occupational exposure as in factory workers or traffic police officers, and second, the recreational exposure as in young population listening to loud music through headphones or people going to nightclubs.<sup>1</sup> Research has shown that noise-induced cochlear damage is a result of oxidative stress in the inner ear. Approximately 5% of the population worldwide suffers from industrial, military, or recreational NIHL at a great economic cost and detriment to the quality of life of the affected individuals.<sup>2</sup> A variety of antioxidants and other chemicals have been used to reduce this oxidative damage

and limit the hearing loss. Previous animal studies showed protective effects of antioxidant medicines against NIHL.<sup>3</sup> It is unclear whether antioxidants would protect humans from NIHL. This study evaluates the protective effects of N-acetyl cysteine (NAC) in NIHL.

## MATERIALS AND METHODS

In this study, 60 workers of local factory working with heavy machinery and ambient noise 85-90 dB were selected. All workers were healthy males between the age of 25-35 years with no pre-existing ear pathology.

The workers were divided into two groups randomly:

Group A: Received a placebo

Group B: Received NAC 1200 mg/day for 15 days.

Both groups were subjected to a base pure-tone audiometry at the beginning of the 8 h shift duties and the again at the end of the duty and there hence after 15 days and 1-month interval.

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The pure-tone audiometry results pre- and post-exposure were compared between the two groups.

### Statistical Significance

Paired *t*-test was used to analyze the results for statistical significance.<sup>4</sup>

## RESULTS

The pre-shift average hearing threshold in either of the groups was as follows (Table 1).

Serial audiograms were done:

1. Post-shift duty
2. 15<sup>th</sup> day
3. 1 month.

In all patients in both the groups, post-noise exposure audiograms showed (Figure 1):

1. Temporary threshold shift mainly in the three frequencies 2 kHz, 3 kHz, and 4 kHz
2. Hearing threshold was normal at 8 kHz which indicated that it is not age related
3. Temporary threshold shift was similar in both right and left ears
4. Maximum threshold shift was observed at 4 kHz.

Table 2 shows average hearing threshold at 4 kHz immediately after 8 h factory shift.

Table 3 shows the results of paired *t*-test was used to analyze the results for statistical significance.

### Confidence Interval

The mean of Group A (Control)–Group B (NAC)=7.67.

95% confidence interval of this difference: From 6.22 to 9.12.

### Intermediate Values Used in Calculations

$t=10.8216$

$df=29$

Standard error of difference=0.708.

### P Value and Statistical Significance

The 2-tailed  $P < 0.0001$  by conventional criteria, this difference in threshold shift between the two groups is statistically significant.

## DISCUSSION

Development of NIHL can be divided into two distinct phases:<sup>5</sup>

**Table 1: Pre-shift baseline pure tone average thresholds**

Group	2000 Hz	3000 Hz	4000 Hz
A	–5 to 0 db	0 to 5 db	0 to 5 db
B	–5 to 0 db	0 to 5 db	0 to 5 db

**Table 2: Average hearing threshold at 4 kHz immediately after 8 h factory shift were as follows**

Number	Auditory threshold at 4 kHz post duty	
	Group A (control) (dB)	Group B (NAC) (dB)
1	40	30
2	40	30
3	35	25
4	40	30
5	35	30
6	30	25
7	40	35
8	40	35
9	40	30
10	35	30
11	35	30
12	35	30
13	40	30
14	40	20
15	30	25
16	40	35
17	40	35
18	40	35
19	40	35
20	35	30
21	35	30
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25	30	25
26	40	35
27	40	25
28	40	30
29	35	30
30	40	25

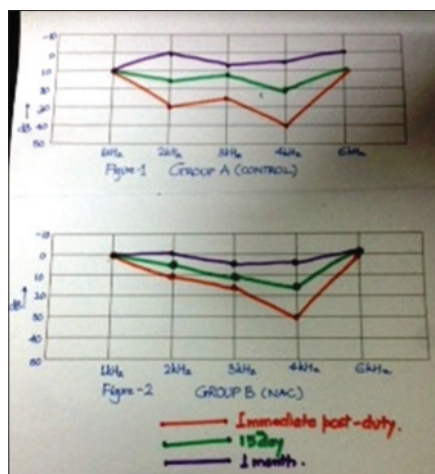
NAC: N-acetyl cysteine

**Table 3: Paired *t*-test was used to analyze the results for statistical significance**

Group	Group A (control)	Group B (NAC)
Sample size	30	30
Mean auditory threshold at 4 kHz	37.67	30.00
SD	3.41	3.94
SEM	0.62	0.72

SD: Standard deviation, SEM: Standard error mean, NAC: N-acetyl cysteine

The first phase: Temporary threshold shift which is some degree of hearing loss see after exposure to loud noise which is completely withdrawn after a period of the rest. Standard threshold shift is described as an average change in hearing from the baseline of 15 dB or more at any frequency 500 through 6 kHz. Recovery time in temporary



**Figure 1: Temporary threshold shifts (TTS) at 2 kHz, 3 kHz & 4 kHz in control group & NAC group**

threshold shift ranges from 48 h to few days depending on the intensity of sound and period of exposure.

Second phase: Permanent threshold shift: Frequent exposure to noise capable of inducing temporary threshold shift after a prolonged period produces permanent threshold shift which does not revert to a normal threshold. The cellular mechanism in the noise-induced cochlear damage involves generation of reactive oxygen species. Thus, the use of agents such as NAC has shown

to produce statistically significant reduction temporary threshold shift.

Less the temporary threshold shift produced, lesser are the chances of temporary threshold shift becoming into permanent threshold shift.

## CONCLUSION

Use of NAC in factory workers exposed to loud sound (>85-90 dB) has shown a significant decrease in temporary threshold shifts which has an overall protective effect in the long run.

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# Airtraq® Optical Laryngoscope versus Coopdech® Video Laryngoscope for Intubation Performance in the Pediatric Patients: A Randomized Single Hospital Study

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## Abstract

**Introduction:** Airtraq® is an optical laryngoscope that allows visualization of the vocal cords without a direct line of sight. The Coopdech Video Laryngoscope® (CVL) allows a direct visualization of the vocal cords on a digital screen and is the world's first and only video laryngoscope with Miller, Macintosh, Bullard and J-shaped blades.

**Aim:** The aim of this study was to evaluate CVL and Airtraq optical laryngoscope (AOL) regarding intubation time, a number of attempts at intubation, need for optimization maneuvers and hemodynamic changes during intubation in pediatric patients.

**Materials and Methods:** A total of 100 children of American Society of Anesthesiologists Class I, aged 6-36 months, undergoing operative procedure under general anesthesia were inducted into this study and were further divided into 2 groups using computer generated tables. Inhalational induction with sevoflurane in oxygen was done after premedication. Atracurium was used to facilitate intubation. Patients were randomly allocated to be intubated with either airtraq pediatric size (AL group) or CVL (CL group) using Miller's 0/1 or Macintosh 2 size blade and intubation time, a number of intubation attempts, optimization maneuvers and hemodynamic parameters were recorded. Data obtained was assessed using appropriate statistical methods using two-tailed *t*-test/Mann-Whitney U-test or Chi-square test as appropriate. Data were expressed as a mean and standard deviation, median and interquartile range. A  $P < 0.05$  was considered statistically significant.

**Results:** Group CL as compared to group AL, had significantly longer intubation time ( $P < 0.05$ ), more median number of intubation attempts. Compared to CVL, airtraq had shorter duration of intubation, lesser attempts at intubation with less number of optimization maneuvers.

**Conclusion:** AOL is better for pediatric intubations than CVL.

**Key words:** Airtraq optical laryngoscope, Coopdech video laryngoscope, Pediatric intubation

## INTRODUCTION

Pediatric airway management is a critical intervention which requires experience, proper planning and in time management for emergent problems. Significant

differences are there in the airway of pediatric subjects compared with adults. These differences are mainly due to the large head, high up larynx, large tongue, large epiglottis, anterior angulation of the vocal cords, and short jaw seen in pediatric subjects.<sup>1</sup> In recent years, many new optical laryngoscopes have been developed for use in pediatric patients. The Airtraq™ (PRODOL, MEDITEC S.A.) is a disposable battery operated optical laryngoscope that allows high-quality viewing of the vocal cords and unlike conventional laryngoscope it does not require a straight line of sight up to the patient's vocal cords.<sup>2</sup> Use of the Airtraq does not require displacement of the tongue and forceful elevation of the epiglottis resulting in less application of

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force compared with the conventional direct laryngoscopy.<sup>3</sup> The Coopdech Video Laryngoscope™ (DAIKEN MEDICAL) allows a direct visualization of the vocal cords on a digital screen and is the world's first and only video laryngoscope with Miller, Macintosh, Bullard and J-shaped blades. Both these variants of optical laryngoscope are easy to use and have a short learning curve. However, there are no studies comparing Airtraq™ with Coopdech Video Laryngoscope™ in pediatric population and controversy still remains regarding which optical laryngoscope is better for use in pediatric patient. Hence, we designed a randomized prospective study to compare both these laryngoscopes regarding the intubation time.

## MATERIALS AND METHODS

After approval from Institutional Ethics Committee and departmental clearance this randomized, prospective, blinded study was conducted under the Department of Anesthesiology and Critical Care, Guwahati Medical College and Hospital from August 2015 to January 2016. Written parental informed consent was obtained for all the patients before inclusion in this study. About 100 children admitted under Pediatric Surgery Department of Gauhati Medical College with the following characteristics American Society of Anesthesiologists (ASA) Class I, boys and girls aged 6-36 months, undergoing elective operative procedure under general anesthesia were included into this study. Exclusion criteria being parental denial, patients with a history of or anticipated difficult airway and intubation, risk of gastric aspiration, cardiovascular, respiratory, metabolic disease, and central nervous system disease. Adequate pre-operative preparation was done in the form of solid food being withheld for 6 h preoperatively and only clear liquids were permitted up to 3 h before induction of anesthesia. Children were pre-medicated with nasal midazolam 0.3 mg/kg 30 min before the anticipated start of surgery. After arrival in the operating room standard, ASA monitors were attached and baseline hemodynamic data were recorded. Inhalational induction with sevoflurane in oxygen-air mixture was done. After induction an intravenous line was established, and fentanyl 2 µg/kg and atracurium 0.5 mg/kg were administered IV. Computer generated tables were used by the anesthetist before induction to randomize patients to undergo intubation with either Airtraq laryngoscope (AL group comprising of 50 patients) or coopdech laryngoscope (CL group comprising of 50 patients). The anesthesiologist participating in the study had more than 10 years of experience in pediatric anesthesia and was well trained with the proper use of Coopdech and Airtraq video laryngoscope for pediatric intubations. 2 sizes of pediatric Airtraq 0, 1 were used for this study one that accepts an endotracheal tube between 2.5-3.5 mm and another that

accepts 4.00-5.50 mm endotracheal tubes. For CL blades, Miller's 0/1 or Machintosh 2 were used for laryngoscopy and intubation. The following parameters were noted Intubation time (primary outcome), number of intubation attempts, number of optimization maneuvers required (repositioning the head or the need for a second assistant to aid tracheal intubation), hemodynamic parameters before during and after intubation (at 1, 3, 5, 7 min). Intubation time was the period from termination of manual ventilation with afacemask to initiation of ventilation through the endotracheal tube. Any attempt at laryngoscopy greater than 120 s were considered as failed intubation.<sup>4</sup> Complications if any were also noted. As there was no previous study comparing both these laryngoscopes so sample size calculation could not be done, we intend to use it as a pilot study based on which controlled trials could be conducted in the future. Data obtained from these patients was entered into Microsoft Excel spread sheet and assessed using (GrapPad InStat - version 3.0) appropriate statistical methods using two-tailed *t*-test/Mann-Whitney U-test or Chi-square test as appropriate. Data were expressed as a mean and standard deviation, median and interquartile range. *P* < 0.05 was considered statistically significant.

## RESULTS AND OBSERVATIONS

The age, height, weight, gender, and duration of anesthesia was found to be comparable between the group AL and group CL (Table 1).

There was asignificant increase in the intubation time in group CL (26.85±7.5 s) compared to group AL (21.75±5.8 s) (Figure 1).

**Table 1: The demographic parameters between the 2 groups AL and CL**

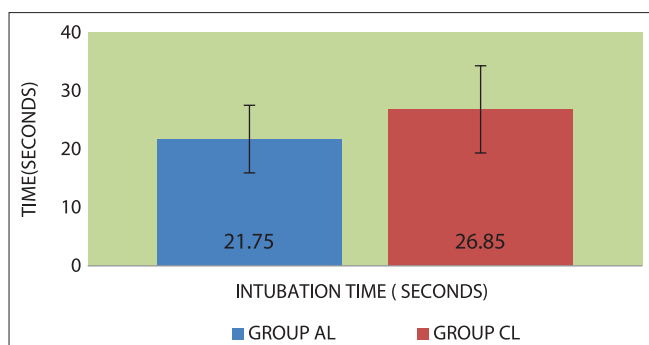
Parameters	AL group (50)	CL group (50)
Age (months)	22±6.5	24±5.4
Height (cm)	102±8.5	105±10.2
Weight (kg)	12±5	11±6.5
Gender (%)		
Male	32 (64)	28 (56)
Female	18 (36)	22 (44)
Duration of surgery (minutes)	68±20.8	72±16.4

AL: Airtraq laryngoscope, CL: Coopdech laryngoscope

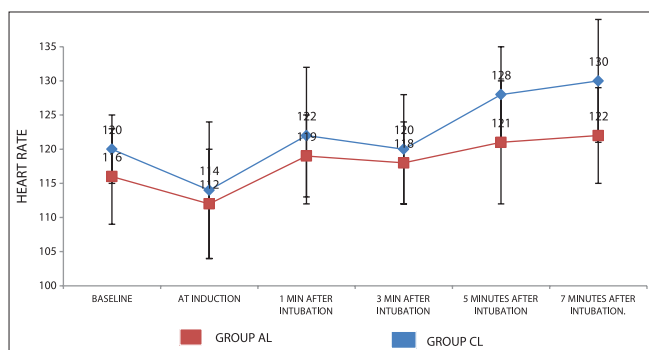
**Table 2: Median attempts at intubation and number of optimization manaeuvers in both groups AL and CL**

Parameters	AL group (50)	CL group (50)	P value
Numbers of intubation attempts	1 (1-1)	2 (1-2)	0.001
Numbers of optimization manaeuvers	0 (0-0)	1 (1-1)	0.001

AL: Airtraq laryngoscope, CL: Coopdech laryngoscope



**Figure 1: Comparison of intubation time between group airtraq laryngoscope and group coopdech laryngoscope ( $P = 0.002$ )**



**Figure 2: Comparison of hemodynamic parameters between two groups airtraq laryngoscope and coopdech laryngoscope at 1, 3, 5, 7 min post intubation**

The median and interquartile range of intubation attempts was 1 (1-1) for AL group compared with 2 (1-2) in CL group ( $P = 0.001$ ). No optimization maneuvers were required in the airtraq group, the median and interquartile range of optimization maneuver was 1 (1-1) for CL ( $P = 0.001$ ) (Table 2).

A significant increase in the heart rate was observed in CL group compared to AL group at 5 and 7 minutes post intubation (Figure 2).

No incidence of failed intubation or complications were noted in either group of patients.

## DISCUSSION

The result of our study indicates that airtraq intubation in pediatric subjects was faster than intubation with coopdech

video laryngoscope (CVL). Airtraq guided intubation time obtained in our study was similar to that obtained by Riad *et al.*<sup>5</sup> in pediatric patients. CVL guided intubation time in our study was more than that obtained by studies using CL for intubation during pediatric resuscitation.<sup>6</sup> The cause for the difference may be as because we used CVL only for elective intubation during surgery and not for emergency intubations during CPR. Lower number of median intubation attempts and optimization maneuvers were noted in Airtraq group of patients. In our study, we reported less alteration of the hemodynamic stress response to intubation with airtraq compared to CVL, with significantly lower heart rates in the airtraq group at 5, 7 minutes post intubation. Maharaj *et al.*<sup>7</sup> also noted similar lower stress response for Airtraq in his study on adult patients. The potential limitations of our study were pediatric patients with difficult airway were not included as well as not encountered in our study population. Our results may not be applicable in all settings as experienced operators may not be available everywhere.

## CONCLUSION

Airtraq optical laryngoscope decreases intubation time, number of intubation attempts, optimization maneuvers in pediatric patients and may result in a lower alteration of heart rate compared to CVL during pediatric intubation.

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# Extra-articular Manifestation of Rheumatoid Arthritis

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## Abstract

**Introduction:** Rheumatoid arthritis is an autoimmune disorder of unknown etiology characterized by symmetric, erosive synovitis, and in some cases, extra-articular involvement. Most patients experience a chronic fluctuating course despite therapy, may result in progressive joint destruction, deformity, disability, and even premature death.

**Materials and Methods:** It is a study conducted on patients admitted to K R Hospital, Mysore, from January 2013 to January 2015, a total of 50 patients were admitted during this period. As per inclusion criteria and exclusion criteria cases are included and excluded, and a pre-structured proforma was used and data were entered. The study is approved by the Institutional Ethical Committee.

**Results:** In the present study, the most common extra-articular manifestation was noted in the cardiovascular system (12%). Next, in the order of involvement were respiratory manifestations (8%) and lymphadenopathy (8%), followed by vasculitis (6%) and rheumatoid nodule (2%).

**Conclusion:** Our study showed male gender, older age group, longer duration of illness, severe degree of anemia, very high erythrocyte sedimentation rate, positive RA factor with higher titer values, all are suggestive of a higher incidence of extra-articular manifestation.

**Key words:** Anti-cyclic citrullinated peptides, Extra-articular manifestations, Rheumatoid arthritis, Rheumatoid arthritis factor

## INTRODUCTION

Diseases of musculoskeletal system are among the most common human afflictions. Their prevalence is highest among the elderly, but these conditions affect all age groups and are associated with disability, impairment, handicaps, and job loss.<sup>1</sup>

The impact of rheumatic diseases is enormous. They account for more impairment and functional limitation among middle age and older adults than any other disease category.

Rheumatoid arthritis (RA) is a chronic inflammatory arthropathy of unknown cause that can affect most joints,

and hence an important cause of potentially preventable disability.<sup>2</sup>

RA is an autoimmune disorder of unknown etiology characterized by symmetric, erosive synovitis, and in some cases, extra-articular involvement. Most patients experience a chronic fluctuating course despite therapy, may result in progressive joint destruction, deformity, disability, and even premature death.

## Epidemiology

RA has been identified in all parts of the world in every ethnic, racial group. Climate, geography, and altitude do not appear to affect the prevalence of the disease. However, climate does appear to influence the symptoms. Those with the disease reported increased discomfort in a wet or humid climate.<sup>3</sup>

The prevalence ranges from 0.1% to 5.3% in all population. The lowest is seen in South African population, and highest prevalence is noted in Chippewa Indians, USA and Pima-Indians, USA.

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The low prevalence in certain developing countries is probably because of mortality associated with infections in RA.<sup>4</sup>

RA is two to three times more frequent in women compared to men. This has been noted in all population and all age groups studied. The prevalence of RA appears to increase in both males and females with age.<sup>5,6</sup>

### Clinical Manifestation

Articular manifestation:

1. Hands
  - a. Joint involvement
  - b. Tendon involvement.

Hasting's classification of rheumatoid hand:<sup>7</sup>

Joint involved	MCP	Synovitis, passively correctable ulnar drift, fixed volar subluxation, ulnar drift
	PIP	Synovitis, boutonniere deformity, flail IP joint
	Thumb	Flail IP joint, boutonniere deformity, duckbill thumb, dislocation
	Wrist	Synovitis, carpal supination, subluxation, radiocarpal dislocation
Tendon involvement	Flexor tendon disease	Loss of active flexion, triggering, tendon rupture, median nerve involvement
	Extensor tendon disease	Synovitis, dorsal mass, extensor tendon rupture, extensor tendon dislocation

MCP: Metacarpophalangeal, PIP: Proximal interphalangeal, IP: Interphalangeal

2. Other joints are an elbow, shoulder, temporomandibular, cricoarytenoid, sternoclavicular and manubriosternal, cervical spine, hip, knee, and ankle joint.

Extra-articular manifestations:

- a. Cardiac involvement
- b. Pulmonary involvement
- c. Ocular involvement
- d. Vasculitis
- e. Skin involvement
- f. Hematological involvement.

## MATERIALS AND METHODS

In this study, 50 cases of RA attending either the outpatient department or admitted to the wards of Krishnarajendra Hospital, and Princess Krishnammanni Tuberculosis and Chest Diseases Hospital attached to Mysore Medical College were selected.

About 50 cases were selected on the basis of the simple random sampling, during the study period January 2013 to June 2015. The cases were diagnosed as RA using the "ACR and European league against rheumatism (EULAR) criteria 2010."

The data were collected in a pretested questionnaire meeting the objective of the study. Analysis was made using the various statistical parameters such as the mean, standard deviation, standard error, *t*-test (unpaired), Chi-square test, and percentages.

### Inclusion Criteria

Subjects fulfilling the following criteria, the "American College of Rheumatism (ACR)" and the EULAR criteria 2010 for RA are as follows:

Joint involvement	1 large joint (knee, ankle, shoulder, elbow)	0
	2-10 large joints	1
	1-3 small joint (PIP, MCP, thumb IP, MTP, wrists)	2
	4-10 small joints	3
Serology	>10 joints (at least one small joint)	5
	Negative RF or negative ACPA	0
	Low positive RF or low positive anti-CCP antibodies (<3 times ULN)	2
	High positive RF or high positive anti-CCP antibodies (>3 times ULN)	3
Acute phase reactants	Normal CRP and normal ESR	0
	Abnormal CRP or abnormal ESR	1
Duration of symptoms (weeks)	<6	0
	>6	1

PIP: Proximal interphalangeal joint, MCP: Metacarpophalangeal joint, IP: Interphalangeal joint, MTP: Metatarsophalangeal joint, RF: Rheumatoid factor, ACPA: Anti-citrullinated peptide antibodies, CCP: Cyclic citrullinated peptides, ULN: Upper limit of normal, CRP: C-reactive protein, ESR: Erythrocyte sediment rate

A score of >6 fulfills requirements for definitive of RA.

### Exclusion Criteria

Patients presenting with polyarthritis but not satisfying the ACR and EULAR criteria 2010.

## OBSERVATION AND RESULTS

Present study shows majority of patient shows 20 to 39 years (58%) as shown in Table 1, and in the extra-articular manifestation majority of patient are older (51.2 years) compared to articular manifestation (33 years) as shown in Table 2. This study also shows that majority are females as shown in Table 1.

In the present study, the most common extra-articular manifestation was noted in the cardiovascular system (12%). Next, in the order of involvement were respiratory manifestations (8%) and lymphadenopathy (8%), followed by vasculitis (6%) and rheumatoid nodule (2%) (Table 3).

The mean Hb was  $10.24 \pm 2.365$  g/dl. The difference in the mean Hb between two groups was statistically significant ( $P < 0.05$ ) (Table 4).

RA factor was positive in 33 (66%) cases. RA titer ranged from 1:16 to 1:64. All the patients in EAG (100%) were rheumatoid factor positive (Table 5).



**Table 1: The age and sex distribution of the cases**

Age group (in years)	NEAG			EAG			Total (%)
	Male	Female	Total	Male	Female	Total	
20-29	3	10	13	1	0	1	14 (28)
30-39	3	9	12	1	2	3	15 (30)
40-49	1	4	5	1	2	3	8 (16)
50-59	0	1	1	3	2	5	6 (12)
>60	0	1	1	4	2	6	7 (14)

NEAG: Non-extra-articular group, EAG: Extra-articular group

**Table 2: The mean age and SD (years) of non-extra-articular group and extra-articular group**

Group	Mean±SD
NEAG	33.6±9.8
EAG	51.2±12.5
Total	42.4±11.15

NEAG: Non-extra-articular group, EAG: Extra-articular group, SD: Standard deviation

**Table 3: Extra-articular manifestations**

Extra-articular manifestation	Male	Female	Total (%)
Cardiac involvement	4	2	6 (12)
Pulmonary involvement	3	1	4 (8)
Lymphadenopathy	1	3	4 (8)
Vasculitis	1	2	3 (6)
Rheumatoid nodule	1	0	1 (2)
Total	10	8	18 (36)

**Table 4: The mean Hb and SD (g/dl) of NEAG and EAG**

Group	Mean±SD
NEAG	11.38±2.59
EAG	9.11±2.14
Total	10.24±2.365

NEAG: Non-extra-articular group, EAG: Extra-articular group, SD: Standard deviation, Hb: Hemoglobin

**Table 5: Rheumatoid factor**

RA titers	NEAG	EAG	Total (%)
1:16	5	3	8 (16)
1:32	7	4	11 (22)
1:64	3	11	14 (28)

NEAG: Non-extra-articular group, EAG: Extra-articular group, RA: Rheumatoid arthritis

## DISCUSSION

The maximum incidence (58%) was observed in the age group of 20-39 years in the present study and is similar to the study of Banerjee (78% in 16-45 year).<sup>5</sup>

In the present study, the most common extra-articular manifestation observed was cardiac involvement (12%)

followed by pulmonary involvement and lymphadenopathy (8% each), vasculitis (6%) and subcutaneous nodule (2%).

In the present study, the incidence of extra-articular manifestations in 50 consecutive RA patients was studied.

In the EAG, all the 18 patients (100%) were RA factor positive, and majority had a higher titer as compared to the NEAG wherein 46.87% were RA factor positive.<sup>8-10</sup>

## CONCLUSION

About 50 cases of RA fulfilling the ARA and EULAR criteria of 2010 were evaluated clinically, bio-chemically, radiographically, echocardiographically and with pulmonary function tests for evidence of extra-articular manifestations.

The mean age was significantly higher in the extra-articular group (EAG) as compared to the non-extra-articular group (NEAG).

The extra-articular manifestations were more common in males as compared to females.

The mean duration of illness was more in the EAG as compared to the NEAG.

There was not much difference in the mode of onset, clinical presentation, type of joint involvement, or the type of deformities between the two groups.

Male gender, older age group, longer duration of illness, severe degree of anemia, very high erythrocyte sedimentation rate, positive RA factor with higher titer values, all are suggestive of a higher incidence of extra-articular manifestations.

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# Classical Single Patch Repair and Revascularization for Post-infarction Ventricular Septal Defect: A Follow-up Study from a Semi-urban Tertiary Care Centre in South India

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## Abstract

**Introduction:** Rupture of ventricular septum is a rare complication of myocardial infarction and occurs in approximately 0.2% of the cases. Surgical management can reduce the chances of mortality in these cases from over 90% to less than 50%. The present study was aimed at finding out the short- and long-term outcomes of surgical management of post-infarction ventricular septal defect (VSD), using classical single patch repair and revascularization procedure.

**Materials and Methods:** A total of 46 patients who underwent surgical repair of post-infarction VSD at a tertiary care hospital in South India were included in the study. All of them had classical single Dacron patch repair and revascularization. The participants were followed up at the end of 2 months, 2 years, and 4 years using a 2D echocardiography, looking for the efficacy of the Dacron patch and possible improvement in left ventricular function. The survival status of the participant and incidence of any new cardiac event was queried at the end of 2 and 4 years.

**Results:** The mean (standard deviation) ejection fraction went up from 26.52% (4.27) during pre-operative period to 33.08% (2.58) at the end of three months ( $P < 0.001$ ). At the end of 2 months after surgery, 41 (89.1%) of the participants were alive. At the end of 2 and 4 years of follow-up, the survival status of the participants was similar, and 38 (82.6%) were alive. However, the short-term survival status was vastly different between those participants who underwent an emergency surgical correction and an elective procedure. 4 (50%) of the participants in the emergency group died in the first 2 months following surgery, while only 1 (2.7%) died in the elective group.

**Discussion and Conclusion:** Our study has shown that post-infarction VSD can be successfully managed at semi-urban centers, with globally acceptable levels of mortality. Emergency surgical intervention for the management of post-infarction VSD was shown to result in high short-term mortality when compared to patients undergoing elective surgeries. Furthermore, single Dacron patch repair with concomitant revascularization was found to be a safe and effective procedure, for the management of the problem.

**Key words:** Low cardiac output, Post-infarct ventricular septal defect, Single Dacron patch repair

## INTRODUCTION

Cardiovascular diseases have become the leading cause of mortality and morbidity across the world. The incidence

of cardiovascular diseases in India is also on the rise and is now one of the top five causes of death in the country.<sup>1</sup> The incidence is predicted to rise manifold and India will be host to more than half of the patients suffering from cardiovascular diseases, by 2030.<sup>2</sup> The Indian population and people of South Asian descent are also genetically susceptible for cardiovascular illnesses. Multiple studies have demonstrated a significantly higher prevalence of cardiovascular risk factors and cardiovascular disease among Indian population, than Caucasians living in the same geographical areas.<sup>3</sup> This warrants an increase

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in research into cardiovascular diseases, especially its epidemiology and intervention measures.

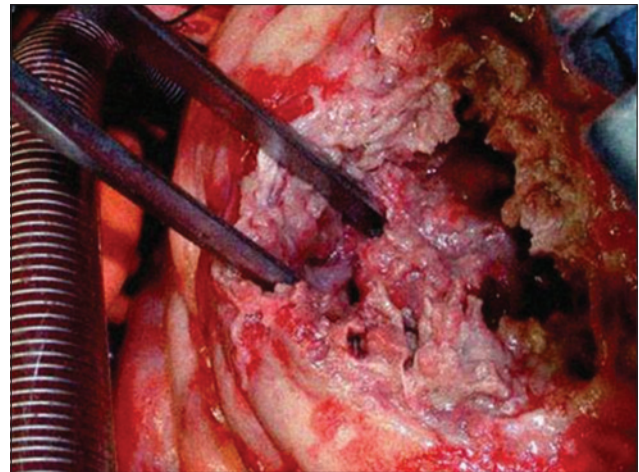
Rupture of ventricular septum is a rare complication of myocardial infarction and occurs in approximately 0.2% of the cases. It has a very high mortality, especially in patients who are medically managed or in whom it is not identified. Surgical management can reduce the chances of mortality from over 90% to less than 50%.<sup>4</sup> Certain studies have demonstrated even higher survival figures post-surgical management of these cases. A study from Hong Kong reported an overall survival of 68%, 55%, and 42% at 1, 5, and 10 years, respectively.<sup>5</sup> Emergency surgeries and surgical intervention within three days of the event have been shown to increase short-term mortality, in the case of surgical management of post-infarction Ventricular septal defect (VSD).<sup>6</sup> It has also been shown that the repair of post-infarction VSD along with a concomitant revascularization procedure can further improve the chances of survival. A systematic review found that out of the 18 papers evaluated for the review, 12 recommended a coronary artery bypass grafting (CABG) along with the repair of ventricular septum.<sup>7</sup>

The present study was aimed at finding out the short- and long-term outcomes of surgical management of post-infarction VSD, using classical single patch repair and revascularization procedure.

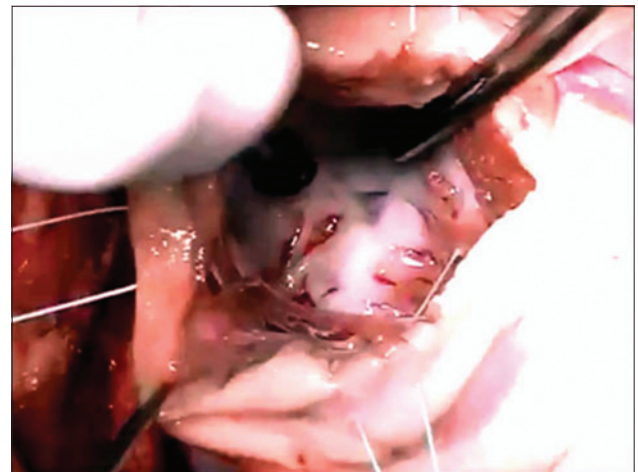
## MATERIALS AND METHODS

About 46 patients who underwent surgical repair of post-infarction VSD at Sri Venkateswara Institute of Medical Sciences, Tirupati, India, were included in the study. All the participants underwent the procedure during the period 2005-2009, and all of them had classical single patch repair and revascularization. The study was cleared by the Institutional Ethics Committee.

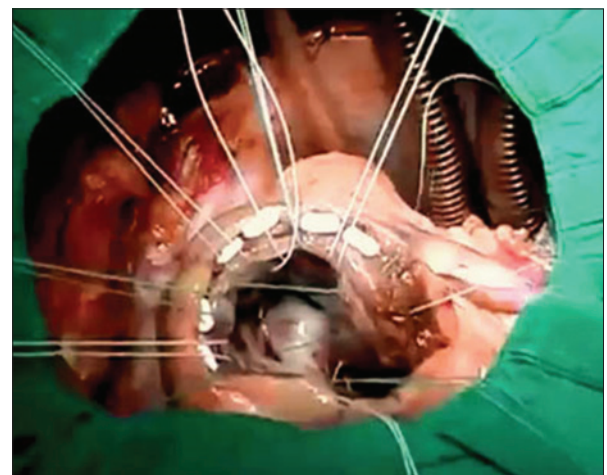
The surgical approach was through a median sternotomy in all participants. Cannulation was done after heparinization (3 mg/kg). Aorto-bicaval cannulation, membrane oxygenators, and blood cardioplegia were used in all patients. Aortic cross-clamp time varied from 40 to 90 min and bypass time varied from 90 to 120 min. The VSD was approached through the infarcted area. The size of the VSD ranged from 2 to 4 cm ( $2.59 \pm 0.48$ ). 14 of the defects were apical, and rest was apico-anterior. These defects were closed with a Dacron patch which was secured using double armed pre pledgeted 2/0 ethibond interrupted sutures, and the ventriculostomy was closed using 2/0 prolene continuous sutures with Teflon felt reinforcement (Figures 1-5).



**Figure 1: Post-infarct ventricular septal defect with ill-defined margins (emergency group)**



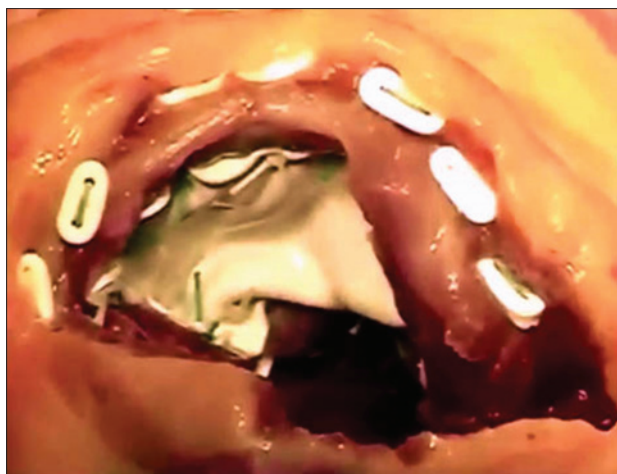
**Figure 2: Post-infarct ventricular septal defect with mature margins (elective group)**



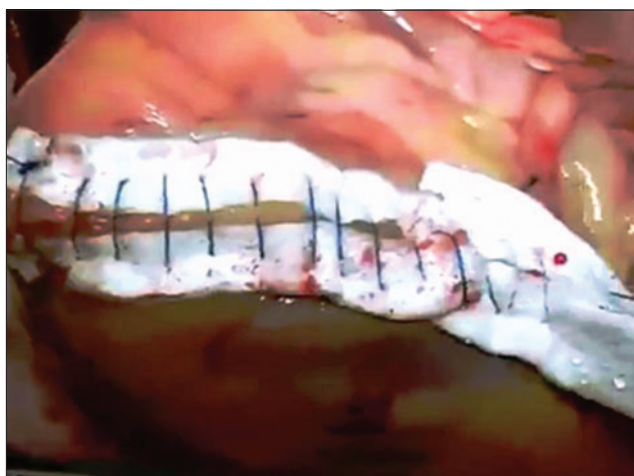
**Figure 3: Pre pledgeted 2/0 ethibond stitches taken at ventricular septal defect margins for fixing the Teflon patch**

Concomitant CABG with reversed saphenous vein graft was done in all the participants. Inotropic support with

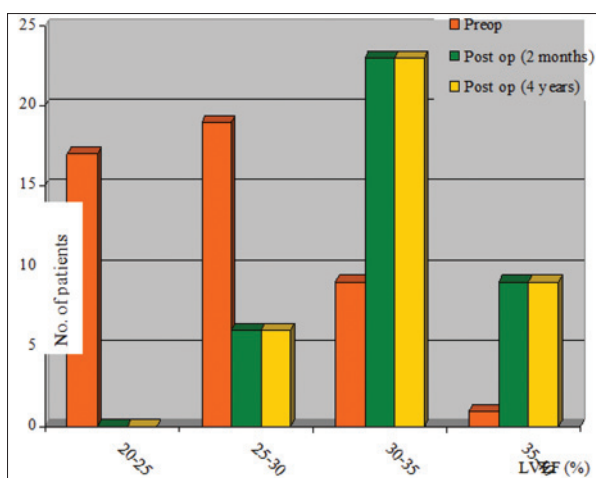




**Figure 4: Ventricular septal defect closed by Teflon patch**



**Fig 5. Ventriculostomy closed with continuous 2/0 prolene suture with Teflon reinforcement**



**Figure 6: Comparison of left ventricular ejection fraction (%)**

intravenous adrenaline, dopamine, or dobutamine was used along with intraarterial blood pressure monitoring. All the patients were electively ventilated for 24-48 h.

The participants were followed up at the end of 2 months, 2 years, and 4 years. At 60 days, the participants were reassessed using a 2D echocardiography, looking for the efficacy of the Dacron patch and possible improvement in left ventricular function. The survival status of the participant and incidence of any new cardiac event was queried at the end of 2 and 4 years.

## RESULTS

The patients who underwent surgical correction of post-infarction VSD from 2005 to 2009 were included in the study. Age ranged between 40 and 70 years with mean age of 59.52 years (5.33). 22 (47.8%) of the participants were under the age of 60 years, and a vast majority (71.3%) were males. Almost 70% of the participants were suffering from diabetes mellitus, while only 30.4% had hypertension. A huge majority (65.2%) of the participants who underwent surgical correction of post-infarction VSD were smokers. About 22 (47.8%) of the participants had single vessel disease, 16 (34.8%) had double vessel disease, and 8 (17.4%) had triple vessel disease. More than 80% of the participants underwent elective surgical procedures after initial stabilization of hemodynamic status (within 6 weeks of the event) while the rest underwent emergency surgical correction due to onset of rapidly progressing cardiac failure (within 5 days) (Table 1).

The systolic function of the patients was assessed at the end of 60 days using the 2D echocardiography. The mean (standard deviation) ejection fraction went up from 26.52% (4.27) during pre-operative period to 33.08% (2.58) during the post-operative period ( $P < 0.001$ ) (Figure 6).

The data were further analyzed to look for factors affecting improvement in ejection fraction. It was found that age ( $P = 0.098$ ), sex ( $P = 0.621$ ), type of coronary artery disease ( $P = 0.589$ ), and mode of surgical procedure ( $P = 0.647$ ) were not significantly associated with improvement in ejection fraction following surgical correction of post-infarction VSD. However, it was seen that the size of VSD is a factor which can predict the improvement in ejection fraction following surgical intervention, with defects less than 3 cm showing a 4.78% improvement and defects of 3 cm or more showing a 10.64% improvement ( $P < 0.001$ ) (Table 2).

The patients were followed up for a total of 4 years to assess the survival status. At the end of 2 months of surgery, 41 (89.1%) of the participants were alive. At the end of 2 and 4 years of follow-up, the survival status of the participants was similar, and 38 (82.6%) were alive. However, the short-term survival status was vastly different

**Table 1: Patient demographics**

Characteristic	Number (%)
Age (years)	
<60	22 (47.8)
>60	24 (52.2)
Sex	
Male	33 (71.3)
Female	13 (28.3)
Diabetes mellitus	
Yes	32 (69.6)
No	14 (30.4)
Hypertension	
Yes	14 (30.4)
No	32 (69.6)
Smoking	
Yes	30 (65.2)
No	16 (34.8)
Type of CAD	
Single vessel	22 (47.8)
Double vessel	16 (34.8)
Triple vessel	8 (17.4)
Mode of surgical procedure	
Emergency	8 (17.4)
Elective	38 (82.6)

CAD: Coronary artery disease

**Table 2: Factors affecting improvement in systolic function following surgical intervention**

Factor/Characteristic	Mean (SD) improvement in LVEF following surgery	P value
Age (years)		
<60	5.18% (5.70)	0.098
>60	7.83% (4.93)	
Sex		
Male	6.51% (5.19)	0.621
Female	7.41% (5.85)	
VSD size		
<3 cm	4.78% (5.18)	<0.001
>3 cm	10.64% (3.45)	
Type of CAD		
Single vessel	6.09% (6.68)	0.589
Double vessel	6.31% (4.54)	
Triple vessel	8.37% (2.44)	
Mode of surgical procedure		
Emergency	7.37% (3.42)	0.647
Elective	6.39% (5.77)	

CAD: Coronary artery disease, VSD: Ventricular septal defect, SD: Standard deviation, LVEF: Left ventricular ejection fraction

**Table 3: Patient survival**

Time lapsed after procedure	n (%)	
	Emergency (8)	Elective (38)
Survival at 60 days	4 (50)	37 (97.3)
Survival at 2 year	4 (50)	34 (89.4)
Survival at 4 years	4 (50)	34 (89.4)

between those participants who underwent an emergency surgical correction and an elective procedure. 4 (50%) of the participants in the emergency group died in the first

2 months following surgery, while only 1 (2.7%) died in the elective group. 50% of the participants in the emergency were alive at the end of 4 years after the surgery, while 89.4% of the participants from the elective group were living after the corresponding follow-up period (Table 3).

## DISCUSSION

Even though the incidence of post-infarction VSD is very low, an understanding of the various considerations in managing such patients is of utmost importance due to the high mortality. The surgical management of such patients involves complex procedures, which are difficult even in the best of centers, manned by highly trained cardiac surgeons.

The overall mortality in the immediate post-operative period was only 10.9% in our study, which is much lower than the mortality rates reported in the literature. A study done in the United Kingdom reported 30-day mortality rates of up to 37% while a study done in a university hospital in Sweden showed that acute mortality was as high as 41%.<sup>8,9</sup> Our center is situated in a semi-urban area with poor access to ambulance services and emergency medical services, and therefore, most of the patients with massive myocardial infarction succumb before they can access medical facilities. This can cause a significant selection bias as only the relatively stable patients undergo surgical management causing inflated survival statistics.

Early surgical intervention has shown to be a risk factor for short-term mortality, in many studies done elsewhere.<sup>6,8</sup> In our study also, this trend is visible as the short-term mortality among those who underwent emergency intervention was as high as 50% while 60-day mortality among those patients who had elective surgery was only 2.7%. Studies have shown that pre-operative cardiogenic shock and early surgical intervention are the most important risk factors for short-term mortality. Furthermore, it has been demonstrated that hemodynamic stabilization along with delayed surgical intervention can improve the mortality statistics.<sup>8</sup>

Some studies have shown that double patch repair was a superior intervention when compared to single patch repair, in the management of post-infarction VSD.<sup>10</sup> However, others state that single patch repair has a comparable efficacy in terms of clinical improvement and left ventricular systolic function and that it is a simpler technique.<sup>11</sup> In the present study, all the patients underwent single patch repair, and the mortality rates were comparable to the best centers in the world. This shows that single patch repair can be used at semi-urban centers also, with acceptable levels of mortality and morbidity. Only a large



randomized control trial can finally settle the debate on the superiority of these interventions.

In our study, all the participants underwent concomitant CABG along with the repair of VSD using single Dacron patch. Some previous studies have indicated that CABG does not improve the short-term or long-term outcomes in patients undergoing surgery for post-infarction VSD.<sup>12</sup> However, most studies have shown that there is a definite benefit for doing a concomitant CABG, which translates into better patient survival.<sup>7</sup> Our study has shown acceptable results for a concomitant CABG through lower long-term mortality rates though we did not have a comparison group.

## CONCLUSIONS

Our study has shown that post-infarction VSD can be successfully managed at semi-urban centers, with globally acceptable levels of mortality. Emergency surgical intervention for management of post-infarction VSD was shown to result in high short-term mortality when compared to patients undergoing elective surgeries. Hemodynamic stabilization and allowing maturation of VSD margins yielded a better outcome. Furthermore, single Dacron patch repair with concomitant revascularization was found to be a safe and effective procedure, for the management of the problem.

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# Awareness of Contact Lens Care among College Students in Saudi Arabia

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## Abstract

**Introduction:** Although there are continuous breakthroughs in the contact lens (CL) industry, to provide safe CLs and to meet the continuous demand, CL-induced ocular complications induced by CL wear, especially corneal ulcer (CU) is still troublesome.

**Purpose:** To evaluate the adherence to the guidelines of CL care practice among the students of Umm Al-Qura University in Makkah, Saudi Arabia.

**Materials and Methods:** A cross-sectional structured questionnaire survey of 31 elements was conducted electronically on 4462 college students from the preparatory year, in the Umm Al-Qura University to evaluate the general knowledge and practice of CL wear, care and its possible complications.

**Results:** A total of 543 (50.1%) students, out of 1074, wore CL. 335 (63.3%) female students used CL for cosmetic reasons which were significantly high ( $P < 0.001$ ). 148 (29.8%) students wore CLs for more than 3 years. Among these CL wearers, 66 (13.3%) students wore CLs for more than 8 h daily, 33.1% wore daily disposable CL, 7.9% wore weekly disposable CL, and 55% wore monthly disposable CL. 58 (11.6%) students slept with the CL. 73 (14.6%) and 34 (6.8%) students wore CL during shower and swimming, respectively. 33 (6.6%) students did not wash their hands before handling CL. 349 (70.4%) students did not rub their CL with fingers before soaking in the solution. 100 (20.1%) did not rinse their CL. About 253 (52.2%) students had ocular complaints. 260 (79.7%) students had some allergic reaction, dry eyes in 132 (40.2%) were advised to quit CL wear by doctors, corneal abrasions in 58 (17.4%), and CUs in 26 (8%). 53 (16.3%) students used CL for more than 3 years ( $P = 0.043$ ), frequent daily use of CL ( $P = 0.019$ ), sleeping with CL ( $P < 0.0001$ ), and water activity as a shower ( $P = 0.002$ ) or swimming ( $P = 0.016$ ) were associated with CU.

**Conclusion:** More than half of our students experienced eye complications due to improper care of CL. Increasing awareness is crucial to avoid identified risk factors for CU.

**Key words:** Contact lens disinfectant solutions, Contact lenses, Corneal ulcer, Keratitis

## INTRODUCTION

Although there are continuous breakthroughs in the contact lens (CL) industry, to provide safe CLs and to meet

the continuous demand, CL-induced ocular complications induced by CL wear, especially corneal ulcer (CU) is still troublesome.<sup>1-5</sup> The at-risk population being young adults, who are the main CL wearers, several studies were conducted among them to evaluate the risk factors for ocular complications. Many risk factors were identified, including, sleeping while wearing CLs.<sup>6-11</sup> The risk of microbial keratitis increased by about five-fold among subject who wear their CLs during sleep.<sup>7</sup> In yet another study, CL wearers who developed CUs were found to wear CLs overnight.<sup>11</sup> Swimming with CL was reported in more than one-third of CL wearers who suffered with CU.<sup>11,12</sup>

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Poor hygiene practices, and failure to follow the instruction of use, are major risk factors for corneal inflammation among CL users.<sup>11</sup> Many earlier reports showed that *Pseudomonas aeruginosa* and *Staphylococcus aureus* have been the most common frequently isolated organisms.<sup>4-6,11,13-15</sup> Therefore, it is utmost important to increase awareness of prospective CL users on proper lens care, especially the use of well-fitting daily-disposable lenses<sup>13,16</sup> and regular after care.

## MATERIALS AND METHODS

A cross-sectional structured questionnaire survey of 31 elements was conducted electronically on 4462 college students from the preparatory year, in the Umm Al-Qura University to evaluate the general knowledge and practice of CL wear, care and its possible complications. Any college student who has ever worn CL for whatever reason and for any period was enrolled in this study. The electronic structured questionnaire was distributed among the students from February 2015 to April 2015. All the questions were prepared in English and answers were also given in English by all the students. The questionnaire consisted of single-response questions and one multiple-response question. The following data were collected: Gender, age, use of CL, use of spectacles, type of CL, water activity, hygiene practice, and complication of CL use.

The nature of the study was explained to all the students at the beginning of the questionnaire. The study followed the tenets of the Declaration of Helsinki and was approved by the Umm Al-Qura University Ethics Committee.

### Statistical Analysis

Statistical analyzes were performed using the Statistical Package for the Social Science (SPSS: An IBM Company, Version 16.0, IBM Corporation, Armonk, NY, USA). Data

are presented as mean  $\pm$  standard deviations, median, range, or percentage where appropriate. One-way ANOVA test followed by *post-hoc* tests (Bonferroni test) or independent *t*-test for quantitative data or chi-square test for qualitative data were used to compare differences between subjects of study where appropriate.  $P < 0.05$  was regarded as significant.

## RESULTS

### General Characteristics of Subjects

About 4462 college students from the preparatory year, Umm Al-Qura University were invited to participate in this study. The response rate was 24.1% (1074/4462). Out of 1074, college students who responded to the questionnaire, 543 (50.1%) students had previous or current CL use, 393 (72.4%) students were currently wearing CL, and the remaining 150 (27.6%) had stopped wearing CL for variable reasons (Figure 1).

The reasons reported by students who stopped CL wearing were; loss of interest after cosmetic purpose use in 32 (26.4%), experiencing complications in 12 (9.9%), failure to keep up with the instructions in 7 (5.79%), discomfort in one (0.8%), no special reason in 38 (31.4%), and 31 (25.6%) did not mention any reason (Figure 2).

### Demographic Characteristics of the Study Group

The characteristics of the study group were listed in Table 1.

Of the total surveyed male students, 677 (63.7%) were 19-year-old. Out of which 349 and 328 were CL wearers and non-wearers, respectively. A total of 691 (65.1%) students were females, the majority of them were CL wearer ( $P < 0.001$ ). CL preference versus glasses significantly differs between CL wearer and non-wearer CL as 326 (60.7%) students of CL wearer were found to prefer CL ( $P < 0.0001$ ). 237 (43.6%) students of CL wearer had

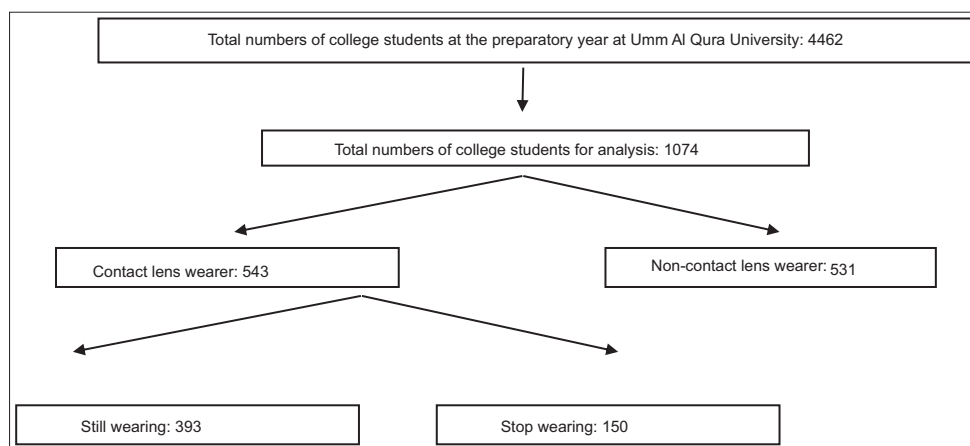


Figure 1: Characteristics of the study group

spectacles compared to 138 (26%) students of the non-CL wearer ( $P < 0.0001$ ).

### Characteristics of CL Wearer

The characteristics of CL wearer are listed in Table 2. The reasons for using CLs varied among students, it was found that 335 (63.3%) of the respondents used them for cosmetic reasons, and 194 (36.7%) students used them to correct vision. Moreover, types of CL varied among users. 7 (1.4%) students wore rigid gas permeable lenses. 491 (98.6%) students wore soft CLs, 69 (13.9%) students wore daily disposables, 39 (7.2%) students wore weekly disposables, 36 (7.8%) students wore monthly disposable, and 353 (71%) students wore conventional lenses.

Of the participants, 358 (70.2%) students had worn CLs for  $<3$  years, and 148 (29.8%) students had worn CLs for more than 3 years. Thus, the minority of participants in this study was experienced wearers. For the daily wearing time, 66 (13.3%) students wore CLs for more than 8 h daily; furthermore, 58 (11.6%) students reported that they slept with their CLs.

Students also reported concomitant water activities and lens wear. 73 (14.6%) of CL wearer recalled that they had been taken shower, while wearing their CLs and 34 (6.8%) of participants reported they engaged in swimming activity while wearing their CLs.

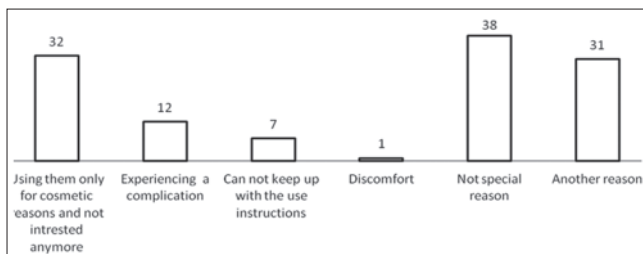


Figure 2: Reasons for stopping contact lens wearing

Table 1: Demographic characteristic of the study groups

Characteristics	Contact lens wearer (n=543)	Non-contact lens wearer (n=531)	P value
Gender (male/female)	78/464	293/227	<0.0001
Age/years			0.24
18 or below	92	93	
19	349	328	
20	60	75	
21	18	15	
22	9	4	
23 or older	13	6	
Had a pair of glasses	237	138	<0.0001
Preference to wear CLs/glasses	326/211	120/348	<0.0001

CL: Contact lens

Table 2: Characteristic of the CL wearer (n=543)

Indication and types of CL	
Reason for CLs	
Vision correction/cosmetic or fashion reason	194/335
Type of used CLs	
Soft/hard	491/7
Type of used CLs	
Disposable/extended wear	173/325
CLs wear modality (%)	
Duration of CLs use	
<6 months	110 (22.2)
6 months-1 year	35 (7.1)
1-2 years	103 (20.8)
2-3 years	100 (20.2)
More than 3 years	148 (29.8)
Frequency of CLs use	
Daily	69 (13.9)
Weekly	39 (7.2)
Monthly	36 (7.8)
Only on special occasions or other events (cosmetically)	353 (71)
The daily wearing time/hours	
<6 h	142 (28)
6-8 h	287 (58)
12-24 h	52 (10.5)
1-2 days	5 (1)
More than 2 days	9 (1.8)
Frequency of sleeping with CLs	
Every day	10 (2)
1-2 days a week	13 (2.6)
1-2 days a month	8 (1.6)
Less than once per month	27 (5.4)
Never	440 (88.4)
Water activities and CLs wear (%)	
Frequency of taking a shower with CLs	
Every day	20 (4)
1-2 days a week	12 (2.4)
1-2 days a month	10 (2)
Less than once per month	31 (6.2)
Never	424 (85.3)
Frequency of swimming with CLs	
Every day	7 (1.4)
1-2 days a week	2 (0.4)
1-2 days a month	4 (0.8)
Less than once per month	21 (4.2)
Never	464 (99.2)
CLs and lens case hygiene practices (%)	
Frequency of share of CLs	
Every day	14 (2.8)
1-2 days a week	9 (1.8)
1-2 days a month	10 (2)
Less than once per month	71 (14.4)
Never	390 (78.9)
Frequency of hand wash before CLs use	
Always	271 (54.5)
Sometimes	152 (30.6)
Rarely	41 (8.2)
Never	33 (6.6)
Rubbing CLs with fingers before soaking them in the solution	
No	280 (56.5)
Yes	147 (29.6)
Not applicable	69 (13.9)
Rinsing CLs case	
No	70 (14.1)
Yes	398 (79.9)

(Contd...)



**Table 2: (Contd...)**

Not applicable	30 (6)
Frequency of change of CLs solution	
Daily	57 (11.5)
On alternate days	47 (9.5)
Weekly	133 (26.9)
Less often than weekly	202 (40.8)
Not applicable	56 (11.3)
Frequency of replace of CLs with new ones	
Daily	22 (4.5)
Weekly	19 (3.9)
Every 2 weeks	21 (4.3)
Monthly	94 (19.4)
Every 6 months	136 (28)
Yearly	193 (39.8)
CLs choose and follow-up schedule (%)	
Ophthalmologist/optometrist/optician prescription for CLs	
No/yes	343/151
Ophthalmologists/optometrists/opticians visit for eye or CLs follow-up	
Once every 2 weeks	4 (0.8)
Once every 6 months	60 (12)
Once a year	121 (24.3)
Never	313 (62.9)

CL: Contact lens

Regarding CL hygiene, the majority of wearers reported that they did not share their CL with others (390 (78.9%) students). 271 (54.5%) students followed hand hygiene before handling CLs while 193 (38.8%) students reportedly rarely followed hand hygiene and 33 (6.6%) indicated that they never washed their hands before handling CLs. Furthermore, 147 (29.6%) students reported that they rubbed their CLs with fingers before soaking in the solution, while 349 (70.4%) replied in the negative. Furthermore, 398 (79.9%) students reported that they rinsed their CLs, while 100 (20.1%) students reported negatively. A changed CL solution occurred in 237 (47.9%) of wearers at least weekly, and the majority of wearers replaced their lens storage case at least once every 6 months, 193 (39.8%) of students replaced their lens storage case yearly.

A total of 151 (30.6%) students had their CL after specialist consultation. 64 (12.8%) students had at least aftercare every 6 months and 121 (24.3%) students consulted specialists for aftercare at least yearly. 313 (62.9%) of the participants did not request any specialist assistance.

### Eye Complications Associated with CL use

Eye complications associated with CL use were listed in Figure 3. Among participants 253 (52.2%) students reported that they had at least one problem related to the use of CL. Out of which 260 (79.7%) of the students quoted allergy either to CL or its solution, followed by dry eyes in 132 (40.2%) students, corneal abrasions in 58 (17.4%) students, CU in 26 (8%) students, and 53 (16.3%) students were advised to quit CL use by their

**Table 3: Risk factors for ocular complication among CLs users**

Factors	Complication		
	Yes	No	P value
Had a pair of glasses	126	92	0.007
Vision correction/cosmetic or fashion reason	98/155	74/156	0.079
Frequency of CLs use			0.006
Daily	43	21	
Weekly	23	13	
Monthly	24	15	
Only on special occasions or other events (cosmetically)	162	180	
The daily wearing time/hours			0.024
<6 h	63	79	
6-8 h	146	131	
12-24 h	33	16	
1-2 days	4	1	
More than 2 days	6	2	
Frequency of sleep with CLs			0.018
Every day	6	2	
1-2 days a week	12	1	
1-2 days a month	5	2	
Less than once per month	15	12	
Never	215	213	
Frequency of taking shower with CLs			0.004
Every day	11	7	
1-2 days a week	9	3	
1-2 days a month	8	2	
Less than once per month	23	7	
Never	201	211	
Rubbing CLs with fingers before soaking them in the solution			0.038
No	145	128	
Yes	80	61	
Not applicable	26	42	
Ophthalmologist/optometrist/optician prescription for CLs			0.029
No/yes	165/88	170/61	
Ophthalmologists/optometrists/opticians visit for eye or CLs follow-up			0.035
Once every 2 weeks	4	23	
Once every 6 months	36		
Once a year	67	51	
Never	146	158	

CL: Contact lens

doctor. 232 (47.8%) of the students faced no problems associated with the use of CL.

### Factors Associated with Eye Complication Due to CL use

Factors associated with Eye complications due to CL use were listed in Table 3. Among several factors studied, we found that CL wearer who had a pair of glasses had less complication ( $P = 0.007$ ). In Addition, prolonged use of CL ( $P = 0.006$ ) and frequent use of them per day ( $P = 0.024$ ) were associated with complication. Sleeping with CL or taking shower reported to be associated with complication ( $P = 0.018$  and  $P = 0.004$ ), respectively. CL users who did not rub their lenses with fingers before soaking them in the solution commonly experienced complications ( $P = 0.038$ ).



Users who choose their CL after specialist consultation and were regularly visiting a specialist did not correlate with complication free and those who encountered complications.

### Factors Associated with CU Due to CL use

Factors associated with CU among CL wearer were shown in Figure 4. Among several factors studied, we found that CU among CL wearer was associated with prolonged period of CL usage ( $P = 0.043$ ), frequent daily use of CL ( $P = 0.019$ ), sleeping with CL ( $P < 0.0001$ ), and water activity in the form of taking a shower or swimming ( $P = 0.002$  and  $P = 0.016$ ).

## DISCUSSION

Across the world, CL is widely distributed among young adults, for reasons such as cosmetic or therapeutic, since its first use in 1887.<sup>17</sup> Then onward, there has been continuous improvement in lens materials, disinfecting, and storing solutions. Nowadays, single solution to rinse, disinfect, and store for CL has replaced the conventional rubbing or enzymatic cleaning.<sup>16</sup> However, CL usage is associated with increased incidence of ocular complication, among them; CU is the most severe one which can predispose to visual loss.<sup>1-5</sup> We found that 543 (50.1%) of respondents

were CL users, 150 (27.6%) of them stop wearing CL for varying reasons. One of the reasons is the occurrence of complications in 12 (9.9%). As all our subjects were in the same year, so no significant difference could be reported in age between CL wearer and non-wearer. Gender was significantly varied between CL wearer and non-wearer. Our finding was consistent with previous reports.<sup>18-21</sup> In our study, we found that cosmetic purpose was the main reason for CL use, our finding was similar to previous reports.<sup>19,22</sup> In our study, ocular complication due to CL use were found in 253 (52.2%) of participants as compared to 79.3% in another study.<sup>19</sup>

Several studies reported the incidence of microbial keratitis among CL users. According to one study microbial keratitis and subsequently, CU occurred in about (1.1-2/10,000, 2.2-4.5/10,000, and 10.3-35/10,000) per year for the rigid CL user, disposable soft CL, and extended-wear soft CL, respectively.<sup>6,17</sup> Another report showed a high incidence of CU (57-86%) among CL users.<sup>23</sup> These high percentages can be explained by the fact that this report (1983) was during the era when CL material and solution were still underdeveloped.

From our study, we stressed the fact that CU as a devastating complication which can end with visual loss. Our results showed that prolonged use CL, frequent daily use CL, and sleeping with CL in addition to participating in water activity in the form of taking a shower or swimming while wearing CL were the major risk factors for CU acquisition among CL users.

The corneal surface is constantly lubricated by the tear film that maintains oxygenation and moisture. Therefore, prolonged use especially overnight can provoke hypoxia and hypercapnia of the corneal epithelium, resulting in ischemic necrosis, which will lead to CU.<sup>9,10,14</sup> Similar to

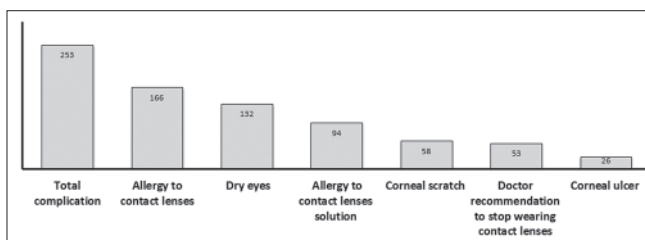


Figure 3: The frequency of eye complication due to contact lens use

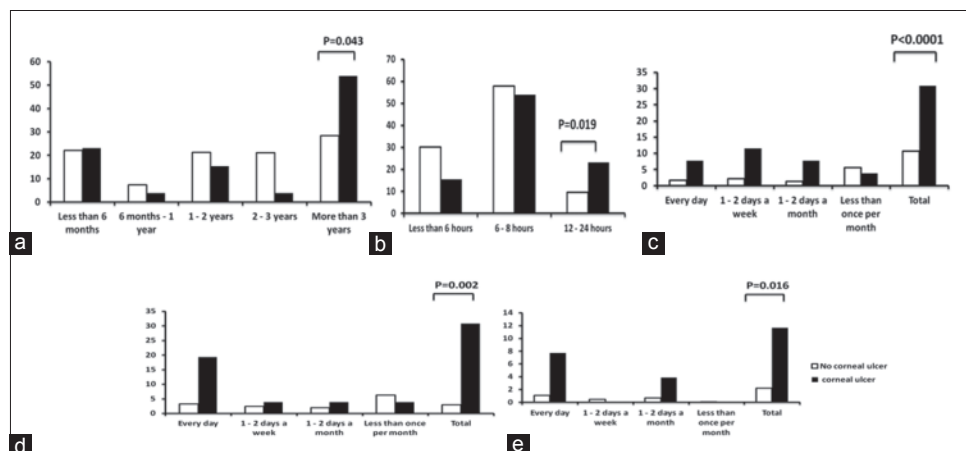


Figure 4: (a) Period of contact lens use, (b) daily use of contact lens, (c) sleeping with contact lens, (d) taking a shower with contact lens, (e) swimming with contact lens

our finding, prolonged use of CL were associated with eye problems.<sup>19</sup> In addition, sleeping with CL was found to be a major risk factor for CU among CL users in several reports.<sup>6-11</sup> Lam *et al.* reported a five-fold increase in the risk of microbial keratitis among patients who wear their CLs overnight.<sup>7</sup> In another study, more than half of CL wearer who had CU reported that they were sleeping with their CLs (11) and swimming (33%) with their CL and (26%) of them do not follow hand reported to be associated with infected keratitis.<sup>11,12</sup> Failure to comply with instruction of use, poor hygiene are risk factor for CU in CL wearer in our study.<sup>22</sup>

Lack of hygiene and improper care of CL can predispose to the colonization of the CL surface with bacteria, leading to biofilms formation, especially with *P. aeruginosa*.<sup>24,25</sup> Previous reports showed that *P. aeruginosa* and *S. aureus* are the most common frequently isolated organism.<sup>4,6,11,13-15</sup> In one study, pseudomonas account for 24% of organisms related to CL-induced ulcer.<sup>11</sup>

These microorganisms contain special structures known as pathogen-associated molecular patterns. These structures activate the innate immune response, mainly toll-like receptors (TLRs) that are expressed throughout the ocular tissue.<sup>26,27</sup> This triggered innate immune response mediates further activation of adaptive immune response. All together develop a defense against microbes which can precipitate corneal inflammation. Up-regulation of TLR was reported in patients with vernal keratoconjunctivitis.<sup>27,28</sup>

Our finding suggested that all the risk factors associated with eye complication among CL wearer are preventable. The prospective CL user must be educated and counseled regarding the proper lens care, duration of usage and hygiene practice while dealing with CL. Prolonged wear of CL, wearing it overnight and swimming or taking a shower while wearing CL must be avoided. CL must be bought from authorized eye care professionals, who can choose well-fitting CL, and provide advice for regular after-care.<sup>13,16</sup> Any individual with known risk factors of developing CU must be advised that if they experience any unexpected symptoms following CL use they must remove CL and seek medical advice as soon as possible for confirmation and early management to prevent loss of vision. Thus, increasing public awareness of prospective CL users on proper lens care and wear duration is crucial.

## CONCLUSION

With the widespread use of CL, CU associated with CL wear became more prevalent. Therefore, it is better to consider the identified risk factors in this study in the care

of CL wearer, which can help to focus effective prevention and treatment strategies.

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# Determinants of Utilization of Janani Suraksha Yojana among Mothers in Selected Communities of Aligarh: A Population-based Cross-sectional Study

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## Abstract

**Background:** Janani Suraksha Yojana (JSY), maternity benefits scheme launched by Government of India in April 2005 with the objective of reducing maternal and neonatal mortality by promoting institutional deliveries by providing cash incentive to beneficiaries as well as promoter.

**Materials and Methods:** A cross-sectional study was conducted under Rural Health Training Centre and Urban Health Training Centre of the field practice area of Department of Community Medicine, J N Medical College Hospital, Aligarh.

**Results:** A total of 300 RDWs (15-49 years) were interviewed out of which 120 (40%) were from urban slums and 180 (60%) from rural areas. The majority of deliveries were at government institution (51%), followed by home (26.3%) and (22.7%) at private hospitals.

**Conclusion:** The majority (73%) of females had institutional delivery. It was found that institutional delivery was influenced by women's age, religion, caste, and educational status. The level of education and younger age was found to have a positive effect on utilization of JSY.

**Key words:** Janani Suraksha Yojana, Recently delivered women, Utilization

## INTRODUCTION

Promotion and protection of maternal and child health has been one of the most important developmental goal in many countries across the globe still mothers continue to die. Worldwide, every day in 2010, about 800 women died during pregnancy and childbirth.<sup>1</sup> More than 60% of mothers died during postpartum period. The risk of death was the highest close to birth and decreased in subsequent days and week.<sup>2</sup> Almost all maternal deaths (99%) occurred in developing countries. More than three-fourth of maternal deaths were concentrated in just two regions of the world,

i.e., 53% in the African region and 25% in South-East Asia. The maternal mortality ratio in developing countries is 240 per 100000 births while in developed countries it is just 16 per 100000 live births. For an emerging global economic power famous for its medical prowess, India continues to have unacceptably high maternal mortality levels. India reported 212/100,000 live births. IMR stood at a high of 47/1000 birth with the majority of maternal and child deaths occurring in five northern states of Bihar, Madhya Pradesh, Orissa, Rajasthan, and Uttar Pradesh (SRS-2011).<sup>3</sup> Combined they accounted for about 55% of child mortality and 65% of maternal deaths in the country. As the risk of death is highest close to delivery and decreases in subsequent days, maximum benefit can be achieved by focusing on this time. Skilled attendance at all births is considered to be the most critical intervention for ensuring safe motherhood.<sup>4,5</sup> But now moving a step forward from training and equipping traditional birth attendants; to use of skilled birth attendant, we aim at achieving universalization of institutional delivery.

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The use of maternal health care services remained low throughout the country despite continued efforts to strengthen the infrastructure, drug supply, and human resource.<sup>6</sup> It was so because these efforts still did not address many of the access barriers faced by the poor. Demand-side financing initiatives are specifically intended to reduce cost-related access barriers for vulnerable groups by giving them purchasing power to use a designated service.<sup>7</sup> The concept involves funneling government or donor funds directly to a selected group. There are various approaches, one of them being a conditional cash transfer (CCT). A traditional CCT bestows a financial incentive directly to the beneficiary if the recipient complies with a certain set of prerequisites.<sup>7,8</sup>

Beginning in 2005, India launched a national CCT program to promote institutional delivery, Janani Suraksha Yojana (JSY). The JSY program is fully funded by the Government of India and operates under the National Rural Health Mission.<sup>9</sup>

Functional nationwide, it is the largest cash transfer program in the world.<sup>10</sup> The eligibility criteria for the program differ depending on the province. Women delivering in non-high focus states (with a relatively better in-facility birth proportion) are only eligible for the cash benefit for their first two live births, and if they have a government issued below the poverty line (BPL) card or belong to a scheduled caste or tribe. While in high focus provinces, (those with a low in-facility birth proportion), it does not include a conditionality component. All women who deliver in a public facility receive the cash incentive. In Uttar Pradesh, a high focus state, rural women receive Rs. 1400, whereas urban women receive Rs1000 upon delivery in a public facility. All services provided in the public health sector are free of charge to the end user. The program is supported in the community through the selection of an accredited social health activist (ASHA). The ASHA is a female resident of the village who is incentivized to motivate women to deliver at public facilities under the program.<sup>11</sup>

To date, there have been few research reports on this large-scale demand-side financing program for maternal health. Previous assessments have been descriptive,<sup>12</sup> process oriented,<sup>13</sup> or based on secondary data collection.<sup>10</sup> There has been few documentation on factors that influence how beneficiaries interact with the services provided. This paper studies the extent of institutional deliveries and factors associated with participating in the cash transfer program in one district in India. It also studies the timeliness of receipt of the cash incentive by mothers.

## MATERIALS AND METHODS

In the present context, this study was conducted to find out the institutional delivery rate, utilization rate of JSY

and to identify the association of the socio-demographic characters with JSY utilization.

A cross-sectional observational study was undertaken in the field practice areas of the Urban and Rural Health Training Centers, Department of Community Medicine, JNMC, AMU, Aligarh, UP. The total population covered under RHTC with 6 villages was 13787 and UHTC with 2 periurban and 2 rural localities was 10932. The study was carried out over a period of 12 months (1 July, 2013, to 30 June, 2014) among recently delivered women. The prevalence of institutional delivery in UP as found in a study by UNFPA 2008 (50.2%) was used for calculation of sample size (95% confidence level, 12% relative precision and 8% non-response). The yielded sample size was 278 which was rounded off to 300 and selected proportionately from the 10 areas. In each area, systematic random sampling was used and all eligible females of the houses were included. For households with no eligible female, next house was taken.

After obtaining informed consent and explaining the study objective, data were collected by interviewing the 300 study subjects, ensuring confidentiality in a non-judgmental manner and in the absence of any family member or local health personnel.

The study variables were related to JSY status, socio-demography, BPL card. Some specific information was also elicited from JSY mothers regarding amount and delay in receipt of financial assistance and pattern of money utilization. The opportunity of contact was taken up for health communication, treatment of minor illness, and eventually, mothers were thanked for their cooperation.

Data entry and management were carried out using MS excel spreadsheet and software. A result was analyzed by calculating descriptive statistics - proportion (%) and association of maternity benefit scheme (JSY) with selected variables using chi-square test and statistical result displayed for significant ( $P < 0.05$ ) items only.

The study obtained clearance from the Institutional Ethics Committee, J N Medical College, Aligarh Muslim University, Aligarh.

## RESULTS

In the current study, majority (45%) of women belonged to the age group 18-24. More than two third (71.3%) of the study population were from rural background, as most of the field practice areas were rural and PPS sampling was done. 67% women were Muslims and 33% were Hindus. Only 2 women belonged to other religion and were Christians.



About 40% of study population belonged to the OBC, 32.8% General and 27.2% to SC/ST category. 76.7% of women had joint family and 23.3% women lived in nuclear family. More than 50% of women were illiterates or had no formal education while 22% of women had education up till middle school and 14% females had attended high school. While 11% had received higher education, i.e., attended college or above. The majority of women (97.7%) under study were housewives. Though some of them used to do field work or making parts of locks in the home, they were not earning independently. Those working outside came from two very different categories; on one side they were unskilled workers while the other halves were qualified, professional females (Figure 1).

### Utilization of Various Components of JSY by Females Delivering at Government Facility

Most (94.7%) of the females delivering in government institution, i.e., eligible for receiving JSY incentive were getting the intended cash benefit. The 5.3% mothers who did not receive the cash were those not aware of the cash benefit or those told to come after some time but did not turn up again (Table 1).

In our study, 18% females either got cash or cheque at the time of discharge from hospital while almost half (48.27%) females received cash incentive within 2 weeks time. In total, 87% females received their payments by 1 month post-delivery (Table 1).

Age of the mother at the time of delivery has a profound influence in choosing the place of delivery. Younger females especially those <25 years had both higher government (51%) and private (45.6%) hospital delivery while home was the favored place of delivery for more than 30 years females. 55.6% of the study population of rural area delivered in a government institution and 19.6% in private hospital while 24.8% had home delivery. Hindu females had a lower home delivery (19%) compared to Muslim females (81%) indicating Hindus preference for institutional delivery. Lower castes (SC/STs) had a highly significant negative association with delivery at a government institution. Education was observed to have

a highly significant relation with the place of delivery, with primary and above education females preferring institutional delivery. Equal number of working mothers (42.9%) delivered in private and government set up while just one female (14.2%) delivered at home (Table 2).

## DISCUSSION

Healthcare sector has been experiencing a regular shift from non-institutional to institutional deliveries over the years. Institutional delivery refers to the childbirth at technology-equipped medical facility under supervision of skilled medical staff to ascertain that health of neonate or mother is not compromised. These include deliveries in government health facilities as well as private institutions such as nursing homes and hospitals. As can be seen in Figure 1, majority of deliveries were at government institution (51%), followed by home (26.3%) and (22.7%) at private hospitals. Thus, majority 73% females of our study had institutional delivery. Institutional deliveries are on a constant rise,<sup>14,15</sup> but a recent hike is seen after few years of implementation of JSY (2012). Similar findings were reported by other researchers also who studied the low performing states.

In Agra 53.20% deliveries took place in an institution,<sup>16</sup> Ved *et al.* identified that there were about 60% institutional delivery in different districts.<sup>17</sup> Roy *et al.* reported 84.9% institutional deliveries, out of which, 79.3% were at government hospitals in Lucknow.<sup>18</sup> Varma *et al.* said 92% of deliveries were in the government hospitals in rural UP.<sup>19</sup> CORT commissioned by UNICEF observed institutional delivery rate to be 55% in UP.<sup>20</sup> UNFPA, in concurrent assessment of the JSY observed 47.5% institutional deliveries in UP.<sup>13</sup>

Contradictory findings were shown by other researchers. Institutional deliveries were found to be 37.1% by Sahu *et al.* in Raipur,<sup>21</sup> 21% by Khan *et al.*<sup>22</sup> and 18.6% by Ansari and Khan in Aligarh;<sup>23</sup> 44% by Population Council in UP.<sup>24</sup>

Most of families in our study were daily wagers, who hardly kept any savings. In such a situation the cash incentive provided in the JSY scheme comes very handy. 94.7% of those delivering at government hospital received cash benefit. Sidney *et al.* in Ujjain reported 100% receipt of the cash benefit.<sup>25</sup> Santhya *et al.* found 92% receipt of cash entitlement in Rajasthan<sup>26</sup> while it was found to be 89% for rural UP.<sup>19</sup> Lim *et al.* found implementation of JSY in 2007-2008 was highly variable by state-from <5-44% of women giving birth receiving cash payments from JSY.<sup>10</sup> Others studies in high performing states too, have reflected lower rates of cash receipt. It was 68% by Singh *et al.*,<sup>27</sup>

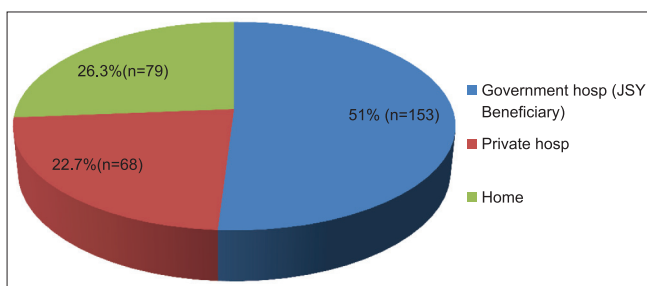


Figure 1: Place of delivery of mothers in our study

53% by Lanjewar *et al.*,<sup>28</sup> 32.8% by Vishwanath *et al.*,<sup>29</sup> 48% by Malik *et al.* in Haryana<sup>30</sup> and 27.3% by Vikram *et al.* in Delhi.<sup>31</sup>

The most judicious time for receipt of cash is before going for delivery so that payments for transport, medicine, etc. can be given. Nevertheless even after delivery, it should be given as soon as possible. Similar to our study, (66% of beneficiaries got incentive within 2 weeks of delivery), in Ujjain too most beneficiaries reported receiving the cash incentive by 2 weeks of delivery,<sup>25</sup> in Rajasthan 50% by a week and 35% by 1 month,<sup>26</sup> in Maharashtra 53% within 1 week of delivery<sup>28</sup> in UP, only 64% received it within 1 month.<sup>19</sup> In high performing states also, like Maharashtra 68% received JSY incentive at the time of discharge<sup>27</sup> while 20.83% JSY mothers received money in

<1-month of delivery in Haryana.<sup>30</sup> Thus, the cash receipt is highly variable across various states irrespective of them being high or low performing, depicting official hurdles to be the same everywhere.

Age of the mother at the time of delivery has a profound influence in choosing the place of delivery. As shown in Table 2 deliveries at government health facility were found to be greatest in 18-24 year age group (51%), followed by 25-30 year age group (41.2%). The home was the favored place of delivery for more than 30 years females. Lim *et al.* found utilization rates steadily declined with age with the youngest women (aged 15-19 years) showing the highest uptake in different districts of India.<sup>10</sup>

While no significant relation between delivery at government facilities and the age was reported by Roy *et al.* in Lucknow<sup>18</sup> and Santhya *et al.* in Rajasthan.<sup>26</sup>

Rural population lag behind in the utilization of maternal and child services. However, better results were reported in rural areas under our study; this may be because most of the villages had good road connectivity to nearby CHC at Jawan. 55.6 % of our study population of rural area delivered in a government institution and 19.6% in private hospital while 24.8% had home delivery. Belonging from a rural area was significantly associated with institutional delivery. Similarly, Lanjewar *et al.* in Maharashtra observed that more women from rural area (85.29%) actually benefitted.<sup>28</sup>

Contrary results were observed by Khan *et al.* in UP and Santhya *et al.* in Rajasthan where residence in remote

**Table 1: Components of JSY (cash receipt)**

Details of cash benefit receipt	n (%)
Receipt of cash benefits by those having government facility delivery (n=153)	
Yes	145 (94.7)
No	8 (5.3)
Time of receipt of cash incentive	
Within 24 h	26 (17.9)
24 h - 2 weeks	70 (48.3)
2 weeks - 4 weeks	31 (21.4)
>4 weeks of delivery	18 (12.4)
Cash incentive given by	
ASHA	15 (9.8)
Health institution staff	121 (79.1)
Others	17 (11.1)
Total	153 (100)

ASHA: Accredited social health activist, JSY: Janani Suraksha Yojana

**Table 2: Distribution of mothers according to area, religion, caste, age group and utilization of JSY (delivery at government facility)**

Socio demographic characteristics	Place of delivery			Total (%) n=300	Chi-square	P value
	Government (n=153)	Private (n=68)	Home (n=79)			
Age group						
18-24	78 (51)	31 (46)	27 (34)	136 (45)	11.29 (4)	0.023
25-30	63 (41)	29 (42)	35 (44)	127 (42)		
>30	12 (8)	8 (12)	17 (22)	37 (13)		
Area						
Rural	119 (78)	42 (62)	53 (67)	214 (71)	6.85 (2)	0.033
Urban	34 (22)	26 (38)	26 (33)	86 (29)		
Religion						
Hindu	61 (40)	23 (34)	15 (19)	99 (33)	10.30 (2)	0.006
Muslim	92 (60)	45 (66)	64 (81)	201 (67)		
Caste						
General	56 (37)	32 (47)	10 (13)	98 (33)	32.71 (4)	0.000
OBC	63 (41)	26 (28)	31 (39)	120 (40)		
SC/ST	34 (22)	10 (15)	38 (48)	82 (27)		
Mother's education						
Illiterate	80 (52)	35 (51)	62 (79)	177 (59)	23.139 (4)	0.000
1 <sup>st</sup> -10 <sup>th</sup> class	63 (41)	23 (34)	16 (20)	102 (34)		
Above 10 <sup>th</sup>	10 (7)	10 (15)	1 (1)	21 (7)		

Delivery at government institution was considered proxy for JSY utilization, as there were no accredited private institutions and none of the home delivered mothers received any cash benefit, JSY: Janani Suraksha Yojana

villages or hamlets of the large village was negatively associated with institutional delivery.<sup>22,26</sup>

Hindu females had a lower home delivery (19%) compared to Muslim females (81%) indicating Hindus preference for institutional delivery which was found to be statistically significant also. Roy *et al.* from Lucknow, reported Hindus to be more likely to get their deliveries done at the government hospital.<sup>17</sup> Santhya *et al.* found that women from religion other than Hinduism were less likely to get the cash benefit (33-35% versus 49%) in Rajasthan.<sup>26</sup> Lim *et al.* found that Muslims in both high-focus and non-high-focus states had lower odds of receiving JSY payments.<sup>10</sup>

In our study, lower castes (SC/STs) had a highly significant negative association with delivery at a government institution. Scheduled castes/tribes were found to be negatively associated with institutional delivery by Khan *et al.* in Aligarh.<sup>22</sup> On the other hand, Roy *et al.* and Lim *et al.* reported that SC/STs had higher preference to get their deliveries at government hospital.<sup>18,10</sup>

Education was observed to have a highly significant relation with the place of delivery, with primary and above education females preferring institutional delivery. Similar to our findings Roy *et al.* also reported significant relation between delivery at government facilities and education status of the RDWs of Lucknow.<sup>18</sup> In Aligarh being non-literate was found to be negatively associated with institutional delivery.<sup>23</sup>

## CONCLUSION

To conclude we can say that acceptance of institutional delivery care has improved a lot as compared to earlier studies in the same area. This is probably in response to JSY. Vertical transfer of cash assistance may result in interjection of new messages to targeted population, catalyzing critical mass movement and urging for behavior change but will only make a difference when health infrastructure is also improved to tackle the problem of overcrowding in hospitals, lack of trained staff at the health facility and uninterrupted supply of delivery kits, IFA tabs and other drugs.

Improvement in overall status of development of women in particular and society in general by ensuring equity in educational and economic opportunities is sure to bring about palpable results in improving service utilization and general health status of the people.

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# Hypoglycemic Effect of *Tinospora cardifolia* in Type II Diabetes Mellitus

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## Abstract

**Introduction:** Aim of the present investigation is to evaluate the hypoglycemic effects of an alcohol extract of dried stem of *Tinospora cardifolia*, an indigenous plant used in Ayurvedic medicine in India.

**Purpose:** To establish the hypoglycemic effect of the drug. To evaluate if there are any renal or hepatic toxicity.

**Materials and Methods:** A total of 50 individuals, 15 normal and 35 diabetic in age group 35-65 were selected for study and extract of *T. cardifolia* in the dose 2 g and 4 g was administered for 2 weeks. Blood sugar was monitored after 1 week and 2 weeks of administration.

**Results:** Mean post prandial blood sugar after 1 h and 2 h was significantly reduced at the end of 2 weeks. Furthermore, there were no significant hepatic and renal toxicity.

**Conclusion:** The drug significantly reduced the blood sugar levels at the end of 2 weeks in the dose of 2-4 g per day. The drug is free from any liver or renal toxicity.

**Key words:** Aliphatic compounds, Alkaloids, Diterpene, Glycosides, Hypoglycemic, Lactones, Liver function test, Phenolics, Polysaccharides, Sesquiterpenoids, Steroids, *Tinospora cardifolia*

## INTRODUCTION

Diabetes mellitus is a heterogeneous group of diseases with disorders metabolism and inappropriate hypoglycemic due to a deficiency either of insulin secretion or to a combination of insulin resistance and inadequate insulin secretion to compensate. It is due to the diversity of etiological, environmental, and genetic factors acting together. It is broadly classified into broad etiopathogenic categories.

Type I diabetes mellitus - the cause is absolute deficiency of insulin secretion and Type II diabetes mellitus - the cause is the combination of resistance to insulin action

and an inadequate compensatory insulin secretory response.

WHO diagnostic criteria for diabetes mellitus - plasma glucose level of 126 mg/dl or higher after an overnight fast on more than one occasion.

A value of 200 mg/dl or above within 2 h after 75 g of oral glucose is of diagnostic value in diagnosis of diabetes mellitus.

Role of *Tinospora cardifolia* as a hypoglycemic agent has been recognized since ancient times. It is a large glabrous deciduous climbing shrub belonging to the family Menispermaceae which is distributed throughout tropical Indian subcontinent and China. It is widely used for its general tonic, antipyretic, antispasmodic, anti-inflammatory, antiarthritic, antiallergic, and antidiabetic properties. A variety of constituents have been isolated from this plant and their structures elucidated. They belong to different classes such as alkaloid, diterpenoids, lactones, glycosides,

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**Table 1: Hypoglycemic effect of *Tinospora cardifolia* after 1 and 2 weeks of treatment in type 2 diabetes patients**

Parameters	Initial readings	1 week of treatment	2 weeks of treatment	P value	Significance
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD		
FBS	122.77 $\pm$ 22.57	112.94 $\pm$ 20.48	104.11 $\pm$ 20.76	<0.001	Highly significant
1 h PPBS	226.87 $\pm$ 59.7	217.77 $\pm$ 54.9	205.61 $\pm$ 56.03	<0.001	Highly significant
2 h PPBS	200.49 $\pm$ 58.69	192 $\pm$ 54.37	180.94 $\pm$ 55.33	<0.001	Highly significant
Serum bilirubin	0.826 $\pm$ 0.22	0.831 $\pm$ 0.25	0.77 $\pm$ 0.20	>0.05	Not significant
SGPT	17.60 $\pm$ 7.21	16.86 $\pm$ 7.01	16.49 $\pm$ 7.08	>0.05	Not significant
Alkaline phosphatase	6.60 $\pm$ 3.24	5.94 $\pm$ 2.72	5.89 $\pm$ 2.56	>0.05	Not significant
Blood urea	24.83 $\pm$ 7.9	23.37 $\pm$ 7.30	23 $\pm$ 6.9	>0.05	Not significant
Serum creatinine	1.09 $\pm$ 0.45	1.07 $\pm$ 0.39	1.05 $\pm$ 0.39	>0.05	Not significant

PPBS: Post prandial blood sugar, FBS: Fasting blood sugar, SGPT: Serum glutamic pyruvic transaminase, SD: Standard deviation

steroids, sesquiterpenoids, phenolics, aliphatic compounds, and polysaccharides.

## MATERIALS AND METHODS

This study was conducted on 15 normal and 35 diabetic individuals in the age group of 35-60 years; they were maturity onset diabetics selected from the inpatient and outpatient department of Katihar Medical College, Katihar. A through medical checkup and medical history recording was done to know any major illness. These diabetics were free from infection or any major illness; they were taking some form of antidiabetic treatment. The control group was selected from medical students, staff, and other volunteers not suffering from any apparent disease. Each of these individuals was subjected to standard glucose tolerance test. Glucose was given orally in the dose of 1 g/kg body weight. Level of blood sugar was estimated from fasting as well as 1 h and 2 h after oral glucose. They were also subjected to various liver function tests (LFT).

### Statistical Analysis

Results were presented as mean  $\pm$  standard deviation (SD). Comparison was made by unpaired *t* test.  $P < 0.001$  was considered significant. Correlation between parameters was performed by pearson correlation analysis.

## RESULTS

Results are summarized in Table 1. The glucose levels decreased significantly after 1 week and 2 weeks of treatment with the extract of *T. cardifolia*. Furthermore, the LFT and renal function test were not significantly altered.

## DISCUSSION

Mean fasting blood sugar (FBS) at the onset of treatment was 122.77 mg/dl. Mean FBS after 1 week of treatment was 112.94 mg/dl and after 2 weeks of treatment was

104.11 mg/dl. At the end of 1 week, there was a reduction in mean FBS by 10% and after 2 weeks there was a reduction by 18.66%. This was highly significant ( $P < 0.001$ ).

Mean 1 h postprandial sugar at onset was 226.87 mg/dl after 1 week was 217.77 mg/dl and at the end of 2 weeks was 205.61 mg/dl. At the end of 1 week, there was reduction of 9.10% ( $P < 0.05$ ) and after 2 weeks reduction of 21.26% noted ( $P < 0.001$ ). This is highly significant.

Mean 2 h postprandial blood sugar at the onset was 200.49 mg/dl, after 1 week of treatment was 192 and after 2 weeks was 180.95 mg/dl. This reduction of 8.49% at the end of 2 weeks was significant ( $P < 0.05$ ).

Thus from the above observation, the hypoglycemic effect of *T. cardifolia* is established. These findings are in accordance with Gupta *et al.*; Yajnic *et al.*; Khory *et al.*<sup>1-3,4,7,8</sup>

Furthermore, the drug has no significant effect on LFT (serum bilirubin, serum glutamic pyruvic transaminase, alkaline phosphatase) and renal function test (blood urea and serum creatinin) levels during or after the treatment which is in agreement with Rege *et al.*; Bhasin; Yajnic *et al.*<sup>5,6,8</sup>

## CONCLUSION

It was found that the drug significantly lowered the blood sugar levels at the end of 2 weeks in the dose of 2-4 g/day. Possible mechanism of action could be by increasing endogenous insulin secretion increasing the uptake of glucose by peripheral tissues and by decreasing glycogenolysis and increasing glycogenesis. The drug is free from any liver or renal toxicity.

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# Post-operative Nausea and Vomiting: Comparison of the Role of Ramosetron and Ondansetron

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## Abstract

**Background:** Post-operative nausea and vomiting (PONV) is the most common symptom having incidence of 53-72% in laparoscopic surgeries. Ondansetron is the most popular drug used for controlling nausea and vomiting postoperatively. Both ondansetron and ramosetron are selective 5HT<sub>3</sub> receptor antagonists. A prospective, randomized, double-blind controlled study was done in patients undergoing laparoscopic cholecystectomy, comparing the efficacy of ondansetron and ramosetron.

**Materials and Methods:** About 150 patients admitted in Teerthanker Mahaveer Medical College for elective laparoscopic cholecystectomy were divided into two groups. These patients were divided into two equal groups ( $n = 75$ ) by computer-generated randomization. The control group was given ondansetron and the experimental group was given ramosetron for preventing PONV.

**Result:** In the early phase (<24 h) of post-operative period, 53.33% in control group and 50.66% in experimental group experienced PONV and retching. However, this was statistically insignificant. Whereas in the late phase (>24 h), the percentages were 28% and 13.33% in control and experimental groups, respectively, which were statistically significant ( $P < 0.05$ ). Besides, this severity of nausea, vomiting, and retching was more in the control group as compared to other.

**Conclusion:** The present study concludes that ramosetron plays a better role in controlling PONV, both in early and late phase as compared to ondansetron in laparoscopic surgeries. The severity of symptoms was also less in patients taking ramosetron.

**Key words:** Laparoscopic cholecystectomy, Ondansetron, Post-operative nausea and vomiting, Ramosetron

## INTRODUCTION

The common symptom which commonly appears after any surgical intervention is post-operative nausea and vomiting (PONV), with the high incidence of 30-40%. The etiology of this symptom can be surgical or drugs of anesthesia. Few individuals have more risk for developing the PONV, the reason for which is not known. It is believed that laparoscopic surgeries have a high incidence of PONV. Laparoscopic cholecystectomy has 53-72% chances of incidence of PONV.<sup>1</sup>

Sometimes, PONV becomes a main cause of delay in discharge of the patient, and thus, the burden on the

hospital increases. It also causes patient uneasiness, thus remains a cause of concern for the anesthesiologists. The drugs such as ondansetron and granisetron are used to control PONV. In severe cases, these drugs are used in combination with other antiemetics such as droperidol and metoclopramide.<sup>2</sup> Recently, a new drug named ramosetron has been introduced which is also a 5HT<sub>3</sub> receptor antagonist. Some studies recommend this drug to be more potent and selective than ondansetron.<sup>1-3</sup> The literature related to studies on the randomized controlled trials or case-controlled studies on the use of ramosetron is lacking.

In 1990, ondansetron was first used for controlling PONV. It is the most popular drug used for controlling nausea and vomiting post-operatively, after radiotherapy and chemotherapy. The drug can be administered orally, intramuscularly, and intravenously. The serious adverse effects of this drug are allergic reactions and ECG abnormalities such as prolonged QT interval.<sup>4</sup>

Both ondansetron and ramosetron are selective 5HT<sub>3</sub> receptor antagonists. These receptors are commonly

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present in vomiting inducing sites such as nucleus tractus solitarius, area postrema, and vagal afferents. These drugs act by inhibiting the binding of serotonin to the 5HT<sub>3</sub> receptors and thus control PONV. These drugs are not only highly selective but also show little affinity for some other receptors such as histamine, dopamine, and acetylcholine (muscarinic) receptors.<sup>5</sup>

These drugs are metabolized in the liver by isoenzymes of cytochrome P450 and do not have any major drug interactions. Thus, these are safe to administer. The only important side effect of the drug is asymptomatic alterations in electrocardiogram, mostly elongation of PT and QTc interval.<sup>6,7</sup>

Since the literature comparing the efficacy of ondansetron and ramosetron is lacking, so we have designed a prospective, randomized, double-blind controlled study in patients undergoing laparoscopic cholecystectomy.

## MATERIALS AND METHODS

The 150 patients aged between 25 and 55 years admitted in Teerthanker Mahaveer Medical College for elective laparoscopic cholecystectomy were divided into two groups. Ethical approval was taken from the Institutional Committee. Patients were informed about the study, and the written consent was taken. About 150 patients were divided into two equal groups ( $n = 75$ ) by computer-generated randomization. The control group was given ondansetron, and the experimental group was given ramosetron for preventing PONV.

In the present study, the dose of the ramosetron and ondansetron used were 0.3 mg and 4 mg, respectively. Patient was pre-medicated with lorazepam (0.5 mg) orally one night before, and the patient was advised to remain nil per orally after midnight. Injection propofol 2 mg/kg and injection fentanyl 1-2 µg/kg were used to sedate the patient. During surgery, anesthesia was maintained with nitrous oxide (66%) and sevoflurane (1-2%) in oxygen. Injection vecuronium 0.1 mg/kg was given which assisted in smooth intubation. After the completion of surgery, injection diclofenac 75 mg IM was administered and later post-operative analgesia was provided by injection tramadol 2 mg/kg IM. Injection neostigmine (0.04 mg/kg) and injection glycopyrrolate (0.01 mg/kg) were given for the reversal of muscle relaxation. Before shifting the patient to post-operative room, ondansetron (4 mg) or ramosetron (0.3 mg) was administered according to the group.

With the help of an autonomous observer who was unaware or blinded of the study was used to monitor the patient for 48 h and record any complaint of nausea,

vomiting, and retching. The patients who experienced significant nausea or >2 episodes of vomiting, injection metoclopramide (10 mg intravenous) was given.

Nausea is defined as a subjectively disagreeable sensation related with consciousness of the desire to vomit. Retching is defined as the irregular, rhythmic contraction of the abdominal muscles without expulsion of gastric contents. Vomiting is defined as the vigorous expulsion of gastric contents from the oral cavity.<sup>8</sup>

Nausea was calculated with the help of visual analog scale which ranges from 0 = No nausea to 10 = Nausea as worst as can be:

- Score > 5 (Severe)
- Score = 5 (Moderate)
- Score < 5 (Mild).

Retching episodes of:

- >2 (Severe)
- =2 (Moderate)
- <2 (Mild).

All the statistical tests were two-tailed. All the values were expressed as a mean  $\pm$  standard deviation. The data were recorded on standardized case report forms and analyzed in SPSS, version 17 (SPSS Inc., USA). A  $P < 0.05$  was considered statistically significant.

## RESULT

In the present study, 150 patients who were divided into two groups underwent elective laparoscopic cholecystectomy in duration of 1 year. The difference in the mean age, height, and weight of these patients was non-significant ( $P > 0.05$ ). The control and experimental groups were also comparable with respect to the duration of surgery, duration of anesthesia, and duration of CO<sub>2</sub> insufflation (Table 1).

In the early phase (<24 h) of post-operative period, 53.33% in control group and 50.66% in experimental

**Table 1: Comparison of demographic data of patients and details of surgery in two groups**

Characteristics	Control group	Experimental group	Significance
Age of patient	40.42 $\pm$ 3.69	40.18 $\pm$ 2.99	NS
Height of patient	160.25 $\pm$ 2.59	159.99 $\pm$ 2.71	NS
Weight of patient	55.18 $\pm$ 3.63	54.98 $\pm$ 3.44	NS
Duration of surgery (min)	60.61 $\pm$ 2.74	59.27 $\pm$ 3.01	NS
Duration of anesthesia	68.11 $\pm$ 3.42	67.82 $\pm$ 3.33	NS
Duration of CO <sub>2</sub> insufflation	62.68 $\pm$ 1.73	61.15 $\pm$ 2.01	NS

NS: Non significant ( $P > 0.05$ ), PONV: Post-operative nausea, vomiting

group experienced PONV and retching. However, this was statistically insignificant. Whereas in the late phase (>24 h), the percentages were 28% and 13.33% in control and experimental groups, respectively, which were statistically significant ( $P < 0.05$ ) (Table 2 and Figure 1).

Severity ratings of nausea, vomiting, and retching observed in patients of the two groups are detailed in Tables 3 and 4; Figure 2.

## DISCUSSION

Any surgical intervention can be followed by PONV, but it is found in more than 50% of the patients undergoing laparoscopic surgery. The most important pathway for PONV is the signals received from cerebrum, receptors of viscera, and chemoreceptor trigger zone (CTZ). Besides, this in laparoscopic surgeries, the CO<sub>2</sub> insufflation also causes peritoneal distension which irritates the neurogenic pathway resulting in PONV.<sup>9</sup>

Various drugs such as anticholinergics, antiserotonins, benzamides, and dexamethasone have been used as prophylaxis or treatment of PONV. However, these drugs are associated with adverse effects such as low blood pressure, dryness in oral cavity, dizziness, and extrapyramidal symptoms. 5HT<sub>3</sub> receptor antagonists are considered as drug of choice for PONV, and they

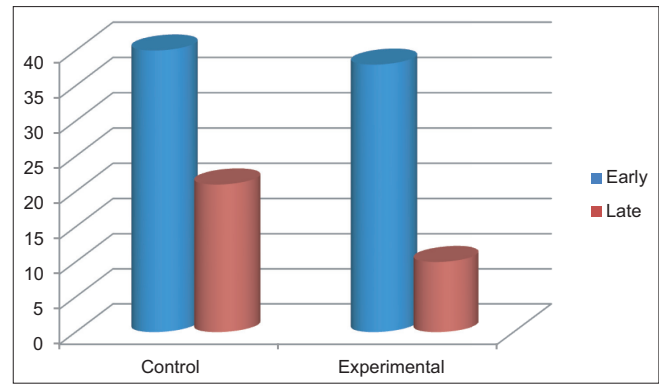


Figure 1: Presence of post-operative nausea and vomiting in early and late phase in both the groups

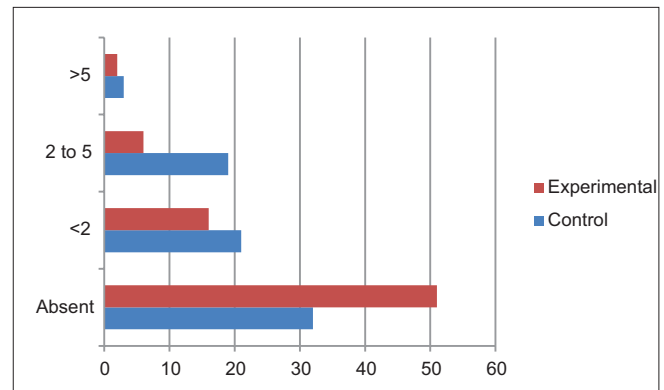


Figure 2: Comparison of number of episodes of vomiting in two groups

Table 2: Comparison of the incidence of PONV and retching in two groups

PONV and retching	Early phase (<24 h)			Late phase (>24 h)		
	Control	Experimental	P value	Control	Experimental	P value
Present	40	38	>0.05	21	10	<0.05
Absent	35	37	>0.05	54	65	<0.05

P<0.05 - significant, PONV: Post-operative nausea, vomiting

Table 3: Comparison of severity of nausea in two groups

Post-operative nausea	Early phase (<24 h)			Late phase (>24 h)		
	Control	Experimental	P value	Control	Experimental	P value
Absent	35	37	>0.05	54	65	<0.05
Mild	11	19	<0.05	10	7	>0.05
Moderate	19	13	<0.05	6	2	<0.05
Severe	10	6	>0.05	5	1	<0.05

P<0.05 - significant

Table 4: Comparison of severity of retching in two groups

Post-operative retching	Early phase (<24 h)			Late phase (>24 h)		
	Control	Experimental	P value	Control	Experimental	P value
Absent	32	41	<0.05	39	53	<0.05
Mild	13	12	>0.05	17	10	<0.05
Moderate	18	10	<0.05	11	7	<0.05
Severe	12	12	>0.05	8	5	>0.05



**Table 5: The comparison of adverse effects of the drugs in two groups**

Side effect	Control group (%)	Experimental group (%)	P value
Sedation	5 (6.6)	2 (2.6)	NS
Headache	3 (4)	1 (1.3)	NS
Weakness	2 (2.6)	1 (1.3)	NS
Dyspepsia	3 (4)	1 (1.3)	NS
Dryness in oral cavity	0 (0)	0 (0)	-

NS: Nonsignificant

act by inhibiting CTZ and the vagal afferents in the gastrointestinal tract.<sup>7,10</sup>

Keeping the demographic profile of the patients and conditions of surgery similar, the comparative study was done to observe the effect of ondansetron and ramosetron on PONV. Besides this, the side effects of these drugs were also studied and compared.

In the early phase of the post-operative period, no statistically significant difference was found in efficacy and side effects of the drugs (Tables 2-5). However, in the late phase of post-operative period, the statistically significant difference was seen in the efficacy of the two drugs. Similar findings were present in the study of Rajeeva *et al.*,<sup>11</sup> who also stated significantly lower frequency of PONV in the ramosetron group when compared to the ondansetron group in the patients after laparoscopic cholecystectomy.

In this study, we also noted the incidence of adverse drug effects in both the groups. These effects were mild and momentary in nature and were statistically insignificant in between ramosetron and ondansetron groups. These findings are supported by Fujii *et al.*<sup>12</sup> in his study.

Some researchers<sup>9-13</sup> believe that use of nitrous oxide during surgery also plays an emetogenic role. Ignoring nitrous oxide and using a continuous infusion of a short-acting opioid might have been a better choice, so the use of nitrous oxide is now controversial. Certain studies<sup>14-16</sup> advocate the use of a combination of drugs in controlling PONV, especially in the patients who are more prone to develop it. Besides this, addition of dexamethasone to the newer 5HT<sub>3</sub> receptor antagonists has been reported more efficacious in patients undergoing laparoscopic cholecystectomy.

The only limitation of our study was that we did not include a placebo group, as this is unethical to expose the patient to distressing symptoms of post-operative period.

## CONCLUSION

The present study concludes that ramosetron plays a better role in controlling PONV, both in early and late phase as compared to ondansetron in laparoscopic surgeries. The severity of symptoms was also less in patients taking ramosetron. Besides this, both the drugs cause lesser side effects.

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# Magnetic Resonance Imaging of Knee Joint: Diagnosis and Pitfalls Using Arthroscopy as Gold Standard

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## Abstract

**Introduction:** Role of magnetic resonance imaging (MRI) in the diagnosis of knee lesions has now become more evident. Efficacy of MRI in comparison to arthroscopy has been studied and proved by many authors reporting high sensitivity and specificity of MRI.

**Objective:** To find out the efficacy of MRI in diagnosing various ligamentous and meniscal injuries in terms of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) and to retrospectively evaluate limitations of MRI.

**Materials and Methods:** Total 50 knee MRI's of patients who were posted for/underwent knee arthroscopy were studied in this prospective study. Images were obtained on a 1.5T magnet or higher magnet. MRI images of these patients were evaluated independently by a radiologist with experience in musculoskeletal radiology. The arthroscopic examination and further management were done by an experienced orthopedic surgeon. Findings of MRI and arthroscopy were correlated. Statistical analysis was used to calculate the sensitivity, specificity, PPV, and NPV to assess the reliability of MRI results.

**Results:** There was male preponderance with 64% males. Maximum patients belonged to 2-4<sup>th</sup> decade of life. Sensitivity, specificity, PPV, and NPV for anterior cruciate ligament (ACL) tear were 100%, 92%, 92%, and 100%, for ACL avulsion were 100%, 100%, 100%, and 100%, and for myxoid degeneration were 100%, 100%, 100%, and 100%, respectively. Sensitivity, specificity, PPV, and NPV for posterior cruciate ligament tear were 100%, 100%, 100%, and 100%, respectively. Sensitivity, specificity, PPV, and NPV for medial meniscus were 100%, 96%, 96%, and 100% and for lateral meniscus were 100%, 100%, 100%, and 100%, respectively.

**Conclusion:** MRI is a non-invasive, radiation-free, and an excellent imaging modality to evaluate ligaments and menisci of the knee joint and surrounding soft tissue. Almost all the ligamentous and meniscal injuries can be diagnosed with a high level of confidence.

**Key words:** Anterior cruciate ligament, Arthroscopy, Meniscus tear, Magnetic resonance imaging

## INTRODUCTION

Since the introduction of magnetic resonance imaging (MRI) for clinical use, in 1984, the role of MRI in the diagnosis of knee lesions has now become more evident.<sup>1,2</sup> Efficacy of MRI in comparison to arthroscopy has been

studied and proved by many authors reporting high sensitivity and specificity of MRI. Because of technical advancement in MRI scanners, it has become very sensitive modality in picking up signals, which at times may lead to misdiagnosis. In this study, we studied MRI of knee joints diagnosing cruciate and meniscal pathologies and pitfalls about T2W hyperintensity in cruciate and menisci and compared it to arthroscopy findings.

## MATERIALS AND METHODS

Total 50 Knee MRI scans of patients who underwent knee arthroscopy from June 2015 to December 2015

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were studied in this prospective study. MRI images were obtained on 1.5T Philips Achieva with patient supine and knee in extension and 5° of external rotation. Pulse sequences used were spin echo (SE), fast SE, gradient recalled echo, short tau inversion recovery (STIR), and proton density in three standard imaging planes, namely, coronal, sagittal, and axial. Slice thickness of 4 mm, FOV of 15 × 15 cm, and 480 × 480 matrix were used. Patients with neoplasm, previous knee surgery and those with contraindication to MRI were excluded from the study. MRI images of these patients were evaluated independently by a radiologist with experience in musculoskeletal radiology.

### Interpretation of Images

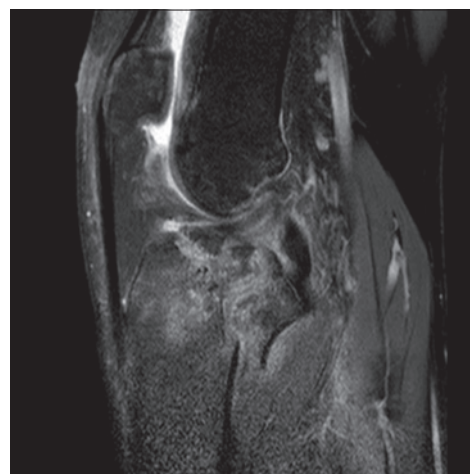
Criteria followed for interpretation of images was as following: (1) The anterior cruciate ligament (ACL) was evaluated on sagittal, coronal, and axial images and categorized as intact or torn. (2) A normal ACL was considered when a hypointense band like structure was seen on T2TSE images. (3) Complete absence of ligament, abnormal signal intensity of the ligament, wavy contour or poor definition of its ligamentous fibers were all considered as complete ACL tear (Figure 1).<sup>3</sup> (4) The detection of discrete area or focus of increased signal intensity within the substance of the ACL was diagnosed as partial tear.<sup>4</sup> (5) The “celery stalk” appearance of the ACL with mucoid degeneration and fusiform enlargement of the ligament was diagnosed as ACL myxoid degeneration (Figure 2).<sup>5</sup> (6) ACL avulsion was considered when bone fragment was noted avulsed from the tibia with an intact ACL and adjacent marrow edema (Figure 3).<sup>6</sup> (7) posterior cruciate ligament (PCL) tear was diagnosed as altered signal intensity in ligament on T2TSE images (Figure 4). Normal PCL is labeled as uniform low-signal-intensity band.<sup>7</sup> (8) Hypointense meniscus on T2TSE images without any altered signal intensity was considered normal. (9) The presence of an intrameniscal high signal intensity was regarded as a tear, and its grading was done according to whether it reaches to the articular surface or not as follows:<sup>8</sup> (a) MR Grade I, a non-articular focal or globular intrasubstance increased signal intensity on T2TSE images, (b) Grade II, a horizontal, linear intrasubstance increased signal intensity usually extends from the capsular periphery of the meniscus without involving an articular meniscal surface on T2TSE images, and (c) A meniscus is considered MR Grade III when the area of increased signal intensity communicates or extends to at least one articular surface on T2TSE images. (10) A bucket-handle tear is diagnosed in case of longitudinal type of tear with displaced fragment.<sup>9</sup> (11) While diagnosing bucket-handle tear presence of following signs was also evaluated: (a) The double PCL sign was positive for the presence



**Figure 1: Sagittal proton density-weighted image through intercondylar notch shows thickened anterior cruciate ligament (ACL) with hyperintense signal in complete ACL tear**



**Figure 2: Sagittal T2W image through the intercondylar notch shows fusiform enlargement of anterior cruciate ligament with myxoid degeneration**



**Figure 3: Sagittal proton density-weighted image through the intercondylar notch shows avulsion of tibial attachment of anterior cruciate ligament (ACL) with the bony fragment. Fibers of ACL appear intact**



of a notch fragment when a band like meniscal fragment was visible under the PCL and created the appearance of a double PCL (Figure 5) on sagittal intermediate-weighted MR images.<sup>10</sup> (b) The flipped-meniscus sign was positive when an anteriorly displaced triangular meniscal fragment was located posterior to the anterior horn of the same meniscus on sagittal intermediate-weighted images.<sup>11</sup> (c) The too-tall anterior horn sign was positive when the anterior horn of the meniscus was too tall or was at least 6 mm in diameter on sagittal intermediate-weighted images.<sup>11</sup> (d) The disproportionate posterior horn sign was positive when the inner portion of the posterior horn was larger than the outer portion on sagittal intermediate-weighted images.<sup>12</sup> (e) The absent bow tie sign was considered to be positive when only one or no meniscal body segment was visible on two consecutive peripheral sagittal sections.<sup>13-15</sup> (f) A root tear is said to be present when a tear was reaching up to meniscotibial attachment of the posterior horn (Figure 6) with presence of ghost meniscus on sagittal images or blunting of the normal meniscotibial attachment and foreshortening of the meniscus toward the posterior aspect of the intercondylar notch on coronal images.<sup>16</sup>

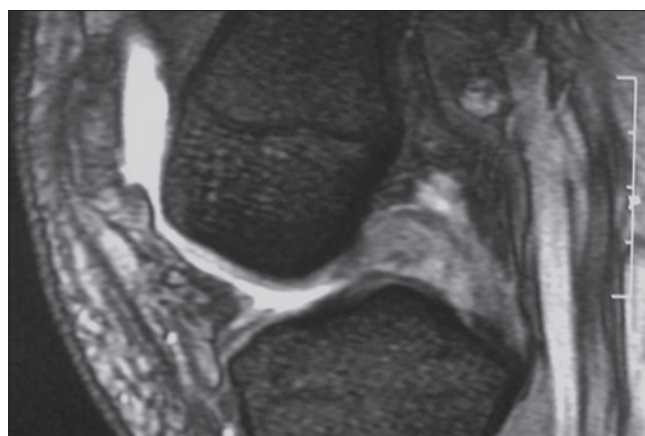
The arthroscopic examination was done by an experienced orthopedic surgeon. Arthroscopy was performed, with spinal anesthesia induced in the patient, using a 30° whole-angle arthroscope (Dyonics, Smith Nephew, Bulgaria) that was 4mm in outer diameter and a one-chip high-resolution camera (Max sar, Germany). High anterolateral and anteromedial portals were routinely used to introduce the arthroscope; accessory portals, including posteromedial, suprapatellar, or high medial portals, were used when necessary. During arthroscopy, a thorough examination of the knee was performed, and the pathological structure was identified. Further surgical intervention was carried out accordingly. The arthroscopic images were digitized on a computer. MRI findings were correlated with arthroscopic findings.

### Statistical Analysis

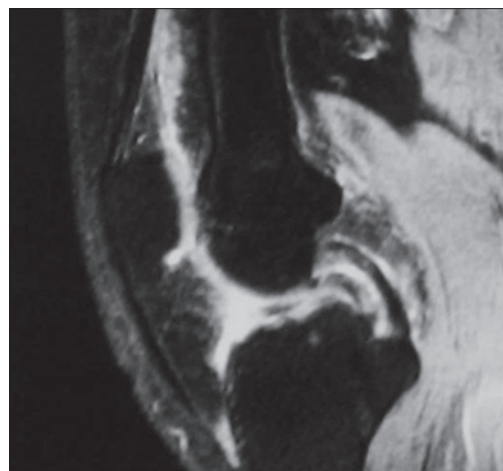
The composite data were tabulated and studies for correlation of MRI findings with arthroscopy findings grouped into 4 categories.

1. True positive
2. True negative
3. False positive
4. False negative.

Statistical analysis was used to calculate the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) to assess the reliability of MRI results.



**Figure 4: Sagittal T2W image through intercondylar notch shows disruption of posterior cruciate ligament with no normal fibers identified**



**Figure 5: Sagittal image through the intercondylar notch in a patient with a bucket-handle tear shows the displaced fragment anterior to the posterior cruciate ligament - the "double posterior cruciate ligament" sign**



**Figure 6: A horizontal root tear of medial meniscus is seen extending to posterior root attachment of medial meniscus to medial tibial eminence**

## RESULTS

Out of 50 patients, there was male preponderance with 64 % males (Table 1).

Maximum patient belonged to 2<sup>nd</sup> decade followed by 3<sup>rd</sup> decade (Table 2).

About 2 patients with a complete tear on MRI had normal ACL on arthroscopy. 1 patient with complete ACL tear on MRI had partial ACL tear on arthroscopy (Table 3).

Posterior horn of medial meniscus was most commonly involved (Table 5).

About 1 patient with Grade III horizontal signal in the posterior horn of medial meniscus was not appreciated on arthroscopy (Table 6).

The bucket-handle tear of medial meniscus was more common. 3 patients were diagnosed as Grade III tear on MRI were the bucket-handle tear on arthroscopy (Table 7).

In cases of the bucket-handle tear, absent bow tie sign was a most common presentation (Table 8).

**Table 1: Sex distribution**

Sex	No. of patients	% distribution
Male	32	64
Female	18	36

**Table 2: Age distribution**

Age distribution	Males	Females	Total (%)
11-20	2	1	3 (6)
21-30	16	1	17 (34)
31-40	9	3	12 (24)
41-50	2	8	10 (20)
51-60	3	4	7 (14)
61-70	0	1	1 (2)

**Table 3: MRI and arthroscopy correlation of ACL pathologies (total patients: 33)**

ACI pathologies	MRI	Arthroscopy	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Complete ACL tear	24	21	100	89.6	87	100
Partial ACL tear	2	2	100	100	100	100
Myxoid degeneration	5	5	100	100	100	100
Avulsion	2	2	100	100	100	100

ACL: Anterior cruciate ligament, MRI: Magnetic resonance imaging

**Table 4: MRI and arthroscopic correlation of PCL tears**

Pathology	Diagnosis on MRI	Diagnosis on arthroscopy (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
PCL tear	2	1	100	97	50	100

PCL: Posterior cruciate ligament, MRI: Magnetic resonance imaging

## DISCUSSION

We evaluated symptomatic knee joints on MRI in 50 patients before surgery, i.e., arthroscopy and MRI findings were compared to arthroscopy findings.

About 64% of patients were males and 36% were females. The age group ranged from 18 to 70 years. We observed maximum patients were in 2<sup>nd</sup> decade.<sup>17</sup>

Sensitivity and specificity of MRI in diagnosing complete ACL tear were 100% and 89.6% and for partial tear was 100% and 100%, respectively. In three patients, complete tear of ACL was given on MRI, on arthroscopy two were intact and one had a partial tear. In one 65-year-old patient with a history of trivial trauma, diffuse hyperintensity was noted in ACL on T2TSE images and was diagnosed as complete ACL tear. However, arthroscopy noted partial tear involving an anteromedial bundle of ACL. Possibly, the patient was having myxoid degeneration with partial tear which made a differentiation between complete and partial tear difficult. In addition, the patient also had degeneration in PCL, bones, and cartilage. Other two patients in their early 40's one male and one female had diffuse T2W hyperintensity, no normal fibrillar pattern of ACL was seen and were diagnosed as a complete tear (Figure 7). ACL in these two patients appeared normal on arthroscopy. Abnormal signal intensity alone may be associated with either a ligamentous sprain or disruption of collagen fibers,<sup>18</sup> which may remain arthroscopically occult. Dowdy *et al.*<sup>19</sup> documented that a positive MRI for an ACL tear combined with a normal arthroscopy did not necessarily represent a false positive MRI and intrasubstance tear may be present which is difficult to detect with arthroscopy. Several prospective studies have shown a sensitivity of 92-100% and specificity 93-100% for the MR imaging diagnosis of ACL tears.<sup>20,21</sup> Our study closely matches to these.

MRI was 100% sensitive and specific in diagnosing ACL avulsion and myxoid degeneration. In patients with myxoid



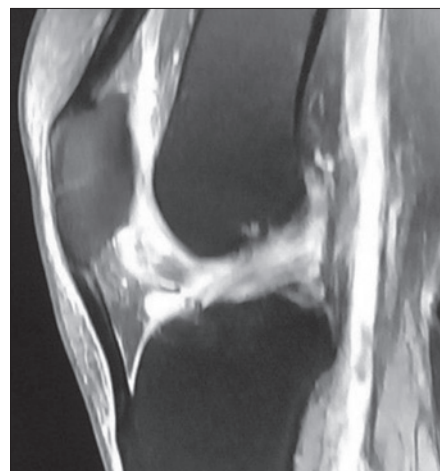
degeneration, a typical celery stalk appearance was observed within bulky ACL. In one patient, myxoid degeneration was associated with a ganglion cyst. It was confirmed on arthroscopy and amber colored fluid oozed out of it on puncturing.

Two patients had altered the signal in PCL on T2TSE images and were diagnosed as tear, out of which one was confirmed on arthroscopy (Table 4). In another patient, PCL was diffusely hyperintense and thickened on T2TSE images hence diagnosed as PCL tear. On arthroscopy, PCL was intact in addition patient was having ACL partial tear, gross degenerative changes in joint and bucket-handle tear of the medial meniscus. The hyperintensity was possibly attributed to degeneration with an element of contusion.

Medial meniscus (80.5%) was more commonly injured than lateral meniscus (19.5%). Our result matches with studies done by Singh *et al.* and Bari *et al.*<sup>22,23</sup> Out of 28 patients of meniscal tear, 13 had purely meniscus injury and 15 had associated ACL injury. Only Grade III signals are considered for statistical analysis. Sensitivity and specificity for medial meniscus tear were 100% and 96%, respectively and for lateral meniscus both were 100%. One patient had Grade III signal reaching up to the inferior surface of the posterior horn of medial meniscus on MRI (Figure 8) was normal on arthroscopy. Possibly, the tear was not reaching up to the inferior surface or a stable tear which was not appreciated on probing during arthroscopy. Normal anatomical structures such as transverse and menisiofemoral ligaments, popliteus tendon, genicular artery, and other artifacts such as capsule attachment, bursae of MCL, can lead to misdiagnosis of tear.<sup>24</sup>

In the present study, 10 patients were diagnosed as having bucket-handle tear. Absent bow tie sign was seen in eight

patients. In the present study, absent bow tie sign was seen to be a most sensitive sign to diagnose bucket-handle tear.<sup>14,15</sup> In three patients, longitudinal to oblique signals were noted in posterior horn reaching up to the inferior surface not fitting into criteria of bucket-handle tear hence diagnosed as simple meniscal tear without mentioning as the bucket-handle tear. On arthroscopy, all three patients had the bucket-handle tear. Possibly while probing the meniscus the fragment got displaced converting it to bucket-handle tear (Figure 9).



**Figure 7: Altered signal intensity in ACL was diagnosed as ACL tear on MRI. However, ACL was normal on arthroscopy in this patient**



**Figure 8: Grade III signal reaching up to inferior articular surface was diagnosed as medial meniscus tear. However, meniscus was stable on probing during arthroscopy**

**Table 5: Grades of meniscal signals on MRI (total patients: 36)**

Grades	Medial meniscus		Lateral meniscus	
	Anterior horn	Posterior horn	Anterior horn	Posterior horn
Grade I	0	0	0	0
Grade II	2	6	0	0
Grade III	0	21	0	7
Total	2	27	0	7

MRI: Magnetic resonance imaging

**Table 6: MRI and arthroscopic correlation of Grade III signal (total patients: 28)**

Meniscus	Grade III signal on MRI	Arthroscopy findings	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Medial meniscus	21	20	100	96	96	100
Lateral meniscus	7	7	100	100	100	100

MRI: Magnetic resonance imaging

**Table 7: Diagnosis of bucket-handle tear on MRI and arthroscopy (total patients: 10)**

Meniscus involved	Diagnosis on MRI	Diagnosis on arthroscopy
Medial meniscus	8	2
Lateral meniscus	9	4

MRI: Magnetic resonance imaging

**Table 8: Correlation of different signs in cases of bucket-handle tear**

Meniscus involved	MRI diagnosis				
	Flipped meniscus sign	Double PCL sign	Absent bow tie sign	Too tall anterior meniscus	Disproportionate posterior horn of meniscus
Medial meniscus	2	2	6	0	0
Lateral meniscus	0	0	2	0	0

PCL: Posterior cruciate ligament, MRI: Magnetic resonance imaging

**Table 9: Diagnosis of root tear on MRI and arthroscopy**

Root tear of meniscus	MRI	Arthroscopy
Medial meniscus	5	5

MRI: Magnetic resonance imaging

**Table 10: Chondral defect**

Pathology	MRI	Arthroscopy
Chondral defect	2	2

MRI: Magnetic resonance imaging

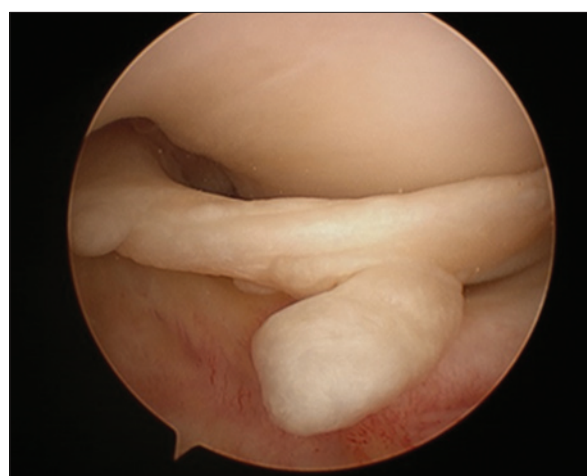
**Table 11: Associated findings**

Pathology	Diagnosis on MRI	Diagnosis on arthroscopy
Parameniscal cyst near medial meniscus	3	3
Parameniscal cyst near lateral meniscus	4	4
Baker's cyst	4	-

MRI: Magnetic resonance imaging

In this study, we had five patients having posterior root tear which were diagnosed on MRI and confirmed on arthroscopy (Table 9). All had horizontal signal intensity on coronal images representing tears. All patients were having medial root involvement. Sensitivity and specificity of our study in diagnosing root tears were 100%. The meniscal roots represent the attachment sites of the menisci to the medial tibial eminence. The posterior meniscal root of the medial meniscus attaches immediately anterior to the PCL. In the coronal plane, the posterior meniscal root is horizontally oriented and extends to attach at the medial tibial eminence.

Two patients with cartilage loss were diagnosed correctly on MRI as focal loss and T2TSE hyperintensity along the curvature of cartilage (Table 10). In seven patients, para meniscal cysts were associated with meniscal tear.

**Figure 9: Arthroscopy image showing bucket-handle tear of medial meniscus**

Other associated findings bone marrow edema, both collateral ligament injuries, Baker's cyst, soft tissue edema, which were not seen on arthroscopy (Table 11).

Interpretation of knee MRI has a long learning curve. Technical factors such as imaging parameters, coil strength, planes of image, quality of imaging equipment also affect interpretation.

## CONCLUSION

The sensitivity and specificity for diagnosing complete ACL tear were 100% and 89.6%, respectively. Intrasubstance T2W hyperintensity in ACL or PCL may represent intrasubstance tear and/or degeneration in situation of trauma to the knee joint. Stable meniscal tear with Grade III signal cannot be appreciated on arthroscopy. In the present study, absent bow tie sign was the most sensitive sign to diagnose bucket-handle tear. Bucket-handle tear can be seen as simple Grade III signal. MRI has 100% sensitivity for root tears.

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# Awareness of Diabetes Mellitus and its Complications among Patients at Tertiary Care Hospital

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## Abstract

**Aim:** To study the awareness of diabetes and its complications among the patients in tertiary care hospital.

**Objectives:** India is one of the fastest growing countries in the world. The initiative is taken to find out the awareness and to find out how aware our patients are about their diabetes and also to find out about advice given by the treating doctor (general practitioner/specialist). All the information is based on a questionnaire.

**Materials and Methods:** All diabetes mellitus Type 2 patients admitted toward and those visiting the outpatient at our center are included in the study. 500 patients were included in this prospective study.

**Results:** In our study, 48% had familial history, 47% did not know the frequency of blood sugar check-up, amazingly 55% did not know the complications, 45% of patient were not aware of insulin and 40% of the patients did not know names of the tablet of their own treatment.

**Conclusion:** The potential benefits of early detection are improved quality of life, decreased hospitalizations. Screening of diabetes is important as it not only detects new cases but identification of many impaired glucose tolerance and impaired fasting glucose pre-diabetes states. Public health policy should be aimed at the aspects. Clinical practitioners should aim at regular health campaigns in community to identify these hidden cases.

**Key words:** Awareness, Diabetes mellitus, Impaired glucose tolerance and impaired fasting glucose

## INTRODUCTION

India has dubious distinction of having the largest number of people with diabetes. India has around 50 million cases of diabetes, expected to be around 80 million by 2025. It is 15-20% of global burden, contributes 1% of world's diabetes research.<sup>1</sup> It is known as diabetes capital of the world. In India, it is no longer a disease of rich and affluent man disease. It is becoming a problem in middle-income group and poor sections of society. Poor diabetic subjects are more prone to complications and morbidity. Till date, no national awareness program has been performed.

Nearly, 25% of Indian city dwellers have not even heard of diabetes according to a study. Screening of patients is necessary to reduce the burden of disease on individuals as well as community and nation.

Screening is defined as "A process of identifying those individuals who are at sufficiently high risk of a specific disorder to warrant further investigation or direct action." Types of screening are (a) entire population, (b) targeted screening, and (c) opportunistic screening.

Diabetes is part of a larger global epidemic of non-communicable diseases and a major public health challenge globally. This affects 6.6% (285 million people) of the world's population in the 20-79 years age group.<sup>2</sup> According to the International Diabetic Federation (IDF), this number might reach 380 million by 2025.<sup>3,4</sup> The IDF in 2007, the country with the largest numbers of people with diabetes is India (40.9 million), followed by China (39.8 million), the United States (19.2 million), Russia.<sup>5,6</sup>

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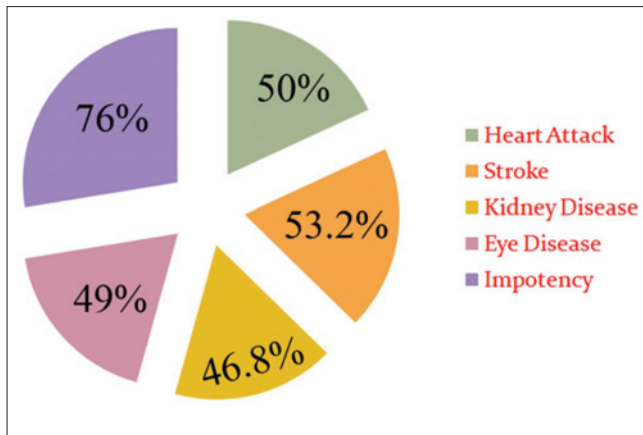


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**Figure 1: Percentage of patients unaware of diabetic complications**

Nearly 15% of the global diabetes burden is in India accounting for 40.9 million people with diabetes. Projections show that this will increase to 70 million by 2025. As India has a population of 1.2 billion, 40% of who are under the age of 18, investment in the health sector of India's future is crucial.

Diabetes is a part of metabolic syndrome with high blood sugar levels with impairment of protein, fat and carbohydrate metabolism. There is increased burden of disease all over the world. Industrialization and westernization of culture have led to a global pandemic. A total number of impaired glucose tolerance (IGT) is more than the diabetes people itself. Screening is important, as in diabetes there is a long asymptomatic period, so major portion of people are undiagnosed and complications can be delayed or prevented if diagnosed early.

A questionnaire-based study was done at our center to find out awareness of diabetes and its complications in the community surrounding the hospital.

## MATERIALS AND METHODS

This is a prospective study, all diabetes mellitus (DM) patients admitted to hospital as IN patients and OUT patients at tertiary care hospital are included in the study and the study is based on a questionnaire and the sample size is 500 patients.

## RESULTS

There were 500 patients included in the study. There were 348 males and 152 females in the study. Only Type 2 DM patients were included in the study.

Questionnaire	Yes (%)	No (%)
When diagnosed, duration known to the patient	82	18
Was the diagnosis based on FBF/PPBS OR RBS	82.8	17.2
Did the patient know where the diagnosis is/was made (GP/hospital)	89.2	10.8
Family history	48	52
Was the patient educated at diagnosis by the doctor who has diagnosed first	55.4	44.6
Were you told about the frequency for blood sugar to be checked initially	53.5	46.5
Were you told about the insulin at any stage during your treatment? Whether discussed	55.4	44.6
Is diet advised to you by the doctor?	68.8	31.2
Was foot care, eye care advised anytime during treatment?	64.3	35.7
Was exercise advice given	71.5	28.5
Do you know the name of your own medications	60	40

Questionnaire	Yes (%)	No (%)
Were you made aware of complications/do you know about the complications		
Heart attack	50	50
Stroke	26.8	73.2
Kidney disease	49.2	50.8
Eye disease	31.25	68.75
Impotency	19.7	80.3

The percentage of patients unaware of diabetic complications like impotency was 76%, 53.2% stroke, 50% Heart attack, 49% eye disease and 46.8% with kidney disease (Figure 1). kindly add this in line 31 of page 2 of results.

In our study, 48% had familial history, 47% did not know the frequency of blood sugar check-up, amazingly 55% did not know the complications, 45% of patient were not aware of insulin and 40% of the patients did not know names of the tablet of their own treatment.

## DISCUSSION

This scenario is seen in worldwide. People are not aware of diabetes disease and its complications, how it affects their personal life and family. Many awareness studies had also similar results. A questionnaire was tested in Onondaga county New York as a community screening program, which showed a sensitivity of 80% and specificity of 35%.<sup>7,8</sup> Public response to screening was seen in few studies in the range of 30-80%.<sup>9,10</sup> Aim of the screening studies should be clean and relevant to the individuals at risk of undiagnosed diabetes or at risk diabetes.

Epidemiological surveys are necessary along side of these tests. Data should be maintained about particular community and periodically it should be screened. The



cost of screening can be reduced if screening data is linked to other programs which are done like cardiovascular screening should be linked to glucose and lipid testing's. National diabetic programs, media awareness programs on television, advertisements of screening program are done all worlds over. RCT'S and observational studies have been done in countries to maintain the data of diabetes patients in their registry.<sup>11</sup>

## CONCLUSION

The potential benefits of early detection are improved quality of life, decreased hospitalizations. Screening of diabetes is important as it not only detects new cases but identification of many IGT and impaired fasting glucose pre-diabetes states. Public health policy should be aimed at the aspects. Clinical practioners should aim at regular health campaigns in community to identify these hidden cases.

In view of above results, authors like to conclude that greater effort is needed to create awareness regarding diabetes disease burden and its complications related to it can be reduced.

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# Comparison of Submucosal Diathermy and Partial Inferior Turbinectomy

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## Abstract

**Introduction:** Nasal obstruction is one among the most common presenting complaints of patients. The most common etiology for nasal obstruction is hypertrophy of the inferior turbinates due to allergic rhinitis or vasomotor rhinitis. The hypertrophy is almost always due to dilatation of the venous sinusoids resulting in swelling of the submucosal layer.

**Objectives:** To compare the results between submucosal diathermy (SMD) and partial inferior turbinectomy (PIT) in terms of post-operative bleeding, nasal crust formation, vestibular skin burn, pain, synechiae formation, and atrophic rhinitis.

**Materials and Methods:** A prospective observational study involving 60 patients with inferior turbinate hypertrophy was done at Sree Gokulam Medical College, TVM from January 2014 to June 2015. Patients were randomly divided into two groups; Group A, underwent SMD and Group B underwent PIT. Post-operative follow-up done at day 1, 1 week, 1 month and 3 months.

**Results:** Occurrence of post-operative reactionary hemorrhage on day 1 was 43.3% in PIT, whereas it was only 10% in SMD. Nasal crust formation was 6.7% in PIT at the end of 3 months while none who underwent SMD had crust formation at the end of 3 months. Vestibular skin burn was observed in 3.3% of SMD patients. 6.7% had nasal pain following PIT while none of the SMD patients had the same. Remote complications such as synechiae and atrophic rhinitis were not reported in either PIT or SMD during the assessment time period.

**Conclusion:** SMD is relatively safe and less invasive than PIT but its effectiveness compared to PIT is short lived. In the long run, PIT was found to be more effective.

**Key words:** Inferior turbinate hypertrophy, Partial inferior turbinectomy, Submucosal diathermy

## INTRODUCTION

One of the common presenting symptoms to ENT Department is a nasal obstruction, which can be due to deviated septum, nasal polyposis, hypertrophied inferior turbinate, vasomotor or perennial rhinitis. Inferior turbinate hypertrophy is a common entity which sometimes do not respond to medical treatment and requires surgery. A minimum of 13 different surgical techniques have been introduced which include

turbinectomy, laser cautery, silver nitrate cautery, electrocautery, submucosal resection with or without lateral displacement, cryotherapy.<sup>1</sup> There is no general agreement about the best modality of treatment. partial inferior turbinectomy (PIT) and submucosal diathermy (SMD) are two popular methods among the various techniques of inferior turbinate reduction. This study aims to compare the results between SMD and PIT in terms of post-operative bleeding, nasal crust formation, vestibular skin burn, pain, synechiae formation, and atrophic rhinitis.

## MATERIALS AND METHODS

A prospective observational study of 60 patients, who attended the ENT OPD with complaints of nasal obstruction due to inferior turbinate hypertrophy was

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done, in the Department of ENT Sree Gokulam Medical College from January 2014 to June 2015. The patients were divided into two Groups A and B of 30 each using table of randomization. Group A patients SMD and Group B underwent PIT.

A thorough history and detailed examination of ear nose and throat were conducted by anterior rhinoscopy, diagnostic nasal endoscopy, and radiologically by sinus X-ray. Routine pre-operative investigations were done on every patient.

Size of inferior turbinate was classified into three grades:  
Grade 1: Normal size inferior turbinate, atrophic without any nasal obstruction

Grade 2: Moderate sized inferior turbinate, touching the septum with nasal obstruction, not responding to local decongestant

Grade 3: Large mulberry turbinate touching the septum with nasal obstruction, not responding to local decongestant.

The procedures were done for both Grades 2 and 3 patients.

Both procedures were done under general anesthesia, with the patient in reclining position and head end of the table raised. Nasal cavity was packed with two cotton pledgets soaked in oxymetazoline and adrenaline.

For SMD, after decongestion the diathermy needle was inserted into the anterior end of inferior turbinate, which was advanced submucosally till the posterior end of the inferior turbinate was reached. The needle was then withdrawn slightly and a current of 50 joules was applied in a triangular fashion at 3 points (superior, medial and inferior).

For PIT, the inferior turbinate was infiltrated with 2% xylocaine + adrenaline up to the posterior end. Using turbinectomy scissors, the medial one-third of the anterior end of the inferior turbinate was resected without any trauma to the bony inferior concha.

Following the procedure, anterior nasal packing was done with antibiotic ointment (soframycin + metrogyl). All patients were given parenteral antibiotics, analgesics, and nasal drops for 7-10 days postoperatively.

Post-operative follow-up was done on day 1 for assessing reactionary hemorrhage. Nasal crust formation was evaluated at 1 week, 1 month and 3 months postoperatively. Vestibular skin burn was assessed on day 1. Assessment of nasal pain was done on post-operative day 1 and day 7. Synechiae formation and atrophic rhinitis were evaluated at 1 month and 3 months.

## RESULTS

Out of the 60 patients recruited for the study, in Group A 12 were males and 18 were females. In Group B, 20 were males and 10 females, with mean age of 27.2 in Group A and 27.8 in Group B.

On the first post-operative day, reactionary hemorrhage was observed in 13 (43.3%) patients who underwent PIT, whereas only 3 (10%) patients who underwent SMD had the same (Figure 1).

Nasal crust formation evaluated at the end of the 1<sup>st</sup> week demonstrated crust formation in 46.7% of patients who underwent PIT and only in 16.7% of patients who underwent SMD. Follow-up at the end of 1 month revealed crust formation in 26.7% of PIT patients and only in 6.7% of SMD patients. Follow-up at the end of the 3<sup>rd</sup> month demonstrated crust formation in 6.7% of PIT patients whereas none of the patients who underwent SMD had crust formation (Figure 2).

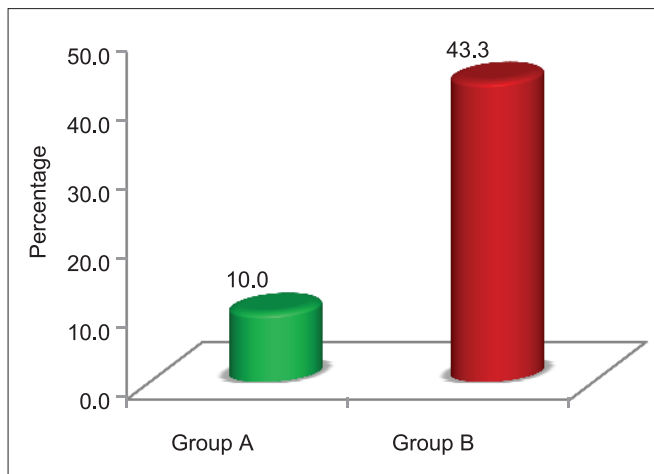
Vestibular skin burn assessed on post-operative day 1 was observed only in 1 (3.3%) patient who underwent SMD. As cautery was not used in PIT vestibular skin burn was not observed in Group B (Figure 3).

The nasal pain was present in 11 (36.7%) patients who underwent PIT and in 4 (13.3%) of patients who underwent SMD on day 1. At the end of the 1<sup>st</sup> week, 6.7% of PIT patients had mild nasal pain, whereas none of the patients who underwent SMD had the same (Figure 4).

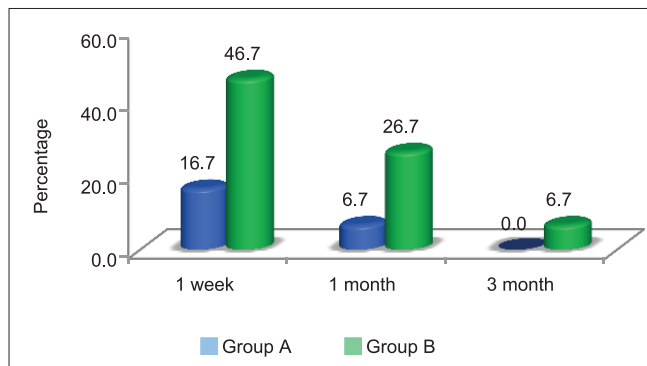
Synechiae formation and atrophic rhinitis were evaluated at 1 month and 3 months postoperatively and none of the patients in both groups had the same.

## DISCUSSION

Nasal obstruction is one among the most common presenting complaints of patients attending the ENT OPD. One of the most common etiology for nasal obstruction is hypertrophy of the inferior turbinates due to allergic rhinitis or vasomotor rhinitis.<sup>2</sup> The hypertrophy is almost always due to dilatation of the venous sinusoids resulting in swelling of the submucosal layer. The majority of the patients responds to antihistamines or local decongestants. Occasionally submucous fibrosis may render the turbinates incapable of decongestion and in such cases surgical management becomes necessary.<sup>3</sup> Even though multiple treatment options are available, there is considerable controversy over the merits of the various techniques.



**Figure 1: Comparison of reactionary hemorrhage (day 1) between both groups**

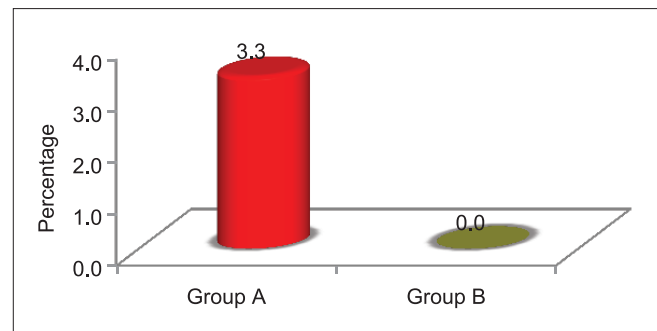


**Figure 2: Comparison of nasal crust formation of between two groups**

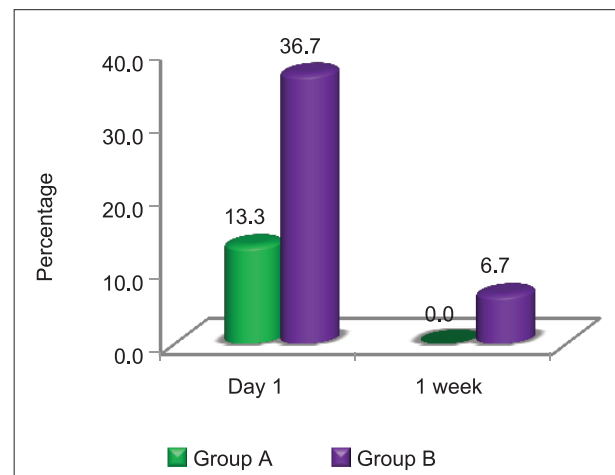
This study is done to evaluate and analyze the impact of partial turbinectomy and SMD on nasal obstruction and to compare the results of either procedures in respect of safety and efficacy. Anterior rhinoscopy and radiological investigations (X-ray PNS) were done. Rhinomanometry was not done due to lack of availability in our institute.

In a study conducted by Thahir *et al.*, bleeding was seen in patients who underwent PIT and anterior nasal packing was required for 48 h. In a study conducted by Imad *et al.*,<sup>4</sup> in 2010 it was found that 40% of patients who underwent PIT had moderate bleeding while only 3% who underwent SMD had minimal bleeding. The studies done by Al-Baldawi<sup>5</sup> revealed that the incidence of reactionary hemorrhage was 12.5% in patients who underwent PIT, whereas none of the patients who underwent SMD had a reactionary hemorrhage. In our study, the reactionary hemorrhage was evaluated on post-operative day 1 which was 43.3% in patients who underwent PIT. Only 10% of the patients who underwent SMD had developed reactionary hemorrhage.

The study conducted by Imad *et al.*,<sup>4</sup> in 2010 revealed that 20% of patients who underwent PIT had crusting at the



**Figure 3: Incidence of vestibular skin burn (post-operative day 1)**



**Figure 4: Comparison of nasal pain of both groups**

end of 2 weeks while none of the patients who underwent SMD had crusting. Incidence of crusting was also reported by Nousheen<sup>6</sup> in her study conducted in 2006. Maskel *et al.*, conducted a study in 2007 and reported that 29.5% of patients who underwent laser turbinectomy had crusting within first 2 weeks.<sup>7</sup> About 5% of those who underwent PIT had developed nasal crust formation and none of the patients who underwent SMD had developed nasal crust formation according to the study by Al-Baldawi.<sup>5</sup> In this study, the incidence of nasal crust formation was assessed at various time intervals in both groups. About 46.7% had developed nasal crust at the end of 1 week in patients who underwent PIT which was further reduced to 26.7% after 1 month. By the end of 3 months, only 6.7% of patients who underwent PIT had nasal crust formation. In those who underwent SMD, the incidence of nasal crust formation was 16.7% after 1 week which further reduced to 6.7% after 1 month. At the end of 3 months, none of the patients who underwent SMD had nasal crust formation.

According to study conducted by Al-Baldawi,<sup>5</sup> 2009 the incidence of vestibular skin burn in patients who underwent PIT was nil whereas those who underwent SMD 2.5% had skin burn. In our study the incidence of



vestibular skin burn was evaluated on post-operative day 1. None of the patients who underwent PIT had vestibular skin burn as no cautery was used, whereas 3.3% of patients who underwent SMD had developed vestibular skin burn which was mild.

According to study by Maskel *et al.*,<sup>7</sup> less pain was reported with laser inferior turbinectomy. In study conducted by Imad *et al.*,<sup>4</sup> in 2010, in Peshawar 32% of patient who underwent PIT had moderate pain whereas 44% of patients who underwent SMD had moderate pain. In a study conducted in Iraq by Al-Baldawi,<sup>5</sup> the occurrence of nasal pain and headache was 12.5% in those who underwent PIT and only 5% of patients who underwent SMD had developed a headache. According to study by Gomma et al, incidence of nasal pain was less in SMD patients during 2 week and 1 month follow up, compared to patients who underwent PIT.<sup>8</sup> Our study also assessed the incidence of headache and nasal pain in both groups. At post-operative day 1 about 36.7% of patients who underwent PIT had headache and nasal pain which was further reduced to 6.7% at the end of 1 week. The incidence of headache and nasal pain in patients who underwent SMD was 13.3% at post-operative day 1 and none of the patients had headache and nasal pain at the end of 1 week.

Nasal synechiae/adhesions were not observed in both groups of patients who underwent PIT or SMD in a study conducted by Al-Baldawi<sup>5</sup> in 2009. The occurrence of synechiae formation was assessed in our study at 1 month and 3 months postoperatively. In those patients who underwent PIT at the end of 1 month and 3 months none had synechiae formation. Similar results also were observed in patients who underwent SMD.

Study done by Al-Baldawi,<sup>5</sup> 2009 revealed that none of the patients had atrophic rhinitis irrespective of the whether they underwent PIT/SMD. In our study, we also assessed the incidence of atrophic rhinitis in both groups at time intervals of 1 month and 3 months. Neither the patients

who underwent PIT nor those who underwent SMD had developed atrophic rhinitis at both time intervals.

## CONCLUSION

This study showed that the Reactionary hemorrhage was more in those who underwent PIT than in those who underwent SMD. Even though the incidence of nasal crust formation was more and was statistically significant during early follow ups in those who underwent PIT, at the end of 3 months it became insignificant. There was a statistically significant occurrence of headache and nasal pain in those who underwent PIT during early post-operative period, but this difference became insignificant when assessed later. Remote sequelae like atrophic rhinitis or nasal synechiae were not observed in any of these groups. Even though the incidence of short-term complications is more with PIT, in the long run it is found to be more effective than SMD.

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# Neurosonogram in Critically Ill Neonates in Neonatal Intensive Care Unit

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## Abstract

**Aim:** Neonates born prematurely and sick full-term neonates are at risk of brain injury. Although advances in neonatal intensive care have greatly improved the survival and outcome of these vulnerable patients, brain injury remains of major concern. Early diagnosis is important for prognostication, optimal treatment, and predicting the neurological outcome.

**Objective:** This study was done to describe the pattern of cranial ultrasound abnormalities in preterm and term critically ill neonates in neonatal intensive care unit (NICU).

**Materials and Methods:** This prospective observational clinical study was done in Vydehi Institute of Medical Sciences Hospital and Research Centre, Bengaluru between January 2014 and July 2015. After obtaining informed consent 100 critically ill neonates admitted to our NICU were included in this study. History and clinical examination followed by appropriate investigations were done. These critically ill neonates were subjected to neurosonography on selected days as per as protocol and different patterns of morphology abnormalities were noted. Clinical correlation with neurosonogram findings was observed and if found abnormal follow-up neurosonogram were done.

**Results:** The incidence of neurosonographic abnormalities in high-risk neonates is 31% in the present study. Of these 41% of these had evidence of intracranial bleed, 25% had cerebral edema, 6% periventricular leukomalacia, 16% hyperechogenic thalami, and one had ventriculomegaly. Of the 31% of neonates with abnormal findings on neurosonogram, 22% had hypoxic-ischemic encephalopathy as per Apgar scoring, 25% had features of sepsis. One neonates with intraventricular bleed on regular follow-up of neurosonogram developed ventriculomegaly.

**Conclusion:** This study signifies the importance of neurosonogram in critically ill neonates as diagnostic tool and as screening modality in NICU. It also emphasizes its use as a screening modality for preterm and birth asphyxia neonates influencing their neurodevelopmental outcome. Neurosonogram is critical as an investigatory modality in NICU for early, safe and easy diagnostic tool for predicting the neurological damage for management in NICU and predicting outcome.

**Key words:** Birth asphyxia, Neonatal intensive care unit, Neurosonogram, Preterm

## INTRODUCTION

Cranial ultrasonography (cUS) is the preferred modality to image the neonatal brain. The advantages of cUS are numerous: It can be performed at the bedside with little disturbance to the infant, it is relatively safe, and can be

repeated whenever needed, enabling visualization of ongoing brain maturation and the evolution of lesions.<sup>1</sup>

Ultrasound is the most widely used cranial imaging modality in the neonatal intensive care unit (NICU). Ultrasound machines are portable, the images can be acquired at bedside conveniently in the NICU, which meets the definition of point-of-care testing. The cumbersome transport of the neonates to the computerized tomography (CT) or the magnetic resonance imaging (MRI) suite is avoided. In addition, ultrasound is cost-effective and considered a safer modality in the pediatric population due to the lack of harming effect of ionizing radiation, as in CT,

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as well as avoiding the need for sedation required for MRI. Ultrasound is the least costly of all modalities for cranial imaging and is readily available in all intensive care units. In the neonate, many sutures and fontanelles are still open and these can be used as acoustic windows to “look” into the brain. The modality is operator-dependent and should be performed by an experienced sonographer, neonatologist, or radiologist. In many cases, a final diagnosis and treatment guidance can be achieved with neurosonography, such as in neonatal germinal matrix hemorrhages, neonatal malformations.<sup>2,3</sup>

Any neonate, regardless of birth weight, size, or gestational age, who has a greater than average chance of morbidity or mortality, due to fetal, maternal or placental anomalies or an otherwise compromised pregnancy, especially within the first 28 days of life is categorized as critically ill neonate. Neurosonogram plays an important role in assessing neurological prognosis of these high-risk infants.<sup>2,4</sup>

Modern machines, with a variety of acoustic windows and sequential scanning giving high-quality images has increased the recognition of features suggestive of developmental, metabolic and infectious disorders.

It detects most of the hemorrhagic, ischemic and cystic brain lesions as well as calcifications, cerebral infections, and major structural abnormalities in critically ill neonates. It is also very helpful in the early diagnosis of the many etiologies of neonatal encephalopathy and seizures in the term infant and the subsequent monitoring of progress of hypoxic-ischemic brain injury.

Most newborn intensive care unit centers perform serial cUS evaluations early in the course of hospitalization for premature infants and often, a follow-up examination is done at a later age. These evaluations are done to document the presence of intracranial hemorrhage, to guide choice of therapies that may exacerbate the risk of further hemorrhage, and to counsel families about neurodevelopment outcomes.<sup>5,7</sup>

Neurosonogram is also very helpful in assessing severity and neurodevelopment outcome in infants with hypoxic-ischemic encephalopathy (HIE) and in seriously ill neonates with cerebral abnormalities, either congenital or acquired, it plays a role in decision making on continuation or withdrawal of intensive treatment.<sup>10</sup>

The quality of neurosonography and its diagnostic accuracy depends on the ultrasound machine and also expertise of the examiner. When performed as per protocol, it is reliable investigation for commonly occurring neonatal events. Neurosonogram can be initiated even immediately after

birth and hence suitable for screening and can be repeated as often as possible without any adverse effects and hence helps in proper follow-up of babies with neurological problems. In this review, we discuss the applications and indications of neonatal cUS.<sup>12</sup>

We list the most frequently occurring abnormalities of the neonatal brain, as seen on cUS in preterm and sick full-term neonates. However, cUS also has several limitations: Quality of imaging depends on the skills and experience of the ultrasonographer, some areas of the brain is difficult to visualize, and several abnormalities remain beyond its scope.<sup>2</sup>

## MATERIALS AND METHODS

This study was conducted in Vydehi Institute of Medical Sciences Hospital and Research Centre, Bengaluru between January 2014 and July 2015. A total of 100 neonates admitted to our NICU who were critically ill were included in the study.

All critically ill neonates admitted to NICU were selected as per the inclusion criteria on non-randomized manner and were subjected to neurosonography on selected days. If neurosonogram revealed any abnormal findings, they were followed up for any sequelae.

All neonates admitted to NICU with prematurity, birth asphyxia, HIE, neonatal convulsions, neonatal sepsis, neonate with traumatic/instrumental delivery, respiratory distress, congenital malformation of central nervous system, and neural tube defects were included in the study.

After obtaining the informed consent from the parents/guardians neonates are included in the study. Factors that identify the neonate as “critically ill” were assessed by taking detailed maternal history looking into perinatal and antenatal records. Clinical examination and in detail neurological system was done.

All routine investigations were done for all babies and neurosonogram of the high-risk neonate fulfilling the inclusion criteria was performed. Follow-up cUS was done in the case of presence of any findings and for preterm neonates. Morphology of cUS findings was studied and recorded and clinical correlation with various findings on neurosonogram was done. Neonates were followed till recovery and discharge from NICU.

The sonograms were performed on a Philips HD 11 XE machine using a multi-frequency high-density

volume - TV/TR probe. A single radiologist to avoid inter-observer variation performed all ultrasounds.

### Statistical Analysis

Descriptive statistical analysis was carried out in this study. Results on continuous measurements are presented on mean  $\pm$  standard deviation (SD) (min-max) and results on categorical measurements presented in number (%). Significance is assessed at 5% level of significance.

Chi-square test was used to find the significance of study parameters and also categorical scale between two or more groups.

## RESULTS

Out of 100 cases included in the study, 31% of the neonates had neurosonographic abnormalities. There were 56% male and 44% female neonates enrolled of which 63% were preterm and 37% term high-risk neonates with birth weight distribution of mean  $\pm$  SD:  $1.84 \pm 0.62$ . Mode of delivery was normal vaginal for 52% neonates and 48% via LSCS for various reasons.

Out of 63 neonates with preterm gestation, 36% had abnormal cUS and out of 37 term critically ill neonates with, 21% had abnormal cUS.

Of 63% of neonates admitted with prematurity, 57% was  $<32$  weeks gestation and 36% had abnormal cUS. Out of 63% preterm neonates, 47% had respiratory distress, 15% had neonatal sepsis, 12% had hypoglycemia, 11% had HIE, 46% clinically had respiratory distress, 7% had neonatal seizures in NICU stay, 3% had hypocalcemia seizures and 1% had documented birth trauma at birth. There were no neonates with congenital malformations or neural tube defect.

Of the preterm neonates having abnormal findings on cUS, 43% had intracranial bleed, 17% had cerebral edema, 4% had thalamic hyperechogenicity, 8% had periventricular leukomalacia (PVL) and 8% with other findings (Table 1).

Correlation of cUS abnormalities and HIE showed that of the 13 of neonates with HIE at birth based on APGAR score, 53% had abnormal cUS abnormalities. Of 13 neonates with HIE, 38% had cerebral edema and 23% had thalamic hyperechogenicities and 30% had intracranial bleeds (Table 2).

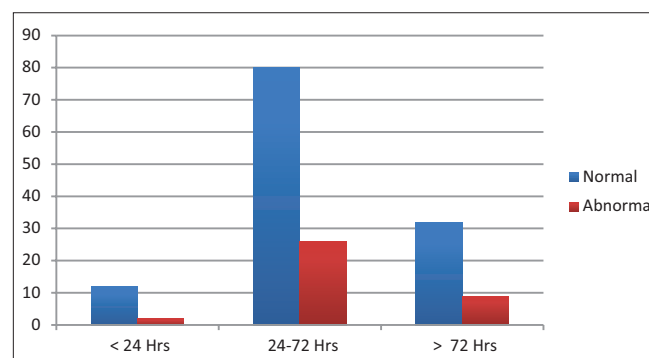
There was statistically significant correlation between findings on cUS and day of life of neonate when cUS was done. Around 16% abnormal findings on cUS were picked

up before 24 h, around 32% picked up during 24-72 h of life and around 25% after 72 h of life (Figure 1).

In the correlation of perinatal risk factors with abnormal cUS findings, there was statistically significant correlation only with PIH ( $P = 0.05$ ). Correlation of APH, PROM, multiple births and birth trauma was statistically not significant.

There was statistically significant correlation between abnormal cry ( $P = 0.052$ ), abnormal tone ( $P = 0.021$ ), abnormal activity ( $P = 0.018$ ), and presence of cyanosis ( $P = 0.035$ ) on clinical examination and presence of abnormalities on cUS.

One preterm neonate on regular follow-up cUS developed findings suggestive of hydrocephalous correlating with clinical outcome. There was no statistically significant correlation between various findings on cUS and clinical outcome of the neonate. 94% of neonates enrolled had good recovery at the time of NICU discharge, 4% died and 2% were discharged from NICU for various reasons before clinical recovery.



**Figure 1: Distribution of high-risk neonates based on timing of cranial ultrasound**

**Table 1: Correlation of gestational age with various cUS findings**

Neurosonogram	Number of neonates n=100 (%)	Gestation age (weeks)		
		<32 n=36 (%)	33-36 n=27 (%)	>37 n=37 (%)
Normal	69 (69)	23 (63)	17 (62)	29 (78)
Abnormal	31 (31)	13 (36)	10 (37)	8 (21)
Intracranial bleed	13 (13)	6 (46)	4	3 (8)
Cerebral edema	8 (8)	2 (15)	2	6 (16)
PVL	2 (2)	0	2	0
Thalamic hyperechogenicity	5 (5)	0	1	3 (8)
CNS malformation	2 (2)	0	1	1 (2)
Miscellaneous	1 (1)	1 (7)	0	0

CNS: Central nervous system, PVL: Periventricular leukomalacia, cUS: Cranial ultrasonography



**Table 2: Correlation of cUS abnormalities in high risk neonates**

Neurosonogram	No of neonate n=100 (%)	Inclusion criteria			
		Preterm n=63 (%)	Sepsis n=22 (%)	Seizure n=13 (%)	HIE n=13 (%)
Normal	69 (69)	40 (63)	12 (54)	7 (53)	6 (46)
Abnormal	31 (31)	23 (23)	8 (36)	6 (46)	7 (53)
Intracranial bleed	13 (13)	10 (15)	2 (9)	4 (30)	4 (30)
Cerebral edema	8 (8)	4 (6)	4 (18)	3 (23)	5 (38)
PVL	2 (2)	2 (3)	1 (4)	0	0
Thalamic hyperechogenicity	5 (5)	1 (1)	2 (9)	0	3 (23)
Miscellaneous	1 (1)	2 (3)	0	0	0

HIE: Hypoxic-ischemic encephalopathy, PVL: Periventricular leukomalacia, cUS: Cranial ultrasonography

## DISCUSSION

The use of neurosonogram in NICU's is rapidly increasing owing to availability and early detection and management.

Neurosonogram is an easy and an affordable non-invasive procedure and treatment is initiated at a very early stage. It can be repeated as necessary, and thereby enables visualization of ongoing brain maturation and the evolution of brain lesions. It can also be used to assess the timing of brain damage.

De Vries and Cowan *et al.* have suggested that neurosonogram and MRI are complementary modalities, with ultrasound as an especially useful tool in the early days, when the infant is unstable for transport and ultrasound findings may be sufficient for major clinical decisions. Current study aims at proving the same.<sup>6</sup>

Each study found 100% correlation between neurosonography findings and neuropathologic data. Ultrasound is also particularly useful in detecting some important congenital malformations such as cystic lesions (hydrocephalus, porencephalic cysts, Dandy-Walker cysts complex, and arachnoid cysts), corpus callosal agenesis and aneurysm of the vein of Galen (color Doppler).

Four studies reported results of a total of 87 autopsies performed on PT infants, neurosonogram was 76% to 100% accurate in detecting Grade 1 lesions of >5 mm and Grade 3 and Grade 4 hemorrhages. Detection of Grade 2 hemorrhages was much less accurate. Correlation of US findings of cystic PVL with neuropathologic data was evaluated in three studies.<sup>10-12</sup>

Dubowitz *et al.*, study showed an incidence 20% of ultrasound abnormalities in apparently well neonates and reported ischemic lesions, such as periventricular and thalamic densities were the most common finding (8%), followed by intracranial hemorrhagic lesions (6%) on cUS. In this study, on cUS, 31% of neonates had abnormal findings. 13% of these had evidence of intracranial bleed, 5% hyperechogenic thalami, 8% had cerebral edema.

Hence, high efficacy of neurosonogram in detecting presence of brain damage and its evolution on regular follow-up guides clinical decisions and prognosis.

## CONCLUSION

This study shows diagnostic importance of neurosonogram in critically ill neonates in NICU.

It also signifies its use as a screening tool in preterm in diagnosis and also for predicting the neurological outcome in critically ill neonates.

Neurosonogram is used as routine in NICUs was found to be an excellent and noninvasive tool for brain imaging during the neonatal period. It enables screening of the brain and serial imaging in high-risk neonates. The study concludes that neurosonogram is critical as an investigatory modality in NICU and effectively documents morphology of brain damage, enabling early intervention and treatment, and may improve clinical outcome.

Finally, it shows the importance of neurosonogram as a routine daily use in NICU for diagnosis and prognostication and, also the need of the neonatologist working in the NICU to expertize the art of neurosonography for safe, early and effective care.

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# Comparison of Transabdominal Preperitoneal and Total Extra Peritoneal: A Prospective Study

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## Abstract

**Background:** Groin hernia surgeries have come a long way since knowledge of modern surgery. Among them, laparoscopic hernia repair is the advanced and better method in terms of cosmesis, bilateral repair, recurrent hernias.

**Aims and Objectives:** To compare operative time and post-operative pain in transabdominal preperitoneal (TAPP) and total extra peritoneal (TEP).

**Materials and Methods:** A total of 40 cases of groin hernia admitted in Sri Siddhartha Medical College, Tumkur, Karnataka, India, between 2013 and 2015 randomly picked for TAPP and TEP surgeries, assigning 20 for each, prospective analysis made results compared and evaluated using FISCHERS test and Chi-square test.

**Results:** Comparatively TEP repair took more time and TAPP repair had more pain.

**Conclusion:** No major complications in both procedures, laparoscopy repair has long learning curve which demands skills, TEP takes more time, and TAPP has more pain.

**Key words:** Duration, Pain, Total extraperitoneal, Transabdominal preperitoneal

## INTRODUCTION

No disease of human body, belonging to the province of the surgeon, requires in its treatment a better combination of accurate, anatomical knowledge with surgical skill than hernia in all its varieties.<sup>1</sup>

Sir Astley Paston Cooper's statement in 1804 still reverberates in the minds of surgeons. Groin hernias are the most common conditions referred to surgeons all over the world and over five lakh hernia repairs are performed annually.<sup>2</sup> The lifetime risk for men is 27% and for women is 3%.<sup>3</sup>

Since Bassini published his landmark paper on the technique of tissue repair<sup>4</sup> in 1887, numerous modifications have been proposed. There has been a revolution in surgical procedures for groin hernia repairs after the introduction of prosthetic material by Usher<sup>5</sup> in 1958.

Ger reported the first laparoscopic hernia repair in 1982 by approximating the internal ring with stainless steel clips.<sup>6</sup> The laparoscopic transabdominal preperitoneal (TAPP) repair was a revolutionary concept in the hernia surgery and was introduced by Arregui *et al.*,<sup>7</sup> and Dion and Morin<sup>8</sup> in the early 1990s. Laparoscopic groin hernia repair can be done by TAPP approach and also by total extra peritoneal (TEP) approach.<sup>9</sup>

The learning curve of laparoscopic repair of inguinal hernia has been made all the more steep because of lack of documentation of results with regard to patient satisfaction, post-operative pain, duration of stay in the hospital, complications and recurrence of hernia, hence making stratification of patients for either TEP or TAPP repair difficult.

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Our purpose in this study is to compare the results of laparoscopic hernioplasty by TEP technique and laparoscopic TAPP technique, and determine if the relative advantages achieved could be put in practice in large scale and also identify criteria which may help stratify the patient to a particular type of repair to obtain encouraging results for that particular patient. The aim of our study is to compare and assess the outcome between laparoscopic TAPP repair and TEP repair of inguinal hernia in terms of duration taken for procedures and post-operative pain.

## MATERIALS AND METHODS

This was a prospective study. This study consisted of 40 patients of inguinal hernia treated with laparoscopic hernia repair, 20 of whom were treated by laparoscopic TAPP mesh repair and the remaining 20 cases treated by TEP mesh repair of inguinal hernia in Sri Siddhartha Medical College and Hospital from October 2013 to March 2015 which included a minimum of 1 year of follow-up.

### Inclusion Criteria

1. Male Patients above 18 years of age
2. Unilateral inguinal hernia (proven by clinical examination and abdominal ultrasound)
3. Patients fit for laparoscopic hernia repair under general anesthesia.

### Exclusion Criteria

Patients with the following conditions are excluded from this study:

1. Female patients
2. Patients with recurrent hernia
3. Patients with bilateral hernia
4. Patients unfit for general anesthesia
5. Hernia with complications (irreducible hernia and strangulated hernia).

All the patients were admitted, and a detailed history and clinical examination was carried out as per written Performa. Preoperatively the patients were be offered options of either laparoscopic TEP or laparoscopic TAPP repair for inguinal hernia, and will be educated about the advantages, disadvantages, type of anesthesia, and also the approximate cost of each of the procedure.

After taking consent for the procedure, the patient is investigated thoroughly. Once the patient is deemed fit for surgery. A dose of prophylactic antibiotic was given 30 min before surgery. A Foleys catheter was inserted. Postoperatively the patients were kept nil by mouth and advised complete bed rest until the effect of anesthesia is completely worn out, until then they are given supportive

maintenance intravenous fluids. Foley's catheter is removed once the patient becomes ambulatory, usually on the first post-operative day. Patients were advised and encouraged to ambulate and start their activities of daily life as early as possible.

Analgesics were given at 12 h interval for a period of 3-5 days, shifted on to oral tablets as early as possible. Patients were observed for any complications such as subcutaneous emphysema, mediastinitis, CO<sub>2</sub> narcosis in the immediate post-operative period and hematoma, seroma, wound sepsis during their stay in the hospital and also assessed for post-operative pain and its severity.

Patients were discharged once free of complications and once they resumed their activities of daily normal life. Patients were discharged within the next day or within 48 h. At discharge, they were advised to come for stitch removal after 7-8 days (1<sup>st</sup> follow-up), and then after 1 week (2<sup>nd</sup> follow-up), and then after 1 month of surgery (3<sup>rd</sup> follow-up). Later on after 3 months of surgery (4<sup>th</sup> follow-up) and after 6 months after surgery (5<sup>th</sup> follow-up) and at 1 year (6<sup>th</sup> follow-up).

### Statistical Methods

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on mean  $\pm$  standard deviation (min-max) and results on categorical measurements are presented in number (%). A significance is assessed at 5% level of significance. Student's *t*-test (two-tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups Chi-square/Fisher Exact test has been used to find the significance of study parameters on a categorical scale between two or more groups.

## RESULTS

### Study Design

This prospective study consisted of 40 patients with diagnosis of inguinal hernia who were admitted to the surgical inpatient ward in Sri Siddhartha Hospital and Medical College, Tumkur and underwent laparoscopic hernioplasty during October 2013 to March 2015.

Total number of cases - 40

Number of laparoscopic (TEP) hernioplasty - 20

Number of laparoscopic (TAPP) hernioplasty - 20.

All cases underwent detailed pre-operative assessment and their pre-operative findings and post-operative complications were meticulously recorded as per protocol. The findings were tabulated and the following observations were made.

This comparative study with 20 patients undergoing laparoscopic TEP procedure and 20 patients undergoing laparoscopic TAPP procedure is undertaken to study the efficacy based on the duration of operation, and post-operative pain. Descriptive statistical analysis has been carried out in the present study.

Table 1 shows patients were aged between 20 and 60 years in laparoscopic TEP group with the mean age being  $41.6 \pm 10.2$  years.

Patients were aged between 20 and 60 years (in laparoscopic TAPP group, with the mean age being  $41.13 \pm 9.6$  years.

In TEP mesh repair group, as shown in Table 2:

- 10 (50%) right sided hernias
- 10 (50%) left side hernias.

And in laparoscopic TAPP mesh repair group there were as follows:

- 9 (45%) right sided hernias
- 11 (55%) left sided hernias.

Table 3 shows the mean operative time was 110 min for laparoscopic TAPP hernia repair and 125 min for laparoscopic TEP hernia repair.

Hence, the overall mean operative time was significantly less in laparoscopic TAPP repair than in laparoscopic TEP repair.

Table 4 shows a comparison of post-operative pain between laparoscopic TEP and laparoscopic TAPP hernia repair.

Post-operative pain was assessed using visual analog scale (score 1-10).

**Table 1: Age distribution of patients studied**

Age group	TAPP	TEP	Total
20-30	5	2	7
30-40	6	6	12
40-50	4	9	13
50-60	5	3	8
Total	20	20	40

Chi-square: 3.71,  $P=0.29$ , Interpretation: Not significant, TAPP: Transabdominal preperitoneal, TEP: Total extra peritoneal

**Table 2: Diagnosis**

Diagnosis	TAPP	TEP	Total
Right direct hernia	0	5	5
Left direct hernia	0	3	3
Right indirect hernia	9	5	14
Left indirect hernia	11	7	18
Total	20	20	40

TAPP: Transabdominal preperitoneal, TEP: Total extra peritoneal

Pain score in laparoscopic TAPP group:

- 6 patients (30%) with a score of <3 (mild pain)
- 10 patients (50%) with a score of 3-6 (discomforting) and
- 4 Patients (20%) with a score of >6 (distressing).

Pain score in laparoscopic TEP group:

- 12 patients (60%) with a score of <3 (mild pain)
- 8 patients (40%) with a score of 3-6 (discomforting)
- No distressing pain seen in TEP group.

The difference between the two groups was statistically significant. TEP group has less pain compared to TAPP group.

There were no major complications, but we had 12 patients with MINOR complications in our study.

There were 5 patients with minor complications in laparoscopic TEP group (25%).

There were 7 patients with minor complications in laparoscopic TAPP group (35%).

The complications observed in our study were as follows:

1. Hematoma - 4 cases
2. Seroma - 7cases.

Patients in laparoscopic TEP group has post-operative stay 4.4 days, when compared to laparoscopic TAPP group who took 4.65 days, with  $P = 0.7$  which is statistically insignificant.

## DISCUSSION

All the patients in our study were males. 55% of the population in the TEP group and 65% in the TAPP group,

**Table 3: Operative time**

Duration of surgery (min)	TAPP	TEP	Total
80-100	5	0	5
100-120	10	6	16
120-140	5	14	19
Total	20	20	40
Mean $\pm$ SD	110.90 $\pm$ 12.02	125.50 $\pm$ 7.46	$P<0.0001$

SD: Standard deviation, TAPP: Transabdominal preperitoneal, TEP: Total extra peritoneal

**Table 4: Post-operative pain**

Post-operative pain (visual analog score)	TAPP	TEP	Total
<3	6	12	18
3-6	10	8	18
>6	4	0	4
Total	20	20	40
Mean $\pm$ SD	4.45 $\pm$ 1.7	3.3 $\pm$ 0.98	$P=0.01$

SD: Standard deviation, TAPP: Transabdominal preperitoneal, TEP: Total extra peritoneal



which shows skilled people preferred laparoscopic repair of inguinal hernia than open with an average of 60% of total study population.

In our study, the mean operative time was 110 min for laparoscopic TAPP hernia repair and 125 min for laparoscopic TEP hernia repair.

Hence, the overall mean operative time was significantly less in laparoscopic TAPP repair than in laparoscopic TEP repair (Figure 1).

The operative time in various studies for laparoscopic TEP and laparoscopic TAPP repair is shown in Table 5.

The study by Hamaza *et al.*, has similar results to our study as long duration in TEP group when compared to TAPP group.

Pain score in laparoscopic TAPP group, 6 patients (30%) with a score of <3 (mild pain), 10 patients (50%) with a score of 3-6 (discomforting) and 4 patients (20%) with a score of >6 (distressing).

Pain score in laparoscopic TEP group, 12 patients (60%) with a score of <3 (mild pain), 8 patients (40%) with a score of 3-6 (discomforting) and no distressing pain in TEP group.

The difference between the two groups was statistically significant. TEP group has less pain compared to TAPP group (Figure 2).

The study conducted by Bansal *et al.*,<sup>13</sup> shows similar results.

There were NO MAJOR complications, but we had 12 patients with MINOR complications in our study. 5 patients in TEP (25%) and 7 patients in TAPP (35%).

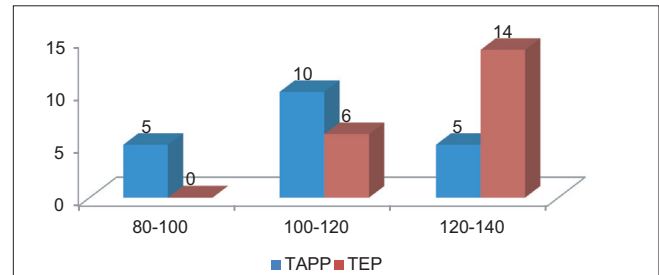
## CONCLUSION

This study supports the view that laparoscopic TEP and TAPP mesh repair for inguinal hernia are safe and efficacious, as we did not encounter any major complications, which demanded conversion. However, comparatively TEP group showed superiority with respect to post-operative pain and early return to normal work. Although the duration of surgery (TEP) lasted little longer, still a long-term randomized control trials with enhanced sample size and reduced confounding factors are required to establish the absolute superiority of one technique over the other.

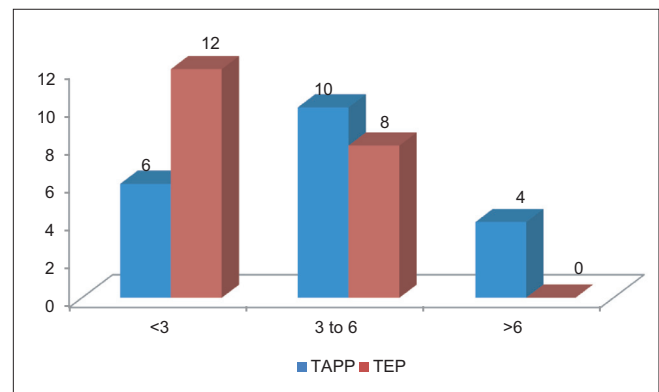
**Table 5: Operative time of different studies**

Study	Laparoscopic TEP hernia repair (in min)	Laparoscopic TAPP hernia repair (in min)
Leibl <i>et al.</i> <sup>10</sup>	56	66
Swanstorm, <i>et al.</i> <sup>11</sup>	(n=158) 57	(n=158) 92
Hamaza, <i>et al.</i> <sup>12</sup>	(n=25) 96.12	(n=25) 77.4

TAPP: Transabdominal preperitoneal, TEP: Total extra peritoneal



**Figure 1: Duration for performing procedures**



**Figure 2: Post-operative pain**

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# Severe Acute Maternal Morbidity (Near Miss) in a Tertiary Care Center in Maharashtra: A Prospective Study

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## Abstract

**Introduction:** Maternal near miss (MNM) has emerged as an adjunct to the investigation of maternal deaths as the two represent similar pathological and circumstantial factors leading to severe maternal outcome.

**Materials and Methods:** A prospective observational study, conducted in Indira Gandhi Government Medical College and Hospital, a tertiary care center, from July 2014 to June 2015. The patients were classified as near miss based on disease specific, organ system dysfunction, and management criteria.

**Results:** The total number of near miss cases was 98. The prevalence of MNM was 2.19%. The mean  $\pm$  standard deviation of age in the present study was  $27.84 \pm 3.43$  years. Majority of cases were nullipara, i.e., 33.68%. Most of the cases were of rural area 63.26%, had received only primary education at 62.25%, were of lower socio-economic status at 66.33%, were unbooked at 80.62%, and 69 cases were referred from periphery. In the present study, out of 98 cases, 88 were antenatal, of which 52 were above 37 weeks of gestation. Majority of cases were delivered by cesarean section, i.e., 46.93%. Hypertensive disorder of pregnancy was the most common factor causing near miss at 51.02%, others were obstetric hemorrhage at 43.87%, maternal medical disease at 13.26%, and obstetric sepsis at 3.06%. Vascular and coagulation system dysfunction was the most common, i.e., 28.57% followed by cardiac, 21.42%; respiratory, 19.38%; immunological, 12.24%; hepatic, 8.16%; cerebral, 6.1%; and renal dysfunction, 5.1%. About 64.28% patients required intensive care unit admission. Multiple management strategies including platelet and blood transfusions, vasopressors, furosemide, mechanical ventilation, dialysis, and hysterectomy were required.

**Conclusion:** MNM is associated with low level of education, low socio-economic status, rural population, low parity, referred cases, and unbooked cases. Hypertensive disorders are still the most common cause of MNM. A multidisciplinary approach is the need of the hour to tackle the problem of MNM.

**Key words:** Maternal morbidity, Maternal near miss, Tertiary care center

## INTRODUCTION

Maternal mortality is one of the important indicators used for the measurement of maternal health. Improvement of maternal health is one of the millennium development

goals (MDG), MDG 5 with Target 5 A that calls for the reduction of maternal mortality ratio by three quarters between 1990 and 2015.<sup>1</sup>

Maternal near miss (MNM) case is defined as “a woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy.”

Maternal mortality is frequently described as “just the tip of the iceberg” indicating that there is a vast base to the iceberg in the form of MNM, i.e., maternal morbidity which has remained largely undescribed.

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MNM has emerged as an adjunct to investigation of maternal deaths as the two represent similar pathological and circumstantial factors leading to severe maternal outcome. As the number of MNM cases is more than the maternal deaths, and the cases are alive to directly inform on problems and obstacles that had to be overcome during the process of health care, they provide useful information on the quality of healthcare at all levels. Thus, there is a need for application of the maternal near miss concept for the assessment of maternal health and quality of maternal care.<sup>2,3</sup>

Near miss audit has been considered a better approach than maternal death audit, and can be used to identify what need to be done to improve the quality of maternal health care. Compared with maternal death review, the fear of blame and punishment is less in near miss review, so, if a near miss review is performed effectively, it can in practice more easily lead to implementation of changes that will improve the quality of services. Near miss cases generally occur more frequently than maternal deaths and therefore a more reliable quantitative analysis can be carried out, which can provide a more comprehensive profile of health system functioning.

Identification of the obstacles and gaps in the health system and a co-ordinated approach to resolve these can ultimately lead to an improved health system. Near miss cases have similar pathways as maternal deaths, with the advantages of offering a larger number of cases for analysis, greater acceptability of individuals and institutions since death did not occur, and the possibility of interviewing the woman herself.

The most vital purpose of the near miss approach is to improve clinical practice and reduce preventable morbidity and mortality through the use of best evidence-based practices.

Hence, we have undertaken this study in our institute, being a tertiary care center catering to a population of not only our district, but nearby states also.

## MATERIALS AND METHODS

The present study was conducted in Indira Gandhi Government Medical College and Hospital, a tertiary care center, from July 2014 to June 2015. Permission from Institutional Ethical Committee was taken. The present study was a prospective observational study.

The total number of deliveries during this period was 4571. The total number of near miss cases in the above study

period was 98. The patients were classified as near miss based on disease specific, organ system dysfunction, and management criteria mentioned below:

### Case Definition

“A woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy.”

The primary obstetric and non-obstetric conditions (the initiating obstetric event): The primary obstetric factors that probably initiated the trail of events leading to near miss are:

1. Hypertension
2. Antepartum hemorrhage (APH)
3. Post-partum hemorrhage (PPH)
4. Pregnancy-related sepsis
5. Abortion-related sepsis
6. Abortion with uterine trauma
7. Ectopic pregnancy
8. Maternal medical disease
9. Anesthetic complication.

Organ dysfunction or failure (list of organ systems involved in the disease): The markers of dysfunction of each organ system are:

### Patient-based

- A. Cardiac dysfunction
  1. Pulmonary edema, a clinical diagnosis requiring intravenous (IV) furosemide or intubation
  2. Cardiac arrest.
- B. Vascular dysfunction: Hypovolemia requiring >5 units whole blood or packed red cells for resuscitation
- C. Immunological dysfunction
  1. Intensive admission for sepsis
  2. Emergency hysterectomy for sepsis.
- D. Respiratory dysfunction
  1. Intubation or ventilation for >60 min for any reason other than general anesthesia
  2. Oxygen saturation on pulse oximetry <90 for >60 min
  3.  $\text{PaO}_2/\text{FiO}_2 < 200$  (partial pressure of  $\text{O}_2$  in arterial blood to percentage  $\text{O}_2$  in inspired air).
- E. Renal dysfunction
  1. Oliguria <400 ml/h not responding to IV rehydration or attempts at using furosemide/dopamine
  2. Blood urea >15 mmol/L or of creatinine <400 mmol/L (serum creatinine 3.5 mg/dl).



- F. Liver dysfunction
  - 1. Jaundice in the presence of pre-eclampsia (140/90 with >1 + proteinuria).
- G. Metabolic dysfunction
  - 1. Diabetic ketoacidosis (DKA)
  - 2. Thyroid crisis.
- H. Coagulation dysfunction: Acute thrombocytopenia requiring platelet transfusion
- I. Cerebral dysfunction
  - 1. Coma >12 h
  - 2. Sub-arachnoid hemorrhage/intracranial hemorrhage.

### Management-based

- A. Intensive care admission; for any reason
- B. Emergency hysterectomy; for any reason
- C. Anesthetic accidents
- D. Severe hypotension with spinal/epidural anesthesia (<90 for 60 min)
- E. Failed tracheal intubation requiring anesthetic reversal.

## RESULTS

The present study was conducted in a tertiary care center from July 2014 to June 2015. The total number of deliveries during this period was 4571. The total number of near miss cases in the above study period was 98. The patients were classified as near miss based on disease specific, organ system dysfunction, and management criteria. The prevalence of MNM cases reported in this study was 2.19%.

Mean  $\pm$  standard deviation (SD) of age in the present study is  $27.84 \pm 3.43$  years. Majority of the cases were nullipara, 33 cases (33.68%); 26 cases (26.54%) were primipara, followed by 39 (39.78%) cases who were multipara. Most of the cases, in this study, 62 (63.26%) were from rural area, while 36 patients (36.73%) were from urban area. In this study, majority of patients, i.e., 61 cases (62.25%) had received their primary education followed by 16 cases (16.32%) who had received secondary education, and only 4 cases (4.08%) who had received higher secondary education and above. There were 17 (17.34%) patients who were illiterate. In the present study, 36 cases (36.74%) belonged to urban area and were classified according to Kuppaswamy (1976) classification, 19 out of 36 cases who belonged to urban area were of middle socio-economic class and 17 of 36 cases belonged to lower socio-economic class. About 62 from 98 cases (63.26%) belonged to rural area and were classified according to Prasad classification. Majority of the rural population, i.e., 48 cases (48.98%) belonged to lower

socio-economic class and the rest of the 14 cases (14.28%) belonged to middle socio-economic class. None of them were in upper socio-economic class. In the present study, out of 98 cases, antepartum admissions were 88 (89.8%), postpartum cases were 8 (8.16%), and post-abortion cases were 2 (2.04%). In the present study, 52 (59.09%) of 88 antenatal patients were beyond 37 weeks, 31 (35.32%) cases were between 33 and 36 weeks, 4 (4.55%) patients were between 29 and 32 weeks, while in 1 (1.14%) patient who belonged to <28 weeks group, the gestational age was 14 weeks. Majority of the cases were unbooked, 79 (80.62%) cases in the present study. Out of 98 cases, 69 cases were referred to our institute. Remaining 29 cases were admitted in our institute directly. Out of 29 cases, 28 were unbooked whereas 1 case was booked in our institute. Out of 69 referred cases, 18 cases were booked and 51 cases were unbooked. Majority of the cases, i.e., 42 (60.87%) were referred from district hospital, out of which 32 cases were unbooked amounting to 46.38%, followed by 15 cases (21.74%) which were referred from rural hospital, booked being 10 (14.49%). Next in order of frequency was referral from primary health center, i.e., 10 cases (14.5%), 7 being unbooked (10.15%). Only 2 cases (2.89%) were referred from private hospital which were unbooked. In the present study, maximum number of cases (46) was delivered by cesarean section amounting to 46.93%. Next in order of frequency were patients who delivered vaginally, that is, 44 (44.89%). 3 patients had abortion, one aborted in our institute while 2 had undergone abortion in rural health center and were referred as post-abortion sepsis. And, the remaining 5 cases were undelivered amounting to 5.12% (Table 1).

In the present study, more than two obstetric events occurred concurrently in the same patient. Hypertensive disorder of pregnancy was a major obstetric factor, that is, 50 patients (51.02%), out of these, 29 (29.59%) had severe pre-eclampsia, 16 (16.32%) had eclampsia, and 5 (5.1%) had HELLP. Next in order of frequency were cases of obstetric hemorrhage, total being 43 (43.87%), out of 43 patients, 12 had APH amounting to 12.24%, 28 (28.57%) had PPH, and 3 cases (3.06%) were of rupture uterus. There were 3 cases of obstetric sepsis. Among nonobstetric conditions, one MNM case suffered from complicated malaria. There were 2 cases of viral hepatitis with hyperbilirubinemia. There were 3 MNM cases who suffered from dengue, 3 MNM cases who had H1N1 influenza, and 4 cases of sickle-cell disease in crisis (Table 2).

In our study, majority of near miss cases, i.e., 28 of 98 (28.57%) had vascular dysfunction and coagulation dysfunction. The treatment modalities adopted for the management of vascular dysfunction were massive blood transfusion in 19 cases and obstetric hysterectomy was done in 9 cases to control the bleeding. Out of 28 cases,

25 patients required vasopressors to tide over the shock. The next organ system dysfunction was cardiac dysfunction (pulmonary edema) occurring in 21 cases of 98. The next organ system dysfunction was respiratory dysfunction, that is, 19 of 98 cases.

There were 12 cases of immunological dysfunction, out of which 3 had obstetric sepsis while 9 cases had nonobstetric source of infection. Out of 9 cases, 1 had malaria, 3 had dengue, 3 had H1N1 influenza, and 2 had viral hepatitis. There were 8 cases of hepatic dysfunction, the marker for which is jaundice in severe pre-eclampsia or acute hyperbilirubinemia. There were 6 cases of cerebral dysfunction with hypertensive disorder of pregnancy as a primary obstetric factor. Out of these, 4 had subarachnoid hemorrhage while in 2 cases coma lasting for more than 12 h (Table 3).

**Table 1: Demographic parameters**

Demographic parameters	Observations (%)
Total number of deliveries at tertiary care institute during the study period	4571
Total number of near miss cases	98
Prevalence	2.19 per 100 deliveries
Mean±SD of age	27.84±3.43 years
Nullipara	33 (33.68)
Primipara	26 (26.54)
Multipara	39 (39.78)
Rural	62 (63.26)
Urban	36 (36.73)
Booked	19 (19.38)
Unbooked	79 (80.62)
Illiterate	17 (17.34)
Primary school	61 (62.25)
Secondary school	16 (16.33)
Higher secondary school and above	4 (4.08)
Lower socio-economic status	Urban 17 (17.35), rural 48 (48.98)
Middle socio-economic status	Urban 19 (19.38), rural 14 (14.28)
Place of referral	
PHC	10 (14.5)
Rural hospital	15 (21.74)
District hospital	42 (60.87)
Private hospital	2 (2.89)
Pregnancy status of near miss cases	
Antepartum	88 (89.8)
Post-partum	8 (8.16)
Post-abortion	2 (2.04)
Gestational age (weeks) (n=88)	
<28	1 (1.14)
29-32	4 (4.55)
33-36	31 (35.32)
>37	52 (59.09)
Mode of delivery	
Vaginal	44 (44.89)
Cesarean section	46 (46.93)
Abortion	3 (3.06)
Undelivered	5 (5.12)

SD: Standard deviation, PHC: Primary health center

In the present study, multiple management measures were often required in the same patient. There were 63 cases which required intensive care unit (ICU) admissions as they could not be managed in obstetric wards and labor rooms. About 28 MNM cases required platelet transfusions due to coagulation dysfunction. About 25 MNM cases required vasopressors to tide over the shock. About 21 cases of hypertensive disorder of pregnancy and obstetric hemorrhage had cardiac dysfunction (pulmonary edema), hence were treated with IV furosemide. There were 19 cases of obstetric hemorrhage with or without severe pre-eclampsia which required massive blood transfusion. There were 13 cases of respiratory dysfunction with SpO<sub>2</sub> <90 for more than 60 min who were intubated and mechanically ventilated. There were 9 MNM cases who had undergone obstetric hysterectomy. Out of 9 cases, 6 cases had PPH, 1 case had APH, and 2 cases had rupture uterus as the primary obstetric event. There were 5 MNM cases with raised serum creatinine of >3.5 mg/dl who responded to renal dialysis (Table 4).

In the present study, there were 60 cases who fulfilled laboratory criteria of near miss. There were 28 cases of

**Table 2: Distribution of cases according to underlying obstetric and non-obstetric conditions (n=98)**

Primary obstetric factor	Number of cases (%)
Hypertensive disorders in pregnancy	50 (51.02)
Severe pre-eclampsia	29 (29.59)
Eclampsia	16 (16.32)
HELLP syndrome	5 (5.1)
Obstetric hemorrhage	43 (43.87)
APH	12 (12.24)
PPH	28 (28.57)
Rupture uterus	3 (3.06)
Obstetric sepsis	3 (3.06)
Maternal medical disease	13 (13.26)
Hepatitis	2 (2.04)
H1N1 influenza	3 (3.06)
Sickle-cell disease in crisis	4 (4.08)
Dengue	3 (3.06)
Malaria	1 (1.02)

APH: Antepartum hemorrhage, PPH: Post-partum hemorrhage

**Table 3: Distribution of cases according to organ system dysfunction (n=98)**

Organ system dysfunction	Number of cases (%)
Vascular	28 (28.57)
Coagulation	28 (28.57)
Cardiac	21 (21.42)
Respiratory	19 (19.38)
Immunological	12 (12.24)
Hepatic	8 (8.16)
Cerebral	6 (6.1)
Renal	5 (5.1)

coagulation dysfunction in whom platelet counts were <50,000/cumm. This was the most common laboratory criterion amounting to 46.66%. SpO<sub>2</sub> <90 for >60 min occurred in 19 of 98 MNM cases, they were cases of respiratory dysfunction treated in ICU. Serum bilirubin >6 mg/dl was found in 8 cases, out of them 3 cases had eclampsia as primary obstetric event, 2 cases were of viral hepatitis, one case was of complicated malaria, and 2 cases were of sickle-cell disease in crisis (Table 5).

In the present study, maximum near miss cases, 73 (74.48%) recovered in 9-14 days in our institute. The mean  $\pm$  SD. hospital stay in this study was  $13.44 \pm 2.19$  days. The range of duration of hospital stay was 8-22 days (Table 6).

In the present study, out of 98 MNM cases, 63 required ICU admission. The mean  $\pm$  SD. duration of ICU stay was  $5.49 \pm 1.95$  days. The range of ICU stay was 2-11 days. The maximum number of cases, 36 (57.14%) stayed in ICU for 5-8 days (Table 7).

## DISCUSSION

The total number of deliveries during the 1 year study period in the Department of Obstetrics and Gynecology were 4571. The total number of near miss cases in the study period was 98. The patients were classified as near miss based on disease specific, organ dysfunction, and management criteria. Hence, the prevalence of MNM cases reported in this study was 2.19%. Reena *et al.*,<sup>4</sup> reported a prevalence of 3.4% MNM based on disease-specific criteria

in a tertiary care hospital in Thrissur, Kerala. Chhabra *et al.*,<sup>5</sup> reported a prevalence of 3.3% in a pilot study on MNM cases in a tertiary care center in Delhi.

Near miss cases admitted in our tertiary care institute were mostly in the age group of 26-30 years, which amounts to 58.17% of the total. Mean age of patients in our study was 27.84 years, which is comparable to a study conducted by Roopa *et al.*,<sup>6</sup> i.e., mean  $\pm$  SD of  $27.3 \pm 4.75$  years.

In the present study, majority of MNM cases were multipara, 62.24% followed by nullipara, 33.68%, and the least being grand multipara, 4.08%, comparable to Kalra and Kachhwaha<sup>7</sup> (multipara, 67.8%; nullipara, 23.2%; and grand multipara, 8.92%) and Shrestha *et al.*,<sup>8</sup> (multipara, 66.4%; nullipara, 30.5%; and grand multipara, 2.71%).

In the present study, majority of MNM cases, i.e., 63.26% resided in rural area and the rest 36.74% in urban area similar to Litorp *et al.*,<sup>9</sup> (41% semiurban and 34% urban).

In the present study, majority of MNM cases, i.e., 62.25% had their primary education completed, followed by 16.33% MNM cases with their secondary education being done and 4.08% with their higher education completed. There were 17.34% MNM cases who were illiterate. Bashour *et al.*,<sup>10</sup> found that 80% of MNM cases in Lebanon (Rafik Hariri University Hospital) had received primary education while the rest 20% had received secondary education.

In the present study, 36 cases (36.74%) belonged to urban area and were classified according to Kuppuswamy (1976) classification, majority of MNM cases, i.e., 19.38% who belonged to urban area were of middle socio-economic class. Rest, i.e., 68 (63.26%) belonged to rural area were classified according to Prasad classification. Majority of the rural population, i.e., 48.98% belonged to lower socio-economic class. None of them were in

**Table 4: Distribution of patients according to management in near miss cases**

Criteria	Number of cases (%)
ICU admission	63 (64.28)
Platelet Transfusion	28 (28.57)
Use of vasopressors	25 (25.51)
IV furosemide	21 (21.42)
Massive blood transfusion	19 (19.38)
Mechanical ventilation	13 (13.26)
Obstetric hysterectomy	9 (9.18)
Need of dialysis	5 (5.1)

ICU: Intensive care unit, IV: Intravenous

**Table 5: Distribution of patients fulfilling laboratory criteria of MNM cases (n=60)**

Criteria	Number of cases (%)
Platelet counts<500,00/cumm	28 (46.66)
SpO <sub>2</sub> <90 for more than 60 min	19 (31.66)
Serum bilirubin>6 mg/dl	8 (13.34)
Serum creatinine>3.5 mg/dl	5 (8.34)
Total	60 (100)

MNM: Maternal near miss

**Table 6: Duration of hospital stay (n=98)**

Duration (days)	Number of cases (%)
<8	1 (1.04)
9-14	73 (74.48)
>15	24 (24.48)
Total	98 (100)

**Table 7: Duration of ICU stay (n=63)**

Duration (days)	Number of cases (%)
1-4	21 (33.34)
5-8	36 (57.14)
>9	6 (9.52)
Total	63 (100)

ICU: Intensive care unit

upper socio-economic class. Reena *et al.*,<sup>4</sup> conducted a cross-sectional study in which the subjects were divided as below: Poverty line and above poverty line according to the ration card issued to them by the state government. The subjects with below poverty line ration cards were considered as having low income. Majority of women (53.3%) with severe obstetric morbidity came from families classified as living below poverty line.

In the present study, 80.62% of MNM cases were unbooked, which was comparable in a study conducted by Shrestha *et al.*,<sup>8</sup> and Roopa *et al.*,<sup>6</sup> in which unbooked cases were 70% and 96.18 %, respectively. In the present study, 70% cases were referral cases, which is comparable to a study conducted by Kalra and Kachhwaha<sup>7</sup> (64.2%) and Purandare<sup>11</sup> (66.9%).

In the present study, 89.8% cases were antenatal, 8.16% cases were post-natal, and the rest 2.04% were post-abortion, which were comparable to the study conducted by Purandare *et al.*,<sup>12</sup> (antenatal care [ANC], 665.22%; post-natal care, 24.6%; abortion, 5.3%; and post-abortion, 1.5%) and Roopa *et al.*,<sup>6</sup> (ANC 74.9%, rest post-natal).

In the present study, majority of near miss cases were above 37 weeks gestation, which is comparable to the study conducted by Kalra and Kachhwaha<sup>7</sup> (50% cases above 29 weeks) and Roopa *et al.*,<sup>6</sup> (81.13 % cases above 29 weeks).

In the present study, 46.93% of MNM cases had cesarean section while 44.89% delivered vaginally, which is comparable to a study done by Almerie *et al.*,<sup>13</sup> (lower segment cesarean section 54.3%, vaginal 45.7%).

In the present study, the major primary obstetric factor was hypertensive disorder of pregnancy amounting to 51.02%, similar to Almerie *et al.*,<sup>13</sup> (52%), followed by obstetric hemorrhage, which amounted to 43.87%, similar to Roopa *et al.*,<sup>6</sup> (44.2%), followed by maternal medical disease, 13.26% (malaria - 1.02%, H1N1 - 3.06%, hepatitis - 2.04%, dengue - 3.06%, and sickle-cell disease in crisis - 4.08%) and the least being obstetric sepsis amounting to 3.06% similar to Purandare *et al.*, (3.8%).<sup>12</sup>

In the present study, majority of near miss cases had vascular dysfunction and coagulation dysfunction, that is, in 28.57% similar to Shrestha *et al.*,<sup>8</sup> (vascular 14% and coagulation 8%), followed by cardiac in 21.42% cases similar to Mantel *et al.*,<sup>3</sup> (20%), respiratory dysfunction in 19.38% cases, immunological dysfunction in 12.24% cases similar to Mantel *et al.*, (18%),<sup>3</sup> hepatic in 8.16% cases similar to Taly *et al.*,<sup>14</sup> (9%), cerebral in 6.1% cases similar to Mantel *et al.*, (5%),<sup>3</sup> and renal in 5.1% cases similar to Shrestha *et al.*, (5%).<sup>8</sup>

In the present study, 64.28% of MNM cases were admitted in ICU which is comparable to a study conducted by Roopa *et al.*,<sup>6</sup> in which 62.6% of patients required ICU admission. In a study conducted by Lotufo *et al.*,<sup>15</sup> 39.6% of cases required massive blood transfusion, while in our institute, 19.38% of patients received massive blood transfusion. About 13.26% of patients required intubation with mechanical ventilation in our ICU, which is comparable to the results of Purandare *et al.*,<sup>12</sup> where 11.7% of MNM cases required intubation with mechanical ventilation. In the present study, 9.18% of patients required obstetric hysterectomy, while in a study conducted by Purandare *et al.*,<sup>12</sup> 14.8% of cases had undergone obstetric hysterectomy.

In the present study, the most common laboratory criteria identified was acute thrombocytopenia (<50,000 platelets) in 46.66 % cases, O<sub>2</sub> saturation <90% for more than 60 min in 31.66% cases, total serum bilirubin >6 mg/dl in 13.34% cases, and serum creatinine >3.5 mg/dl in 8.34% cases. Oliveira and da Costa<sup>16</sup> had 255 MNM cases in their study. They found that platelets were <50,000 in 32.5% cases, serum creatinine was >3.5 mg/dl in 16.1% cases, SpO<sub>2</sub> <90% was in 10.6% cases, serum bilirubin was >6 mg/dl in 7.5% cases, PaO<sub>2</sub>/FiO<sub>2</sub> <200 in 7.1% cases, DKA was present in 3.1% cases, and pH was <7.1 in 2.7% cases.

In the present study, the mean duration of hospital stay was 13.44 ± 2.19 days (range 8-22 days), which was comparable to a study conducted by Souza *et al.*,<sup>17</sup> (mean hospital stay of 10.3 days, range: 13-24 days).

In the present study, the mean ICU stay was 5.49 ± 1.95 (range 2-11 days), which was comparable to a study conducted by Lotufo *et al.*,<sup>15</sup> and Almerie *et al.*<sup>13</sup>

## CONCLUSION

This study showed that among patients with MNM, there is a high frequency of women who have a low level of education, who are primiparous and who have had cesarean section. In addition, our study revealed that hypertensive disorder of pregnancy is still the most frequent underlying condition among such cases.

Maternal death and MNM cases are the indicators of the quality of health care provided. Obstetric ICU set up with a team approach consisting of treatment by obstetricians, intensive care specialists, and anesthesiologists are essential to save a maternal life. In our study, 63 cases were managed by multidisciplinary approach. The most vital purpose of the near miss approach is to improve clinical practice and reduce preventable morbidity and mortality through the use of best evidence-based practice.



The most important factor associated with MNM found in our study was the referral status of women. All women need access to quality maternal health services that can diagnose and manage life-threatening complications. Many of the cases were unbooked, belonging to low socio-economic status. The emergency obstetric care and Janani Suraksha Yojna are already implemented, but from our study, it appears that the patients and their relatives have failed to avail them. Hence, there is a need to take steps to sensitize the population where literacy is poor and who hail from the rural areas about these facilities. It will help in improving maternal health in long run and even reduce the MNM cases.

The study has tried to understand the social causes responsible for maternal morbidity. Major initiatives are needed within the health system to improve the overall wellbeing of the community. What we need is a multi-disciplinary approach aimed at cutting each thread of the web of causation of mortality and morbidity in pregnancy among near-miss women.

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# Comparison of Efficacy of One-minute Endoscopy Room Test and Giemsa Stain in Detecting *Helicobacter Pylori* in Chronic Gastritis

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## Abstract

**Background:** *Helicobacter pylori* is the most common cause for gastritis in patients with dyspepsia where gastric mucosal biopsies are indicated to identify different forms of gastritis. The most commonly used classification of gastritis is updated Sydney system. This study was done to find the efficacy of two tests - one-minute endoscopy room test (OMERT) and Giemsa stain for the identification of *H. pylori* in biopsies with chronic gastritis.

**Objectives:** To detect the efficacy of OMERT and Giemsa stain in the identification of *H. pylori* infection in patients undergoing endoscopy with histopathological diagnosis of chronic gastritis.

**Materials and Methods:** The endoscopic biopsies from November 2013 to May 2015 were included for the study. One of the biopsied tissues was directly immersed in OMERT solution and remaining were fixed in 10% formalin and processed and stained with hematoxylin and eosin, and Giemsa stain. The sensitivity and specificity of *H. pylori* detection by OMERT and Giemsa stain in histopathologically diagnosed cases of chronic gastritis were compared. *In-situ* and invasive carcinomas, polyps, and gastroesophageal junction biopsies were excluded from the study.

**Results:** Out of 53 cases studied, chronic non-specific gastritis was the most common type accounting for 21 cases, followed by 12 cases of chronic superficial gastritis, 10 cases of *H. pylori* gastritis, 9 cases of chronic active gastritis, and 1 case of chronic atrophic gastritis. *H. pylori* was positive in 13 (24.5%) cases by OMERT and 10 (18.9%) cases were positive by Giemsa stain. Both the techniques showed similar accuracy (83%).

**Conclusion:** In the present study, both OMERT and Giemsa stain were found to be having similar accuracy (83%). The sensitivity of OMERT was higher (78%), whereas Giemsa stain showed more specificity (92%). To avoid diagnostic pitfalls, the combination of two techniques is preferable rather than a single technique.

**Key words:** Chronic gastritis, Giemsa stain, *Helicobacter pylori*, Histopathology, One-minute endoscopy room test

## INTRODUCTION

Gastritis is defined as inflammation of the gastric mucosa and is the most common non-functional cause for dyspepsia. There are various classifications of gastritis taking into account morphology, topography, epidemiology,

and endoscopy. Most of the gastritis was deemed idiopathic, until the discovery of *Helicobacter pylori*.<sup>1-3</sup>

The most common cause of gastritis is *H. pylori*. It has been linked with benign, premalignant, and malignant lesions of digestive system including chronic gastritis, intestinal metaplasia, adenocarcinomas of the distal part of stomach, and lymphomas of mucosa-associated lymphoid tissue.<sup>4,5</sup>

Marshall and Warren discovered *H. Pylori*, in 1983, using Warthin-Starry silver stain.<sup>1</sup> Various stains including hematoxylin and eosin (H and E), Giemsa, toluidine blue, and genta have been used in detecting *H. pylori*.<sup>6</sup>

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The histological method was considered as the “gold standard” for demonstrating *H. pylori* in endoscopic biopsies. A heavy bacterial load is apparent on routine H and E stained sections but a low density of organisms, requires special staining techniques.<sup>7</sup>

*H. pylori* can be easily identified as a purple curve shaped microorganism against a blue background on Giemsa stain.<sup>6</sup>

One-minute endoscopy room test (OMERT) is an invasive endoscopy test, which does not need complex procedures and stains. The presence of *H. pylori* can be diagnosed within maximum of 5 min, which helps in immediate initiation of treatment and it has a high sensitivity.<sup>8</sup>

Since *H. pylori* is one among the treatable causes of gastritis, and it is a part of the etiological classification of chronic gastritis in updated Sydney system, it is mandatory to document whether *H. pylori* is present or absent in a given gastric biopsy.<sup>9</sup> Hence, the present study was conducted to compare the accuracy of Giemsa stain and OMERT test to identify the bacilli in chronic gastritis.

## MATERIALS AND METHODS

This study was undertaken in the Department of Pathology, Sri Manakula Vinayagar Medical College and Hospital, Puducherry. The study was conducted from November 2013 to April 2015 for 18-month after obtaining clearance from the Ethical Committee. Clinical details including age, gender, clinical diagnosis and endoscopy findings were noted on histopathologically diagnosed cases of gastritis.

### Inclusion of Samples

The gastric biopsy specimens, taken from antrum, fundus, corpus, and incisura angularis of the stomach, received in the Department of Pathology were included.

### Collection of Specimen

Biopsies were taken with a flexible fiberoptic gastroscope OLYMPUS.

One of the bits was immersed in urea solution for OMERT. This test utilizes 10% urea solution at pH 6.8 and addition of 1% freshly prepared phenol. The presence of *H. pylori* is indicated by the change of color of the solution from yellow to pink within 5 min (Figure 1).<sup>8</sup>

Remaining tissue bits were fixed in 10% buffered formalin and were taken for conventional processing. After processing, tissues were embedded in paraffin wax. Sections were cut serially at a thickness of 4-5  $\mu$ . Multiple sections were taken from each block and were stained for hematoxylin and eosin (H and E) and Giemsa.

The H and E stained slides were analyzed, and the samples which were histopathologically diagnosed as chronic gastritis only were included for the study. The classification was based on Sydney system.

### Exclusion Criteria

The biopsies with *in-situ* or invasive carcinoma on histopathologic examination were excluded from the study. Furthermore, the biopsies taken from the esophagogastric junction, inadequate biopsies, and gastric polyps were excluded.

## RESULTS

A total of 53 endoscopic gastric biopsy specimens diagnosed as gastritis of any type across all ages were taken for the study over a period of 18-month. Of the total 53 cases, 21 cases were diagnosed as chronic non-specific gastritis, 12 cases were chronic superficial gastritis, 10 cases of chronic *H. pylori* gastritis, 9 cases of chronic active gastritis, and a single case diagnosed as chronic atrophic gastritis.

Among these 53 cases, *H. pylori* was positive in 13 cases by OMERT and 10 cases were positive on Giemsa stain (Figure 2).

In comparison to Giemsa stain, OMERT showed more number of positive cases (24.5%) (Table 1).

Among the two techniques used in the study, OMERT was more sensitive (70%) while Giemsa stain was more specific with 92% specificity. However, the accuracy level of both the tests was equal (83%) (Table 2).

In 70% of the *H. pylori* positive cases, the mucinous epithelium was found to be intact with significant *P* value (Table 3 and Figure 3).

Both *H. pylori* and non - *H. pylori* gastritis showed mild degree of vascularity with moderate degree of inflammation. Moderate activity was seen in *H. pylori* gastritis, whereas in non-*H. pylori* gastritis, majority showed nil activity. Intestinal metaplasia was more frequently seen

**Table 1: *H. pylori* positivity on OMERT and Giemsa stain**

<i>H. pylori</i>	<i>n</i> (%)	
	OMERT	Giemsa
Positive	13 (24.5)	10 (18.9)
Negative	40 (75.5)	43 (81.1)
Total	53 (100)	53 (100)

*H. pylori*: *Helicobacter pylori*, OMERT: One-minute endoscopy room test

**Table 2: Level of accuracy of OMERT in comparison with Giemsa**

Technique	Positive	Negative	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
OMERT	13	40	70	86.05	53.85	92.5	83.02
Giemsa	10	43	53	92	70	86	83

OMERT: One-minute endoscopy room test, PPV: Positive predictive value, NPV: Negative predictive value

True positive: 7	False positive: 3
True negative: 37	False negative: 6

**Table 3: Nature of epithelium in relation to *H. pylori* status**

<i>H. Pylori</i> on Giemsa	Mucinous epithelium			Statistics
	<i>n</i> (%)			
	Intact	Ulcer	Total	
Positive	7 (70.0)	3 (30.0)	10 (100)	$\chi^2=4.121$ df=1 <i>P</i> =0.042
Negative	15 (34.9)	28 (65.1)	43 (100)	
Total	22 (41.5)	31 (58.5)	53 (100)	

*H. pylori*: *Helicobacter pylori*

**Table 4: Comparison of morphological parameters with *H. pylori* status**

<i>H. pylori</i>	n (%)		Statistics
	Positive (n=10)	Negative (n=43)	
Inflammation			
Mild	2 (20)	8 (18.6)	$\chi^2=1.792$ df=2 P=0.4082
Moderate	7 (70)	22 (51.2)	
Severe	1 (10)	13 (24.5)	
Activity			
Mild	3 (30)	6 (14.0)	$\chi^2=3.502$ df=2 P=0.1736
Moderate	5 (50)	3 (7.0)	
Severe	2 (20)	1 (2.3)	
Vascularity			
Mild	6 (60)	22 (51.2)	$\chi^2=0.6099$ df=2 P=0.7372
Moderate	2 (20)	14 (26.4)	
Severe	2 (20)	7 (16.3)	
Metaplasia			
Mild	2 (20)	17 (39.5)	$\chi^2=0.3041$ df=2 P=0.8589
Moderate	1 (10)	5 (11.6)	
Severe	0 (0)	1 (2.3)	
Dysplasia			
Nil	10 (100)	40 (93.0)	$\chi^2=0.7395$ df=1 P=0.3898
Severe	0 (0)	3 (7.0)	

*H. pylori*: *Helicobacter pylori*

in non-*H. pylori* gastritis. No dysplasia was seen in *H. pylori* positive gastritis (Table 4).

## DISCUSSION

In our study, 53 patients with dyspepsia were evaluated on gastric endoscopic biopsies for histopathological gastric mucosal changes and *H. pylori* positivity over a period of 18-month.

**Table 5: Comparison of *H. pylori* positivity with previous studies**

Study	Country	Positivity for <i>H. pylori</i> (%)	Method used for identification
Rokkas <i>et al.</i> <sup>10</sup>	England	45	Histopathology
Pettross <i>et al.</i> <sup>11</sup>	USA	43	Culture, Silver stain
Abdulla <i>et al.</i> <sup>12</sup>	Indonesia	68	Culture, Silver stain, Rapid urease test
Present study	India	18.9	Giemsa stain
		24.5	OMERT

*H. pylori*: *Helicobacter pylori*, OMERT: One-minute endoscopy room test

**Table 6: Comparison of *H. pylori* detection by OMERT and Giemsa stain with previous study**

Technique	Jeelani Romshoo <i>et al.</i> <sup>8</sup> (%)	Present study (%)
OMERT		
Sensitivity	80	70
Specificity	92.86	86.05
Giemsa		
Sensitivity	74	53
Specificity	78.57	92

*H. pylori*: *Helicobacter pylori*, OMERT: One-minute endoscopy room test

The biopsies taken from the esophagogastric junction, gastric polyps, carcinoma, and inadequate biopsies were excluded from the study.

In 1984, Marshall and Warren, in their study showed that among 20 cases of chronic gastritis, 12 were positive for *H. pylori* (60%).<sup>2</sup> Our study showed a lesser positivity which can be attributed to the following reasons.

The environmental factors in the population under study may be a factor. Furthermore, in many of the previous studies, culture also was used which was highly sensitive and capable of demonstrating the organism even when the load was less (Tables 5 and 6). Among the 53 cases in our study, 26 cases showed intestinal metaplasia and 31 cases had mucosal ulceration. Both these changes are known to alter the pH of gastric mucosa, and render it unfavorable for the growth of *H. pylori* which requires a slightly alkaline pH.<sup>13</sup>

Misra *et al.*, in their study showed that the numbers of *H. pylori* positive cases were increased with the increasing grades of gastritis, and the association was found to be statistically significant.<sup>14</sup> In our study, the number of cases of *H. pylori* was seen more with moderate severity of





Figure 1: One-minute endoscopy room test: Positive (pink); negative (light yellow)

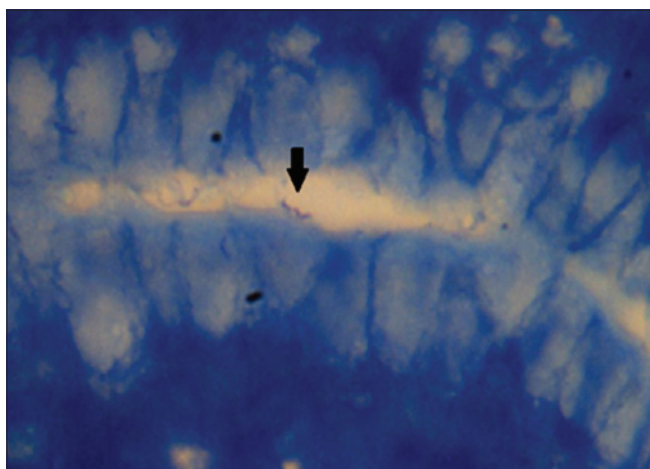


Figure 2: *Helicobacter pylori*, curved metachromatic bacilli (arrow) - Giemsa,  $\times 100$

inflammation and was found to be statistically insignificant (Figure 4).

Although both the tests had good sensitivity and specificity with same accuracy level (83%), we encountered a few minor pitfalls.

#### Pitfalls in OMERT

OMERT showed false positivity in three cases. This may be due to immersing the endoscopic biopsy forceps into the container containing the solution thereby rendering the solution alkaline, which causes color change to pink, the criteria for positivity. Hence, the biopsy bit to be immersed should be taken by a sterile needle from the scope forceps and then placed in the solution.

#### Pitfalls in Giemsa Stain

Giemsa stained sections, in few cases showed stain particles or other non-metachromatic bacteria which caused

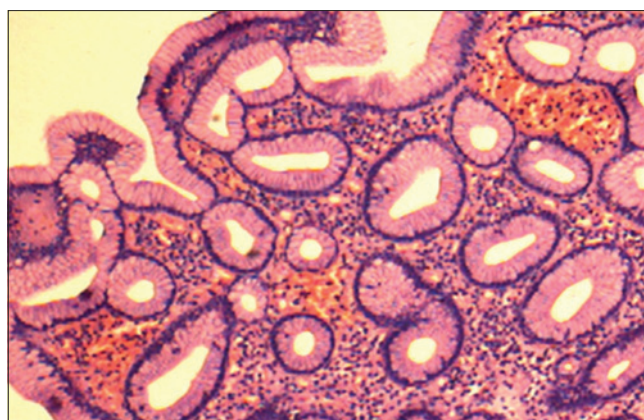


Figure 3: Mucosa with intact surface epithelium, regular glands, mild inflammation and hemorrhage in the lamina propria, hematoxylin, and eosin,  $\times 10$

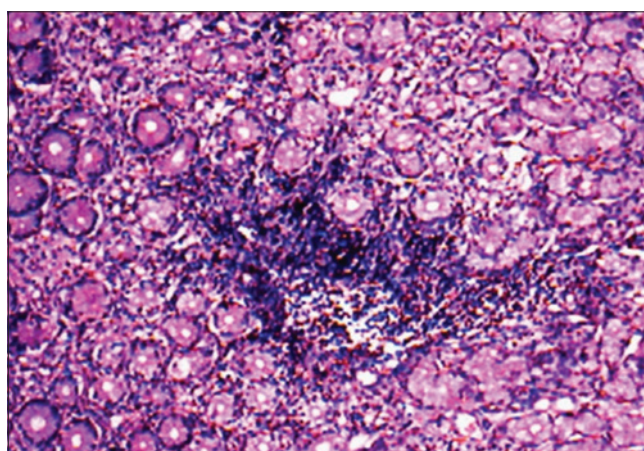


Figure 4: Dense inflammation in the lamina propria, hematoxylin and eosin,  $\times 10$

difficulty in identifying the *H. pylori*. However, *H. pylori* was identified only based on the curved architecture and metachromatic staining characteristic which made this method very specific.

In the present study, *H. pylori* was found in 18.9% and was associated with moderate inflammation and activity. Both Giemsa stain and OMERT were having similar accuracy levels (83%); however, OMERT was more sensitive, and Giemsa stain was more specific.

## CONCLUSION

The present study had 53 cases of histopathologically diagnosed gastritis for 18-month, and histopathological parameters were analyzed along with *H. pylori* status in all these patients by two methods (OMERT and Giemsa stain).

Among the 53 cases, *H. pylori* was positive in 13 (24.5%) cases by OMERT and 10 (18.9%) cases were positive by

Giemsa stain. OMERT test showed higher sensitivity (70%), whereas Giemsa stain showed higher specificity (92%). However, the accuracy levels of both techniques were similar (83%). The presence of *H. pylori* is directly proportionate to the degree of inflammation and activity in chronic gastritis.

Non-invasive tests for detection of *H. pylori* may be preferred choice for clinicians, but histopathological demonstration of the organism has the advantage of accuracy. Furthermore, it gives us a chance to study the associated histopathological changes which may be of prognostic value.

In view of avoiding, the pitfalls of each technique and to avail the advantage of morphological correlation, the combination of both techniques will be beneficial.

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# Susceptibility to Pulmonary Tuberculosis as a Function of ABO-Rh Blood Group Antigens

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## Abstract

**Background:** Earlier studies have proved a strong correlation between ABO blood groups and specific diseases, but for pulmonary tuberculosis (PTB) no consensus has been reached as the study results have been variable.

**Aims:** This study was done to establish any possible correlation between ABO blood groups/Rh D status and sputum acid-fast bacillus positive PTB and also to find out the frequency distribution of ABO blood groups in a population of Odisha, an eastern state of India.

**Materials and Methods:** Blood grouping was done for 122 smear positive PTB cases (study group) during the study period of September 2010 - August 2012. During the same period, blood group data of 2842 healthy blood donors (control group) were collected. This data were analyzed using Chi-square test to establish any possible correlation.

**Results:** Blood Groups "A" and "B" have a significant association with sputum smear positive PTB ( $P = 0.005$  and  $0.0002$ , respectively). Rh D status has no correlation with sputum positive PTB ( $P = 0.073$ ). Most common blood groups among residents of the coastal belt of Odisha are blood Group "O" (36.6%) and "B" (33.3%).

**Conclusions:** Individuals having blood Group "A" or "B" are more likely to suffer from tuberculosis compared to blood Group "O" and "AB" in Eastern India. The reason for this vulnerability is not known.

**Key words:** ABO blood group, Acid-fast bacillus, Pulmonary tuberculosis, Rh D status, Sputum

## INTRODUCTION

More than 130 years have passed since Sir Robert Koch first discovered the causative agent of tuberculosis (TB), i.e., *Mycobacterium tuberculosis*<sup>1</sup> but it still remains a major health problem globally. According to the World Health Organization Global TB Report 2015, 9.6 million people fell ill, and 1.2 million people died of TB in the year 2014.<sup>2</sup> TB is an infectious disease transmitted most commonly through droplet nuclei released into the atmosphere by people suffering from pulmonary TB (PTB) through

coughing, sneezing, and speaking. Identified risk factors for TB are overcrowding, poor ventilation, young age, low socioeconomic status, addictions such as alcohol and smoking, occupational risk such as health care workers, human immunodeficiency virus infection (HIV), diabetes, and malnutrition.<sup>3</sup> Apart from these well-established factors other markers or individual trait increasing the incidence and prevalence of TB has been debated in view of geographical and ethnic. One of such debated factor is relation blood group and TB.

Landsteiner, in the year 1901, discovered ABO blood group system and marked the era of safe blood transfusion.<sup>4</sup> It also provided a strong factor contributing to identity and individuality of people. Since then, the association of ABO blood groups with various diseases has intrigued many researchers. Susceptibility to TB as a function of blood group has been studied previously, and the results were variable. We conducted this study to look for association

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of ABO and Rh typing with sputum positive PTB and also to find out frequency distribution of blood groups in healthy adults in Odisha, India.

## MATERIALS AND METHODS

The study was conducted from September 2010 to August 2012 in the Sriram Chandra Bhanja Medical College and Hospital, a Tertiary Care Hospital catering to the coastal area of Odisha and parts of West Bengal from September 2010 to August 2012.

In patients (TB ward) of the Department of Pulmonary Medicine who were sputum smear positive for acid-fast bacillus (AFB) in microscopy were recruited into the study and formed the “Study group.” The sputum AFB microscopy was done according to the standard Revised National TB Control Program protocol in the designated microscopy center of the hospital. During the same period, blood group data of healthy subjects coming to the blood bank as donors were collected and they formed the “control group.” Study subjects in both the groups were explained about the nature and objective of the study in their own language and consent was taken. Those who agreed to participate in the study were subjected to blood grouping test by standard tube agglutination reaction in the blood bank in the Department of Transfusion Medicine. The Institutional Ethical Committee clearance was taken beforehand, and data were kept confidential.

Data were entered and analyzed in Epi-info Version 2007. Categorical variables were expressed regarding numbers and proportions. Chi-square test was used for showing an association.  $P < 0.05$  was considered significant.

## RESULTS

A total number of study participants in the study group were 122 and in the control group were 2842. Frequency distribution of ABO blood groups among cases and controls is summarized in Table 1. A total number of subjects having blood Group A were 624 (21.95%) and 40 (32.8%) in control and study group, respectively, which showed a statistically significant difference ( $P = 0.005$ ).

The proportion of subjects with blood Group B in the study group was (18%) and was less as compared to control group (34.06%). This difference was statistically significant ( $P < 0.001$ ). Although percentages of study subjects having blood Groups “O” and “AB” were more in the study group compared to the control group, it did not show any statistical significance. Analysis of Rh D typing as a separate predictor for TB did not show any statistical significance ( $P = 0.073$ ) (Table 2). Rh D status within individual blood groups also did not show any significant associations with sputum positive PTB patients as shown in Table 3. Most common blood group among the healthy control group was “O Rh+” (36.6%) closely followed by B Rh+ (33.3%). In the study group of AFB positive PTB cases, blood Group “O Rh+” was most common (39.3%) followed by “A Rh+” (32.8%).

## DISCUSSION

The antigens of the ABO blood group system (A, B, and H determinants, respectively) are complex carbohydrate molecules expressed on the surface of RBC membranes.<sup>5</sup> They are also present on the surface of a variety of human cells and tissues, including the epithelium, sensory neurons, platelets, and the vascular endothelium,<sup>6</sup> due to their extensive distribution in human body association of these blood group antigens with various cardiological, oncological, and other diseases were suspected, studied, and proved.<sup>7,8</sup> Individuals with blood Group O are more prone to develop peptic ulcer disease and those with blood Group A are more prone to have gastric carcinoma. Carcinoma cervix and pernicious anemia are found more often in persons with blood Group A.<sup>9</sup> Blood Group O individuals are less susceptible to rheumatic heart disease,<sup>10</sup> and there is some association between blood Group O and HIV infection.<sup>11</sup>

Many studies with similar intent were conducted earlier. Viskum,<sup>12</sup> suggested blood Groups O and AB individuals are more susceptible to TB. However, a study by Rao *et al.*, concluded that blood Groups O and A were the most common blood groups associated with PTB.<sup>13</sup> A study in Gujarat, a significant association was discovered between blood Group AB and pulmonary TB.<sup>14</sup> Similarly, Jain<sup>15</sup> had

**Table 1: Distribution of ABO blood groups in sputum positive PTB cases (study group) and healthy adults (control group)**

Blood group	Study group n (%)	Control group n (%)	Total n (%)	OR	95% CI	P-value
A	40 (32.8)	624 (21.95)	664 (22.4)	1.73	1.17-2.55	0.005
B	22 (18)	968 (34.06)	990 (33.4)	0.42	0.27-0.68	0.0002
AB	12 (9.8)	183 (6.43)	195 (6.58)	1.58	0.86-2.93	0.138
O	48 (39.3)	1067 (37.54)	1115 (37.62)	1.08	0.74-1.56	0.688
Total	122	2842	2964			

OR: Odds ratio, CI: Confidence interval,  $P < 0.05$  considered significant, PTB: Pulmonary tuberculosis

**Table 2: Distribution of Rh D antigen type in sputum positive PTB (cases) and healthy adults (controls)**

Rh type	Study group	Control group	P-value
Positive	122	2767	0.073
Negative	0	75	

P<0.05 considered significant. PTB: Pulmonary tuberculosis

**Table 3: Association of Rh D status within individual blood group with sputum positive PTB**

Blood group	Study group n (%)	Control group n (%)	P-value
A Rh D+	40 (32.8)	602 (21.18)	0.636
Rh D-	0	22 (0.78)	
B Rh D+	22 (18)	946 (33.29)	1.0
Rh D-	0	22 (0.77)	
AB Rh D+	12 (9.8)	179 (6.29)	1.0
Rh D-	0	4 (0.14)	
O Rh D+	48 (39.3)	1040 (36.59)	0.625
Rh D-	0	27 (0.95)	

P<0.05 considered significant. PTB: Pulmonary tuberculosis

similar observations for AB blood group and pulmonary TB. People with blood Group O showed protection from TB in a Chinese population.<sup>16</sup>

Some of the studies also reported no association between TB and ABO blood groups. Buchannan and Hingley<sup>17</sup> in their study with 2,446 subjects concluded that there was no relation between blood groups and any disease. Shenoy and Daftary<sup>18</sup> too ruled out any such correlation between TB and blood groups. Reddy and Reddy<sup>19</sup> Reddy and Usha<sup>20</sup> and co-workers conducted two different studies in Chittoor district of Andhra Pradesh and Warangal district of Telangana region found no association between ABO-Rh and PTB.

Some studies found Rh D positivity increases risk of TB,<sup>13</sup> some studies observed Rh D negativity renders individuals more susceptible.<sup>21</sup> However, there are studies which find no such associations.<sup>22,18</sup> The present study did not show any correlation between Rh D status and TB.

Most common blood group among Punjabis<sup>23</sup> and Bengalis<sup>24</sup> was blood Group "B." Blood Group "O" was commonly observed in people of Kashmir and South Rajasthan<sup>15</sup> and North Rajasthan.<sup>25</sup> According to previously published data,<sup>26</sup> most common blood group in Odisha is blood Group "O" followed by blood Group "B." The present study is in agreement with this data, blood Group O and "B" being the two most common blood groups.

### Limitations

The limitations of study are:

1. Small number of subjects in study group
2. It was not a multicenter study.

## CONCLUSION

In the present study, it was found that individuals are having blood Groups "A" and "B" are more likely to suffer from TB compared to those with blood Group "O" and "AB." The reason for this vulnerability is not known. Rh D status has no effect on susceptibility to TB. To confirm or negate the findings of this study large multicenter randomized controlled trial should be done.

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# Expression of Human Epidermal Growth Factor Receptor 2/neu in Carcinoma Breast with Reference to Prognostic Index

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## Abstract

**Introduction:** In India, breast carcinoma is the second most common cause of death even though it arises in an exposed organ which is readily accessible for self-examination and diagnosis. A better understanding of various prognostic parameters has assumed a great therapeutic importance.

**Aim:** The aim of the study was to investigate the correlation of human epidermal growth factor receptor 2 (HER2)/neu status with important clinicopathologic prognostic parameters of carcinoma breast in particular with Nottingham prognostic index (NPI).

**Methodology:** Immunohistochemical techniques were used to evaluate HER2/neu in paraffin-embedded tissue specimens of 50 cases of carcinoma breast. The patients' age and the size of the tumor were noted. The histologic subtype, Nottingham modification of Scarff Bloom Richardson (NSBR) grade, lymph node staging, and NPI groups were assessed.

**Results:** Of the 50 cases of carcinoma breast, 17 (34%) were HER2/neu positive. The HER2/neu positivity increased with age (62.5% in patients of the 7<sup>th</sup> and 8<sup>th</sup> decades) and was statistically significant ( $P = 0.05$ ). The HER2/neu positivity increased with tumor size, with positivity of 0% in <2 cm and 40% in >2 cm tumor but was not statistically significant ( $P = 0.149$ ). The HER2/neu positivity was more in invasive duct carcinoma (IDC), not otherwise specified (NOS) type (100%), higher NSBR grade (94.1% in Grades 2 and 3), higher score of lymph node staging (82.4% in score 2 and 3), and in poorer NPI prognostic groups (87.2%) but were not statistically significant ( $P = 0.681, 0.102, 0.139, 0.177$ , respectively).

**Conclusion:** The HER2/neu expression was more frequent in tumor >2 cm, in IDC, NOS type, in higher NSBR grade, carcinoma breast with lymph node metastasis, and in poorer NPI prognostic groups indicating that HER2/neu may be a powerful predictor for poor prognosis.

**Key words:** Carcinoma breast, Human epidermal growth factor receptor 2/neu, Immunohistochemistry, Nottingham modification of Scarff Bloom Richardson grade, Nottingham prognostic index prognostic groups

## INTRODUCTION

Breast carcinoma is the most common malignant tumor worldwide and is the second-leading cause of death in women due to cancer.<sup>1</sup> In India, breast carcinoma is the second most common cancer in women after carcinoma cervix. In India,

most of the patients present with palpable mass with 50% having lymph node metastasis at the time of their first visit.<sup>2</sup>

Stratification of patients after taking into consideration of various prognostic parameters has assumed a great therapeutic importance.<sup>1</sup> As a result, there have been outstanding advances in breast cancer management with the development of more effective treatments leading to a significant decline in breast cancer deaths and improved outcome in women living with breast disease over the last few decades.<sup>3</sup>

Many prognostic and predictive factors have been identified by the College of American Pathologists to guide the clinical

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management of women with breast cancer. The prognostic factors include invasive carcinoma or *in-situ* carcinoma, distant metastasis, lymph node metastasis, tumor size, locally advanced disease, histological grade, histological subtype, inflammatory carcinoma, estrogen receptor (ER)/progesterone receptor (PR) status, and overexpression of human epidermal growth factor receptor (HER2)/neu.<sup>4</sup>

In the current management guidelines, ER/PR status and overexpression of HER2/neu are the most useful predictive factors for response to specific therapeutic agents.<sup>2</sup>

HER2/neu, otherwise known as neu or c-erbB-2, is a product of an oncogene. Presently, immunohistochemistry (IHC) is the center stage in the demonstration of monoclonal antibodies for evaluating HER2/neu protein expression in breast carcinoma.<sup>5</sup> HER2/neu expression is an independent prognostic factor in patients with breast carcinoma and has greater prognostic value than most currently used prognostic factors including ER, PR status.<sup>6</sup> HER2/neu positive cancer patients exhibit resistance to tamoxifen but not to aromatase inhibitors or ovarian ablation.<sup>7</sup>

The presence of HER2/neu is related to a high-grade tumor and poorer prognosis but the favorable response to monoclonal antibody therapy and disease survival.<sup>8</sup> Therefore, there is a growing clinical demand for analysis of the HER2/neu status of current and archived breast cancer specimens.<sup>9</sup>

## METHODOLOGY

A total of 50 cases of mastectomy specimens of carcinoma breast with axillary clearance received in the Department of Pathology, MIMS, Mandya, during the study period from January 2010 to October 2012 were evaluated.

The study was approved by the Institutional Ethical Committee. On arrival to the department, the specimens were subjected to adequate fixation using 10% neutral buffer formalin. After examination of the specimen for gross details, representative bits were subjected to routine processing for paraffin embedding. From the paraffin-embedded blocks, 4-5  $\mu$  thick section were taken and stained with hematoxylin and eosin (H and E) stain.

According to the WHO classification system, the tumors were histologically typed. The Nottingham modification of Scarff Bloom Richardson (NSBR) grading system<sup>10</sup> was used for grading (Table 1) which is based on the architecture pattern, nuclear atypia, and mitotic rate of the tumor.

The combined score of architecture, nuclear atypia, and mitotic figures/10 high power field is added to get a total score. Grade 1 breast carcinomas include scores of 3-5, Grade 2 includes score of 6-7, and Grade 3 includes score of 8-9.

Each case was assessed considering important prognostic parameters such as size of tumor, histological grade, and metastasis to axillary lymph nodes to calculate the Nottingham prognostic index (NPI)<sup>11</sup> which is as follows: NPI = score of lymph node stage [1-3] + score of histological grade as NSBR system (1-3) + maximum diameter in centimeters  $\times 0.2$ . The scoring of the lymph node is as follows: Score 1 - No lymph node metastasis; score 2 - Metastasis to 1-3 lymph nodes; and score 3 - Metastasis to  $>4$  lymph nodes.

After calculation of the NPI score, all the 50 cases of carcinoma breast were divided into 6 prognostic groups (Table 2).<sup>11</sup>

Sections of 3-4  $\mu$  thickness on silane-coated slides from the representative areas of all the 50 cases were subjected to IHC study for HER2/neu. The polymer-based IHC kit of BioGenex RTU (ready to use) was used. The cell membrane of tumor cells was stained in various intensities when there was overexpression of HER2/neu protein. The HER2/neu positivity was assessed by a semi-quantitative method based on the number of tumor cells showing positivity and the staining intensity. A score of 2+ and 3+ HER2/neu expressions (Figures 1 and 2) was considered as positive for immunostaining (Table 3).

Correlation of HER2/neu expression with important prognostic parameters such as patient's age, size of tumor,

**Table 1: Histological grade using NSBR system<sup>10</sup>**

Score	Architecture (%)	Nuclear atypia	MF/HPF
1	>75 tubule formation	Mild	0-5
2	10-75 tubule formation	Moderate	6-10
3	<10 tubule formation	Severe	>10

MF/HPF: Mitotic figures/high power field, NSBR: Nottingham modification of Scarff Bloom Richardson

**Table 2: NPI prognostic groups<sup>11</sup>**

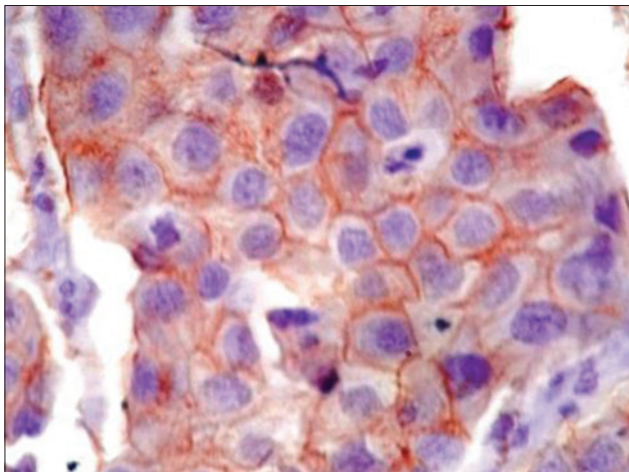
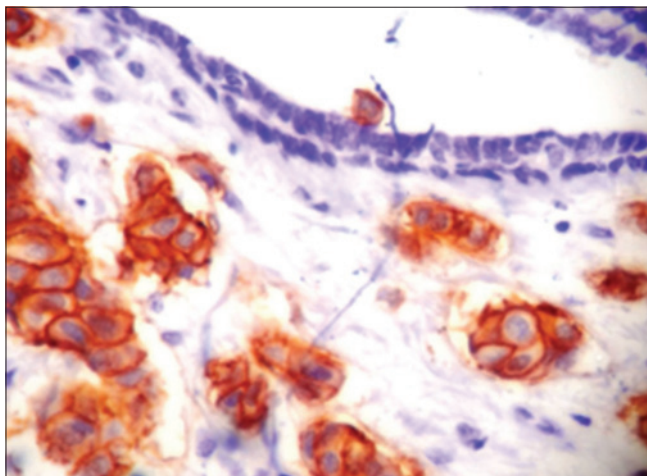
Prognostic group	NPI score
EPG	2.08-2.4
GPG	2.42-3.4
MPG I	3.42-4.4
MPG II	4.42-5.4
PPG	5.42-6.4
VPPG	6.42-6.4

EPG: Excellent prognostic group, GPG: Good prognostic group, MPG: Moderate prognostic group, PPG: Poor prognostic group, VPPG: Very poor prognostic group, NPI: Nottingham prognostic index

**Table 3: Assessment of HER2/neu protein overexpression**

Staining pattern	Score
No or membrane staining in <10% of cells	0
Faint and part of membrane staining in >10% of cells	1
Weak to moderate complete membrane staining in >10% of cells	2
Strong complete staining in >10% of cells	3

HER2: Human epidermal growth factor receptor

**Figure 1: Weak moderately complete membranous human epidermal growth factor receptor 2/neu immunostaining (score of 2+) in invasive duct carcinoma cells (DAB, x400)****Figure 2: Strong complete membranous human epidermal growth factor receptor 2/neu immunostaining (score of 3+) in >10% of invasive duct carcinoma cells (DAB, x400)**

histologic subtype, NSBR grade of tumor, lymph node staging, and mainly with NPI groups was done.

#### Plan of Data Analysis

The collected data were entered in Excel sheet and analyzed using Epi Info software, and the descriptive statistics, Chi-square test, Student's *t*-test, McNemar's test, and other

**Table 4: Prognostic parameters of carcinoma breast among 50 patients**

Characteristics	n (%)
Age (years)	
Range	25-80
Mean	47
Tumor size (cm)	
<2	04 (08)
2-5	30 (60)
>5	16 (32)
Histologic type	
IDC, NOS type	44 (88)
Infiltrating lobular Ca	02 (04)
Papillary Ca	01 (02)
Atypical medullary Ca	01 (02)
Tubular Ca	01 (02)
Metaplastic Ca	01 (02)
NSBR grade	
Grade 1	12 (24)
Grade 2	25 (50)
Grade 3	13 (26)
Lymph node stage	
Score 1	20 (40)
Score 2	16 (32)
Score 3	14 (28)
NPI groups	
EPG	02 (04)
GPG	06 (12)
MPG I	08 (16)
MPG II	14 (28)
PPG	12 (24)
VPPG	08 (16)

NPI: Nottingham prognostic index, IDC: Invasive duct carcinoma, EPG: Excellent prognostic group, GPG: Good prognostic group, MPG: Moderate prognostic group, PPG: Poor prognostic group, VPPG: Very poor prognostic group, NSBR: Nottingham modification of Scarff Bloom Richardson, NOS: Not otherwise specified

applicable tests were applied for the data. The  $P < 0.05$  was considered statistically significant.

## RESULTS

The age of 50 patients with carcinoma breast ranged from 25 to 80 years, and the mean age was 47 years. The majority (60%) of the patients were in the 5<sup>th</sup> and 6<sup>th</sup> decades of life (Table 4).

On gross examination, the size of the tumor among the 50 cases of breast carcinoma ranged from 1 to 11 cm. In 4 (8%) cases, the tumor size was <2 cm, in 30 (60%) cases the size ranged from 2 to 5 cm, and in 16 (32%) cases the size was >5 cm (Table 4).

Of the 50 cases of invasive carcinoma breast, 44 (88%) cases were invasive duct carcinoma (IDC), not otherwise specified (NOS) type, 2 (4%) cases were infiltrating lobular carcinoma, and 1 (2%) case each of tubular carcinoma, papillary carcinoma, atypical medullary carcinoma, and metaplastic carcinoma was observed (Table 4).

**Table 5: Correlation of HER2/neu with prognostic parameters**

Characteristics	HER2/neu negative n=33 (%)	HER2/neu positive n=17 (%)	P value
Age (years)			0.05
≤39	10 (30.3)	02 (11.8)	
≥40	23 (69.7)	15 (88.2)	
Size of tumor (cm)			0.149
<2	04 (12.1)	00 (00.0)	
2-5	18 (54.6)	13 (76.5)	
>5	11 (33.3)	04 (23.5)	
Histologic type			0.681
IDC, NOS type	27 (81.9)	17 (100)	
Infiltrating lobular Ca	02 (06.1)	00 (00)	
Papillary Ca	01 (03.0)	00 (00)	
Atypical medullary Ca	01 (03.0)	00 (00)	
Tubular Ca	01 (03.0)	00 (00)	
Metaplastic Ca	01 (03.0)	00 (00)	
NSBR grade			0.102
Grade 1	11 (33.3)	01 (05.9)	
Grade 2	15 (45.5)	10 (58.8)	
Grade 3	07 (21.2)	06 (35.3)	
Lymph node stage			0.139
Score 1	17 (51.5)	03 (17.6)	
Score 2	09 (27.3)	07 (41.2)	
Score 3	07 (21.2)	07 (41.2)	
NPI groups			0.177
EPG	02 (06.1)	00 (00)	
GPG	06 (18.2)	00 (00)	
MPG I	09 (27.3)	02 (11.8)	
MPG II	06 (18.2)	05 (29.4)	
PPG	05 (15.1)	07 (41.2)	
VPPG	05 (15.1)	03 (17.6)	

HER2: Human epidermal growth factor receptor, NPI: Nottingham prognostic index, NSBR: Nottingham modification of Scarff Bloom Richardson, IDC: Invasive duct carcinoma, EPG: Excellent prognostic group, GPG: Good prognostic group, MPG: Moderate prognostic group, PPG: Poor prognostic group, VPPG: Very poor prognostic group, NOS: Not otherwise specified

Among the 50 cases of carcinoma breast, as per the NSBR grading system, 12 (24%) cases were of Grade 1, 25 (50%) cases were of Grades 2, and 13 (26%) cases belonged to Grade 3 (Table 4).

When lymph node staging was done in 50 cases of carcinoma breast, 20 (40%) cases were of score 1, 16 (32%) cases were of score 2, and 14 (28%) cases were of score 3 (Table 4).

As per NPI prognostic groups, 2 (4%) cases were in EPG, 6 (12%) cases were in GPG, 8 (16%) cases were in MPG I, 14 (28%) cases were in MPG II, 12 (24%) cases were in PPG, and 8 (16%) cases were in VPPG (Table 4).

### Immunohistochemistry of HER2/neu

Among the 50 cases of breast carcinoma, maximum (62.5%) HER2/neu positivity was seen in the age group of 60-80 years and least (16.7%) in the age group of 21-39 years (Table 5). A statistically significant association of HER2/neu with age was seen ( $P=0.05$ ).

All the cases with the tumor size of <2 cm were negative for HER2/neu. HER2/neu positivity was seen in 13 (43.3%) of 30 cases with tumor size between 2 and 5 cm and 4 (25%) of 16 cases with tumor size >5 cm (Table 5). No statistically significant association of HER2/neu with tumor size was present ( $P=0.149$ ).

The HER2/neu was expressed in 17 (34%) of 50 cases of carcinoma breast, and all the positive cases were IDC and NOS type. All the other histologic subtypes were negative for HER2/neu (Table 5). No statistically significant association of HER2/neu with histologic type was present ( $P=0.681$ ).

While correlating the overexpression of HER2/neu with NSBR histologic grading, the percentage of HER2/neu positivity increased with grade and was 8.3% (1 of 12 cases) in Grade 1, 40% (10 of 25 cases) in Grade 2, and 46.2% (6 of 13 cases) in Grade 3. No statistically significant association of HER2/neu with NSBR histologic grading was present ( $P=0.102$ ).

The percentage of HER2/neu positivity increased with lymph node staging. HER2/neu positivity in the primary breast tumor was seen in 15% (3 of 20 cases) of score 1 lymph node staging, 43.7% (7 of 16 cases) of score 2, and 50% (7 of 14 cases) of score 3 lymph node staging. However, no statistically significant association of HER2/neu with lymph node staging was seen  $P=0.139$ .

Correlation of HER2/neu positivity with NPI showed that all cases belonging to EPG and GPG were negative for HER2/neu. The positivity for HER2/neu was seen in 2 (18.2%) cases of MPG I, 5 (45.5%) cases of MPG II, 7 (58.3%) cases of PPG, and 3 (37.5%) cases of VPPG. No statistically significant association of HER2/neu with NPI was present ( $P=0.177$ ).

## DISCUSSION

It is tragic that carcinoma breast is the second most common cause of death in women even though these neoplasms arise in an exposed organ, which is readily accessible for self-examination and diagnosis. There are outstanding advances in understanding breast cancer, and various prognostic factors are defined which can increase the survival rate.

Prognostic information is important in counseling patients about the likely outcome of their disease, choosing appropriate treatment, and the design of clinical trials. Prognostic factors fall into two groups - Those related to the extent of carcinoma (tumor burden or stage) and those related to the underlying biology of cancer.



The present study investigated the correlation of expression of HER2/neu with important clinicopathologic prognostic parameters of carcinoma breast.

In the present study, the mean age of 50 patients with carcinoma breast was 47.2 years and was similar to studies of Ayadi *et al.*,<sup>12</sup> (51.5 years), Azizun-Nisa *et al.*,<sup>13</sup> (48.3 years), Moradi-Marjaneh *et al.*,<sup>14</sup> (47.4 years), and Al-Moundhri *et al.*,<sup>15</sup> (49.6 years). The HER2/neu expression increased with age and positivity of 16.7% was seen in 21-39 year age group patients who increased to 62.5% in patients of 60-80 year age group. Similar results were seen in a study done by Al-Moundhri *et al.*,<sup>15</sup> where 12 out of 13 patients above 40 years of age were positive for HER2/neu. This may be related to the accumulation of somatic mutations with age.<sup>16</sup>

The results of HER2/neu positivity were relatively different in diverse studies. We found HER2/neu expression of 34% in the present study. Literature reports positive results ranging from 15 to 93.4%.<sup>12-14,17-19</sup> Possible sources of this variation may be attributed to different tissue fixation procedures, properties of different antibodies, scoring methods applied for HER2/neu positivity, the different stains used for staining, and microwave procedure of the tissue during antigen retrieval of IHC staining process (Table 6).

Tumor size is one of the most useful predictors of behavior in breast carcinoma. None of tumors <2 cm were positive for HER2/neu and 36.9% of tumors >2 cm showed HER2/neu positivity. Similarly, other studies<sup>17,14,18-20</sup> also showed a higher rate of HER2/neu expression in larger tumor with the statistically significant association (Table 7).

In the present study, all the HER2/neu positive cases were seen in infiltrating duct carcinoma, NOS type. Similarly, in the study by Saleh and Abdeen<sup>19</sup> and Naeem *et al.*,<sup>20</sup> 71.7% and 90.9% of infiltrating duct carcinoma, NOS type cases showed HER2/neu positivity. This suggests that HER2/neu positivity is common in infiltrating duct carcinoma, NOS type. In contrast, Ayadi *et al.*,<sup>12</sup> reported 16.8% and 25% HER2/neu positivity in ductal and non-ductal carcinomas, respectively.

An increasing percentage of HER2/neu positivity was seen with increasing NSBR histologic grade in studies done by Moradi-Marjaneh *et al.*,<sup>14</sup> Ivkovic<sup>17</sup> Lovekin *et al.*,<sup>18</sup> Saleh and Abdeen,<sup>19</sup> Naeem *et al.*,<sup>20</sup> and also in the present study (Table 8).

An increased expression of HER2/neu in cases of carcinoma breast with lymph node metastases was seen in studies by Azizun-Nisa *et al.*,<sup>13</sup> (89.3%), Moradi-Marjaneh

*et al.*,<sup>14</sup> (76.9%), Ivkovic<sup>17</sup> (52.2%), and Naeem *et al.*,<sup>20</sup> (91.0%). Similarly, the present study also showed an 85% of HER2/neu positivity in cases of carcinoma with lymph node metastasis suggesting that HER2/neu positivity increases the risk of metastasis.

Lovekin *et al.*,<sup>18</sup> in 1991, found that HER2/neu positivity is associated with poorer prognosis while following up 782 patients of carcinoma breast and concluded that HER2/neu is an independent predictive factor for the shorter survival rate in invasive carcinoma of breast. The NPI is a well-established and widely used method of predicting survival of operable primary breast carcinoma. The NPI is compiled from tumor grade, tumor size, and lymph node status of the primary tumor. No studies correlating the NPI and HER2/neu status with the best of our knowledge have been done so far. In the present study, most of the positive cases were seen in very poor (37.5%),

**Table 6: Incidence of HER2/neu expression in various studies**

Study	Incidence positive/total (%)
Ayadi <i>et al.</i> <sup>12</sup>	28/155 (18.1)
Azizun-Nisa <i>et al.</i> <sup>13</sup>	56/150 (37.4)
Moradi-Marjaneh <i>et al.</i> <sup>14</sup>	165/319 (51.7)
Tatjana <i>et al.</i> <sup>17</sup>	23/120 (20.0)
Lovekin <i>et al.</i> <sup>18</sup>	70/480 (15.0)
Saleh and Abdeen <sup>19</sup>	155/166 (93.4)
Present study	17/50 (33.0)

HER2: Human epidermal growth factor receptor

**Table 7: Correlation of HER2/neu positivity with tumor size**

Study	Tumor size			P value
	<2 cm	2-5 cm	>5 cm	
Moradi-Marjaneh <i>et al.</i> <sup>14</sup>	46.0	46.0	62.0	0.016
Tatjana <i>et al.</i> <sup>17</sup>	0.0	18.1	47.6	<0.0001
Lovekin <i>et al.</i> <sup>18</sup>	3.0	11.0	21.0	<0.0001
Saleh and Abdeen. <sup>19</sup>	5.9	92.9	87.7	<0.005
Naeem <i>et al.</i> <sup>20</sup>	0.0	18.2	81.8	>0.05
Present study	8.3	40.0	46.2	0.102

HER2: Human epidermal growth factor receptor

**Table 8: Correlation of HER2/neu positivity with NSBR histologic grades**

Study	NSBR histologic grades (%)			P value
	Grade 1	Grade 2	Grade 3	
Moradi-Marjaneh <i>et al.</i> <sup>14</sup>	46.0	46.0	62.0	0.016
Tatjana <i>et al.</i> <sup>17</sup>	0.0	18.1	47.6	<0.0001
Lovekin <i>et al.</i> <sup>18</sup>	3.0	11.0	21.0	<0.0001
Saleh and Abdeen <sup>19</sup>	5.9	92.9	87.7	<0.005
Naeem <i>et al.</i> <sup>20</sup>	0.0	18.2	81.8	>0.05
Present study	8.3	40.0	46.2	0.102

HER2: Human epidermal growth factor receptor, NSBR: Nottingham modification of Scarff Bloom Richardson



poor (58.3%), and moderate prognostic Group II (45.5%). None of the cases in excellent and good prognostic groups were positive for HER2/neu.

## CONCLUSION

The aim of this study was to determine the frequency of expression of HER2/neu with various prognostic indices in carcinoma breast, particularly to NPI, which has been aptly brought out in this study. The HER2/neu positivity rate was high in patients of the 5<sup>th</sup> and 6<sup>th</sup> decades and was statistically significant.

Although there is no statistical association of HER2/neu with tumor size, histologic subtype, NSBR histologic grade, lymph node status, and NPI, its expression was more frequent in cases with tumor size >2 cm, infiltrating duct carcinoma, NOS type, higher NSBR grade, carcinoma breast with lymph node metastases, and higher NPI score indicating that HER2/neu may be a powerful predictor for poor prognosis.

Further studies have to be done to determine the significance of correlation of HER2/neu with NPI and to find if this correlation has an advantage over NPI alone in predicting the survival rate of breast carcinoma patients.

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# Reduction in Corneal Diameter Following Cataract Surgery: A Comparison between Those Who Underwent Small Incision Cataract Surgery and Phacoemulsification at a Tertiary Care Hospital in South India

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## Abstract

**Introduction:** The prevalence of blindness in the country has progressively come down over the last three decades due to a dramatic increase in the number of cataract surgeries performed. However, surgically induced astigmatism (SIA) is one of the complications of cataract surgery and can cause residual vision problems to those undergoing the procedure. Those undergoing manual small incision cataract surgery (MSICS) are considered as more at risk for developing astigmatism than patients undergoing phacoemulsification (PE).

**Materials and Methods:** Patients diagnosed to have age-related cataract and undergoing surgical intervention through MSICS or PE at Pushpagiri Medical College Hospital were included in the study. Visual acuity and corneal diameters were assessed before and 30 days after the surgical intervention.

**Results:** A total of 61 participants were included in the study, 33 of them underwent MSICS and 28 had a PE procedure. The mean change in K1 corneal diameter was significantly lower in the case of MSICS than PE ( $P = 0.035$ ) while the mean change in K2 diameter was comparable between the groups ( $P = 0.452$ ). The changes in K1 corneal diameter was not affected by other factors like age, sex, or presence of comorbidities. In addition, the changes in K2 corneal diameter were not affected by any factors such as the type of surgery, age, sex, or presence of comorbidity.

**Conclusion:** The study has shown that there is a significant change in corneal diameter in those patients undergoing surgical management of cataract. These changes in corneal diameter may be responsible for the rising incidence of SIA, and it is important to document these measurements. We need bigger studies with large sample sizes to establish the causal association between changes in corneal diameter and SIA.

**Key words:** Aphakia, Cataract extraction, Cornea/abnormalities, Microsurgery/methods, Phacoemulsification/methods, Postcataract/pathology

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## INTRODUCTION

Cataract is the most common cause of blindness in India, with almost 75% of a total load of blindness due to this condition. The prevalence of blindness in the country has progressively come down over the last three decades due to a dramatic increase in the number of cataract

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surgeries performed. However, even then, the absolute number of blind persons in the country has increased, due to an increase in the proportion of people above the age of 50 years.<sup>1</sup> The Indian government is a signatory to the World Health Organization convention by the name Vision 2020, which aims to reduce the prevalence of avoidable blindness by as much as 95% by the year 2020. The National Programme for Control of Blindness (NPCB), which was launched as a centrally sponsored scheme in 1976, had an ambitious target to reduce the prevalence of blindness to <0.3% by 2000, but the data from various community surveys have shown that it has failed miserably.<sup>2</sup> Certain studies have shown that the prevalence of blindness (vision of <6/60 in the better eye) is as high as 1.84% and the total number of blind in the country may be 18 million. Furthermore, these studies show that more than 60% of the blindness is due to treatable causes such as cataract and refractive errors.<sup>3</sup> Subsequently, the NPCB has revamped itself to counter the challenge of blindness in the country. The program which used to be cataract-centric has now expanded to include refractive errors, glaucoma, diabetic retinopathy, ocular trauma, etc. The government has built more than 300 eye surgery suites and has trained over 2000 ophthalmic surgeons through the program. Ophthalmic units and dedicated eye wards have been established at district and sub-district levels. Now, more than 95% of the cataract surgeries involve intraocular lens (IOL) implantation, up from <10% in 1995.<sup>4</sup>

The IOL revolution has transformed the surgical management of cataract, through improvements in visual acuity following surgery and reduced complication rates. Extracapsular cataract extraction (ECCE) followed by posterior chamber IOL insertion was the most popular method for a long period. However, the advent of technological innovations such as foldable intraocular lens and phacoemulsification (PE) equipment decreased the popularity of ECCE.<sup>5</sup> Techniques like PE and Manual Small Incision Cataract Surgery (MSICS) are the most popular among the different cataract surgery methods. Certain studies have shown that both these techniques are comparable in terms of improvement in visual acuity and incidence of complications and that there is a cost advantage for MSICS over PE.<sup>6</sup> However, a systematic review done by the Cochrane collaboration shows that the short term uncorrected visual acuity is better in patients who undergo PE. There was no concrete evidence on long-term visual acuity and the differences in complications were not significant between the procedures. The review goes on to recommend MSICS for centers with high volumes as a priority, due to better cost-effectiveness offered by the procedure over PE.<sup>7</sup>

Surgically induced astigmatism (SIA) is one of the complications of cataract surgery and can cause residual vision problems to those undergoing the procedure. Those undergoing MSICS is considered as more at risk for developing astigmatism than patients undergoing PE.<sup>8</sup> Studies have indicated that corneal diameter can be a factor which can predict the incidence of astigmatism in patients who undergo cataract surgery. It was shown that those patients with a higher white to white corneal diameter was less at risk of developing corneal astigmatism as compared to patients with lesser diameter.<sup>9</sup> Shorter axial length, shallow anterior chamber, lower intraocular pressure and advancing age, has been shown as risk factors for SIA, in those undergoing cataract surgeries.<sup>10</sup> Even though SIA is a problem with significant morbidity, the literature available on the problem and its possible risk factors are very few. In this study, we aim to study the changes in corneal diameter, which is considered as a risk factor for astigmatism, among patients undergoing cataract surgery using PE or MSICS techniques.

## MATERIALS AND METHODS

The study was conducted at the Department of Ophthalmology of Pushpagiri Medical Hospital, Tiruvalla, Kerala, India. The study was planned during the period August to September 2015, and the data collection was done during October to December 2015.

Patients diagnosed to have age-related cataract and undergoing surgical intervention at Pushpagiri Medical College Hospital were included in the study. The patients having congenital or pediatric cataract and those with secondary cataracts due to any cause were excluded from the study. Those patients who were not willing for a 30 days follow-up after surgical intervention were also excluded. Written informed consent was obtained from the participants 1 day before the surgery.

The demographic and clinical characteristics of the participants like age, sex, and presence of comorbidity were found out before the surgery. Prior to the surgical intervention, the visual acuity of the participants was tested using a Snellen's chart, by the ophthalmic surgeon concerned. The Vertical and Horizontal corneal diameters were found out using a standardized keratometer (Model: KMS 6, manufactured by Appasamy Associates, Chennai, India).

All the patients underwent PE or MSICS. The methods were decided after taking into account the choice and financial status of the patient, and also clinical considerations. The investigators had no role in influencing the patient

regarding the choice of surgical technique, or in deciding the course of clinical management of the problem. The surgical interventions were performed by ophthalmic surgeons with considerable experience in performing these procedures. Both the surgical procedures were performed on an in-patient basis, even though some centers prefer to perform PE as a day care procedure. The participants were followed up on an out-patient basis, looking for any complications because of the surgical procedure. Visual acuity and corneal diameters were found out at the end of 1 month of follow-up.

The data collection was done using a structured questionnaire and was digitized using Epi-Data, which is a free data entry software for epidemiological studies. The data were analyzed using Epi-Info 7.0; a free statistical package brought out by Centres for Disease Control, USA.

## RESULTS

A total of 61 participants were included in the study, 33 of them underwent MSICS and 28 had a PE procedure. A majority of the participants were above 60 years of age, and more than 60% were females. 52% of those undergoing surgery had diabetes mellitus, and 40.9% was on treatment for hypertension. More than 60% of the participants were having immature cataracts, and the rest had mature cataracts. None of the participants were in the stage of hypermaturity. The baseline clinical and demographic correlates were comparable between the participants undergoing MSICS and PE (Table 1).

The mean K1 diameter fell from 44.50 to 44.01 in case of patients undergoing MSICS, and from 44.59 to 43.48 in

patients undergoing PE. The mean K2 diameter was also reduced after the participants underwent cataract surgery, from 44.81 to 44.28 in the case of MSICS and from 44.27 to 44.01 in PE. The mean change in K1 diameter was significantly lower in the case of MSICS than PE ( $P = 0.035$ ) while the mean change in K2 diameter was comparable between the groups ( $P = 0.452$ ) (Table 2).

The data were further analyzed to look for possible factors which will affect the changes in corneal diameter. The mean reduction in K1 corneal diameter was significantly affected by the choice of surgery, with those undergoing PE having a larger reduction in diameter ( $P = 0.035$ ). The changes in K1 corneal diameter was not affected by other factors like age, sex or presence of comorbidities. Furthermore, the changes in K2 corneal diameter were not affected by any factors such as type of surgery, age, sex, or presence of comorbidity (Tables 3 and 4).

## DISCUSSION

A vast majority of the patients undergoing surgery for cataract was aged above 60 years, and this reflects

**Table 2: Changes in corneal diameter following cataract surgery**

Corneal diameter	Mean (SD)	
	MSICS (n=33)	PE (n=28)
Pre-op K1	44.50 (1.55)	44.59 (1.39)
Pre-op K2	44.81 (1.58)	44.27 (1.53)
Post-op K1	44.01 (1.62)	43.48 (1.38)
Post-op K2	44.28 (1.69)	44.01 (1.52)
Change in K1	0.500 (1.14)	1.109 (1.03)
Change in K2	0.529 (1.47)	0.267 (1.16)

SD: Standard deviation, MSICS: Manual small incision cataract surgery, PE: Phacoemulsification

**Table 1: Baseline clinical and demographic correlates**

Characteristic	MSICS (n=33) (%)	Phacoemulsification (n=28) (%)
Age		
Up to 59	5 (15.2)	1 (3.6)
60 and above	28 (84.8)	27 (96.4)
Sex		
Male	10 (30.3)	14 (50)
Female	23 (69.7)	14 (50)
Diabetes		
Yes	14 (42.4)	18 (64.3)
No	19 (57.6)	10 (35.7)
Hypertension		
Yes	10 (30.3)	15 (53.6)
No	23 (69.7)	13 (46.4)
Stage of cataract		
Immature	20 (60.6)	17 (60.7)
Mature	13 (39.4)	11 (39.3)
Hypermature	0	0

MSICS: Manual small incision cataract surgery

**Table 3: Factors affecting changes in corneal diameter (K1)**

Characteristic	Mean (SD) change in corneal diameter	P value
Type of surgery		
MSICS	0.500 (1.14)	0.035 <sup>#</sup>
PE	1.109 (1.03)	
Age		
Up to 59	0.358 (0.65)	0.342
60 and above	0.825 (1.16)	
Sex		
Male	1.021 (0.79)	0.183
Female	0.623 (1.29)	
Diabetes		
Yes	0.768 (1.26)	0.939
No	0.791 (0.99)	
Hypertension		
Yes	0.748 (1.27)	0.858
No	0.801 (1.04)	

<sup>#</sup>Statistically significant, SD: Standard deviation, MSICS: Manual small incision cataract surgery, PE: Phacoemulsification



**Table 4: Factors affecting changes in corneal diameter (K2)**

Characteristic	Mean (SD) change in corneal diameter	P value
Type of surgery		
MSICS	0.528 (1.47)	0.452
PE	0.267 (1.16)	
Age		
Up to 59	0.475 (1.42)	0.342
60 and above	0.401 (1.33)	
Sex		
Male	0.108 (1.17)	0.183
Female	0.604 (1.41)	
Diabetes		
Yes	0.507 (1.42)	0.939
No	0.300 (1.24)	
Hypertension		
Yes	0.346 (1.39)	0.858
No	0.452 (1.31)	

SD: Standard deviation, MSICS: Manual small incision cataract surgery, PE: Phacoemulsification

the nature of the problem whereby the prevalence of age-related cataract goes up exponentially with age.<sup>11</sup> The very high prevalence of diabetes mellitus and hypertension among the study participants concurs with the statistics available from other parts of Kerala which shows that the state is fast becoming the capital of metabolic diseases in the country.<sup>12</sup> Furthermore, it is important to note that majority of the participants were undergoing surgery for the problem at a relatively early stage (immature), and this may be due to the advancement of medical facilities in the state of Kerala. The state of Kerala has been at the forefront of medical revolution in India, with easily accessible and decentralized facilities available at government subsidized rates and this has massively improved the health coverage in case of common problems like cataract.<sup>13</sup>

In a time when SIA has been recognized as a major complication of cataract surgery, the study of corneal diameter is important. Multiple studies have showed an association between SIA and corneal diameter, and these studies go on to recommend routine measurement of corneal diameters before the patient undergoes surgical management of cataract.<sup>9</sup> In our study, it was found that the reduction in corneal diameter K1 was significantly lower in case of patients undergoing MSICS, when compared to the patients who had PE. This result contradicts studies done previously, which shows that patients undergoing MSICS are more at risk for developing SIA, though we are unsure of the exact correlation between changes in corneal diameter and incidence of astigmatism.<sup>8</sup> Many review articles also suggest that the incidence of SIA is significantly lower in case of PE, when compared to patients undergoing MSICS.<sup>14</sup> Therefore, the contradictory result in our study

may have been due to the fact that the sample size of the study was low, and that MSICS is performed in our center by more experienced ophthalmic surgeons with considerable operating experience.

## CONCLUSION

The study has shown that there is a significant change in corneal diameter in those patients undergoing surgical management of cataract. These changes in corneal diameter may be responsible for the rising incidence of SIA, and it is important to document these measurements. A large study with a longer follow-up period is warranted, to find out the association between changes in corneal diameter and visual acuity. Furthermore, we need bigger studies with large sample sizes to establish the causal association between corneal diameter and SIA.

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# Total Thyroidectomy for Benign Thyroid Disease: A Prospective Study

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## Abstract

**Background:** The extent of thyroidectomy (subtotal to total) for benign thyroid disease was controversial till recent times. Theoretically, total thyroidectomy is a logical and optimal surgical procedure for benign thyroid disease affecting the entire thyroid gland as it has the advantage of immediate and permanent cure with no recurrence. Total thyroidectomy is currently the preferred treatment for benign thyroid disease. However, practically surgeons choose to avoid it and stick on to subtotal thyroidectomy due to the risk of damage to surrounding vital structures (parathyroids and recurrent laryngeal nerve [RLN]).

**Aim of the Study:** To evaluate the efficacy and safety of total thyroidectomy in the management of benign thyroid disease in terms of permanent complications, i.e., Hypoparathyroidism and RLN palsy.

**Methodology:** This prospective study was conducted on 236 patients in surgical unit of Mahatma Gandhi Memorial Hospital, Kakatiya Medical Collage, Warangal, Telangana, India, from October 2010 to November 2015. Patients with benign thyroid disease were operated with total thyroidectomy and results were analyzed.

**Results:** About 222 patients were without any post-operative complications (94.06%), and 15 patients were with different post-operative complications (6.35%). Six patients presented with post-operative transient hypocalcemia (2.54%). One patient remained as permanent hypoparathyroidism (0.42%). Two patients developed permanent unilateral RLN palsy (0.84%). One Patient developed hematoma due to reactionary hemorrhage (0.42%). No patient developed permanent bilateral RLN palsy (0%) and there was no mortality (0%).

**Conclusion:** Total thyroidectomy if performed by experienced surgeons is quite safe and preferred option for management of benign thyroid disease to avoid future re-occurrences.

**Key words:** Benign thyroid disease, Hypoparathyroidism, Recurrent laryngeal nerve palsy, Total thyroidectomy

## INTRODUCTION

Thyroid surgery is the one of the common endocrine surgeries performed today. The thyroid gland is situated in a critical area in the neck surrounded by many vital structures (parathyroids and recurrent laryngeal nerve [RLN]). The complications related to the surgery were very high in the olden days. Hence, Germans and French

initially called these operations “fool hardly performances.” A magnificent surgeon “Theoder Kocher” reduced mortality of thyroid gland surgeries from 50% to <4.5%, and he advocated methodical surgical dissection of the thyroid gland. Theoretically, total thyroidectomy is a logical and optimal surgical procedure for benign thyroid disease affecting the entire thyroid gland as it has the advantage of immediate and permanent cure with no recurrence. Practically, surgeons choose to avoid it and stick on to subtotal thyroidectomy due to the risk of damage to surrounding vital structures. Now, there is a change in a surgical practice from sub-total thyroidectomy to total thyroidectomy for benign thyroid disease.<sup>1</sup> It was increasingly being done almost all over the world almost for the past 40 years.<sup>2</sup> The efficacy of total thyroidectomy being measured in terms of permanent complications,

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i.e., hypoparathyroidism and RLN Palsy. Currently, RLN palsy and hypoparathyroidism rates are evaluated in the literature between 1% and 4%, i.e., RLN palsy (1%) and permanent hypoparathyroidism (1-4%).

## METHODOLOGY

### Inclusion Criteria

Patients with benign thyroid disease (toxic and non-toxic multinodular goiters, large diffuse colloid goiters, Grave's disease)

### Exclusion Criteria

Patients with malignant thyroid disease, patients with RLN palsy, patients with hypoparathyroidism, and patients with recurrent thyroid disease.

A total number of samplings (236 patients) were included in the study.

All the patients ( $n = 236$ ) selected as per criteria from October 2010 to November 2015 were admitted in surgical unit-2 of Mahatma Gandhi Memorial Hospital, Kakatiya Medical College, Warangal, Telangana State, India, after Ethical Committee Approval and patient consent. All the patients were underwent pre-operative preparation including biochemical (T3, T4, and thyroid-stimulating hormone serum calcium), pathological (fine-needle aspiration cytology), radiological (ultrasonography and X-ray neck AP, lateral), ENT (indirect laryngoscopy [IDL]) and antithyroid drugs for toxic goiters. All the cases were operated with the procedure of total thyroidectomy by different surgeons of our team by collar incision and following standard methodological thyroid dissection as mentioned in the literature. Parathyroids identified and taken care of its blood supply (Figure 1). Recurrent laryngeal nerve and superior laryngeal nerve were safeguarded (Figure 2). Perfect hemostasis secured with care. Wound closed in layers after keeping suction drain. The immediate and delayed post-operative complications of all cases were recorded and analyzed.

## RESULTS

About 236 ( $n = 236$ ) patients were operated with the procedure of total thyroidectomy for benign thyroid disease. Out of 236 patients, 198 patients were females (83.89%) and 38 patients were males (16.10%). The age range was from 23 to 64 years with median age of 41 years. The operative procedure of total thyroidectomy was done for different types of benign thyroid diseases after necessary pre-operative preparation. 148 patients were with non-toxic multinodular goiters (62.71%), 50 patients were with large

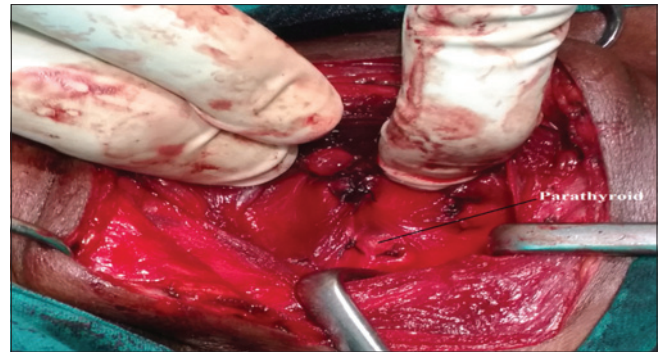


Figure 1: Parathyroid safeguarded

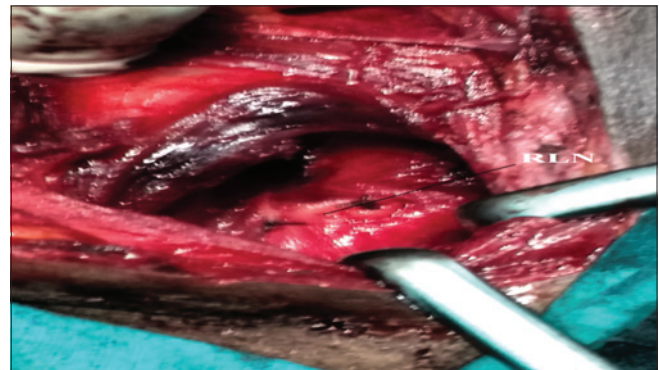


Figure 2: Recurrent laryngeal nerve safeguarded

discomfort diffuse colloid goiters (21.18%), 22 patients were with toxic multi-nodular goiters (MNG) (9.32%), and 16 patients were with primary thyrotoxicosis (Grave's disease) (6.77%). All the patients were operated and observed for post-operative complications. 222 patients were without any post-operative complications (94.06%), and 15 patients were with different post-operative complications (6.35%). 6 patients developed transient hypocalcemia (2.54%) which were treated immediately with intravenous calcium gluconate and followed by serial serum calcium levels and one patient remained as persistent hypoparathyroidism (0.42%), which was confirmed by serum parathormone levels. 4 patients had post-operative hoarseness of voice (1.69%), and they were followed by IDL. 2 patients recovered and another 2 patients remained as persistent unilateral vocal cord paralysis (0.84%). One patient developed a hematoma (0.42%), in which the patient had a history of trauma at thyroid region and profused bleeding during surgery due to the abnormal vasculature. The patient was treated with re-exploration and ligation of the bleeding vessel. No patient with bilateral vocal cord paralysis (0%), no patient with airway obstruction (0%), and no mortality (0%). Hypoparathyroidism and RLN palsy occurred in one single patient of huge thyroid (MNG) which was refused by all other surgical units of our hospital. Another RLN injury occurred while attempting the control of bleeding (Tables 1-3).



**Table 1: Total thyroidectomy for benign thyroid disease**

Benign thyroid disease	No of patients (236) (%)
Non-toxic MNG	148 (62.71)
Large discomfort diffuse colloid goiter	50 (21.18)
Toxic MNG	22 (9.32)
Primary thyrotoxicosis (Grave's disease)	16 (6.77)

MNG: Multinodular goiter

**Table 2: Different complications after total thyroidectomy for benign thyroid disease**

Name of the complications	No of patients (236) (%)
Patients without complications	222 (94.06)
Patients with complications	15 (6.35)
Transient hypocalcemia	06 (2.54)
Transient vocal cord paralysis	04 (1.64)
Persistent unilateral vocal cord paralysis	02 (0.84)
Persistent hypoparathyroidism	01 (0.42)
Bilateral vocal cord paralysis	None
Airway obstruction	None
Mortality	None

**Table 3: Comparison of present and previous study results with permanent complications of hypoparathyroidism and unilateral RLN palsy in total thyroidectomy for benign thyroid disease**

Name of the study	Permanent hypoparathyroidism (%)	Permanent unilateral RLN palsy (%)
Present study	0.4	0.8
Accetta <i>et al.</i> , 2011 <sup>3</sup>	0.0	1.5
Barczynski <i>et al.</i> , 2011 <sup>4</sup>	0.1	0.69
Guraya and Eltinay, 2007 <sup>5</sup>	0.6	3.0
Chiang <i>et al.</i> , 2006 <sup>6</sup>	3.7	1.86
Bron and O'Brien, 2004 <sup>7</sup>	1.0	1.3

RLN: Recurrent laryngeal nerve

## DISCUSSION

The extent of thyroidectomy (subtotal to total) for benign thyroid disease was controversial till recent times.<sup>5</sup> While doing sub-total thyroidectomy particularly for MNG, the surgeon commonly encounters that there is no apparently normal thyroid tissue remaining, so surgeon chooses to leave a small portion of abnormal thyroid tissue. This leaving behind a small portion of diseased thyroid tissue is unlikely to prevent the need of long-term thyroxine replacement therapy, whereas the attempt to suppress regrowth of that remaining thyroid tissue by thyroxine is not guaranteed. Hence, recurrent thyroid disease following sub-total thyroidectomy is a significant problem.<sup>8</sup> Re-operation for recurrent thyroid disease has increased the risk of either permanent hypoparathyroidism or RLN palsy.<sup>9</sup> Moreover, as per available literature, there

is 30% risk of secondary thyrotoxicosis and 10% risk of follicular carcinoma thyroid in MNG. The incidence of permanent complications after total thyroidectomy varies considerably from center to center. However, the incidence is acceptably low in experienced hands. Apart from taking care of vital structures, practically total thyroidectomy is easier than sub-total thyroidectomy which avoids the struggle of leaving the tissue. Our study results were compared with other previous study results in Table 3, and our results are within their study limits of complications. Our study shows lower incidence of permanent hypoparathyroidism (0.42% vs. 3.7%) and RLN palsy (0.84% vs. 3%). Some other studies shown better results (0.42% vs. 0.0 and 0.84%) in terms of permanent complications. Total thyroidectomy can be preferred with minimal surgical complications. Here, we attained these acceptable results due to capsular dissection and ligation of multiple vessels.<sup>10</sup> The only argument against total thyroidectomy is the potential risk of complications; however, there is good evidence shows that with increase of experience the use of appropriate technique and quality of training total thyroidectomy can be preferred with minimal surgical complications.<sup>11,12</sup>

## CONCLUSION

Total thyroidectomy for benign thyroid disease if performed by experienced surgeons with minimal permanent complications (hypoparathyroidism and RLN palsy) is quite safe preferred option for surgical management of benign thyroid disease to avoid future recurrences and increased risk of complications with re-operative surgery.

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# Mastoiditis and Sinonasal Pathologies on Cranial Computed Tomography Imaging: A Correlative Study

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## Abstract

**Background:** Sinonasal pathologies are commonly found in the general population on routine computed tomography (CT) examinations of the brain and paranasal sinuses (PNS). Many of these patients have associated mastoiditis.

**Objectives:** This study was performed to evaluate the association between sinonasal pathologies and occurrence of mastoiditis.

**Materials and Methods:** This retrospective case-control study was carried out on 77 consecutive patients (Male: 50, Female: 27; age group 4-88 years). The CT images of brain and PNS were reviewed to evaluate for mastoiditis and associated sinonasal pathologies. An equal number of age- and sex-matched controls without mastoiditis was randomly chosen from the cranial CT studies of the general population. The presence of sinonasal pathologies in the mastoiditis group (cases) was compared with those in non-mastoiditis group (controls).

**Results:** Out of the 77 patients with signs of mastoiditis, 50 were males (64.9%) and 27 were females (35.1%). Among the 77 cases with mastoiditis, 75 had deviated nasal septum (DNS). The cases with right mastoiditis had right sided DNS in 67.4%. Similarly, the cases with left mastoiditis had leftward DNS in 71%. Bilateral mastoiditis was found in 35.1%. S-shaped DNS was found in 4 cases, and all of them had bilateral mastoiditis. An interesting finding in our study was a strong association of septal spur with mastoiditis on the same side (about 54-57%). All the patients ( $n = 4$ ) with adenoid hypertrophy had mastoiditis. Concha bullosa, agger nasi cells, Haller cells, and ethmoid bulla did not show a significant statistical association. Comparatively, the control subjects had much lesser abnormalities in the PNS in all the age groups.

**Conclusion:** Mastoiditis is significantly associated with sinonasal pathologies.

**Key words:** Deviated nasal septum, Mastoiditis, Spur, Sinonasal

## INTRODUCTION

The middle ear or the tympanic cavity is an air-containing space within the temporal bone, which communicates with the nasopharynx via the eustachian tube and with the mastoid air cells via the mastoid aditus. It constitutes an extension of the upper respiratory tract and is subject to viral and bacterial invasion by the way of the Eustachian tube.<sup>1-3</sup> Certain anatomic variations are thought to be predisposing factors for the development of sinus diseases, and thus may lead to mastoid infections. Multidetector

computed tomography (MDCT) imaging of the cranium, temporal bone, and paranasal sinuses (PNS) offers precise information regarding the anatomy and variations in these regions and confirms the presence of infection in the middle ear cavity. High-resolution CT of the temporal bone is very useful as a surgical guide map to the operating surgeon.<sup>4</sup>

This study was designed to evaluate the statistical association of occurrence of sinonasal pathologies in patients with mastoiditis and compare them with that of the general population without mastoiditis.

## MATERIALS AND METHODS

A retrospective review of the imaging findings of 77 patients aged between 4 and 88 years with CT features of acute or chronic mastoiditis during from January 2016

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to March 2016 was performed. All the patients who underwent volume CT study of temporal bones, PNS, or cranium with coverage of PNS and mastoids were incorporated in the study. On the basis of the CT findings of existing mastoiditis, images were evaluated for any abnormalities in the PNS. Those patients with evidence of sinonasal surgery on CT images were excluded from the study. Age- and sex-adjusted controls without mastoiditis were chosen randomly from the CT scans of the general population performed during the same study period.

### CT-scan Protocol

The study was performed on a 128 slice Philips Ingenuity CT scanner. No consent was obtained from the patients as the study is retrospective in nature.

The study protocol included cranial CT with the acquisition of contiguous axial sections of 0.6 mm thickness. The sections were reformatted to the coronal plane using a high-resolution bone algorithm. The images were reformatted and viewed on Philips ingenuity workstation.

## RESULTS

The study population consisted of 77 cases and 77 controls out of which 50 were males (64.9%) and 27 were females (35.1%). The cases had mastoiditis and the controls did not.

Age of the case and control population ranged between 4 and 88 years with a mean age of 43.4 years for the cases and 44 years for the controls.

Right sided mastoiditis was seen in 39% of the cases. Left sided mastoiditis was found in 26% of the cases. 35% of the cases had bilateral mastoiditis. Out of these 77 subjects, 75 had DNS (97.4%).

Rightward DNS was seen in 43 subjects and right mastoiditis was found in 29 of these subjects (67.4%). Spur toward right side was seen in 16 subjects and 9 out of them had ipsilateral mastoiditis (56.2%).

Leftward DNS was seen in 28 subjects, out of which 20 patients had left mastoiditis (71%). Spur toward left side was seen in 11 subjects and ipsilateral mastoiditis was found in 6 of them (54.5%). S-shaped DNS was found in 4 subjects, and all of them had bilateral mastoiditis (100%).

In the control population, 21 out of 77 patients had DNS accounting for about 27.3%. Out of them, 11 had rightward DNS, 9 patients had leftward DNS, and 1 had S-shaped DNS. Nasal turbinate hypertrophy was observed in 60 of the cases and only 10 of the controls.

Adenoid hypertrophy was observed in 4 cases, and all of them had bilateral mastoiditis. None of the controls had adenoid hypertrophy. Bilateral concha bullosa was observed in 11 cases, and all of them had bilateral mastoiditis. Left concha bullosa was seen in 1 case along with ipsilateral mastoiditis. In comparison, concha bullosa was observed in only 3 of the control group.

The involvement of PNS was also found to be considerably less in the control cohort than the cases. Frontal sinusitis was found in 9 cases and 5 controls; ethmoid sinusitis was found in 11 cases and 2 controls and maxillary sinusitis was found in 33 cases and 5 controls. Sphenoid sinusitis was found in 3 of the cases and 4 of the controls. Infected right sided Agger nasi cells were found in 2 cases with rightward DNS and ipsilateral frontal sinusitis. There was ipsilateral mastoiditis in both these cases.

Prominent infraorbital ethmoid air cells were seen in 2 cases with leftward DNS and ipsilateral maxillary sinusitis. There was associated ipsilateral mastoiditis in both of them.

The mastoiditis cohort had a higher prevalence of sinonasal pathologies than the control group.

## DISCUSSION

PNS are the air-containing spaces in the skull. Abnormalities of PNS such as deviated nasal septum, hypertrophy of turbinates, concha bullosa, and adenoid hypertrophy, can predispose the individuals for sinus infection and in turn increase the chances of middle ear infections.<sup>5</sup>

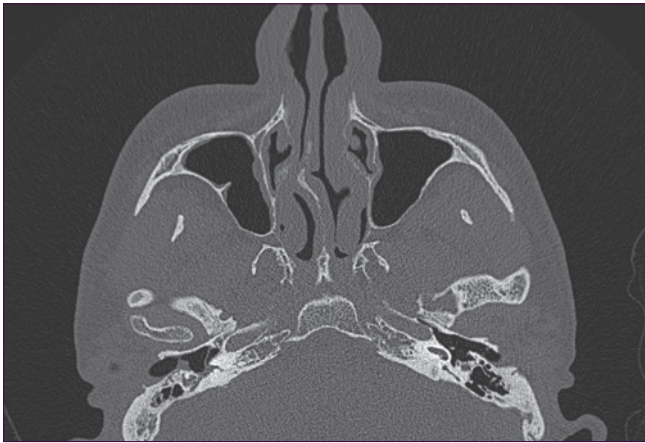
The association between sinus diseases and middle ear infections was studied very early, way back in 1934 by Cullom.<sup>6</sup> He compared the X-ray prevalence of sinusitis and mastoiditis and found a very high association between sinus pathologies and mastoiditis. Almost all the patients of mastoiditis in his study had ipsilateral sinusitis. However, as our study is performed on cranial CT images with scope for more objective evaluation of images, the association between mastoiditis and sinonasal pathologies is found to be high but not absolutely as seen in Cullom's study.

In a study of 100 patients with DNS and PNS, Moorthy *et al.*<sup>7</sup> found that about 35 patients had significant sinusitis on CT scans of the PNS, and 20 of these patients had ear complaints and tubotympanic type of CSOM. In our study, rightward DNS was seen in 43 subjects and right mastoiditis was found in 29 of them. Leftward DNS was observed in 28 subjects, out of which 20 had left mastoiditis. There is a strong association of septal spur and ipsilateral mastoiditis in our study (54-56%).





**AQ1** **Figure 1:** Coronal CT image of the Mastoid aircells showing soft tissue attenuation (Black arrow) in the right mastoid.



**AQ1** **Figure 2:** Axial CT image of the same patient showing rightward DNS (Black arrow).

Gencer *et al.*<sup>8</sup> studied the possible associations of DNS on mastoid pneumatization and chronic otitis. They found that the mastoids on the ipsilateral side of severe DNS were smaller than the contralateral side and thus predisposed to infection. In our study, mastoiditis was predominantly found on the ipsilateral side of the DNS. It was especially associated when spur was there toward the same side.

Rao *et al.*<sup>9</sup> classified the septal deviations into 7 types and studied the relation between deviation and sinus pathology. According to them, Type I: DNS referred to midline septum or mild deviations in vertical or horizontal plane, without extension throughout the vertical length of the septum; Type II: Anterior vertical deviation; Type III: Posterior vertical deviation (Osteomeatal and middle turbinate area); Type IV: S-shaped DNS - posterior to one side and anterior to the other side; Type V: Horizontal spur on one side with or without high deviation to the opposite side; Type VI: Type V with a deep groove on the concave side; Type VII: Combination of more than one types.

They found that mild deviations (Types I and II) did not result in significant sinusitis. In our study also, the controls that had nasal septal deviation without significant sinus/mastoid pathology had milder deviations. The presence of septal spur was classified as Type V in their study and was associated with significant sinus pathology.

In our study also, the septal spur was associated with ipsilateral sinusitis as well as mastoiditis. The association between the spur and ipsilateral mastoiditis in our study was about 54-56%.

The prevalence of sinonasal pathologies between the males and females did not have any differences as per the study of Polat *et al.*<sup>3</sup> In our study also, there was no significant gender difference in sinonasal as well as mastoid pathologies. Hence, sex may not play any significant role in the causation of sinusitis/mastoiditis.

Sinonasal diseases as well as mastoiditis may occasionally present with severe complications such as brain abscess or lateral sinus thrombosis. Fink *et al.*<sup>4</sup> observed the association between thrombosed lateral venous sinuses and mastoiditis and found that 39% of the patients with thrombosis of lateral venous sinus had ipsilateral mastoiditis. However, in our study, lateral venous sinus thrombosis/brain abscess or intracranial complications were not observed in any of the patients.

In our study, concha bullosa, agger nasi cells, Haller cells, and ethmoidal bulla did not show statistically significant association with mastoiditis. Comparatively, the control subjects had much lesser abnormalities in the PNS in all the age groups as compared to the mastoiditis group.

## CONCLUSION

Sinonasal pathologies and mastoid infections have close association. Sinus pathologies and DNS are commonly found in patients with mastoiditis.<sup>10</sup> Many patients with mastoiditis may also have ipsilateral nasal septal spur. Not many imaging studies are available to evaluate the association between sinonasal pathologies and mastoiditis. Larger studies are required to further our knowledge on the exact causal association.

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Author Queries???

AQ1: Kindly provide citation in text part for two figures

# Ultrasound-guided Percutaneous Aspiration of Breast Abscesses: An Outpatient Procedure

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## Abstract

**Introduction:** Most breast abscesses occur as a complication of mastitis secondary to bacterial infection. Mastitis usually affects lactating women, but it can also occur in non-lactating women. Ultrasound-guided percutaneous aspiration of breast abscess is minimally invasive and dynamic procedure.

**Aim and Objective:** To evaluate the efficacy of ultrasound-guided percutaneous aspiration in treating breast abscess as an outpatient procedure.

**Materials and Methods:** Ultrasound-guided percutaneous aspiration of breast abscess done in our radiology department on Aloka prosound alpha 7 ultrasound scanner and clinical and ultrasound follow-up done. Repeat aspiration done if abscess present on follow-up. Data were statistically analyzed.

**Results:** Most common diameter was 3-5 cm and amount of pus aspirated was 41-70 ml. Maximum 2 aspirations were required. In our study, 90% patients were cured by ultrasound-guided needle aspiration. Treatment failure was reported in 10% cases.

**Conclusion:** Ultrasound-guided needle aspiration of breast abscess is safe, effective, easily available, patient-friendly outpatient procedure without the development of any cosmetic issue.

**Key words:** Breast abscess, Percutaneous needle aspiration, Ultrasonography

## INTRODUCTION

Mastitis is the inflammation of breast tissue. Most breast abscesses occur as a complication of mastitis. Mastitis usually affects lactating women, but it can also occur in non-lactating women. A breast abscess is defined as localized infection with a collection of pus in the breast parenchyma. Bacteria can enter through a crack in the skin of the breast or a cracked nipple. Despite breast abscess becoming less common in developed countries, it has remained one of the leading cause of morbidity in women in developing countries.<sup>1</sup> The frequency of breast abscess is quite high in

India, generally related to poor nutrition, standard of living. Non-lactating breast abscess is not as common in India as in the western countries. The conventional treatment of breast abscess is by surgical incision and drainage. This often requires hospitalization, general anesthesia, and regular post-operative dressing.<sup>2</sup> It is most expensive and placement of surgical drains are unpleasant.<sup>3</sup> In the era of cosmesis, minimally invasive, less painful, more conservative approach in the management of breast abscess by ultrasonography (USG)-guided percutaneous needle aspiration with antibiotic coverage is very feasible.<sup>1,3-5</sup>

## Aim and Objective

To assess the efficacy of ultrasound-guided percutaneous aspiration of breast abscess as an outpatient procedure.

## MATERIALS AND METHODS

In our prospective study, population analyzed was presented with mastitis who were referred to our

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department for sonography with clinical suspicion of breast abscess. There were 30 patients with breast abscesses randomized for USG-guided percutaneous aspiration on an outpatient basis with antibiotic coverage and repeat aspiration if necessary during the period from March 2012 to December 2015. All patients were from the outpatient department. A detailed history was taken and clinical examination was done. Characteristic of breast swelling, size of swelling, duration, history of fever, past history, and current lactation history were noted. All the necessary investigations were done accordingly.

The procedure of ultrasound-guided percutaneous aspiration was explained in detail to the patient. Informed written consent was taken in every patient. Ultrasound imaging features of the lesion like the initial size with long axis diameter was taken. Whether the lesion was uniloculated or multiloculated with internal septation and echoes was noted. All breast abscesses smaller than 7 cm in diameter were managed by ultrasound-guided percutaneous aspiration with all aseptic precaution under local anesthesia of 2 ml 2% lignocaine. On USG, abscesses were round to oval or irregular predominantly anechoic lesions with internal echoes (Figure 1). They were either uniloculated or multiloculated with internal septations. Ultrasound-guided needle aspiration was performed using 18 G needle and 20 ml disposable syringe in each case (Figure 2) pus aspirated till the abscess cavity was collapsed (Figure 3). Amount of pus aspirated was recorded, and some aspirate was sent for culture and sensitivity. These patients were given oral amoxicillin and clavulanic acid 625 mg BD daily for 7 days. Follow-up ultrasound examination done in all cases USG-guided aspiration was repeated on third and consecutively on the 7<sup>th</sup> day if required and again follow-up was done on the 14<sup>th</sup> day. At every follow-up, a clinical assessment with USG was done to assess complete resolution of the abscess. If the abscess persisted after three aspirations till 14<sup>th</sup> day, it was considered as treatment failure and hence incision and drainage were advised.

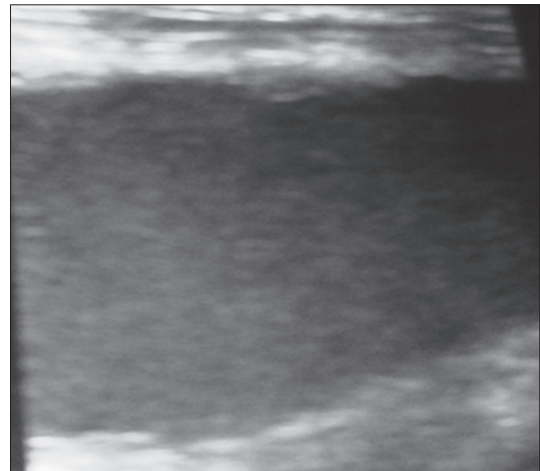
The following information was recorded in the database for each patient, viz., age, parity, lactational status, ultrasound measurement and features, pus volume removed, number of aspirations required, pus culture, and healing time. Lactating patients were encouraged to continue breastfeeding from the affected and unaffected breast.

## RESULTS

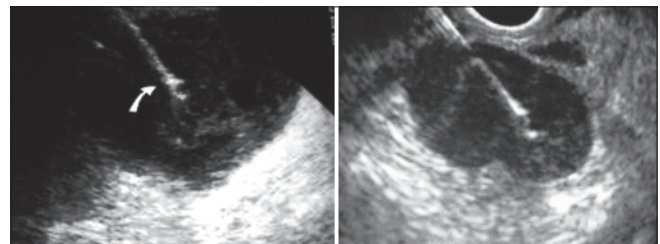
Distribution of patients according to signs and symptoms were done. All the patients were presented with painful swelling (100%). Only 14 patients were presented with fever (46.66%). Axillary lymphadenopathy was present in

5 (16.66%) patients. 15 patients (50%) were presented with the cracked nipple. Out of 30 patients, 27 were lactating (90%) and remaining 3 (10%) were non-lactating. There were 24 (80%) primigravida patients.

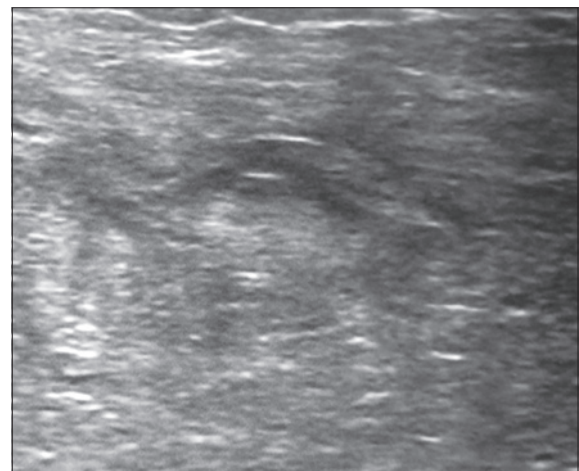
Failure was seen in three patients as two out of them developed skin changes and repeated collection even after 3 aspirations, and they had multiloculated abscesses.



**Figure 1: Image showing anechoic loculated collection with internal echoes in the breast**



**Figure 2: Ultrasound images showing breast abscesses with internal echoes and septations. Percutaneous aspiration needle is seen in the cavity of breast abscesses**



**Figure 3: Ultrasound image showing collapsed abscess cavity after aspiration procedure**



Remaining one patient was positive for tubercular breast abscess and shifted to antitubercular treatment.

In 25 patients (83.33%) pus culture was positive for *Staphylococcus aureus*.

Healing time approximately was 2 weeks for all cured patients. All patients were treated as outdoor patients. Only three patients from this group required hospitalization due to failure and underlying causes. Satisfaction rate was 100%, and no scar remained in all the patients.

## DISCUSSION

The present study was carried out on the patient population with mastitis, who presented to the Department of Radiology between March 2012 and December 2015 for USG. There were total 30 patients with breast abscesses randomized for ultrasound-guided percutaneous aspiration. The mean age was 26 years which is correlated with the findings of Chandika *et al.*, mean age 23.12 years.<sup>6</sup> In our study, 27 patients were lactating, i.e. 90% of the total patients were lactating and only 3 patients (10%) were non-lactating. All lactating patients (90%) continued breastfeeding in the treatment period satisfactorily and no milk fistula developed. The findings were correlated with Schwarz and Shrestha lactating (83%) and non-lactating (17%) while the study of Chandika *et al.*, found 66.2% of lactating patients.<sup>6,7</sup> We found 9 (36%) patients with fever. Similar findings were found in the study of Sarhan *et al.*, 12 patients (28%) out of 43 with fever.<sup>8</sup>

In our study, USG long axis diameter of the abscess ranged in size from 1.5 to 7 cm (average size 3.5 cm) (Table 1) correlated with findings of Christensen *et al.*, (3.5 cm) and Chandika *et al.*, (3.49 cm).<sup>6,9</sup> In our study, cure rate with one aspiration was in 10 patients (33.33%), two aspirations required in 14 patients (46.66%), and three aspirations required in 3 patients (10%) with failure in 3 patients (10%) (Table 4). In study of Sarhan *et al.*, they mentioned cure rate with one aspiration in 23 patients (53.4%), two aspirations in 9 patients (21%), and three aspirations in 8 patients (18.6%) with failure in 3 patients (7%).<sup>8</sup>

In our study, pus volume ranges from 10 to 130 ml (avg 40 ml) (Table 2). Elagili *et al.*, mentioned the volume range of 1-200 ml.<sup>3</sup> Leborgne and Leborgne observed the range of 1-225 ml with the initial aspiration of 28 ml.<sup>10</sup> *S. aureus* was the most common pathogen in 25 patients (83.3%) in our study which is correlated with Ulitzsch *et al.*, (89%).<sup>5</sup> In our study, the cure rate was 90% (Table 5). Our results showed that most of the patients with breast abscesses (90%) can be treated with repeated aspirations

(Table 3) with antibiotic coverage correlated with findings of Chandika *et al.*, with cure rate (93.1%). Karstrup *et al.*, (95%) and Sarhan *et al.*, reported cure rate of 93% with antibiotic therapy.<sup>6,8,11</sup> Ulitzsch *et al.*, reported cure rate of 97.67% and Elagili *et al.*, mentioned cure rate 83% (Tables 1-5).<sup>3,5</sup>

In our study, no scarring was found and all patients continued breastfeeding (100%) correlated with the study of Saleem *et al.*, and Ulitzsch *et al.*<sup>1,5</sup> They also found 100% results in their study. Eryilmaz *et al.*, reported that

**Table 1: Distribution of patients according to size of abscess**

Size of abscess in cm	Number of patients (n=30)	Percentage
<3	5	16.66
3-5	20	66.66
5-7	5	16.66

Maximum number of patients were presented with size <5 cm

**Table 2: Distribution of patients according to volume of pus**

Volume of pus in ml	Number of patients (n=30)	Percentage
<20	4	13.33
20-40	10	33.33
41-70	12	40
71-100	2	6.66
>100	2	6.66

In most of the patients pus volume drained was <70 ml

**Table 3: Healing time in number of patients**

Duration of days	Number of patients (n=30)	Percentage
Up to 5	10	33.33
6-10	15	50
>10	5	16.66

Maximum Healing time required was upto 2 weeks

**Table 4: Distribution of number of patients as per number of aspirations done**

Number of aspirations	Number of patients (n=30)	Percentage
1 Aspiration	10	33.33
2 Aspirations	14	46.66
3 Aspirations	3	10
Failure	3	10

Most of the patients were cured with 2 aspirations

**Table 5: Response to treatment**

Number of patients	Cured with respective treatment (%)	Recurrence/failure (%)	Tuberculous breast abscess (%)
30	27 (90)	2 (6.66)	1 (3.33)

Failure was seen in 6.6% patients

the risk factor for failure of needle aspiration of breast abscess was abscess size more than 5 cm.<sup>12</sup> We also found failure in 2 (6.66%) patients with abscess size >5 cm with multiloculation. One patient was positive for tuberculous breast abscess was shifted to antituberculous treatment. Healing time was 2 weeks consistent with finding of Chandika *et al.*, and Strauss *et al.*<sup>6,13</sup> All 27 patients (90%) in our study treated on outpatient basis consistent with study of Christensens *et al.*, 77 patients (87%).<sup>9</sup> USG-guided aspiration of breast abscess is very cost effective treatment as it is outpatient procedure without hospitalization and no general anesthesia and repeated dressing required consistent with findings of Chandika *et al.*, (93.11%).<sup>6</sup> No breast abscess recurrence was observed in all cured patients. The procedure is highly accepted by all the patients with 100% satisfaction consistent with study of Ulitzsch *et al.*, and Christensen *et al.*<sup>5,9</sup>

## CONCLUSION

USG-guided percutaneous aspiration of breast abscess represented a minimally invasive, simple outpatient department procedure without the need of general anesthesia with superior cosmetic results, high satisfaction rate in lactating, and non-lactating women. It is very promising, feasible, and efficient alternative method of treatment to conventional incision and drainage in properly selected patients.

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# Analysis of Germ Cell Tumors of Ovary in a Tertiary Care Hospital: A Two Year Retrospective Study

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## Abstract

**Background:** Germ cell tumors of the ovary are a rare and complex group of heterogeneous neoplasm that comprises both benign and malignant histologies. A mixture of histologic subtypes may be present within any single germ cell tumor.

**Aim:** Aim of this study was to evaluate germ cell tumors in our institution.

**Materials and Methods:** All cases of ovarian tumors during the period from May 2013 to June 2015 were retrieved from the record files of the Department and germ cell tumors were selected for analysis.

**Results:** A total of 110 patients were included with a mean age of 28 years. Teratomas were most frequently found (mature: 98 cases, immature: 01 case), followed by dysgerminoma (05 cases), yolk sac tumor (02 cases), embryonal carcinoma (01 case), squamous carcinoma arising in mature teratoma (01 case), and mixed germ cell tumor (01 case). Abdominal mass (58 cases) and abdominal pain (35 cases) were most common presenting symptoms.

**Conclusion:** Mature teratoma is the most common germ cell tumor, most commonly occurring in the 3<sup>rd</sup> decade. Dysgerminoma is the most common malignant germ cell tumor occurring in the 11-20 years age group.

**Key words:** Dysgerminoma, Germ cell, Ovary, Teratoma

## INTRODUCTION

Ovarian cancers are common among females comprising 30% of cancers of the female genital tract and 6% of all cancers in females.<sup>1,2</sup> Germ cell tumors constitute 15-20% of all ovarian tumors. 95% of germ cell tumors are dermoid cysts (mature cystic teratomas), and most of the remainder are malignant.<sup>3</sup> In children and adolescents, more than 60% of ovarian neoplasms are of germ cell origin and one-third are malignant.<sup>4</sup> Germ cell tumors comprise 23% of ovarian tumors in East India.<sup>5</sup> They account for two-thirds of the ovarian cancers during the first two decades of life.

Most subtypes occur in pure form, but approximately 10% are composed of two or more subtypes. Most malignant germ cell tumors are composed of premature elements; however, in the case of adults, they almost always develop in dermoid cysts and are encountered in older women. In the present study, we analyzed the germ cell tumors reported in our institute.

## MATERIALS AND METHODS

The study was a hospital-based retrospective study carried out in the Department of Pathology, Gauhati Medical College & Hospital. All cases of ovarian tumors during the period from May 2013 to June 2015 were retrieved from the record files and analyzed. The study focuses on clinical presentation with respect to age, presenting complaints, gross features, and histologic types. The tissues were routinely fixed with 10% formalin, and the slides were stained with hematoxylin and eosin stain and also with special stains whenever required.

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## RESULTS

A total of 365 cases of ovarian tumors have been reported in the same period and among them, 110 cases (30%) were germ cell origin. The age distribution has been calculated in Table 1. The age range in our series was 08-58 years with a mean age of 28 years. The most common age group affected was 21-30 years. Most of the malignant cases (11/12, 91.3%) were in women of <30 years. The most common presenting complaint was abdominal mass (58/110, 52.7%), followed by abdominal pain (35/110, 31.8%) (Table 2 and Figure 1). Out of 110 cases, all were unilateral except 02 cases of mature cystic teratoma. The size of the tumors ranged from 07 to 25 cm with an average size of 15.5 cm. All the malignant tumors were more than 12 cm in size.

Grossly, majority cases were cystic (65/110, 59.09%) followed by solid/cystic (35/110, 31.8%) and least frequent being solid tumors (Table 3 and Figure 2). Both sided ovaries were equally involved. The number and percentage of different types of germ cell tumors are shown in Tables 4 and 5. The most common germ cell tumor was mature cystic teratoma (98/110 cases) comprising 88.18% of all germ cell tumors. Malignant germ cell tumors comprised 10.9% of the cases (12/110). The most common malignant germ cell tumor was dysgerminoma (06/12). Others were yolk sac tumor (02 cases), one each of immature teratoma, embryonal carcinoma, squamous carcinoma arising in mature teratoma, and mixed germ cell tumors (mature teratoma + embryonal carcinoma).

## DISCUSSION

Germ cell tumors are a heterogeneous group, majority originating at different stages of development of germ

cells.<sup>1</sup> Some are composed of undifferentiated cells (dysgerminoma, embryonal carcinoma) while in others there is differentiation toward embryonic (teratoma) or extraembryonic (choriocarcinoma, yolk sac tumor)

**Table 1: Age distribution of the cases**

Age (years)	Number of cases (110)	Percentage
1-10	1	0.9
11-20	18	16.36
21-30	52	47.27
31-40	22	20
41-50	11	10
51-60	6	5.45

**Table 2: Presenting complaints in order of frequency and their percentage**

Clinical symptom	Number of cases	Percentage
Abdominal mass	58	52.72
Abdominal pain	35	31.8
Irregular menstruation	5	4.54
GI disturbance	3	2.72
Urinary symptoms	4	3.64
Incidental findings	5	4.54

GI: Gastrointestinal

**Table 3: Gross appearance of the tumors**

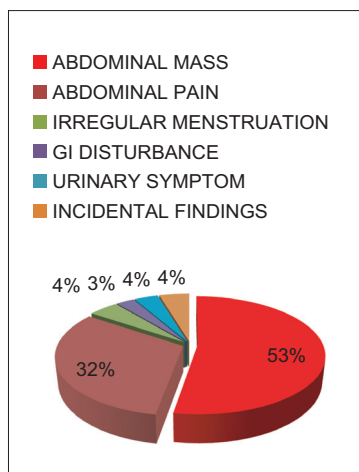
Gross	Number of cases	Percentage
Cystic	65	59.09
Solid/cystic	35	31.8
Solid	10	9.09
Total	110	100

**Table 4: Frequency and percentage of benign and malignant germ cell tumors**

Tumors	Number of cases	Percentage
Benign	98	89
Malignant	12	11
Total	110	100

**Table 5: Frequency and percentage of different types**

Germ cell tumor	Incidence	Percentage
Benign	98	89.09
Mature cystic teratoma	98	89.09
Malignant	12	10.9
Dysgerminoma	6	8.18
Yolk sac tumor	2	1.81
Immature teratoma	1	0.9
Embryonal carcinoma	1	0.9
Squamous carcinoma arising in mature teratoma	1	0.9
Mixed germ cell tumor (mature teratoma+embryonal carcinoma)	1	0.9



**Figure 1: Presenting complaints in order of frequency and their percentage**



structures.<sup>6</sup> They account for 30% of all ovarian tumors.<sup>5,7</sup> In the current study, they constituted 30% of all ovarian tumors.

### Benign Germ Cell Tumors

Mature cystic teratoma is the most common germ cell tumor comprising more than 95% of all germ cell tumors.<sup>1</sup> Mondal *et al.*, and Jha and Karki have reported 68.9% and 95% of all germ cell tumors.<sup>4,8</sup> In our study, (98/110, 89.09%) was mature cystic teratoma. Grossly, the tumors were unilocular cysts filled with hair and cheesy material. Microscopically, tumors showed a predominance of skin and its appendages. Glial tissue was seen in 04 cases. Choroid plexus was seen in one case and respiratory epithelium noted in 15 cases (Figures 3 and 4).

The majority of mature cystic teratomas are known to occur in <50 years with a peak incidence between 20 and 29 years.<sup>1,6</sup> In our series, the majority were below 50 years of age (Figure 5).

All the cases were unilateral except 02 cases which showed the bilateral involvement of the ovaries. The size ranged from 07 to 25 cm with an average size of 12.5 cm.

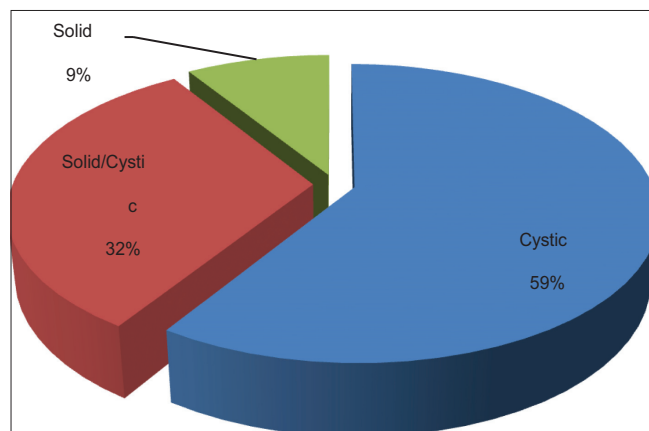


Figure 2 : Macroscopic/gross finding of the tumors

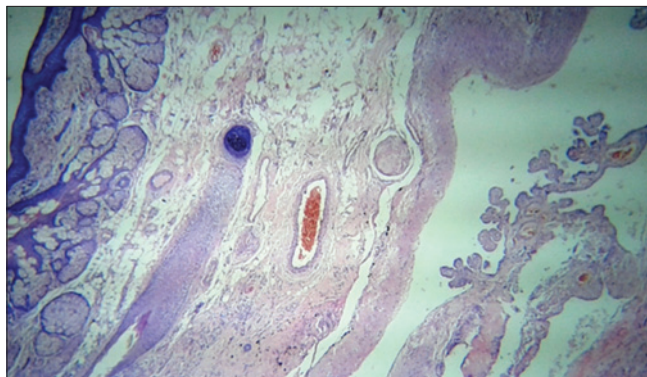


Figure 3: Lower power view of mature teratoma showing different elements derived from three germ layers

In contrast to primitive germ cell tumors, which are almost always encountered in girls and women of reproductive age group. The dermoid cyst is occasionally encountered in postmenopausal women, where ovaries no longer contain recognizable germ cells. This can be interpreted as indicative of leisurely growth of a tumor that originated years earlier.<sup>9</sup>

### Malignant Germ Cell Tumor

Immature teratoma represents 03% of teratomas, 01% of all ovarian cancers, and 20% of malignant ovarian germ cell tumors.<sup>1</sup> They occur predominantly in children and young women, the average age at presentation being 20 yrs (Figure 5). In our study, one case of immature teratoma was seen in an 18 years female. A mixture of mature and immature components was seen including immature cartilage, immature mesenchyme, and primitive neuroepithelium. Based on the amount of neuroectodermal component, it was assigned as Grade 2 (Figures 6 and 7).

Approximately, 02% of dermoid cysts contain adult type malignant tumors, 80% of which are squamous cell carcinomas<sup>9</sup> and are typically seen in postmenopausal women. In a study of 87 ovarian teratomas, Papadis *et al.*, reported 05% cases with malignant changes.<sup>10</sup> We found one case of squamous cell carcinoma arising in a mature teratoma which comprised 0.9% of germ cell tumors of ovaries in our study.

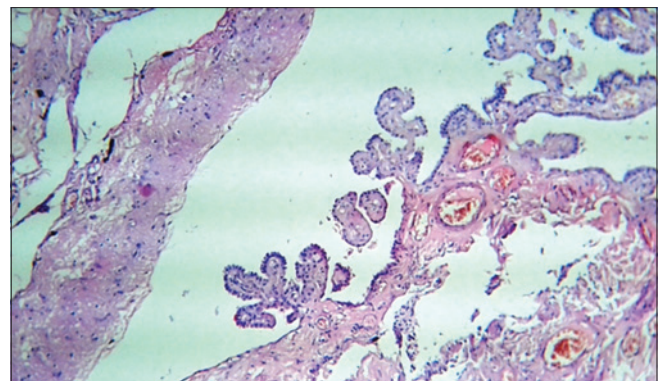


Figure 4: Low power view of mature teratoma showing glial tissue and choroid plexus

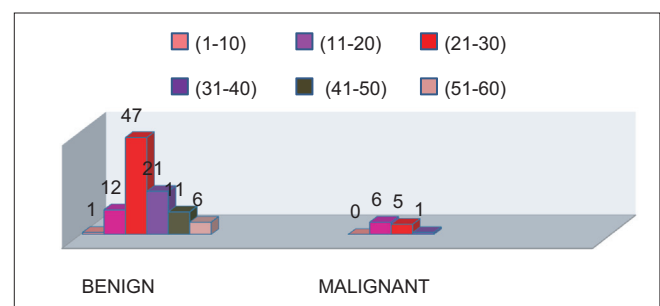


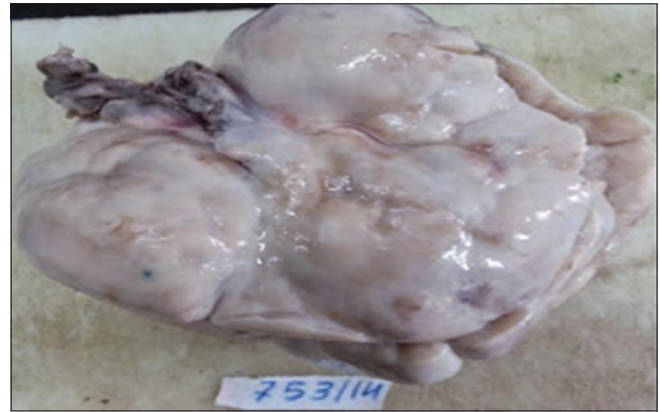
Figure 5: Age incidence in benign and malignant germ cell tumors

Dysgerminoma is the most common malignant germ cell tumor of ovary and account for nearly half of all such tumors.<sup>5</sup> There were 06 cases of dysgerminoma out of total 12 malignant germ cell tumors in our study comprising 50% of malignant germ cell tumors and 5.5% of all germ cell tumors. All the cases were in 21-30 years age group (Figure 8). Microscopy showed the classical pattern of dysgerminoma.

Yolk sac tumors, also known as endodermal sinus tumor, is the second most common malignant germ cell tumors of the ovary.<sup>6</sup> We found, 02 cases of yolk sac tumor where one was 17 years and other was 21-year-old (Figure 9). They showed the classical reticulocystic pattern and Schiller-Duval bodies (Figures 10 and 11). Characteristic hyaline globules were noted in both the cases.

Mixed germ cell tumors are composed of at least two different germ cell components, of which at least one is primitive.<sup>1</sup> The relatively frequent finding of different neoplastic germ cell elements in gonadal tumors of germ cell origin is considered a strong argument for common histogenesis of this group of neoplasms.<sup>11</sup> Histologically, the most common combination is the dysgerminoma and

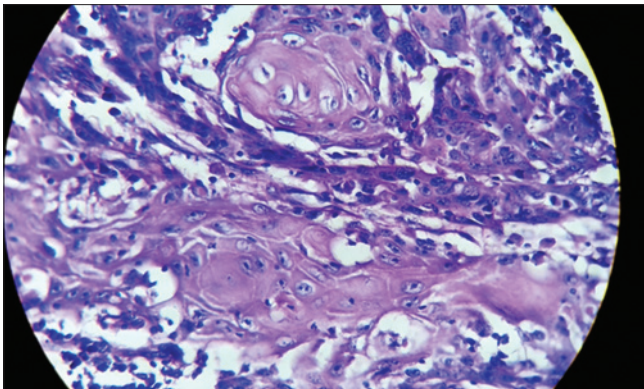
yolk sac tumor accounting for one-third of cases.<sup>12</sup> We reported a case of mature cystic teratoma with embryonal carcinoma in a 27-year-old female (Figure 12). Embryonal carcinoma of the ovary is usually present along with other



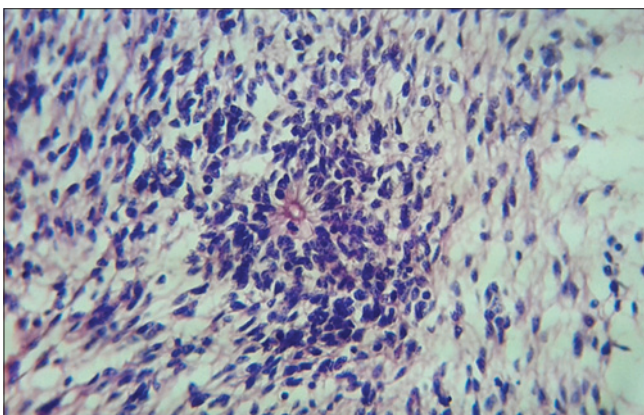
**Figure 8: Specimen of dysgerminoma (solid tumor with lobulated surface)**



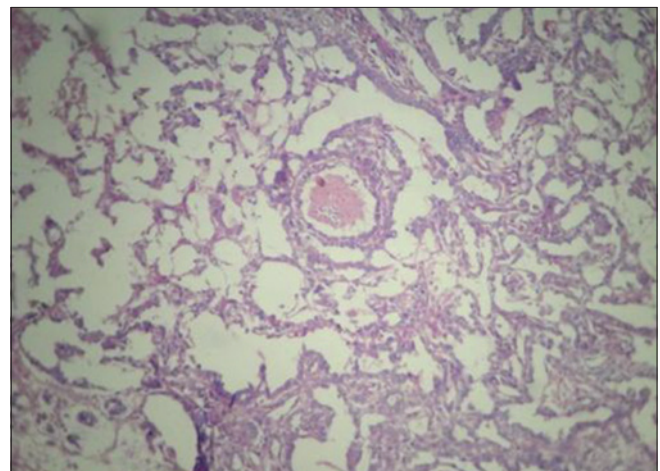
**Figure 9: Specimen of yolk sac tumor showing solid-cystic, friable with necrotic cut surface**



**Figure 6: High power view of squamous cell carcinoma (in mature teratoma case)**

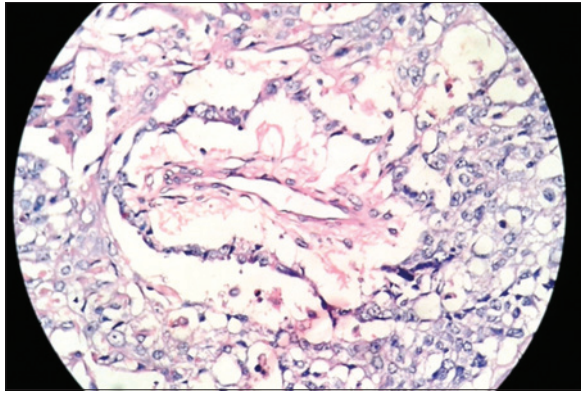


**Figure 7: High power view of immature teratoma showing neuroepithelium**

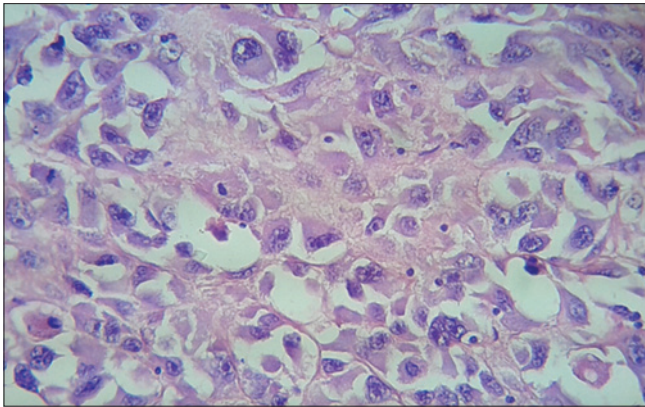


**Figure 10: Low power view of yolk sac tumor showing reticular/microcystic pattern**





**Figure 11: High power view of yolk sac tumor showing Schiller–Duval body**



**Figure 12: High power view of embryonal carcinoma**

components. It may secrete estrogen and can present with precocious puberty or irregular vaginal bleeding.<sup>13</sup> Extensive review of literature shows that the combination of mature with malignant germ cell elements is extremely rare with very few reported cases worldwide.<sup>14</sup>

## CONCLUSION

Among ovarian neoplasms, germ cell tumors are relatively uncommon. Benign tumors were more commonly

encountered of which majority were mature cystic teratomas. Malignant Germ cell tumors were seen in younger age group, and most frequent type was dysgerminoma.

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# Saliva as a Non-invasive Tool in Evaluation of Type 2 Diabetes Mellitus

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## Abstract

**Introduction:** Diabetes mellitus is a chronic metabolic disorder and a leading cause of mortality and morbidity globally with an estimated prevalence of 70 million by 2025.

**Materials and Methods:** In total, 75 persons were included in this study. They were divided into 3 groups, each group consisting of 25 persons. Cases were selected from both the sexes and of age 40-70 years. Group I: Non-diabetes persons (controls), Group II: Controlled diabetes, Group III: Uncontrolled diabetes. All individuals were subjected to collection of blood and saliva for estimation of Glycosylated hemoglobin, fasting glucose, electrolytes, salivary pH and flow rate.

**Results:** In this study, fasting serum glucose and salivary glucose levels are comparable to other studies and shows statistical significance ( $P = 0.005$ ), and hence, it can be utilized to evaluate glucose levels in diabetics. Regarding electrolytes, salivary calcium was decreased in uncontrolled diabetes (Group III) when compared to non-diabetics and controlled diabetics, whereas sodium and potassium showed no significant difference. Salivary pH and flow rate did not show any significant difference between the groups, whereas body mass index, waist circumference shows a statistically significant increase in uncontrolled diabetes.

**Conclusion:** This study gives evidence that saliva can be utilized as a non-invasive tool for evaluation of glucose in type 2 diabetes mellitus patients. In this study even though salivary calcium is significantly lower in uncontrolled diabetes, this cannot be taken as a marker for uncontrolled diabetes since this could be due to other confounding factors.

**Key words:** Body mass index, Diabetes mellitus, Fasting glucose, Waist circumference

## INTRODUCTION

Diabetes mellitus is a clinically and genetically heterogeneous group of disorders affecting the metabolism of carbohydrates, lipids, and proteins. It is a complex multisystem disorder characterized by a relative or absolute insufficiency of insulin secretion or concomitant resistance to metabolic action of insulin on target tissues. Currently, we have 40.9 million people suffering from diabetes and the predicted estimate by the year 2025 is around 70 million.

The interest has been recently increasing in non-invasive diagnostic testing for glucose and other parameters. Tests based on saliva have made substantial roads into diagnosis. It has been noted from various studies that salivary glands are affected directly or indirectly in diabetic mellitus. The complications include xerostomia, tooth loss, gingivitis and periodontitis, odontogenic abscesses, soft tissue lesions of the tongue, and oral mucosa. Multiple physiological factors contribute to compromised salivary function. Autonomic neuropathies, microvascular changes, hormonal imbalances or a combination of these are responsible for salivary hypofunction and dehydration in diabetics. Evaluation of salivary parameters has been shown to be cost-effective and non-invasive for screening, diagnosis and monitoring of diabetes when compared to blood investigations which are painful and causes physical trauma and mental stress to patients, hence the need for this study.

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## MATERIALS AND METHODS

This is a prospective, randomized, cross-sectional study. The study was conducted in Meenakshi Ammal Dental College and Hospital, Chennai and Ethical Clearance was obtained for the same. A total no of 75 patients were included in this study, in which 50 patients were suffering from type 2 diabetes mellitus (which included both controlled and uncontrolled diabetics) and 25 non-diabetes persons (controls). The study population included both the genders, with an age range of 40-70 years.

The study population will be divided into 3 groups:

Group 1: Non-diabetics (control)

Group II: Controlled diabetic patients

Group III: Uncontrolled diabetic patients.

### Inclusion Criteria

- Voluntary participation,
- Age inclusion: 40-75 years, and
- Sex included both the genders.

### Exclusion Criteria

- Patients suffering from type 1 diabetes mellitus, pregnancy, physically and mentally challenged patients, chronic renal failure, hyperthyroidism, pancreatitis and pancreatic cancer, hypercholesterolemia. Medications, such as steroids, tricyclic antidepressants, epinephrine, diuretics, estrogen, lithium, and salicylates, were also excluded.

All patients were explained in detail about this study, and informed consent was obtained in their native languages to prevent language bias and later was subjected to collection of saliva and blood examination.

- Unstimulated saliva of 2 ml for 5 min will be collected and salivary flow rate and pH, levels of glucose, sodium, potassium, and calcium levels will be evaluated.
- 8 ml of venous blood will be collected and subjected to fasting glucose estimation, glycosylated hemoglobin (HbA1C), sodium, potassium, and calcium.

The testing of both salivary and serum samples was done in aseptic conditions. After 8 ml of venous blood sample was obtained from each subject, blood was immediately transferred into vacutainers and processed. The unstimulated saliva of 2 ml was collected for about 5 min immediately after blood collection in pre-weighed containers and estimated for same parameters with salivary flow rate and pH in subjects from all the groups. pH was estimated through salivary digital pH meter model no 111, which gave accurate data. The specimens were analyzed in room temperature and were fed into automated analyzer for

interpretation of the following parameters. Fasting blood glucose in serum and saliva, HbA1c was measured through the following methods: Electrochemical colorimeter using a glucosometer (Freestyle Precision - Abbotts Diabetes Care Inc.), yielding blood glucose in milligrams per deciliter (mg/dL), HbA1c: High-pressure liquid chromatography (D-10 hemoglobin testing system - Bio-Rad Inc.), which gives the % of HbA1c fraction. Electrolytes levels of sodium and potassium in both serum and saliva were measured by Roche 9180 electrolyte analyzer, whereas for salivary and serum calcium estimation Optima 1 from Labindia manufacturers was done and described in Meq/l.

The results thus got were tabulated, and statistical analysis was done with statistical methods such as scatter plot and ANOVA.

## RESULTS

In this study, fasting serum glucose and salivary glucose levels are comparable to other studies and shows statistical significance ( $P = 0.005$ ) and hence it can be utilized to evaluate glucose levels in diabetics (Figures 1 and 2). Regarding electrolytes, salivary calcium was decreased in uncontrolled diabetes (Group III) when compared

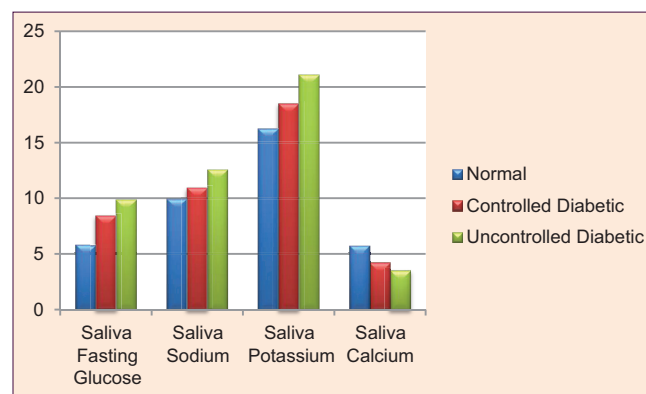


Figure 1: Salivary parameters in all groups

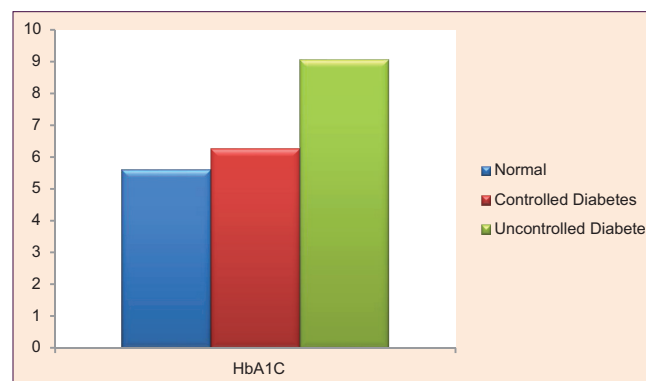


Figure 2: Glycosylated hemoglobin in serum in all groups

to non-diabetics and controlled diabetics, whereas sodium and potassium showed no significant difference (Figures 1, 3 and 4). Salivary pH and flow rate did not show any significant difference between the groups (Figures 5 and 6), whereas body mass index (BMI), waist circumference shows a statistically significant increase in uncontrolled diabetes (Figure 7).

## DISCUSSION

Salivary parameters are altered by metabolic, nutritional, neurological abnormalities, the hydration status of a

person and by drugs such as anticholinergics, diuretics, antihistamines, and antihypertensives.<sup>1</sup> Among the metabolic disorders, diabetes mellitus is the most significant disorder associated with varied oral manifestation ranging from xerostomia to serious bacterial and fungal infections leading to morbidity and mortality along with alterations in levels of glucose, electrolytes, pH and flow rates of saliva. This is due to salivary gland dysfunction because of microvascular complications and autonomic neuropathy, particularly in uncontrolled diabetes. These parameters need to be assessed for the early detection and proper management of diabetic patients. Hence, we planned to do this study in a tertiary care hospital in South India to assess the possibility of utilizing saliva as a noninvasive alternative tool to blood in the monitoring of diabetes mellitus.

High salivary glucose level is a consequence of high plasma glucose level which diffuses in saliva, according to Lasini *et al.*, 2002.<sup>2</sup> This high salivary glucose in conjunction with overall diminished flow of saliva has also been reported to be responsible for xerostomia in diabetic patients. This study showed a statistically significant correlation between saliva and serum glucose levels (fasting and HbA1c glucose levels) in uncontrolled diabetic patient group ( $P = 0.01$  level) which was in concordance with studies conducted

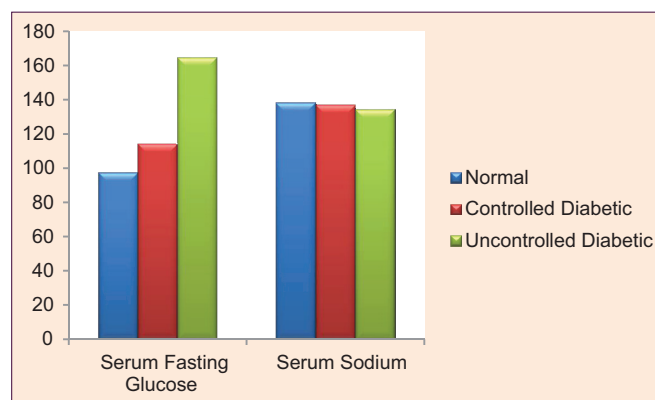


Figure 3: Serum parameters in all the 3 groups

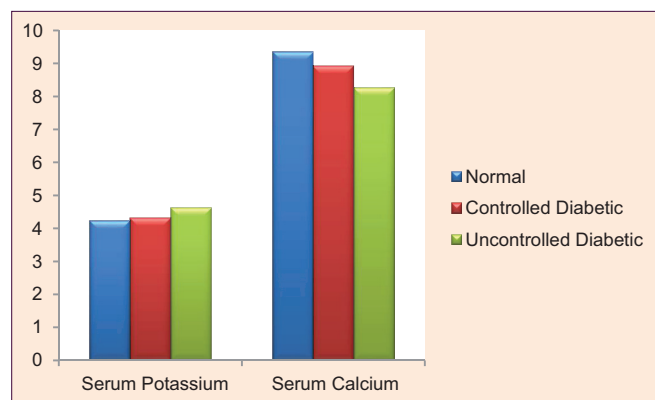


Figure 4: Salivary PH (Serum Potassium / Serum Calcium)

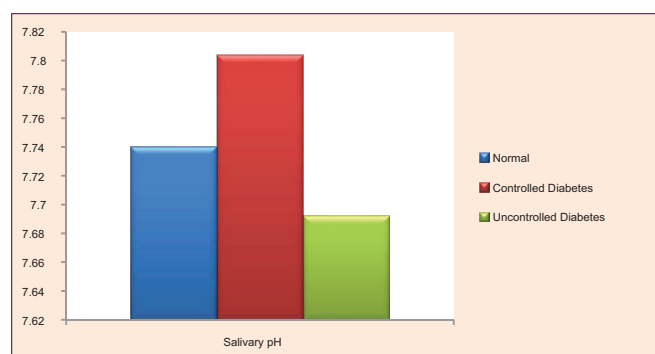


Figure 5: Salivary PH

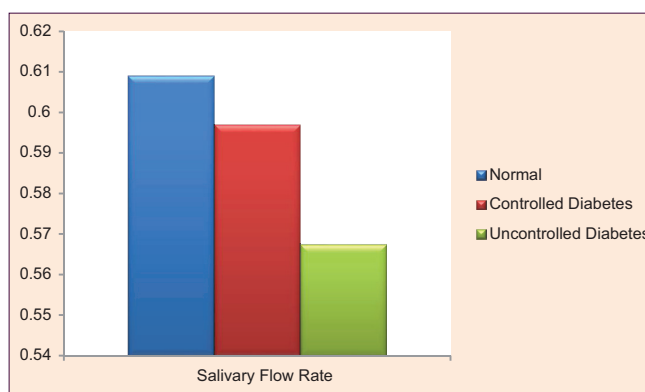


Figure 6: Salivary flow rate

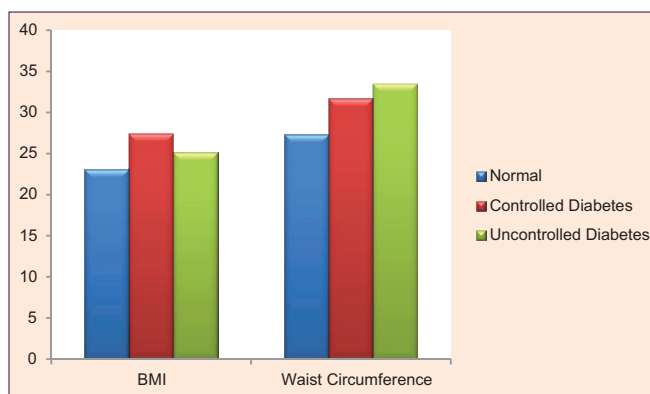


Figure 7: Comparison of body mass index and waist circumference in all groups

by Ben-Arey *et al.*, 1993, Ayadin, 2004 and Vasconcelous *et al.*, 2010, Agrawal *et al.*, 2013,<sup>3</sup> Jha *et al.*, 2014. However, the following studies did not show any correlation with our study, López *et al.*, 2003,<sup>4</sup> Carda *et al.*, 2006<sup>5</sup> and Hegde *et al.*, 2010<sup>6</sup> who found no correlation between glucose concentrations in blood and saliva in diabetic patients.<sup>1</sup>

Increased salivary glucose is attributed to the fact that glucose is a small molecule that easily diffuses through semi-permeable membranes. Thus, large amounts of glucose become available to saliva when blood glucose levels are elevated, as in diabetes.<sup>7</sup> Alterations in the permeability, occurring as a result of basement membrane changes in diabetes, may be an additional explanation for the increased concentration of glucose in saliva.<sup>3,6</sup> This alters the microvasculature structure and makes it more permeable. The end result is a leaky microvasculature and a leaky basement membrane, which explains the increased passage of glucose from the blood into the saliva in diabetes mellitus.<sup>1,4,8</sup> Little is known concerning the relationship between diabetes and salivary biochemical parameters and the effect of these changes on oral health. Hence, in this study, we tried to study the level of electrolytes in saliva of Type 2 diabetes mellitus.

Lasisi *et al.*,<sup>2</sup> states saliva contains large quantities of potassium and bicarbonate ions. The concentrations of both sodium and chloride ions are several times less in saliva than in plasma. In this study, we found no significant difference in salivary sodium of healthy and diabetic persons, and this was a similar finding in studies by Carda *et al.* 2006,<sup>5</sup> Kallapur *et al.*,<sup>9</sup> 2013, Shirzaiy *et al.*,<sup>10</sup> 2013. However, Hegde, *et al.*, 2014, proved that the concentration of sodium (Na), potassium (K) and -chloride (Cl) ions in saliva was higher in diabetic patients. Sharon *et al.*, 1985, in an animal study had proposed that in diabetes mellitus an autonomic neuropathy exists which causes sympathetic-parasympathetic imbalance. This imbalance may perhaps exert a continuous stimulation on the salivary glands, bringing about increased potassium secretion into the saliva.<sup>11</sup> Yavuzylmaz *et al.*,<sup>11</sup> 1996, Mata *et al.*, 2004<sup>12</sup> proved that the concentration of potassium can be reduced in diabetics when compared to normal persons, whereas, Andelski-Radicevic *et al.*, 2006, stated that the concentration of potassium in saliva of diabetic patients was higher than in healthy subjects, due either increased activity of Na K ATPases or due to the changes in the basal membrane of salivary gland acini or decrease in salivary secretion.<sup>13</sup> This study showed no significant difference between serum and salivary potassium levels. Diabetic patients have demonstrated an increase in calcium concentration in saliva compared to the control group according to Harrison *et al.*, 1984, Mata *et al.*, 2004. Busato *et al.*, 2011, it was considered that a high concentration of calcium in saliva is favorable indicator of oral health.<sup>14</sup>

However, the results in this study were no significant correlation with this fact, revealing a decrease in salivary calcium concentration in controlled diabetics ( $P = 0.01$ ) uncontrolled diabetics ( $P = 0.05$  level). The decrease in salivary calcium in diabetics and may be attributed to increase in the of concentration of specific proteins special bonds with calcium phosphate and sometimes with hydration status of the individual. According to Lopez *et al.*, 2003 Iqbal *et al.*, 2011, Kumar 2012, Prathiba *et al.*, 2013. Resting saliva is the mixture of secretions which enter the mouth in the absence of exogenous stimuli. Normal resting whole saliva flow rates range from 0.3 to 0.5 ml/min, whereas hyposalivation with symptoms of dry mouth appears in the range of 0.10-0.01 ml/min, with a decrease in flow rate.<sup>15</sup> This study showed no statistically significant difference between normal, diabetic and non-diabetic patients. This contradicted findings of Cherry-Peppers *et al.*, 1992, Karjalainen *et al.*, 1996, Lopez *et al.*, 2003, Prathiba *et al.*, 2013, who concluded that salivary flow rate was significantly diminished in diabetics as compared to that in non-diabetics due to excessive thirst and dry mouth, poor glycemic control increased diuresis and fluid loss. Several studies which were done on resting salivary pH estimated a range of 5.5-7.9 in normal individuals. The pH of saliva is maintained by carbonic acid and bicarbonate system, phosphate system and protein system of buffers. Prathiba *et al.*, 2013, Kennath, 2014 showed a significant decrease in pH in diabetics in comparison to non-diabetic subjects. This study, however, failed to demonstrate such a correlation between the diabetics and non-diabetics.

The WHO, 1998 reports indicated that the risk for diabetes increased three times in subjects with BMI more than 30 kg/m. The stronger association with weight gain in earlier adulthood than in later adulthood might be explained by the longer duration of exposure to cumulative excessive body fat. As postulated that the duration of obesity is a significant risk factor for type 2 diabetes, independently of the current degree of obesity, this study showed a positive correlation that showed increased BMI in uncontrolled diabetics.<sup>16-18</sup> This was in concordance with studies by Chan *et al.*, 1994, Willet *et al.*, (1999) and Anja Schienkiewitz *et al.*, 2006. Ishikawa-Takata, 2002<sup>19</sup> however proved that the risk for diabetes in subjects with BMI <29 kg/m<sup>2</sup> was not significant. There is a good indication of waist circumference being an important indicator of progression to diabetes than BMI. According to Williamson *et al.*, 2000, a variety of intervention studies show that patients with type 2 diabetes who succeed in losing weight often enjoy modest improvements in glycemic control and cardiovascular risk profiles,<sup>20</sup> as long as the weight loss is maintained.<sup>21</sup> Pinkney, 2002, suggested that obesity is a major potentially modifiable risk factor for type 2 diabetes. This is similar to the association between obesity and diabetes shown in

other studies in uncontrolled diabetes patients ( $P = 0.000$ ) present study also showed a significant correlation between waist circumference and uncontrolled diabetes. Henry *et al.*, 2004, states that weight loss in overweight patients with type 2 diabetes rapidly reverses the state of insulin resistance and can restore normal blood glucose concentrations. Hence, there is a strong scope of waist circumference being an important indicator of progression to diabetes. This is due to a hypothesis that waist circumference relates to that, central obesity has been associated with decreased glucose tolerance, alterations in glucose-insulin homeostasis, reduced metabolic clearance of insulin, and decreased insulin-stimulated glucose disposal.<sup>22</sup>

## CONCLUSION

This study along with many other studies indicates that saliva may be utilized as a non-invasive tool for evaluation of type 2 diabetes mellitus. Further research on larger samples with more clinical trials and in depth analysis for the imbalance of electrolytes which varies from one study to another should be done. This should be correlated with oral manifestations and other comorbidities to make saliva as a reliable tool.

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# Evaluation of Results of Hip Arthroscopic Surgery for Femoroacetabular Impingement

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## Abstract

**Background:** Femoroacetabular impingement (FAI) is an increasingly recognized disorder. FAI is the result of abnormal contact between the proximal femur and acetabulum and can result in intra-articular pathology and eventual osteoarthritis. Open surgical hip dislocation procedure described by Ganz is gold standard. Recently, arthroscopic-based treatment has been developed. Our study aims to present clinical outcome in a single-center cohort of patients treated arthroscopically for hip-related pain due to FAI.

**Materials and Methods:** A total of 55 patients from 2013 to 2016 were included in this prospective case series (50 male; mean age 35 years; [range: 15-50]). The indication for arthroscopic treatment of hip-related pain was mechanical hip symptoms and radiological findings of FAI. To evaluate hip function and pain level at 1-year follow-up by modified Harris Hip Score (mHHS), hip outcome score (HOS), and a numeric rating scale (NRS) pain score.

**Results:** Radiologically, 45 patients had both cam and pincer lesion. After 1 year, the impingement test was negative or mildly positive in 91% cases. mHHS, HOS, and NRS pain score significantly improved from previous status ( $P < 0.001$ ). There was a significant reduction of the alpha angle from the pre-operative value ( $P < 0.001$ ). Total hip replacement was done in three patients, and two patients were scheduled for replacement after the follow-up period.

**Conclusions:** Although our study has several limitations such as lack of control group, small sample. We have found there was a significant statistical improvement by arthroscopic treatment of FAI. Further studies are needed to determine failure rates and risk factors.

**Key words:** Arthroscopy, Femoroacetabular impingement, Hip, Labral tear

## INTRODUCTION

Femoroacetabular impingement (FAI) is an increasingly recognized disorder. FAI is described as the abnormal contact between the anterior acetabular rim and femoral neck. There are two primary mechanisms of FAI: Cam and pincer impingement. Cam impingement defined as an abnormally shaped femoral head-neck junction converging into the acetabular rim. Pincer impingement described as acetabular over coverage of the femur. FAI has been identified as a common cause of hip pain in young, active

patients with non-dysplastic hips. It is considered as a major factor in the development of osteoarthritis.<sup>1</sup>

The aim of surgical treatment is to reshape cam deformities that cause bony contact during normal hip motion and repair of associated labral and acetabular cartilage pathology.<sup>2,3</sup> Ganz *et al.*<sup>4</sup> described surgical hip dislocation technique. It has the advantage of complete visualization of the proximal femur and acetabulum without compromising the femoral head vasculature. Several investigators who have used this open technique have reported good early and midterm clinical success with minimal complications.<sup>5-11</sup> However, this is a major surgery, which necessitates the use of a trochanteric osteotomy and hip-joint dislocation with a high chance of injury to vascular supply of femoral head.

With the advancement of arthroscopy technique and a better understanding of hip pathology, hip arthroscopy is a new modality in treating FAI. This is a minimally

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invasive technique which has the advantages of early and faster rehabilitation. Early outcomes in the arthroscopic treatment of FAI are equivalent to the open technique.<sup>12-16</sup> The superiority of the open surgical dislocation technique originally considered the gold standard for FAI treatment, has been questioned in several meta-analyses.<sup>17-19</sup>

In this prospective study, we evaluate clinical results of arthroscopic treatment of FAI performed by a single experienced surgeon. According to our hypothesis, the arthroscopic approach will yield faster initial recovery, with statistically significant outcomes at longer follow-up.

## MATERIALS AND METHODS

This is a prospective study. The study was conducted in our institution after getting ethical permission. All the patients were counseled about the advantages, disadvantages, and complications of the procedure. After getting written consent from patients, we performed the arthroscopic procedure. The study period was from January 2013 to January 2016. The inclusion criteria were younger patients (50 years of age or younger), mechanical symptoms (hip pain, restricted hip motion), at least 6 months of failed conservative treatment, a positive impingement test, and radiographic criteria for FAI. We excluded patients who had previous hip surgery, Legg-Calve-Perthes disease, slipped capital femoral epiphysis, hip dysplasia, trauma, and osteonecrosis. A positive anterior impingement test was defined as forced internal rotation/adduction in 90° of flexion was painful, and for posterior impingement with painful forced external rotation in full extension.

Radiographical definition of cam deformity on anteroposterior radiographs was Pistol-grip deformity, caput-collum-diaphyseal angle  $<125^\circ$ , horizontal growth plate sign and on cross-table radiographs alpha angle  $>50^\circ$ , femoral head-neck offset  $<8$  mm, offset ratio  $<0.18$  femoral retrotorsion. Radiographical definition of pincer deformity on anteroposterior radiographs was focal acetabular retroversion (Figure of 8 configuration due to overlapping of anterior and posterior wall of acetabulum), lateral center edge angle  $>39^\circ$  reduced extrusion index, acetabular index  $\leq 0^\circ$ , posterior wall sign. Radiographic signs on cross-table radiograph were linear indentation sign. Magnetic resonance arthrogram was not performed routinely in all patients due to high cost. If there was any ambiguity about the source of pain, diagnostic injection of local anesthetic under fluoroscope guidance was performed to clarify the intra-articular source of pain.

Intra-articular cartilage status of the femoral head and acetabular joint surface was described using the

International Cartilage Repair Society (ICRS) grading.<sup>19</sup> All surgical treatments were performed by one experienced surgeons.

In general, two portals, the anterior and the anterior paratrochanteric were used. 70° optics was used in all cases. First, the central compartment was viewed and operated. The acetabular labrum was debrided or repaired (Figure 1). Afterward, the peripheral compartment was operated by releasing traction and viewing the peripheral region of the femoral head-neck junction. Once the region of the cam-type impingement was defined by local morphological changes or dynamic examination of the joint, osteochondroplasty was performed (Figure 2). The procedure was considered finished when rubbing of the neck against the acetabular rim was no longer seen in 90° flexion, adduction, and internal hip rotation of 30° was performed. 1-year post-operative data collection was performed at average 16 months after surgery

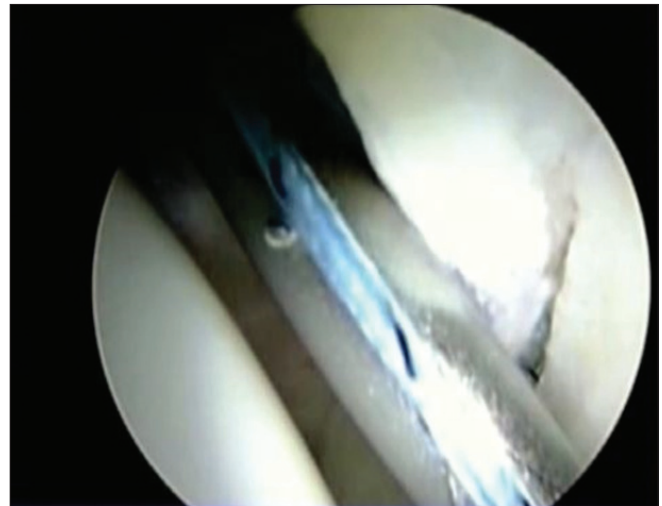


Figure 1: Repair of pincer lesion



Figure 2: Repair of cam lesion

(range: 12-22). The difference between pre-operative and post-operative values was analyzed using the Student's *t*-test. *P* values below 0.05 were considered to be statistically significant.

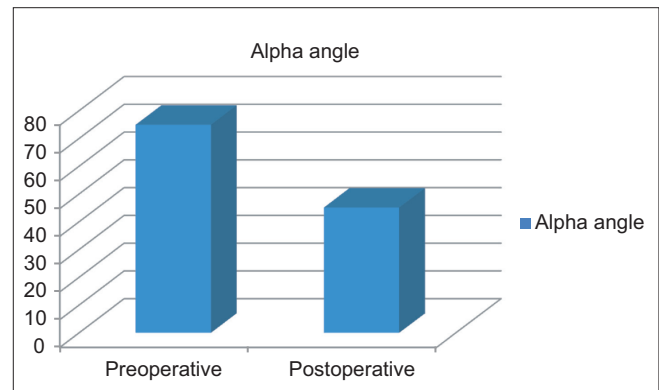
## RESULTS

A total of 55 patients were treated by hip arthroscopy procedure. Among them, 50 patients were male and 5 were female. The average age of patients was 35 years. Most of them were associated with sports activity. Only one patient had radiologically cam deformity and nine patients had isolated pincer deformity. The remaining 45 patients have both cam and pincer lesion (Table 1). On arthroscopic examination, 91% cases labral lesion was found. According to ICRS classification, the cartilage status of acetabulum, Grade 0: 8%; Grade 1: 20%; Grade 2: 43%; Grade 3: 19%; Grade 4: 10% were found. On 78% cases, labral reattachment was done. CAM and pincer deformity resection were done in 96% and 92% cases, respectively.

All patients were treated arthroscopically. We had found significant improvement from their previous status. All the patients had positive impingement test before surgery. In a follow-up at least 1 year after, 91% cases impingement test was negative or mildly positive and only in 9% cases it was positive ( $P < 0.001$ ). Modified Harris Hip Score (mHHS), hip outcome score (HOS), numeric rating scale (NRS) pain score significantly improved from previous status (Table 2). According to mHHS at minimum 1 year follow-up, excellent result ( $>90$ ) was found in 29 patients (52.72%) good result (80-89) found in 9 patients (16.36%), fair result (70-79) found in 12 patients (21.81%), and poor ( $<70$ ) found in 5 patients (9.11%). There was a significant reduction of the alpha angle from the pre-operative value ( $P < 0.001$ ) (Figure 3). We observe during analysis of mHHS, HOS, NRS pain score that significant improvement occurred

during first three months postoperatively (Figures 4-6). No significant difference in 1-year follow-up between labral fixation and labral resection was found. The average traction time during surgery was  $52.3 \pm 14.5$  min (median = 45).

One patient had partial sciatic nerve neuropraxia which was improved completely. There was no post-operative femoral neck fracture, infection, or osteonecrosis.



**Figure 3: Preoperative and postoperative angles as measured on cross-table lateral radiographs for hips with cam impingement revealed significant improvements**



**Figure 4: Progressive analysis of modified Harris hip score revealed statistically significant improvement postoperatively without further significant improvement after 3 months**

**Table 1: Radiological parameters of hip joint**

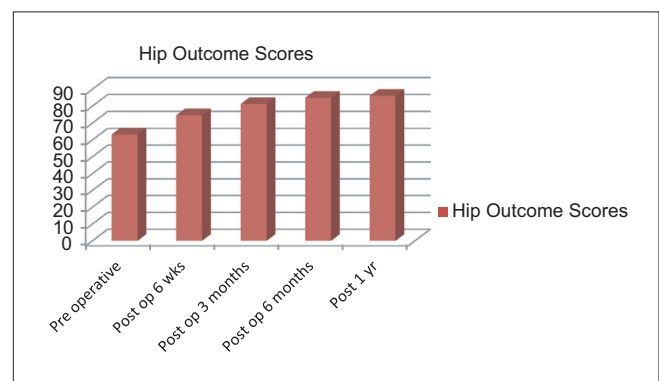
Parameters	Mean±SD
Alpha angle	74.9±8.7
CE angle (center edge angle)	31.6±6.3
JSW (mm)	3.4±0.3

JSW: Joint space width

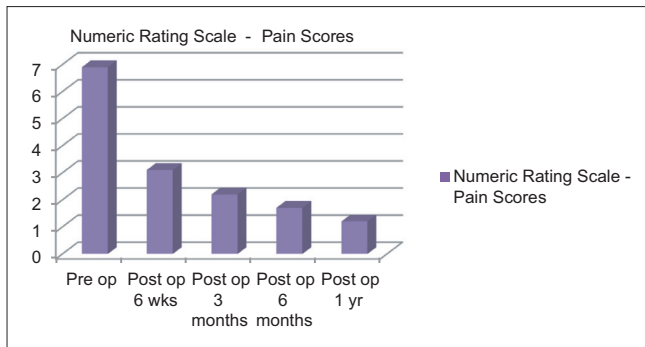
**Table 2: Patient reported outcome scores**

Parameters	Mean±SD		<i>P</i> value
	Preoperatively	Postoperatively	
mHHS	69.34±16.8	85.3±17.1	<0.001
HOS	68.27±17.0	86.1±17.4	<0.001
NRS	6.74±2.7	2.5±1.2	<0.001

mHHS: Modified hip score, HOS: Hip outcome score, NRS: Numeric rating scale



**Figure 5: Progressive analysis of hip outcome score revealed statistically significant improvement postoperatively without further significant improvement after 3 months**



**Figure 6: Progressive analysis of numeric rating scale - pain score revealed statistically significant improvement postoperatively without further significant improvement after 3 months**

The failure case was defined as 10 point drop in mHHS and HOS, respectively, from pre-operative to follow-up. According to this, 9.5% cases were failure. Total hip replacement (THR) was done in three patients. Two patients were operated for THR after the follow-up period. All these patients mean age was 47 years, and they had cartilage injury ICRS Grade 4 at the acetabular rim and ICRS Grade 3 on the femoral head.

## DISCUSSION

The goal of surgical management of FAI is removal or reorientation of acetabular over coverage by labral repair/refixation or labral debridement and is reshaping of the proximal femur. This concept has been pioneered by Ganz. The procedure has been traditionally done with surgical hip dislocation doing a trochanteric osteotomy. Beck *et al.*<sup>10</sup> published that excellent results were found in 13 patients among 19 patients on 4.7 years follow-up. Peters and Erickson<sup>5</sup> reviewed 30 hips undergoing open reconstruction. Their observation that significant improvement of mHHS from a mean of 70 preoperatively to 87. Four hips required total hip arthroplasty because of progressive osteoarthritis and pain. Espinosa *et al.*<sup>2</sup> compared the effect of labral debridement versus repair/refixation and found better outcomes at 2 years' follow-up in the labral repair group with respect to pain and progression of osteoarthritis. Overall, the results of open management have been promising in the absence of significant chondral damage at the time of surgery.

Although there is increasing interest in arthroscopic management of FAI.<sup>20-28</sup> A systemic review of 45 elite athletes with FAI treated arthroscopically, concluded that all patients had symptomatic relief and returned to their sport.<sup>20,25</sup> In another review of over 320 patients treated arthroscopically, 90% had the elimination of the impingement sign and were reportedly satisfied with their

results.<sup>28</sup> Our study showed significant improvement of patients in respect of the impingement test, mHHS, HOS score, and NRS pain score at early follow-up. With up to 3 years' follow-up, the scores have remained relatively stable. Total hip arthroplasty had been required and performed in 3 patients and scheduled in 2 patients.

Several studies have found a correlation between chondral damage in FAI patients and subjective outcome. Haviv *et al.*<sup>29</sup> examined the impact of cartilage injury on clinical outcome of cartilage damage in FAI patients. They found no difference in improvement of mHHS improvement between different degrees of cartilage injury. Philippon *et al.*<sup>16</sup> found that poor cartilage status leads to a poor subjective outcome. The present study did not find any difference in mHHS outcome between cartilage injuries ICRS Grades 1-2 (16 patients) and Grades 3-4 (35 patients). The mHHS was 82.5 and 85.0, respectively. However, all failures that had THR reoperation had severe cartilage injuries Grade 4.

A total of 78% of the patients had a labral refixation after removal of acetabular bone tissue. The patients with labral refixation did not have poorer subjective outcome than patients without this procedure. Larson and Giveans<sup>30</sup> demonstrated that labrum refixation led to improved subjective outcome compared to labral resection in two patient cohorts with labral damage. Another prospective randomized study by Krych *et al.*<sup>31</sup> showed the same improvement of outcome scores.

The THR reoperation rate in the present study is similar to other published studies. In 96 patients, Larson and Giveans found a 3% THR reoperation rate.<sup>15</sup> All had Grade 4 acetabular chondral lesions with delamination of cartilage from the subchondral bone. Overall higher age, higher degree of cartilage injury and/or osteoarthritis is predictors for THR reoperations.<sup>16,29</sup>

The present study has several limitations. One of the most important is the lack of control group consisting of non-operated/conservatively treated FAI patients. There are several strengths in this present study. This study is a consecutive, prospective case series including a relatively large cohort of 55 patients. The study had excellent completeness with 100% and 75% at 1 year and longtime follow-up, respectively.

## CONCLUSION

Arthroscopic management of patients with pain related to mechanical hip symptoms and radiological findings of FAI will benefit from hip arthroscopy with resection of



cam and pincer bony deformities. Significant improvement in outcomes measures, with good to excellent results, is being observed in 75% of hips at a minimum follow-up of 1 year. Alteration in the natural progression to osteoarthritis and sustained pain relief as a result of arthroscopic management of FAI remain to be seen. In conclusion patients with their functional level will increase and their pain level will decrease significantly. Further studies are needed to determine failure rates and outcome risk factors.

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# Levobupivacaine versus Ropivacaine: A Comparative Study of the Analgesic and Hemodynamic Spectrum

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## Abstract

**Introduction:** Levobupivacaine and ropivacaine are both newer long-acting local anesthetic drugs increasing the spectrum of local anesthetic armamentarium that were developed following reports of bupivacaine-related severe toxicity.

**Materials and Methods:** After taking permission from the Ethical Committee and proper informed consent from the patients, a comparative study between 0.5% levobupivacaine and 0.75% ropivacaine was carried out over 90 American Society of Anesthesiologists I (ASA I) and ASA II patients appearing for lower limb surgeries in Shri Ram Murti Smarak Institute of Medical Science hospital in Bareilly. A bolus of 20 ml of both the drugs was given via epidural route to both the groups comprising 45 patients each who were randomly selected by closed envelope method.

**Results:** Both the drugs are found to be equally potent in terms of analgesic and hemodynamic parameters. Both the drugs have near equal sensory onset (L = 9.6 s and R = 9.48 s,  $P > 0.05$ ), and complete sensory regression taking place nearly 190 min for both the drugs. The duration of analgesia for both the drugs was around 175 min with no statistical difference. Both the drugs exhibited comparable hemodynamic response with heart rate, systolic and diastolic blood pressure being stable and comparable without any statistical difference.

**Conclusion:** It is concluded that both 0.5% levobupivacaine and 0.75% ropivacaine are potent enough to carry out lower limb surgeries with stable hemodynamic parameters.

**Key words:** Hemodynamic, Levobupivacaine, Ropivacaine

## INTRODUCTION

The search for an ideal local anesthetic agent has been long and arduous. The drug with the perfect balance of sensory and motor block durations with minimal cardiovascular, neural, and other systemic changes has always eluded researchers.<sup>1</sup>

The past millennium has exclusively been dominated by bupivacaine as the first line choice of local anesthetic agent

for the regional, intrathecal, and epidural block by most anesthetists. However, in the early 1970s, the recognition of acute life-threatening cardiotoxicity of bupivacaine led to the search for a local anesthetic agent comparable with bupivacaine but with lower cardiotoxicity resulting in development of a relatively new amide, ropivacaine, registered for use in 1996, but introduced in India only in 2009.<sup>2,3</sup>

Ropivacaine is produced as pure “S” enantiomer with lower lipid solubility, easier reversibility after inadvertent intravascular injection, significant reduction in central nervous system toxicity, lesser motor block and greater differentiation of sensory and motor block.

In equal concentrations, ropivacaine and bupivacaine produced similar sensory and motor block after epidural administration with slightly longer block duration with

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bupivacaine. Increasing concentrations caused quicker onset, greater intensity, slower regression, and longer duration of motor blockade. Motor blockade of 0.75% ropivacaine was comparable to 0.5% bupivacaine.

Levobupivacaine was another pure left isomer of bupivacaine that was developed for local anesthetic use due to its decreased toxicity but clinical efficacy comparable with bupivacaine.<sup>4</sup>

Levobupivacaine and ropivacaine are both newer long-acting local anesthetic drugs increasing the spectrum of local anesthetic armamentarium that were developed following reports of bupivacaine-related severe toxicity. Both of these agents are pure left isomers, and based on their three-dimensional structure; they have less toxicity to both the central nervous system and the heart. The clinical profiles of levobupivacaine and ropivacaine are similar to that of racemic bupivacaine, and the minimal differences among the three agents are mainly related to the slightly different anesthetic potency. They produce effects similar to other local anesthetics via reversible inhibition of sodium ion influx in nerve fibers. We prefer to use both of these drugs because of their similarity.<sup>5</sup>

## MATERIALS AND METHODS

After obtaining Ethical Committee approval and informed consent from patient, the study entitled will be carried out on 90 patients of both the sexes between 18 and 65 years of age and group of American Society of Anesthesiologists (ASA) Grade I and II physical status, scheduled for elective lower limb surgeries in Shri Ram Murti Smarak Institute of Medical Sciences Hospital, Bareilly.

Patients refusing for regional anesthesia, with ASA Grades III and IV, having contraindication to regional anesthesia, patients with congenital abnormalities of lower spine and meninges, patients with history of allergy to local anesthetics, surgeries of duration exceeding 3 h, patients receiving drugs such as angiotensin-converting enzyme inhibitors, calcium channel blockers, addiction to narcotics, sedatives, and adrenergic receptor antagonists, patients with body mass index <20 or more than 30 and failed epidural cases are excluded from the study.

Patients were randomly assigned to receive one of the two local anesthetic drugs for epidural anesthesia. Patients are randomized according to the closed envelope technique.

Routine pre-operative evaluation of each patient was performed the day before surgery. The method of anesthesia was explained to the patients, and questions about the procedure were answered. Injection ondansetron 0.08 mg/kg

was given as premedication to the patients. In the operating room, an 18-G intravenous (IV) cannula was inserted, and 15 ml/kg balanced crystalloid solution was administered to all patients. Standard monitoring was used throughout the study including electrocardiography, non-invasive blood pressure (BP), heart rate (HR), and pulse.

All patients received epidural anesthesia using a standard midline approach in the sitting position. The insertion area was prepared using antiseptic solution, and then 2 ml of 2% lidocaine was applied into the skin and subcutaneous tissue to induce local anesthesia. Then, an 18-G Tuohy needle and a frictionless glass syringe were used to find the epidural space at the L<sub>3</sub>-L<sub>4</sub> or L<sub>4</sub>-L<sub>5</sub> interspaces using the loss of resistance technique. Patients in Group L received 20 ml of 0.5% and those in Group R received 20 ml of 0.75% ropivacaine for epidural anesthesia. After negative aspiration of blood, 3 ml of the study drug were injected as a test dose. Approximately 3-5 min later, the remaining dose was administered. An epidural catheter was not applied. After completion of the epidural injection, patients were placed in the supine position. Mean arterial pressure (MAP), HR, and hemoglobin O<sub>2</sub> saturation values (SpO<sub>2</sub>) were recorded every 5 min throughout surgery. An observer blinded to the group assignments recorded the evolution of sensory block (using the pinprick sensation test) and motor block by modified Bromage scale (0: No impairment, 1: Unable to raise extended legs but able to move knees and ankles, 2: Unable to raise extended legs as well as unable to flex knees, able to move feet, and 3: Unable to flex ankle, feet, or knees). The levels of the sensorial and motor block were recorded every 2 min. Maximum sensorial and motor block levels were also recorded.

It was planned to treat bradycardia (HR <50 beats/min) with atropine (0.01 mg/kg) and hypotension (decrease in systolic arterial BP 30% lower than baseline) with IV boluses of crystalloid solution or injection mephentermine (6-12 mg). Patients were not sedated during surgery.

## RESULTS

It is evident from the Table 1 that the sensory onset time of ropivacaine group is shorter than that of levobupivacaine group, but the difference in time is statistically insignificant ( $P > 0.05$ ) (Figure 1).

**Table 1: Time of sensory block onset up to T-12 (in min)**

Onset	Mean±SD (n=45)		P value
	Group L	Group R	
Sensory block (min)	9.66±1.99	9.48±1.92	0.668 (>0.05)

SD: Standard deviation

It is clear from Table 2 and Figure 2 that the time of sensory regression time of ropivacaine is less.

The duration of analgesia for Group L was  $175.38 \pm 13.6$  min and for Group R was  $170.8 \pm 19.81$  min (Table 3 and Figure 3).

So, the duration of analgesia in levobupivacaine group was slightly longer than ropivacaine group, and the difference in time was statistically insignificant.

As indicated by mean and  $P$  values in Table 4, the HR was comparable, and the difference between the two groups was statistically insignificant ( $P > 0.05$ ). The HR rose for

the first 3 min in both the groups and then came down to baseline after around 30-45 min (Figure 4).

As indicated by mean and  $P$  values in Table 5, the systolic BP (SBP) was comparable, and the difference between the two groups was statistically insignificant ( $P > 0.05$ ). The HR rose for the first 3 min in both the groups and then came down to baseline after around 30 min (Figure 5).

As indicated by mean and  $P$  values in Table 5, the SBP of both the drugs is comparable at different time intervals. After the initiation of epidural anesthesia, BP started falling for both the drug groups for the first 15 min. The fall in BP was more in levobupivacaine group than the ropivacaine group, but the difference between them was statistically insignificant. After that, the BP started returning to baseline values nearly 45 min later.

**Table 2: Time of sensory regression up to S-1 (in min)**

Time of regression of block (min)	Mean $\pm$ SD (n=45)		P value
	Group L	Group R	
Sensory	190.27 $\pm$ 18.61	187.67 $\pm$ 23.92	0.566 ( $P>0.05$ )

SD: Standard deviation

**Table 3: Duration of analgesia**

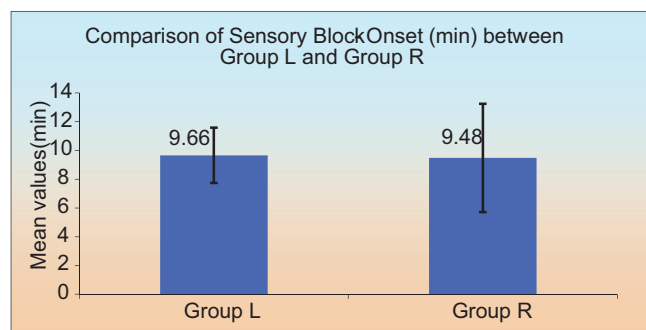
Duration	Mean $\pm$ SD (n=45)		P value
	Group L	Group R	
Analgesia duration	175.38 $\pm$ 13.60	170.80 $\pm$ 19.81	0.205 ( $P>0.05$ )

SD: Standard deviation

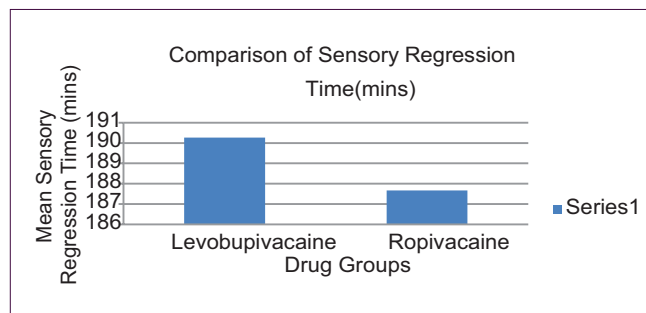
**Table 4: Variation in HR (bpm)**

HR (beats/min)	Mean $\pm$ SD (n=45)		P value
	Group L	Group R	
Baseline (min)	80.73 $\pm$ 6.98	81.04 $\pm$ 5.58	0.816 ( $P>0.05$ )
0	84.64 $\pm$ 4.64	85.33 $\pm$ 4.72	0.487 ( $P>0.05$ )
3	92.00 $\pm$ 5.07	91.96 $\pm$ 4.96	0.967 ( $P>0.05$ )
6	88.40 $\pm$ 5.36	90.04 $\pm$ 4.60	0.122 ( $P>0.05$ )
9	86.11 $\pm$ 5.57	86.51 $\pm$ 4.97	0.720 ( $P>0.05$ )
12	86.56 $\pm$ 6.11	86.98 $\pm$ 6.30	0.711 ( $P>0.05$ )
15	83.98 $\pm$ 6.30	83.78 $\pm$ 5.22	0.870 ( $P>0.05$ )
30	81.56 $\pm$ 9.51	83.18 $\pm$ 8.33	0.392 ( $P>0.05$ )
45	82.73 $\pm$ 5.13	82.91 $\pm$ 7.14	0.892 ( $P>0.05$ )
60	81.93 $\pm$ 3.84	82.09 $\pm$ 3.73	0.846 ( $P>0.05$ )
75	80.02 $\pm$ 5.76	80.02 $\pm$ 5.76	1.000 ( $P>0.05$ )
90	79.13 $\pm$ 4.71	79.84 $\pm$ 4.61	0.471 ( $P>0.05$ )
105	78.76 $\pm$ 6.28	79.16 $\pm$ 5.28	0.744 ( $P>0.05$ )
120	77.42 $\pm$ 4.01	77.58 $\pm$ 4.52	0.863 ( $P>0.05$ )
135	77.96 $\pm$ 4.96	77.58 $\pm$ 4.19	0.697 ( $P>0.05$ )
150	78.71 $\pm$ 6.84	78.20 $\pm$ 6.09	0.709 ( $P>0.05$ )
165	78.47 $\pm$ 5.57	78.18 $\pm$ 7.08	0.830 ( $P>0.05$ )
180	76.82 $\pm$ 4.22	76.98 $\pm$ 4.74	0.870 ( $P>0.05$ )
195	82.29 $\pm$ 5.01	82.24 $\pm$ 4.75	0.966 ( $P>0.05$ )
210	82.73 $\pm$ 6.17	82.73 $\pm$ 6.17	1.000 ( $P>0.05$ )
225	79.20 $\pm$ 5.74	79.20 $\pm$ 5.74	1.000 ( $P>0.05$ )
240	76.62 $\pm$ 4.65	76.62 $\pm$ 4.65	1.000 ( $P>0.05$ )
255	78.09 $\pm$ 5.49	78.09 $\pm$ 5.49	1.000 ( $P>0.05$ )
270	75.98 $\pm$ 4.30	75.93 $\pm$ 4.87	0.960 ( $P>0.05$ )
285	79.93 $\pm$ 4.87	76.80 $\pm$ 5.14	0.900 ( $P>0.05$ )
300	78.58 $\pm$ 3.59	78.73 $\pm$ 3.79	0.842 ( $P>0.05$ )

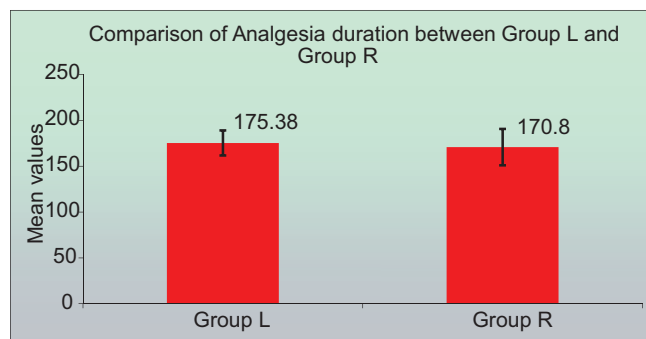
HR: Heart rate, SD: Standard deviation



**Figure 1: Comparison of sensory block onset time (min) in the two drug groups**



**Figure 2: Comparison of sensory regression time (min)**



**Figure 3: Comparison of analgesia duration between Group L and Group R**



**Table 5: Variation in SBP (mmHg)**

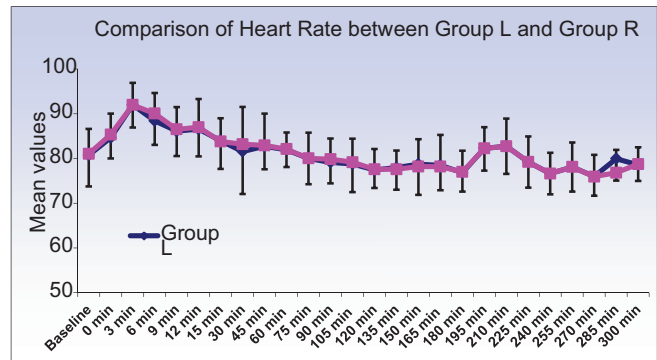
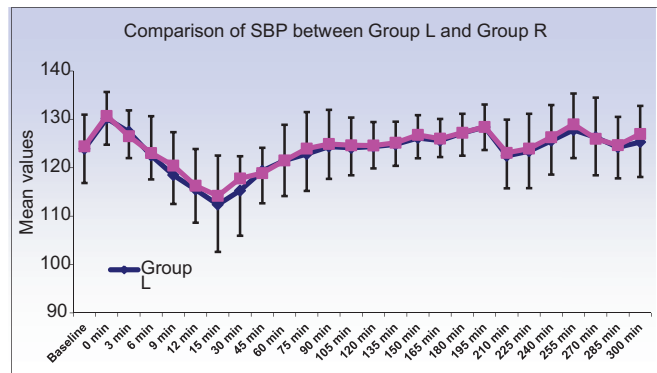
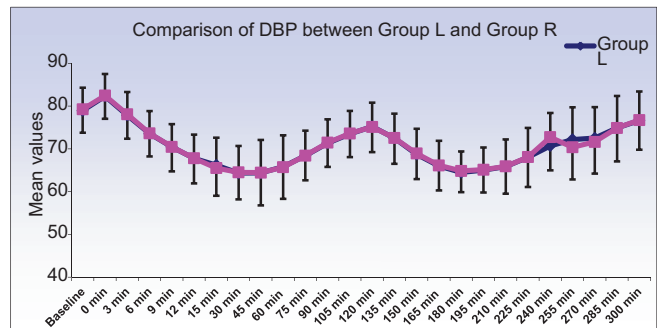
SBP	Mean±SD (n=45)		P value
	Group L	Group R	
Baseline (min)	123.91±7.08	124.42±6.54	0.723 ( $P>0.05$ )
0	130.18±5.41	130.71±4.94	0.627 ( $P>0.05$ )
3	127.44±5.44	126.53±5.32	0.424 ( $P>0.05$ )
6	122.53±4.93	123.04±7.60	0.706 ( $P>0.05$ )
9	118.49±5.99	120.44±6.92	0.155 ( $P>0.05$ )
12	115.51±6.86	116.29±7.59	0.611 ( $P>0.05$ )
15	112.38±9.77	114.20±8.32	0.344 ( $P>0.05$ )
30	115.27±9.33	117.80±4.58	0.105 ( $P>0.05$ )
45	119.36±6.72	118.89±5.25	0.714 ( $P>0.05$ )
60	121.51±7.36	121.51±7.36	1.000 ( $P>0.05$ )
75	122.84±7.63	123.96±7.56	0.489 ( $P>0.05$ )
90	124.38±6.68	124.91±7.04	0.713 ( $P>0.05$ )
105	124.11±5.66	124.64±5.72	0.658 ( $P>0.05$ )
120	124.38±4.51	124.60±4.83	0.822 ( $P>0.05$ )
135	124.82±4.41	125.16±4.37	0.720 ( $P>0.05$ )
150	126.16±4.19	126.80±4.08	0.462 ( $P>0.05$ )
165	125.60±3.38	126.02±4.07	0.594 ( $P>0.05$ )
180	127.16±4.68	127.24±3.91	0.922 ( $P>0.05$ )
195	128.40±4.75	128.44±4.62	0.964 ( $P>0.05$ )
210	122.47±6.74	123.09±6.87	0.666 ( $P>0.05$ )
225	123.42±7.65	123.96±7.18	0.734 ( $P>0.05$ )
240	125.58±6.99	126.31±6.65	0.611 ( $P>0.05$ )
255	127.80±5.80	128.98±6.35	0.361 ( $P>0.05$ )
270	126.29±7.85	126.84±8.49	0.867 ( $P>0.05$ )
285	124.24±6.44	124.67±5.84	0.745 ( $P>0.05$ )
300	125.31±7.21	126.98±5.80	0.230 ( $P>0.05$ )

SD: Standard deviation, SBP: Systolic blood pressure

**Table 6: Variation in DBP (mmHg)**

DBP	Mean±SD (n=45)		P value
	Group L	Group R	
Baseline (min)	78.93±5.36	78.63±5.45	0.876 ( $P>0.05$ )
0	82.29±5.21	82.44±5.42	0.890 ( $P>0.05$ )
3	77.82±5.47	78.07±5.69	0.836 ( $P>0.05$ )
6	73.56±5.25	73.64±5.41	0.937 ( $P>0.05$ )
9	70.44±5.34	70.47±5.73	0.985 ( $P>0.05$ )
12	67.80±5.51	67.80±5.88	1.000 ( $P>0.05$ )
15	66.18±6.42	65.51±6.47	0.625 ( $P>0.05$ )
30	64.33±6.35	64.51±6.31	0.894 ( $P>0.05$ )
45	64.36±7.71	64.44±7.66	0.956 ( $P>0.05$ )
60	65.80±7.38	65.71±7.40	0.955 ( $P>0.05$ )
75	68.40±5.83	68.42±5.78	0.986 ( $P>0.05$ )
90	71.33±5.56	71.44±5.65	0.925 ( $P>0.05$ )
105	73.49±5.36	73.60±5.55	0.923 ( $P>0.05$ )
120	75.22±5.57	75.13±5.90	0.942 ( $P>0.05$ )
135	72.49±5.73	72.53±6.01	0.971 ( $P>0.05$ )
150	68.69±6.01	68.91±6.00	0.861 ( $P>0.05$ )
165	65.98±5.88	66.13±5.84	0.900 ( $P>0.05$ )
180	64.49±4.89	64.84±4.95	0.881 ( $P>0.05$ )
195	65.02±5.31	65.13±5.34	0.921 ( $P>0.05$ )
210	65.87±6.33	65.91±6.41	0.974 ( $P>0.05$ )
225	68.04±6.84	68.07±7.00	0.988 ( $P>0.05$ )
240	70.69±7.68	70.73±7.74	0.978 ( $P>0.05$ )
255	72.18±7.54	72.36±7.51	0.911 ( $P>0.05$ )
270	72.51±7.22	72.62±7.40	0.943 ( $P>0.05$ )
285	74.87±7.47	74.87±7.80	1.000 ( $P>0.05$ )
300	76.62±6.77	76.73±6.92	0.939 ( $P>0.05$ )

SD: Standard deviation, DBP: Diastolic blood pressure

**Figure 4: Comparison of heart rate between Group L and Group R****Figure 5: Comparison of systolic blood pressure between Group L and Group R****Figure 6: Comparison of diastolic blood pressure between Group L and Group R**

As indicated by mean and  $P$  values in Table 6, the diastolic BP of both the drugs is comparable at different time intervals. After the initiation of epidural anesthesia, BP started falling for both the drug groups for the first 30 min. The difference between them is statistically insignificant (Figure 6).

## DISCUSSION

The property of isomerism occurs when two or more compounds have the same molecular composition, but a different structure which often results in different

properties. There are two types of isomerism - structural and stereoisomerism.<sup>6</sup>

Stereoisomerism describes those compounds which have the same molecular formula and chemical structure, but the atoms are orientated in a different direction. There are two isomers, each a mirror image of the other, called enantiomers. They are also called optical isomers because they rotate the plane of polarized light either to the right referred to as +, dextro, d or D isomer, or to the left referred to as -, laevo (levo), l or L isomer. More recently, this classification has been replaced by the R-/S- notation, which describes the arrangement of the molecules around the chiral center (R is for rectus the Latin for right, and S for sinister, left). The R enantiomer rotates light to the right and the S enantiomer to the left. As with other isomers, they can have different properties.

The molecule of bupivacaine, a long-acting local anesthetic, has an asymmetric carbon atom. For this reason, with this asymmetric carbon as a chiral center, bupivacaine exhibits this phenomenon. In the commercial presentation of this local anesthetic, there is a 50:50 proportion: Levobupivacaine, L (-) isomer, and dextro bupivacaine D (+) isomer. This preparation which contains both enantiomers is called a racemic mixture.<sup>7,8</sup>

Local anesthetics inhibit the sodium channels on neural membranes. Therefore, they cause a loss of conduction on neural structure and a loss of sensorial innervation. Systemic toxicity results from excessive blood levels of local anesthetics in central nerve system and cardiovascular system when they are injected IV by mistake. They cause directly negative inotropy, myocardial conduction abnormalities, and arrhythmias. Arrhythmogenic effects of these drugs are related with repolarization of potassium, sodium, and calcium channels. Consequently with this mechanism, cardiac impulse conduction slows down, QRS complex widens, PR distance gets longer, atrioventricular block occurs, and fatal ventricular arrhythmias such as ventricular tachycardia or ventricular fibrillation occur.

Levobupivacaine and ropivacaine, two new long-acting local anesthetics, have been developed as an alternative to bupivacaine, after the evidence of its severe toxicity. Both of these agents are pure left isomers and, due to their three-dimensional structure, seem to have less toxic effects on the central nervous system and the cardiovascular system. Many clinical studies have investigated their toxicology and clinical profiles: Theoretically and experimentally, some differences have been observed, but the effects of these properties on clinical practice have not been shown. By examining randomized, controlled trials that have compared these three local agents, this review supports the evidence that both levobupivacaine and ropivacaine have a clinical profile

similar to that of racemic bupivacaine and that the minimal differences reported between the three anesthetics are mainly related to the slightly different anesthetic potency, with racemic bupivacaine > levobupivacaine > ropivacaine. However, the reduced toxic potential of the two pure left isomers suggests their use in the clinical situations in which the risk of systemic toxicity related to either overdosing or unintended intravascular injection is high such as during epidural or peripheral nerve blocks.<sup>5,6</sup>

Age, sex, psychological, or pharmacological factors effect the post-operative pain scores. The type of surgery plays also an important role. The pain therapy after abdominal and thoracic surgeries is adequately successful using epidural patient-controlled analgesia. There are several agents in this area but on the other side, the hemodynamic and cardiac side effects restrict their use. Bupivacaine is a long-acting amide and widely used as a local anesthetic for epidural anesthesia. It has a beneficial ratio of sensory to motor block in epidural anesthesia. This agent provides also high-quality analgesia in the post-operative period. However, bupivacaine-induced cardiotoxicity in patients following accidental intravascular injection limits its use. It has also potential for neurotoxicity. Sudden cardiac arrests and a high proportion of maternal deaths were reported. Therefore, a local anesthetic which has similar effects as bupivacaine but has less side effects on cardiovascular system was needed. Bupivacaine is used as a racemic mixture of equimolar amounts of R(+)- and S(-)- bupivacaine. R(+)- bupivacaine is found more toxic to both the central nervous system and the cardiovascular system. Levobupivacaine (S-1-butyl-2-piperidylformo-2', 6'-xylidide hydrochloride) is the pure S(-)-enantiomer of racemic bupivacaine. Preclinical animal and volunteer studies showed less cardiac toxicity than bupivacaine. It seems to be an alternative local anesthetic agent in epidural anesthesia.<sup>9</sup>

About 0.5% levobupivacaine and 0.75% ropivacaine both have nearly equal onset and duration of the sensory block. Both the drugs had sensory onset below 10 min. The sensory regression of both the drugs is around 190 min. The difference between their sensory onset and regression time of the two drugs are statistically insignificant. Both the drugs are equianalgesic, and although levobupivacaine was found to have a little longer duration of analgesia, the difference in time was statistically insignificant. So, both the newer local anesthetic drugs are equianalgesic and show stable cardiovascular profiles, which are effective and potent enough to carry out any infraumbilical surgeries.<sup>10</sup>

## CONCLUSION

Hemodynamically, both the drug groups showed comparable and stable results. None of the patients needed any intraoperative analgesic top ups, and HR, MAP, SpO<sub>2</sub>

in both the groups were stable. Few patients whose SBP dipped below 90 mmHg, they were treated with injection ephedrine and injection atropine 0.6 mg was given whose HR fell below 50 bpm. Oxygen saturation was comparable in both the groups, and no incidence of hypoxemia was observed during the study.

From the above-mentioned observations, we conclude that both 0.5% levobupivacaine and 0.75% ropivacaine can be successfully used in lower limb surgeries, and both the drugs in their respective concentrations are equally potent. The side effects are minimal in both the drug groups and both the drugs exhibited stable and comparable hemodynamic profile. While ropivacaine might have an edge over levobupivacaine as previously various animal and human volunteer studies have shown that ropivacaine is potentially less toxic than levobupivacaine.

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# Submucosal Diathermy for Nasal Obstruction: A Case Study of 30 Cases

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## Abstract

**Introduction:** Most common etiology for nasal obstruction is hypertrophy of the inferior turbinates due to allergic rhinitis or vasomotor rhinitis.

**Objectives:** To compare the pre-operative and post-operative subjective, objective parameters, and post-operative complications of 30 patients with nasal obstruction due to inferior turbinate hypertrophy following submucosal diathermy (SMD).

**Materials and Methods:** A prospective observational study involving 30 patients with nasal obstruction due to inferior turbinate hypertrophy was done at Sree Gokulam Medical College, TVM from January 2014 to June 2015. Patients were evaluated preoperatively and postoperatively based on subjective and objective parameters. Post-operative evaluation was done at day 1, 1 week, 1 month, and 3 months based on subjective and objective parameters and post-operative complications.

**Results:** Snoring among the study population decreased from 23.3% to 13.3% at the end of 1 month and was further reduced 6.7% at the end of 3 months. Feeling of nasal obstruction, present in all patients was reduced to 43.3%, 33.3%, and 20% at the end of 1 week, 1 month, and 3 months postoperatively. Among pre-operative objective parameters, cold spatula test that was showing decreased fogging for all patients initially showed increased fogging in 66.7%, 76.7%, and 86.7% at the end of 1 week, 1 month, and 3 months postoperatively. Anterior rhinoscopy showing large turbinate in all patients preoperatively and showed a reduction in turbinate size in 63.3%, 73.3%, and 83.3% at the end of 1 week, 1 month, and 3 months, respectively. Radiological evidence of enlarged inferior turbinate present in all patients was reduced to 16.7% at the end of 3 months. The occurrence of post-operative reactionary hemorrhage on day 1 was 10%. Nasal crust formation was not seen in any of the patients. Vestibular skin burn was observed in 3.3% of patients. None of the patients had nasal pain. Remote sequelae, such as synechiae and atrophic rhinitis, were not reported in any of the patients during the assessment period.

**Conclusion:** SMD is an effective, safer, and less invasive technique in the management of inferior turbinate hypertrophy with less bleeding, pain, and crusting.

**Key words:** Inferior turbinate hypertrophy, Nasal obstruction, Submucosal diathermy

## INTRODUCTION

Nasal obstruction is one of the common presenting complaints to an ENT OPD.<sup>1</sup> Major etiologies include deviated septum, nasal polyposis, hypertrophied inferior turbinate, vasomotor, or perennial rhinitis. Out of which inferior turbinate hypertrophy is a common cause,

which may sometimes respond to medical management by topical decongestants. Physiological functions of inferior turbinate include resistor function, diffusor, and protective function. Disorders affecting inferior turbinate include compensatory hypertrophy, protrusion of the os turbinate, hyperplasia of the end of the turbinate.<sup>2</sup> Severe cases of inferior turbinate hypertrophy do not respond to medical treatment and requires surgery. Multiple surgical techniques have been made available for the management of the same.<sup>3</sup> Some of them are turbinectomy, laser cautery, radioablation, turbinoplasty, cryosurgery, electrocautery, submucosal diathermy (SMD), and submucosal resection with or without lateral displacement. Surgeons are still under dispute regarding which surgical technique serves the best in treating the hypertrophy.<sup>1</sup> This study aims to

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compare the pre-operative and post-operative subjective, objective parameters, and post-operative complications following SMD.

## MATERIALS AND METHODS

A prospective observational study of 30 patients who attended the ENT OPD with complaints of nasal obstruction due to inferior turbinate hypertrophy was done in the Department of ENT Sree Gokulam Medical College from January 2014 to June 2015.

A thorough history and detailed examination of ear nose and throat were conducted by anterior rhinoscopy, DNE, and radiologically by sinus X-ray. Routine pre-operative investigations were done for every patient.

Size of inferior turbinate was classified into three grades:<sup>4</sup>  
Grade 1: Normal size inferior turbinate, not atrophic without any nasal obstruction

Grade 2: Moderate sized inferior turbinate, touching the septum with nasal obstruction, responding to local decongestant

Grade 3: Large mulberry turbinate touching the septum with nasal obstruction, not responding to local decongestant.

The procedure was done for both Grades 2 and 3 patients.

Pre-operative subjective parameters assessed were the presence of snoring and feeling of nasal obstruction. Pre-operative objective parameters assessed were cold spatula test showing a decreased fogging, anterior rhinoscopy showing enlarged inferior turbinate and X-ray paranasal sinuses (PNS) showing large sized turbinate.

The procedure was done under general anesthesia, with the patient in reclining position and the head end of the table raised. Nasal cavity was packed with two cotton pledgets soaked in oxymetazoline and adrenaline. After decongestion, the diathermy needle was inserted into the anterior end of the inferior turbinate, which was advanced submucosally till the posterior end of the inferior turbinate was reached. The needle was then withdrawn slightly, and a current of 50 joules was applied in a triangular fashion at 3 points (superior, medial, and inferior).

Following the procedure, anterior nasal packing was done with antibiotic ointment (soframycin+metrogyl). All patients were given parenteral antibiotics, analgesics, and nasal drops for 7-10 days postoperatively.

Postoperatively, subjective parameters such as persistence of snoring and relief of nasal obstruction were assessed.

Post-operative objective parameters that were assessed include cold spatula test showing increased fogging, anterior rhinoscopy showing reduced turbinate size, and X-ray PNS showing persistent large sized turbinate. In addition, the occurrence of post-operative complications such as reactionary hemorrhage, nasal crust formation, vestibular skin burn, headache and nasal pain, synechiae formation, and atrophic rhinitis were also assessed. Post-operative assessment of persistent snoring was done at 1 month and 3 months. Nasal obstruction was evaluated at 1 week, 1 month, and 3 months postoperatively. Cold spatula test and anterior rhinoscopy were done at 1 week, 1 month, and 3 months postoperatively. X-ray PNS for the evaluation of the persistent large sized turbinate was done postoperatively at the end of 3 months. Follow-up was done on day 1 for assessing reactionary hemorrhage. Nasal crust formation was evaluated at 1 week, 1 month, and 3 months postoperatively. Vestibular skin burn was assessed on day 1. Assessment of nasal pain was done on a post-operative day 1 and day 7. Synechiae formation and atrophic rhinitis were evaluated at 1 month and 3 months.

## RESULTS

Out of the 30 patients recruited for the study, 12 were males and 18 were females, with a mean age of 27.2 (Figure 1).

Preoperatively, 23.3% of patients suffered from snoring. Postoperatively, snoring was reduced to 13.3% after 1 month and by the end of 3 months, it was 6.7%. All patients complaint of nasal obstruction preoperatively. Following the procedure, the feeling of nasal obstruction was reduced to 56.7% by the end of 1 week and was further reduced to 66.7% at the end of 1 month. 80% of the patients were relived of nasal obstruction by the end of 3<sup>rd</sup> month postoperatively (Figure 2).

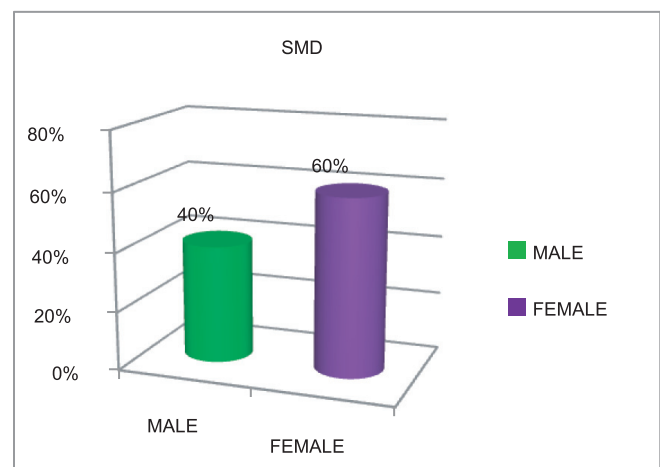


Figure 1: Percentage distribution of sample in group according to sex

Cold spatula test done preoperatively revealed reduced fogging in all 30 patients, whereas the test when done postsurgery showed improvement in fogging in 66.7%, 76.7%, and 86.7% patients at the end of 1 week, 1 month, and 3 months. Both anterior rhinoscopy and X-ray PNS revealed large sized turbinate in all patients when assessed preoperatively. Only 36.7%, 26.7%, and 16.7% of the patients had persistent large sized turbinate postoperatively when assessed by both anterior rhinoscopy and X-ray PNS at 1 week, 1 months, and 3 months, respectively (Figure 3).

On the first post-operative day, reactionary hemorrhage was observed in 3 (10%) patients.

Nasal crust formation evaluated at the end of 1<sup>st</sup> week demonstrated crust formation in 16.7% of patients. Follow-up at the end of 1 month revealed crust formation in 6.7% of patients. Follow-up at the end of 3<sup>rd</sup> month

demonstrated that none of the patients had crust formation (Figure 4).

Vestibular skin burns assessed on post-operative day 1 was observed only in 1 (3.3%) patient.

The nasal pain was present in 4 (13.3%) of patients on day 1. At the end of 1<sup>st</sup> week, none of the patients had the same (Figure 5).

Synechiae formation and atrophic rhinitis were evaluated at 1 month and 3 months postoperatively, and none of the patients had the same.

## DISCUSSION

Nasal obstruction is one among the most common presenting complaints of patients attending the ENT OPD. One of the most common etiologies for nasal obstruction is hypertrophy of the inferior turbinates due

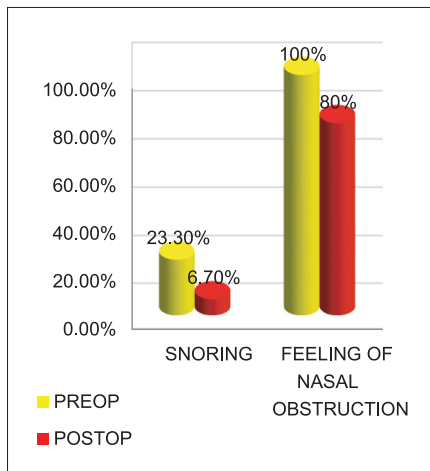


Figure 2: Pre-operative and post-operative (3<sup>rd</sup> month) incidence of snoring and feeling of nasal obstruction

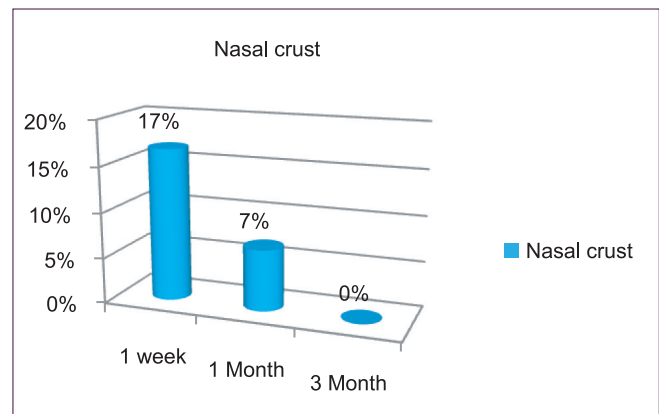


Figure 4: Incidence of nasal crust formation at various time intervals

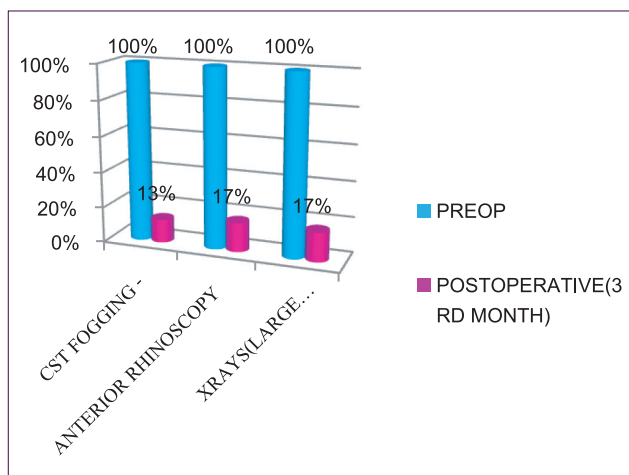


Figure 3: Pre-operative and post-operative (3<sup>rd</sup> month) assessment of objective parameters

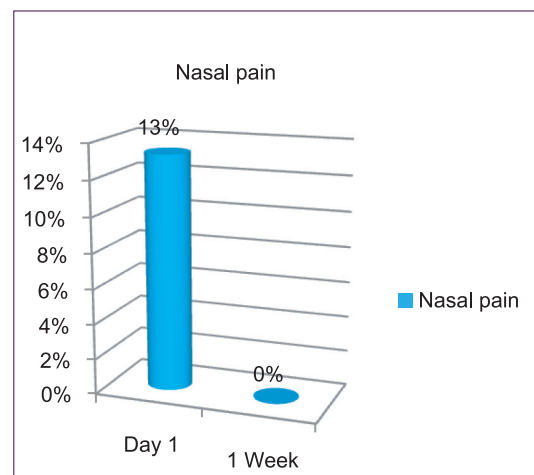


Figure 5: Incidence of nasal pain at various time intervals following submucosal diathermy

to allergic rhinitis or vasomotor rhinitis. The hypertrophy is almost always due to dilatation of the venous sinusoids resulting in swelling of the submucosal layer.<sup>5</sup> The majority of the patients responds to antihistamines or local decongestants. Occasionally, sub mucous fibrosis may render the turbinates incapable of decongestion and in such cases surgical management becomes necessary.<sup>5</sup> Even though multiple treatment options are available, there is considerable controversy over the merits of the various techniques.

This study is done to compare the pre-operative and post-operative subjective, objective parameters, and post-operative complications of 30 patients with nasal obstruction due to inferior turbinate hypertrophy following SMD. Cold spatula test, anterior rhinoscopy, and radiological investigations (X-ray PNS) were done. Rhinomanometry was not done due to lack of availability in our institute.

In a study conducted by Al-Baldawi,<sup>4</sup> in 2009, about 90% of patients had the disappearance of snoring on the side where SMD was performed. In a study conducted Anil and Mahjabeen *et al.*, in 2013,<sup>6</sup> 80% patient had the disappearance of snoring who underwent SMD. In our study, disappearance of snoring was observed in 86.7% after 1 month 93.3% of patients at the end of 3 months in those who underwent SMD.

A study done by Al-Baldawi,<sup>4</sup> in 2009, demonstrated an improvement in feeling of nasal obstruction in 82.5% of patients, who underwent SMD. In a study conducted by Luczaj and Rogowski (Polland)<sup>7</sup> demonstrated an improvement in nasal obstruction for 98% of the patients. Fradis *et al.*,<sup>8</sup> 2000 (U.S.A) demonstrated an improvement in nasal obstruction in 76% of the patients. Warwick-Brown and Marks<sup>9</sup> 1987 (U.K) demonstrated an improvement in 60% of the patients following SMD. Our study showed an improvement in the nasal airway for 80% of the patients who underwent SMD.

Improvement of fogging in cold spatula test was observed in 87.5% of patients who underwent SMD in a study conducted by Al-Baldawi<sup>4</sup> in 2009. In our study, it was observed that the improvement in fogging was 66.7%, 76.7%, and 86.7% at the end of 1 week, 1 month, and 3 months, respectively, and these results were similar to that observed in other studies.

A study done by Al-Baldawi,<sup>4</sup> 2009 (Iraq) showed a reduction in the size of the turbinates in 85% of the patients who underwent SMD. The anterior rhinoscopic examination was done postoperatively at different time intervals for assessing decrease in the size of the turbinates.

At the end 1-week, anterior rhinoscopic examination revealed reduced size turbinates in 63.3% of patients and by the end of 1<sup>st</sup> month, 73.3% of patients had reduced turbinates. The anterior rhinoscopic picture after 3 months showed reduced turbinates in 83.3% of patients who underwent SMD. Radiological examination (X-ray PNS) which was done after 3 months showed reduced 83.3% patients.

In a study conducted by Imad *et al.*,<sup>10</sup> in 2010, it was found that only 3% who underwent SMD had minimal bleeding. The studies done by Al-Baldawi<sup>4</sup> revealed that the incidence of reactionary hemorrhage was none of the patients who underwent SMD had a reactionary hemorrhage. In our study, the reactionary hemorrhage was evaluated on post-operative day 1 which was 10%.

A study conducted by Imad *et al.*,<sup>10</sup> in 2010, revealed that at the end of 2 weeks none of the patients who underwent SMD had crusting. None of the patients who underwent SMD had developed nasal crust formation according to the study by Al-Baldawi<sup>4</sup> In this study, the incidence of nasal crust formation was assessed at various time intervals. The incidence of nasal crust formation was 16.7% after 1 week which further reduced to 6.7% after 1 month. At the end of 3 months, none of the patients who underwent SMD had nasal crust formation.

According to a study conducted by Al-Baldawi,<sup>4</sup> 2009 the incidence of vestibular skin burn in patients who underwent SMD was 2.5%. In our study, the incidence of vestibular skin burn was evaluated on post-operative day 1. 3.3% of patients who underwent SMD had developed vestibular skin burn which was mild.

In a study conducted by Imad *et al.*,<sup>10</sup> in 2010, in Peshawar, 44% of patients who underwent SMD had moderate pain. In a study conducted in Iraq by Al-Baldawi,<sup>4</sup> the occurrence of nasal pain and headache was only 5% of patients who underwent SMD. Our study also assessed the incidence of a headache and nasal pain. At post-operative day 1, the incidence of nasal pain in patients was 13.3% at post-operative day 1, and none of the patients had nasal pain at the end of 1 week.

Nasal synechiae/adhesions were not observed in patients who underwent SMD in a study conducted by Al-Baldawi<sup>4</sup> in 2009. The occurrence of synechiae formation was assessed in our study at 1 month and 3 months postoperatively. None had synechiae formation at the end of 1 month and 3 months.

A study done by Al-Baldawi,<sup>4</sup> 2009 (Iraq) revealed that none of the patients who underwent SMD had atrophic rhinitis.

In our study, we also assessed the incidence of atrophic rhinitis at time intervals of 1 month and 3 months. None of the patients had the same.

## CONCLUSION

This study showed the following results:

- Improvement in airflow postoperatively 80% of the patients who underwent SMD.
- The relief from snoring postoperatively was seen 93.3% of the patients who underwent SMD.
- By the end of 3 months, there was an improvement in fogging in 86.7% of cases as seen in cold spatula test.
- The anterior rhinoscopic examination was conducted postoperatively by the end of the 3<sup>rd</sup> month showed that 83.3% of patients who underwent SMD had reduced turbinates.
- The radiological examination (X-ray PNS) taken postoperatively at 3 months revealed reduced turbinate in 83.3% patients.
- This study showed that the incidence in reactionary hemorrhage was 10%.
- Only 3.3% patients had vestibular skin burn.
- None of the patients had nasal crust formation,

headache, nasal pain synechia, and atrophic rhinitis by the end of the assessment period.

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# Can Intercostal Nerve Blockade be an Effective Alternative to Thoracic Epidural Analgesia for Acute Post-thoracotomy Pain Relief?

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## Abstract

**Introduction:** The pain that occurs the following a thoracotomy procedure, which is also known as post-thoracotomy pain, is quite commonly very severe and a major source of concern in the post-operative period. This study was designed to evaluate the effectiveness of intercostal nerve blockade as compared to thoracic epidural analgesia to alleviate acute post-thoracotomy pain.

**Materials and Methods:** A total of 60 patients undergoing elective pulmonary resection through a posterolateral thoracotomy were randomly allocated to receive either single-dose epidural analgesia using 0.2% ropivacaine (Group E,  $n = 30$ ) or temporary intercostal nerve blockade using 0.2% ropivacaine (Group I,  $n = 30$ ). Adequacy of analgesia was assessed in post-operative period using a visual analog score at 30 min interval.

**Results and Observation:** Duration of static analgesia (analgesia at rest) in Group E was  $214 \pm 10.2$  min and in Group I was  $210 \pm 8.35$  min, but the difference is statistically insignificant ( $P = 0.1019$ ). Duration of dynamic analgesia (analgesia at coughing) in Group E was  $200 \pm 17.89$  min and in Group I was  $193 \pm 16.76$  min, but the difference is statistically insignificant ( $P = 0.1233$ ).

**Conclusion:** A value of 10 ml of 0.2% ropivacaine in thoracic epidural route provides almost equal ( $P > 0.05$ ) duration of post-operative static and dynamic analgesia as compared to 20 ml of 0.2% ropivacaine in intercostal nerve blockade in post-thoracotomy patients in early post-operative period.

**Key words:** Intercostal nerve blockade, Post-thoracotomy pain, Ropivacaine, Thoracic epidural analgesia, Visual analog score

## INTRODUCTION

Post-thoracotomy pain is very severe, probably the most severe pain experienced after surgery. Acute post-thoracotomy pain is due to skin and muscle injury, retraction, resection, or fracture of ribs, dislocation of costovertebral and costochondral joints, injury of intercostal nerves and further irritation of the pleura by chest tubes.<sup>1</sup> Treatment of acute post-thoracotomy pain is particularly

important not only to keep the patient comfortable but also to minimize pulmonary complications.<sup>1</sup> Suboptimal pain relief not only will lead to increased patient suffering but also to increased morbidity after operation. In particular, poor cough and clearance of secretions may lead to atelectasis and pneumonia, which additionally prolongs immobility, and may lead to complications such as deep vein thrombosis and pulmonary embolism.<sup>1</sup> Poorly treated acute post-thoracotomy pain may lead to chronic post-thoracotomy pain syndrome.<sup>2</sup>

Many methods of acute post-thoracotomy pain management have been tried with varied success, for example Intercostal nerve block, intrapleural analgesia, cry analgesia, lumbar epidural, thoracic epidural, paravertebral block, intravenous (IV) narcotics, intrathecal or epidural narcotics, non-steroidal anti-inflammatory drugs (NSAIDs), and transcutaneous nerve stimulation.<sup>3,4</sup>

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In many centers, epidural anesthesia has emerged as the gold standard for pain control. However, this method is not suitable for all patients specially in those with altered coagulation profile and may be associated with potential risks such as dural perforation, bleeding, infection, hypotension, and urinary retention.<sup>5-7</sup> There are also other potential problematic issues with epidural pain control, such as delaying the start of an operative procedure, technical failures of 13-15%<sup>8,9</sup> and the costs of post-operative pain management by a separate pain team. Another method of pain control, which has gained popularity in some centers, is the use of intercostal nerve blockade.<sup>10,11</sup> As with epidural anesthesia, this method allows local administration of drugs to the pain causing anatomic region, but potentially with lower risks and discomfort to the patient. There may also be fewer delays in surgery, and the technical failure rate should be lower since it is placed under direct vision. Moreover, it is much more cost-effective than thoracic epidural analgesia. The present study is designed to compare visual analog scale (VAS) in patients receiving thoracic epidural analgesia versus patients receiving intercostal nerve blockade for acute post-thoracotomy pain relief.

## MATERIALS AND METHODS

After obtaining Institutional ethical committee clearance, this prospective, randomized, single-blinded, single hospital study included 60 cases (69 cases enrolled for the study, of which 60 cases completed the study as per protocol analysis) of both sexes, aged 18 years or more, posted for elective thoracotomy. An informed consent was obtained from each participating patient. The patients were randomly divided into Group E and Group I of 30 patients each. Randomization was by sequential allocation of eligible patients to computer generated random numbers. An anesthesiologist who was not involved in the study performed the analysis of variables and recording of data. The blinding was opened only after the clinical phase was over.

The patients were kept nil orally overnight before surgery. Diazepam 0.1 mg/kg and ranitidine 3 mg/kg were given orally on the night before surgery. On arrival to the operation theatre, an IV line was secured with 18 G cannula and lactated ringers solution was started. All anesthetic equipment were checked. Standard American Society of Anesthesiologists monitors attached to the patient and invasive blood pressure monitoring established and samples taken for arterial blood gases, serum electrolytes, etc. In all patients of Group E, a 20 G epidural catheter through 18 G Tuohy needle was placed in sitting position under aseptic and antiseptic precautions at a mid-thoracic level (T4-T7) before the induction of general anesthesia. Patients of both

the Group E and I were pre-medicated with glycopyrrolate (0.2 mg) IV, midazolam (1-2 mg) IV, palonosetron (0.075 mg) IV, and fentanyl (1 mcg/kg) IV. After 3 min of pre-oxygenation, patients were induced with propofol (2-3 mg/kg) IV. Neuromuscular block was achieved with vecuronium bromide (0.1 mg/kg) IV, followed by an intubation with an adequate size endotracheal tube. Anesthesia was maintained with isoflurane in oxygen and nitrous oxide (4:2) along with divided doses of vecuronium bromide. Intraoperative analgesia was provided by paracetamol 1000 mg IV infused over 15 min and fentanyl citrate infused at a rate of 0.5 mcg/Kg/h.

Unilateral thoracotomy was performed through the fifth or sixth intercostal space via a poster lateral incision. Toward the end of surgery, at the time of rib approximation, patients of Group E ( $n = 30$ ) received a 10 ml bolus of 0.2% ropivacaine through the epidural catheter and patients of Group I ( $n = 30$ ) received 20 ml of 0.2% ropivacaine to block 5 intercostal nerves (4 ml per nerve) near the angle of ribs; 1 nerve at the level, 2 nerves above and 2 below the level of thoracotomy using a 22 G needle. The intercostal nerve block was given by the operating surgeon. The infusion of fentanyl was terminated before the initiation of epidural analgesia in all patients of Group E and before the institution of the intercostal nerve block in all patients of Group I. After skin closure, the neuromuscular blockade was reversed with a combination of neostigmine and glycopyrrolate and the patient was extubated and shifted to intensive care unit for 24 h. Analgesia was assessed every 30 min using a (VAS; 0 mm = no pain and 100 mm = worst pain imaginable) both at rest and during coughing minutes till 1 h after rescue analgesics were started. Duration of post-operative analgesia was deemed from the time of extubation till VAS score became  $\geq 4$ . Rescue analgesics as per departmental protocol (fentanyl patch [25 mcg/h], and injection diclofenac 75 mg IV) were started once the VAS  $> 4$  in both groups and the timing of administration of this medication was recorded. No medication was given through the epidural catheter after the initial bolus dose of 10 ml ropivacaine 0.2% and catheter were removed after 24 h.

The data were collected by an independent anesthetist in the post-operative care unit blinded for the technique used for each patient.

## Statistical Analysis of Data

The data were entered into MS Excel spreadsheets and statistical analyses were done by using "GraphPad InStat - Version 3" software. Data were presented as a mean  $\pm$  standard deviation for demographic data and duration of analgesia, and compared by "unpaired Student's *t*-test." A  $P < 0.5$  was considered as statistically significant.

## RESULTS AND OBSERVATION

### Demographic Parameters

Demographic data of 60 patients are compared in Table 1. There is no statistically significant difference between the groups in terms of age, weight, height, gender distribution, and duration of surgery.

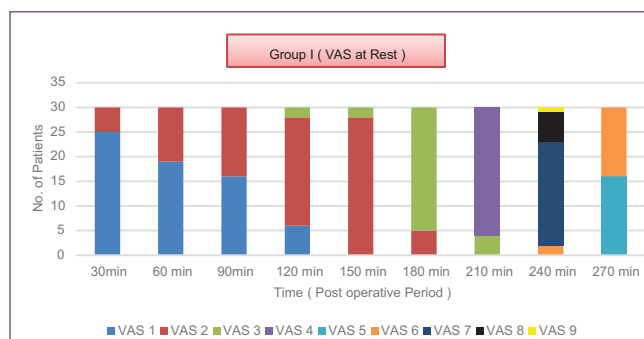
### VAS Score at Rest

As shown in Figures 1 and 2, most of the patients in both the groups attained VAS score (at rest) 4 at 210 min. As shown in Figure 3, both the groups showed almost similar variation in median VAS score at rest in post-operative period. Median VAS score at rest became 4 and 7 at 210 and 240 min, respectively. As soon as patients feel pain (VAS score  $\geq 4$ ) rescue analgesics were started, so the median VAS score came down to 5 at 270 min. As shown in Figure 4, duration of static analgesia (analgesia at rest) in Group E was  $214 \pm 10.2$  min and in Group I was  $210 \pm 8.35$  min, but the difference is statistically insignificant ( $P = 0.1019$ ).

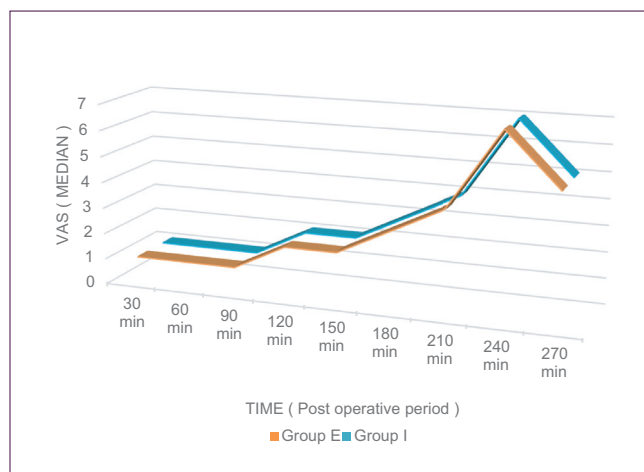
### VAS Score at Coughing

As shown in Figures 5 and 6, most of the patients in both the groups attained VAS score (at coughing) 4 at 210 min and few patients at 180 min. As shown in Figure 7, both

the groups showed almost similar variation in median VAS score at coughing in post-operative period. Median VAS score at coughing became 4 and 8 at 210 and 240 min, respectively. As soon as patients feel pain (VAS score  $\geq 4$ ) rescue analgesics were started, so the median VAS score at coughing came down to 7 at 270 min. As shown in Figure 8, duration of dynamic analgesia (analgesia at



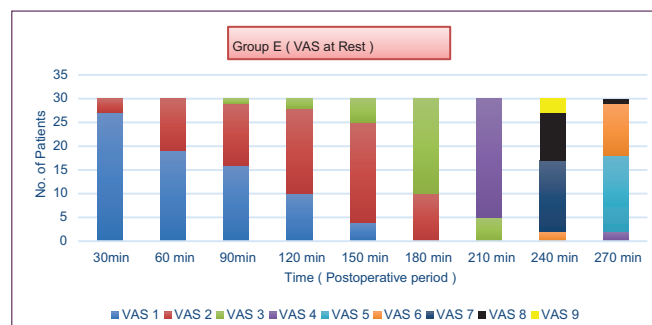
**Figure 2: Distribution of patients of Group I according to visual analog scale score at rest at 30 min interval in post-operative period**



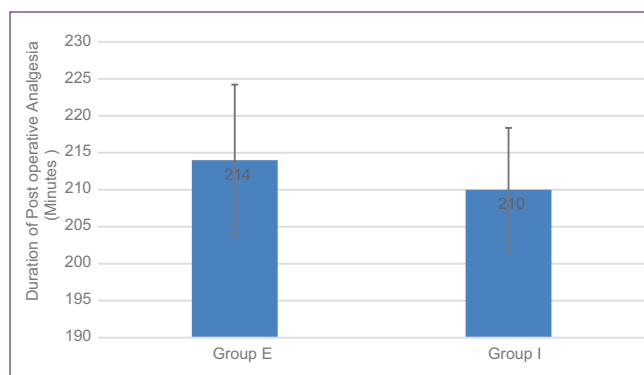
**Figure 3: Comparison of variation of median visual analog scale score at rest between Group E and I at 30 min interval in post-operative period**

Demographic parameters	Group E	Group I	P value
Age (years)	37.57±12.78	32.47±10.93	0.1021
Weight (kg)	45±7.62	42.1±8.53	0.1702
Height (cm)	145.27±10.1	140.3±10.65	0.0687
Sex (male:female)	20:10	23:07	
ASA physical status I/II (n)	25:5	24:6	
Duration of surgery (min)	95.5±25.3	104±16.1	0.1260
Surgical procedures			
Lobectomy	2	4	
Decortication	19	17	
Pericardiectomy	3	2	
Closed mitral valvotomy	3	4	
Tumor excision	2	1	
Foreign body removal	1	2	

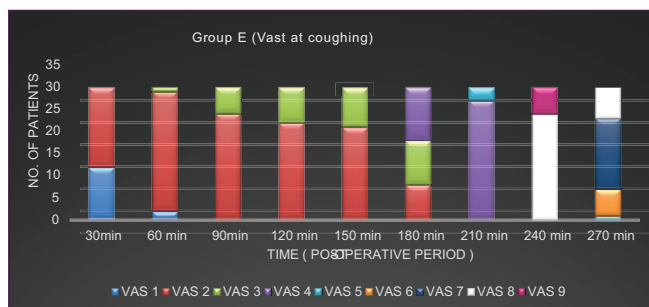
ASA: American Society of Anesthesiologists



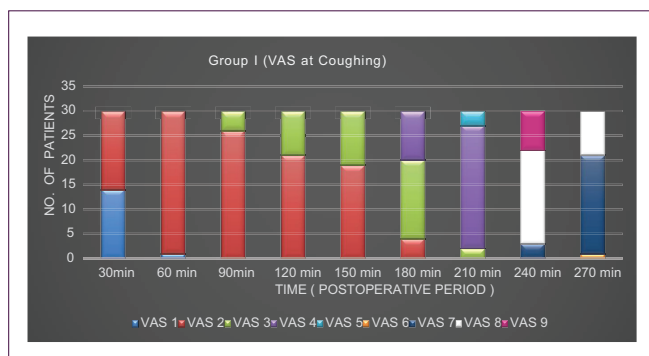
**Figure 1: Distribution of patients of Group E according to visual analog scale score at rest at 30 min interval in post-operative period**



**Figure 4: Comparison of duration of static analgesia between Group E and I in post-operative period**



**Figure 5: Distribution of patients of Group E according to visual analog scale score at coughing at 30 min interval in post-operative period**



**Figure 6: Distribution of patients of Group I according to visual analog scale score at coughing at 30 min interval in post-operative period**

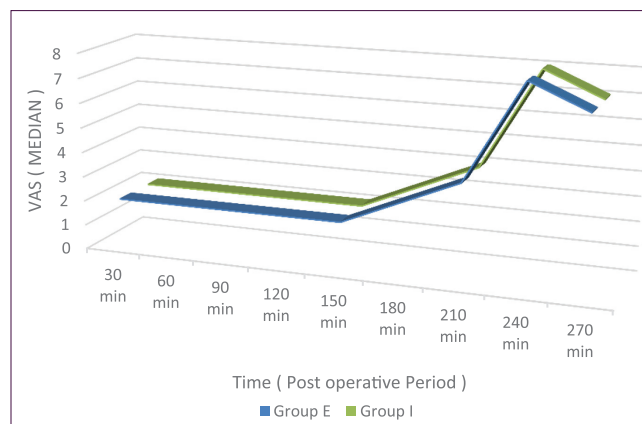
coughing) in Group E was  $200 \pm 17.89$  min and in Group I was  $193 \pm 16.76$  min, but the difference is statistically insignificant ( $P = 0.1233$ ).

The *post hoc* power analysis of our study revealed a power of 90% with an  $\alpha$  of 0.05 (two-tailed) and a  $\beta$  of 0.10.

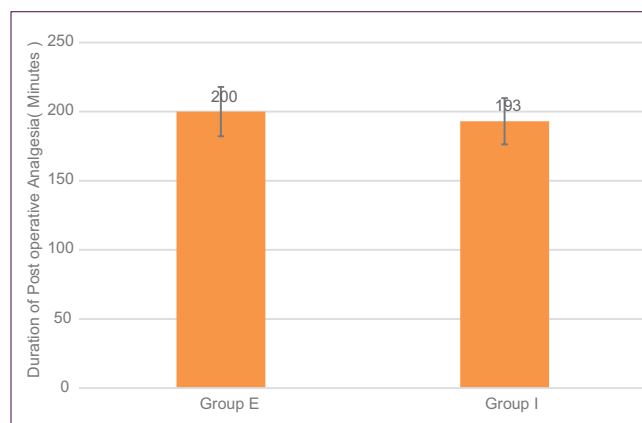
## DISCUSSION

This study was designed to evaluate the effectiveness of intercostal nerve blockade as compared to thoracic epidural analgesia to alleviate acute post-thoracotomy pain. To make the analgesic efficacy comparable between Group E and Group I, single dose thoracic epidural analgesia was performed in Group E and single dose intercostal block was performed in Group I. On the basis of animal and volunteer studies, it was concluded that ropivacaine seems to be less neurotoxic and cardiotoxic than bupivacaine.<sup>12</sup> Epidural ropivacaine causes less motor block than bupivacaine.<sup>13,14</sup> Hence, ropivacaine was selected for the study.

About 0.2% ropivacaine was found adequate for thoracic epidural analgesia and intercostal nerve block for post-



**Figure 7: Comparison of variation of Median VAS score at coughing between Group E and I at 30 minutes interval in postoperative period**



**Figure 8: Comparison of duration of dynamic analgesia between Group E and I in post-operative period**

thoracotomy pain relief.<sup>15,16</sup> 0.8 ml/thoracic segment of local anesthetic solution is required for thoracic epidural analgesia and anesthesia.<sup>17,18</sup> Hence, we used 10 ml of local anesthetic solution to cover thoracic dermatomes. For each intercostal nerve blockade, we used 4 ml local anesthetic solution,<sup>19</sup> to block 5 intercostal nerve, i.e., 1 nerve at the level of incision, 2 above it and 2 below it.<sup>20</sup> Although epidural opioid improves the duration and quality of block when used as an adjuvant with a local anesthetic, it carries the risk of respiratory depression, sedation, pruritus, nausea, urinary retention. This study did not use epidural opioids, which could have led to alteration of pain scores seen in previous reports.<sup>21,22</sup>

In our study, we found that 10 ml of 0.2% ropivacaine in thoracic epidural (epidural catheter placed between T4 and T7) provide duration of analgesia of  $214 \pm 10.2$  min while the patient is at rest (static analgesia) and of  $200 \pm 17.89$  min while the patient coughs (dynamic analgesia) in immediate post-operative period in post-thoracotomy patients. Studies



show that 0.2-0.75% ropivacaine provides 180-350 min of analgesia when used in epidural route with an onset within 15-20 min.<sup>23,24</sup>

In our study, we found that 20 ml 0.2% ropivacaine in provided  $210 \pm 8.35$  min of static analgesia and  $193 \pm 16.76$  min dynamic analgesia in immediate post-operative period in post-thoracotomy patients when used for intercostal nerve blockade of 5 nerves (4 ml/nerve), i.e., 1 at the site of incision, 2 above it and 2 below it. Studies show that 0.2-0.5% ropivacaine provides 240-420 min of analgesia when used for peripheral nerve blocks with an onset within 5-20 min.<sup>23,24</sup>

About 10 ml of 0.2% ropivacaine in thoracic epidural route provides almost equal ( $P > 0.05$ ) duration of post-operative static and dynamic analgesia as compared to 20 ml of 0.2% ropivacaine in intercostal nerve blockade in post-thoracotomy patients.

Till now no previous study till has compared single dose thoracic epidural analgesia with single dose intercostal nerve blockade for acute post-thoracotomy pain relief.<sup>21,25-35</sup>

Previous studies mostly compared continuous thoracic epidural analgesia with either single dose intercostal nerve blockade<sup>25-34</sup> or continuous intercostal block.<sup>21,35</sup>

Asantila *et al.*,<sup>25</sup> compared five methods for post-thoracotomy pain treatment. In their study continuous extradural local anesthetic block seemed to be somewhat better than a single intrathoracic intercostal block, but the difference was not statistically significant. Sabanathan *et al.*,<sup>36</sup> demonstrated in a prospective double-blind trial that continuous extrapleural intercostal nerve block with bupivacaine provided significantly better pain relief and pulmonary function after thoracotomy. Their results are difficult to compare with ours because of differences in methodology.

Most of the previous studies found continuous thoracic epidural analgesia superior to single dose intercostal nerve blockade for acute post-thoracotomy pain relief.<sup>25,28-34,35</sup>

Few studies concluded intercostal nerve blockade to be more or as effective as thoracic epidural analgesia for post-thoracotomy pain management during early post-operative period.<sup>21,26,27</sup>

Perttunen *et al.*,<sup>26</sup> found Intercostal nerve block to be more effective than epidural analgesia to decrease dynamic pain in the early post-operative period following thoracotomy.

Sanjay *et al.*,<sup>29</sup> compared thoracic epidural analgesia with intercostal nerve block for acute post-thoracotomy pain relief. They found that pain scores were similar in both the groups for the first 4 h after surgery. Thereafter, the pain scores were significantly higher ( $P < 0.05$ ) in intercostal group as compared to thoracic epidural group for the remainder of the observation period. The minor differences in outcome between our study and this study are probably due to difference in local anesthetic used and methodology. They used 0.25% bupivacaine and we used 0.2% ropivacaine. They used VAS and observer verbal rating score at 1 h interval, and we used VAS at 30 min interval. They used continuous thoracic epidural analgesia, but we used single dose thoracic epidural analgesia.

Fentanyl patch (25 mcg/h) was applied and injection diclofenac (75 mg/1 ml) were started once the VAS  $> 4$  in both groups, could not provide same quality of analgesia as provided either by thoracic epidural analgesia or by intercostal nerve block alone, as evident by median VAS of 5 at rest at 270 min and 7 at coughing at 270 min in both the groups, i.e., 1 h after the rescue analgesic started.

As shown in Table 2, incidence of ipsilateral shoulder tip pain is same in both the groups, i.e. 3/30 or 10%. Previous studies have reported incidence of ipsilateral shoulder tip pain following thoracotomy to be 31-85%.<sup>37-43</sup> The low incidence of ipsilateral shoulder tip in our study is probably due to only 4½ h of post-operative observation, which is far less in comparison to several days of post-operative observation in previous studies. 10% incidence of urinary retention was seen in Group E, but no such case reported in Group I.

Limitation of the study was that we did not investigate about pulmonary function test of the patients in post-operative period.

## CONCLUSION

It is of utmost importance to reduce the incidence of pain following thoracotomy. Both techniques studied

**Table 2: Comparison of complications in Group E and Group I in post-operative period**

Complications	Group E	Group I
Hypotension	1	0
Respiratory depression	0	0
Bradycardia	1	0
Ipsilateral shoulder tip pain	3	3
Urinary retention	3	0
Local anesthetic systemic toxicity	0	0

by us provide equal duration and quality analgesia in the immediate post-operative period and either technique is superior to parenteral analgesia by opioids and NSAIDs. Hence, it can be recommended that intercostal nerve block is an effective alternative to thoracic epidural analgesia for acute post-thoracotomy pain relief in the early post-operative period, for those patients who do not qualify for epidural analgesia due to technical failures or contraindications.

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# Study of p53 in Cervical Intraepithelial Neoplasia and Carcinoma Cervix with Clinico-pathological Correlation

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## Abstract

**Introduction:** Cervical carcinomas are the third leading cause of mortality in women in developing countries. Various clinical, pathological, and molecular-based screening methodologies have been developed for early detection of cervical carcinoma.

**Aim:** The aim of this study was to determine the frequency and pattern of p53 expression in normal, cervical intraepithelial neoplasia (CIN), and invasive carcinoma with clinico-pathological correlation.

**Methodology:** A total of 30 cases of cervical biopsy/hysterectomy specimens of carcinoma cervix and 30 cases of hysterectomy specimens for other gynecologic causes received at the Department of Pathology, from January to December 2012 were examined for gross and microscopic features. Immunohistochemistry was used to study the p53 expression in normal and neoplastic cervical epithelium. The p53 expression was correlated with various clinico-pathological prognostic parameters.

**Results:** Of the 30 cases of carcinoma cervix, 86.7% of the cases showed p53 positivity. The normal cervical epithelium in 90% cases was p53 negative and other 10% showed basal layer positivity. The single case of CIN III showed p53 positive cells in all the layers of squamous epithelium. The p53 positivity showed a statistically significant association with squamous cell carcinoma (SCC) histologic type ( $P = 0.044$ ). One of the adenosquamous carcinoma and single adenocarcinoma case were p53 negative. Large cell keratinizing subtype of SCC showed higher p53 positivity than large cell non-keratinizing with no statistical significance. The p53 positivity increased with the age, parity, clinical stage, and grade of the disease with no statistical significance.

**Conclusion:** Our study indicates that p53 may be used as an adjunct in differentiating CIN from invasive carcinoma. The p53 may be a predictor for poor prognosis as its expression increased with prognostic parameters such as histologic type, grade, and stage of carcinoma cervix.

**Key words:** Cervical carcinoma, Clinico-pathological prognostic parameters, Immunohistochemistry, p53

## INTRODUCTION

Cervical carcinoma is the second most common cancer in Indian women. Screening has been used as an effective method for identifying pre-neoplastic lesions early, thereby reducing mortality. The various strategies evaluated for the screening of cervical carcinoma are a cytological

examination of Pap smears, visual inspection techniques, and primary biomarkers such as human papillomavirus (HPV) DNA and secondary biomarkers such as p53, p50, and c-fos.<sup>1</sup> The p53 was discovered, in 1979, using serologic and virologic approaches by various authors such as Chang *et al.*, Kress *et al.*, Lane and Crawford, Linzer and Levine, Meleio *et al.*, and DeLeo *et al.* Normally, p53 is expressed in small amounts with a short half-life, and it controls the outgrowth of genetically damaged potentially neoplastic cells, either by causing pause in the cell cycle or by promoting apoptosis.<sup>2</sup> The immunohistochemical (IHC) detection of p53 protein in cervical carcinoma may be caused due to p53 mutation or abnormal accumulation of inactivated p53 protein in the absence of gene mutation.<sup>3</sup> Inactivation of p53 either by complexing with high-risk HPV E6 protein

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(in HPV-positive tumors) or mutation (in HPV-negative tumors) represents a key step in cervical carcinogenesis.<sup>4</sup>

An association between p53 protein accumulation and aggressive behavior of cervical carcinoma including a genetic propensity toward metastasis, and recurrence has been observed.<sup>5</sup> It has also been suggested that p53 increased proportionally to the grade of intraepithelial neoplasia and invasive cervical carcinoma,<sup>6</sup> thereby, played a role in the progression of the disease. Chemotherapeutic drugs may also be more effective against high-stage, p53-mutated cancers than earlier stage cancers.<sup>7</sup>

Gene sequencing, IHC analysis, and functional tests have been used to assess p53 function in human tissues. However, nuclear positivity of p53 by IHC is a rapid preliminary indicator of p53 status in tumors.

This study was undertaken to assess the presence and pattern of p53 immunoreactivity in normal cervical epithelium, intraepithelial cervical neoplasia, and invasive cervical carcinoma. We also explored the role of p53 as a potential biomarker by correlating p53 expression with clinico-pathological parameters.

## METHODOLOGY

A prospective study was conducted from January 2012 to December 2012 in the Department of Pathology of a teaching hospital after taking permission from the Institutional Ethical Committee. It included a total of 60 cases, of which, 30 cases were cervical biopsy/hysterectomy specimens with the clinical diagnosis of cervical malignancy. The other 30 were hysterectomies done for non-neoplastic gynecologic reasons used to study normal cervical epithelium. Details of presenting complaints and FIGO staging were obtained from the patient records. The specimens were adequately fixed in 10% neutral buffered formalin. Gross examination of the neoplastic specimens was done as per the protocol offered by Royal College of Pathologist dataset. The non-neoplastic hysterectomies were grossed using routine histopathology protocol. Representative bits were taken, routinely processed and paraffin embedded. Sections of 5-6  $\mu$  thickness were stained with hematoxylin and eosin. The cases were evaluated for the presence of malignancy and the histologic subtype of the tumor as per the WHO classification. The tumors were graded using modified Broder's grading,<sup>8</sup> which is based on differentiation, nuclear pleomorphism, and mitotic figures. Squamous cell carcinoma was further subtyped according to Wentz and Reagen classification into large cell non-keratinizing (LCNK), large cell keratinizing (LCK), and small cell type.<sup>8</sup>

All the 60 cases were subjected to IHC study for p53 using polymer based ready to use IHC kit of Biogenex. The p53 antibody was applied on 3- $\mu$  thick sections. Heat-induced epitope retrieval was performed using trisodium citrate buffer at pH of 6-6.2 followed by peroxidase block, incubation with primary antibody for 120 min and secondary antibody for 30 min. Diaminobenzidine was then added, and finally, slides were counterstained with hematoxylin. Positive and negative controls were used. Uterine cervix in non-neoplastic hysterectomies was used to study the expression of p53 in normal cervical epithelium.

## Method of Assessment of p53 Expression

Nuclear staining either as coarse or fine granular brown dots was considered positive. The intensity of staining and p53 grade was assessed by semi-quantitative method (Tables 1 and 2).

The p53 score was obtained as the sum of intensity and grade of p53 positivity. The correlation of p53 expression with clinico-pathological parameters was done.

## Plan of Statistical Analysis

The collected data were entered into Excel sheet and analyzed using Epi Info software. Descriptive and analytical statistics (using Chi-square test) were applied to the data. The  $P < 0.05$  was considered statistically significant.

## RESULTS

Among the 30 cases of neoplastic lesions, the patients' age ranged from 31 to 70 years with a mean age of 48.4 years. All women in our study were married and had experienced childbirth. The mean parity was 3.5 with most (53.3%) women having parity of 3-5. There was equal

**Table 1: Intensity of p53 staining<sup>9</sup>**

Staining pattern	Intensity
Absent	0
Mild	1+
Moderate	2+
Severe	3+

**Table 2: Grading of p53 staining<sup>9</sup>**

Percentage of positive tumor cells in 10 HPF	Grade
1-5	1
6-25	2
26-50	3
51-75	4
>75	5

representation of pre- and post-menopausal women in our study.

Among the 30 cases in the neoplastic group, the most common clinical presentation was abnormal bleeding (70%) followed by white discharge per vaginum (46.7%) and lower abdominal pain (20%). On clinical examination, most (21 of 30 cases; 70%) women had exophytic lesions, which bled on touch, followed by 7 cases (23.3%) of ulcerative lesions and in 2 cases (6.7%) of the unhealthy cervix with no apparent growth. Most of the cases in our study were of FIGO stage 2B (29.6%) followed by 3A (25.9%), 3B (22.2%), 2A (18.5%), and 1 (3.8%).

Among the neoplastic group of 30 cases, 29 were cervical biopsies and 1 was Wertheim's hysterectomy specimen. On microscopic evaluation, 1 case was cervical intraepithelial neoplasia (CIN) III, and other 29 cases were invasive carcinoma, of which 26 cases were squamous cell carcinoma (SCC), 2 were adenosquamous carcinoma (ADSC), and one adenocarcinoma (ADC). In our study, most (86.2%) of the tumors were of Broder's Grade II (moderately differentiated [MD]), followed by 6.9% each of Grade I (well differentiated) and Grade III (poorly differentiated). According to Wentz and Reagen classification of 26 cases of SCC, 16 cases (61.5%) were LCNK and 10 cases (38.5%) were LCK.

### Analysis of p53 Expression

Among the 30 cases with normal cervical epithelium, 27 cases (90%) were negative for p53 expression, whereas 03 cases (10%) showed positivity in only the basal layer of squamous epithelium (Figure 1). No positivity was seen in the normal endocervical epithelium. Among the 30 cases with neoplastic lesions, 26 (86.7%) cases showed p53 positivity (Table 3). In our study, 50% cases of carcinoma cervix had p53 score of 3-5, 30% had score of 6-8, and

20% had score of 0-2. In our study, 56.7% had  $\geq$  Grade 3 of p53 positivity (Table 4).

While correlating age with p53 expression, women in the 5<sup>th</sup> and 6<sup>th</sup> decades showed 100% p53 positivity as compared to 88.9% in 3<sup>rd</sup> decade and 72.7% in 4<sup>th</sup> decade. Women with high parity ( $>5$ ) showed 100% positivity with a higher p53 score as compared to women with parity of 0-2 and 3-5 (Table 4). However, the association of p53 expression with age and parity was not statistically significant. Equal p53 positivity was observed in pre- and post-menopausal women.

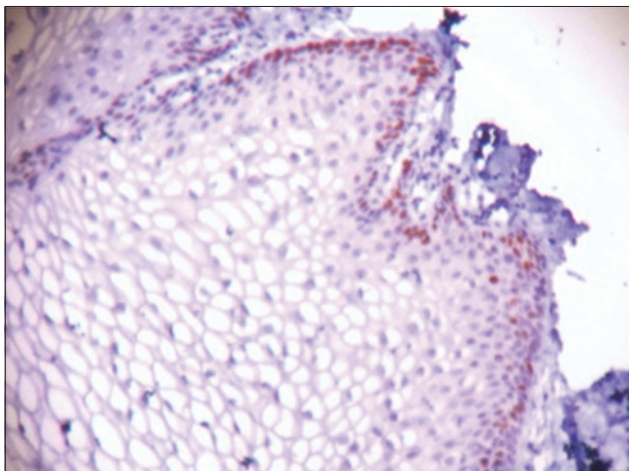
FIGO clinical stage was correlated with p53 expression in terms of positivity, p53 grade and p53 score. More number of cases in the higher clinical stage of 3A (100%) and 3B (83.3%) showed p53 positivity but were not statistically significant ( $P = 0.315$ ). While correlating p53 grade with FIGO stage, higher grade was seen in advanced stage of 3A and 3B (40% cases in each stage). However, this relation was not statistically significant ( $P = 0.315$ ). While correlating p53 score with FIGO stage, higher score (6-8)

**Table 3: Correlation of p53 expression with clinical parameters**

Clinical parameters	p53 positive n=26 (%)	p53 negative n=04 (%)	Total (n)	P value
Age (years)			30	0.542
31-40	08 (88.9)	01 (11.1)	09	
41-50	08 (72.7)	03 (27.3)	11	
51-60	07 (100)	00 (0.00)	07	
61-70	03 (100)	00 (0.00)	03	
Parity			30	0.437
0-2	09 (75.0)	03 (25.0)	12	
3-5	15 (93.7)	01 (6.30)	16	
$>5$	02 (100)	00 (0.00)	02	
FIGO stage			27	0.315
1	01 (100)	00 (0.00)	01	
2A	03 (60.0)	02 (40.0)	05	
2B	07 (87.5)	01 (12.5)	08	
3A	07 (100)	00 (0.00)	07	
3B	05 (83.3)	01 (16.7)	06	

**Table 4: Correlation of p53 score with age and parity**

Clinical parameters	p53 score (%)			P value
	0-2 (n=06)	3-5 (n=15)	6-8 (n=09)	
Age (years)				0.412
31-40	1 (11.1)	5 (55.6)	3 (33.3)	
41-50	3 (27.3)	7 (63.7)	1 (9.00)	
51-60	1 (14.3)	2 (28.6)	4 (57.1)	
61-70	1 (33.3)	1 (33.3)	1 (33.4)	
Parity				0.317
0-2	3 (25.0)	7 (58.3)	2 (16.7)	
3-5	3 (18.8)	7 (43.7)	6 (37.5)	
$>5$	0 (0.00)	1 (50.0)	1 (50.0)	



**Figure 1: Microphotograph showing basal staining in normal cervical epithelium (DAB, x20)**

was seen in the advanced clinical stage of 3B (50% cases). However, this relation was not statistically significant ( $P = 0.168$ ) (Tables 3 and 5 and 6).

One case of CIN III in our study was p53 positive (Figure 2). Among the invasive carcinomas, 92% (24 of 26 cases) of SCC (Figure 3) and 50% (1 of 2 cases) of ADSC were p53 positive (Table 7). A single case of ADC was p53 negative (Figure 4). The relation between the histologic type and p53 positivity was statistically significant ( $P = 0.044$ ). The p53 was positive in 87.5% of LCNK and 100% cases of LCK but was not statistically significant ( $P = 0.8$ ) (Table 7). While correlating p53 score with the

histologic type of cervical carcinoma, high score (6-8) was observed in SCC and was statistically significant ( $P = 0.041$ ) (Tables 5 and 6).

While correlating p53 expression with modified Broder's grading, both cases (100%) of Grade III showed p53 positivity with high p53 grade and score, whereas 88% of MD (Figure 3) and 50% of well-differentiated cervical

**Table 5: Correlation of p53 grade with clinico-pathological features**

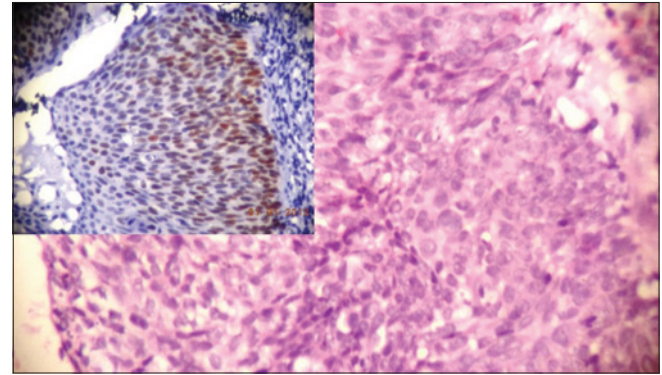
Characteristics	p53 Grade (n (%))				
	1	2	3	4	5
Histologic type					
CIN III	0 (0.00)	1 (100)	0 (0.00)	0 (0.00)	0 (0.00)
SCC	3 (12.5)	4 (16.7)	9 (37.5)	3 (12.5)	5 (20.8)
ADC	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
ADSC	1 (100)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Broder's grade					
WD	0 (0.00)	0 (0.00)	1 (100)	0 (0.00)	0 (0.00)
MD	4 (18.2)	4 (18.2)	8 (36.4)	3 (13.7)	3 (13.7)
PD	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	2 (100)
FIGO stage					
1	0 (0.00)	0 (0.00)	1 (100)	0 (0.00)	0 (0.00)
2A	1 (33.3)	0 (0.00)	1 (33.3)	0 (0.00)	1 (33.4)
2B	3 (42.9)	0 (0.00)	3 (42.9)	0 (0.00)	1 (14.2)
3A	0 (0.00)	3 (42.9)	2 (28.7)	1 (14.2)	1 (14.2)
3B	0 (0.00)	1 (20.0)	0 (0.00)	2 (40.0)	2 (40.0)

CIN: Cervical intraepithelial neoplasia, SCC: Squamous cell carcinoma, ADC: Adenocarcinoma, ADSC: Adenosquamous carcinoma, WD: Well differentiated, MD: moderately differentiated, PD: Poorly differentiated

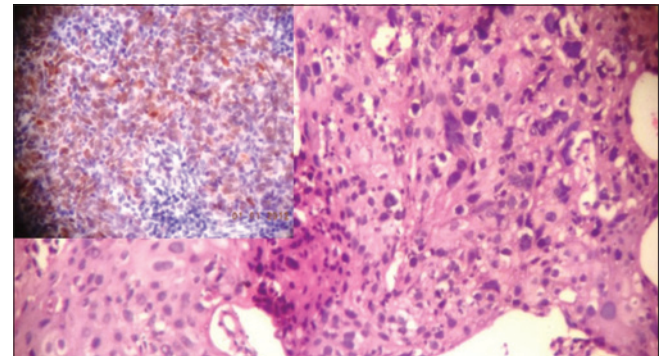
**Table 6: Correlation of p53 score with clinico-pathological features**

Characteristics	p53 score (n (%))		
	0-2	3-5	6-8
Histologic type			
CIN III	00 (0.00)	01 (100)	00 (0.00)
SCC	03 (11.5)	14 (53.8)	09 (34.7)
ADC	01 (100)	00 (0.00)	00 (0.00)
ADSC	02 (100)	00 (0.00)	00 (0.00)
Broder's grade			
WD	01 (50.0)	01 (50.0)	00 (0.00)
MD	05 (20.0)	13 (52.0)	07 (28.0)
PD	00 (0.00)	00 (0.00)	02 (100)
FIGO stage			
1	00 (0.00)	01 (7.70)	00 (0.00)
2A	03 (50.0)	01 (7.70)	01 (12.5)
2B	02 (33.3)	05 (38.5)	01 (12.5)
3A	00 (0.00)	05 (38.5)	02 (25.0)
3B	01 (16.7)	01 (7.70)	04 (50.0)

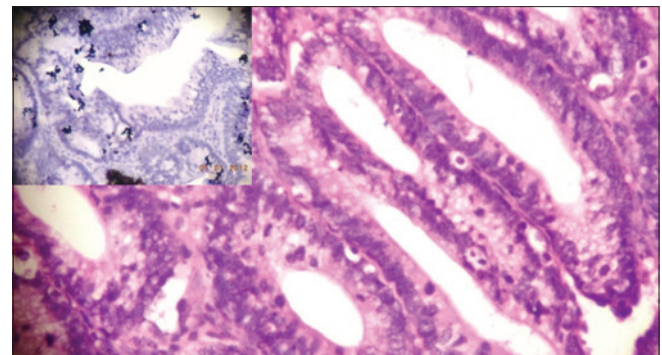
CIN: Cervical intraepithelial neoplasia, SCC: Squamous cell carcinoma, ADC: Adenocarcinoma, ADSC: Adenosquamous carcinoma, WD: Well differentiated, MD: moderately differentiated, PD: Poorly differentiated



**Figure 2: Microphotograph showing cervical intraepithelial neoplasia (CIN) III (H and E, x40); Inset: Microphotograph showing Grade 2 p53 positivity in all the layers of lining epithelium of CIN III (DAB, x40)**



**Figure 3: Microphotograph showing moderately differentiated squamous cell carcinoma (SCC) (H and E, x20); Inset: Microphotograph showing Grade 5 of positivity in SCC (DAB, x40)**



**Figure 4: Microphotograph showing well differentiated adenocarcinoma (H and E, x40); Inset: Microphotograph showing negative p53 expression in adenocarcinoma (DAB, x40)**



cancers showed p53 positivity (Tables 5-7). However, the relation between modified Broder's grade and p53 positivity ( $P = 0.419$ ), p53 grade ( $P = 0.237$ ), and p53 score ( $P = 0.301$ ) was not statistically significant.

## DISCUSSION

Cervical carcinoma was the third leading cause of death in developing countries, with India accounting for 25% of these deaths in 2012.<sup>1</sup> The expression of p53 may be combined with cervical cytology as a screening measure to detect precancerous lesions and reduce the mortality from cervical cancer.

In our study of 30 cases of cervical carcinoma, most were observed in elderly women with a mean age of 48.4 years. This finding was similar to studies done by Rajaram *et al.*<sup>9</sup> (52.1 years), Tjalma *et al.*<sup>10</sup> (52 years), Tan *et al.*<sup>11</sup> (51.1 years), and Tan *et al.*<sup>12</sup> (50.3 years). In our study, cervical carcinoma was seen in women with high parity with a mean of 3.5, similar to a study done by Rajaram *et al.*<sup>9</sup> (5.23) in Delhi suggesting that in India, cervical carcinoma occurred in women with high parity. However, in the study done by Lindström *et al.*<sup>13</sup> in Sweden, most of the cervical cancer patients had parity of 2.7. This difference could be attributed to the different sociodemographic profile of the two populations. In our study, most (70%) patients presented with abnormal bleeding and on examination had exophytic growth (70%), similar to the study done by Rajaram *et al.*<sup>9</sup> In the present study, most patients presented at a later stage of the disease, which has been the scenario in various other studies.<sup>10,13-15</sup> SCC was the most common histologic type of cervical cancer encountered in our study, with most tumors being MD. These findings were in concordance with study done by Win *et al.* (72.5%).<sup>14</sup>

The pathogenesis of cervical cancer is thought to occur through a multistep process involving HPV infection in more than 95% of the cases.<sup>9</sup> The viral proteins E6/E7 of HPV functionally interfere with cell cycle control by inactivating tumor suppressor gene p53 and the retinoblastoma protein.<sup>16</sup> Positive staining for p53 protein by IHC is considered to be abnormal and felt to be a poor prognostic predictor in many types of malignancies, although conflicting results are available in literature.<sup>3</sup>

In our study, 90% of the cases with normal squamous epithelium were negative for p53 similar to other studies.<sup>10,16,17</sup> In the remaining 10% cases, the p53 positive nuclei were restricted to the basal layer only, similar to studies done by Vasilescu *et al.*<sup>16</sup> and Hunt *et al.*<sup>18</sup>

In the present study, the incidence of p53 positivity in neoplastic lesions was 86.7%. In various studies, the range of nuclear p53 positivity in cervical carcinoma was observed to be 25.2-85.7%. Few studies<sup>12,14,19,20</sup> have showed high p53 positivity similar to our study, whereas others<sup>21,22</sup> have showed a lower positivity of p53 in cervical cancer (Table 8). The varying range in different studies could be attributed to the composition of the study population, different specimen fixation techniques, and antigen retrieval methods.

The p53 expression increased with advancing age (88.9% in 3<sup>rd</sup> decade and 100% in 5<sup>th</sup> and 6<sup>th</sup> decade), similar to study done by Madhumati *et al.*<sup>6</sup> Increased p53 positivity was seen in women with high parity (93.7% in parity of 3-5 and 100% in parity of >5); however, it was not statistically significant (Table 3). Grade of p53 positivity increased with advancing clinical stage with Grade 5 positivity in 4 of 5 cases of 3B (Table 5), similar to study done by Bahnassy.<sup>23</sup> This increase may be due to increased abnormality in control of p53 expression or degradation or as a result of increased incidence of p53 mutation in later clinical stages.<sup>11</sup>

**Table 7: p53 expression in various histologic types of cervical carcinoma**

Histopathological Characteristic	Number of cases	p53 positive (%)	p53 negative (%)	P value
Microscopic type	n=30	n=26	n=04	
CIN III	01	01 (100)	00 (0.00)	0.044
SCC	26	24 (92.3)	02 (7.70)	
ADSC	02	01 (50.0)	01 (50.0)	
ADC	01	00 (0.00)	01 (100)	
Broder's grade	n=29	n=25	n=04	
I	02	01 (50.0)	01 (50.0)	0.419
II	25	22 (88.0)	03 (12.0)	
III	02	02 (100)	00 (0.00)	
Subtypes of SCC	n=26	n=24	n=02	
LCNK	16	14 (87.5)	02 (12.5)	0.884
LCK	10	10 (100)	00 (0.00)	
Small cell	00	00 (0.00)	00 (0.00)	

CIN: Cervical intraepithelial neoplasia, SCC: Squamous cell carcinoma, ADC: Adenocarcinoma, ADSC: Adenosquamous carcinoma, LCK: Large cell keratinizing, LCNK: large cell non-keratinizing

**Table 8: p53 incidence in various studies**

Study (year)	p53 incidence (%)
Oka <i>et al.</i> <sup>21</sup>	52.1
Haenrgen <i>et al.</i> <sup>19</sup>	85.7
Ngan <i>et al.</i> <sup>22</sup> (2001)	25.2
Tjalma <i>et al.</i> <sup>10</sup>	42.0
Win <i>et al.</i> <sup>14</sup>	80.0
Tan <i>et al.</i> <sup>12</sup>	76.0
Tan <i>et al.</i> <sup>11</sup>	85.2
Madhumati <i>et al.</i> <sup>6</sup>	45.5
Baskaran <i>et al.</i> <sup>20</sup>	83.0
Present study (2013)	86.7



Bahnassy *et al.*<sup>23</sup> in their study of 110 cases of SCC and CIN concluded that aberrations of p27, cyclin E, CDK4, and p16<sup>INK4A</sup> are early events in HPV 16 and 18 associated cervical carcinoma, whereas cyclin D1 and p53 pathway abnormalities are considered as late events. In contrast, Tjalma *et al.*<sup>10</sup> observed higher p53 positivity in Stage 1A, 1B, and 2B, and Ikuta *et al.*<sup>17</sup> observed that p53 expression was an indicator of unfavorable prognosis in Stage 1B of SCC. Vasilescu *et al.* in their study concluded that p53 was a prognostic factor for the aggressiveness of tumor when more than 30% positivity was seen in tumor nuclei.<sup>16</sup>

Our study had a single case of CIN III, which was p53 positive. Unlike normal cervical epithelium where p53 positivity was observed in the basal layer, in CIN III, the p53 positivity was present in all the layers of squamous epithelium (Figure 2). Jeffers *et al.*<sup>24</sup> and Hunt *et al.*<sup>18</sup> observed similar patterns in their studies. Tan *et al.* have observed similar findings.<sup>11</sup> In the studies done by Baskaran *et al.*<sup>20</sup> and Bahnassy *et al.*,<sup>23</sup> a gradual increase in p53 positivity was observed as the lesion progressed from CIN to ISCC. This finding was utilized by Singh *et al.*<sup>25</sup> in cytology smears where they found that abnormal expression of p53 was noted in cervical dysplasia, and it increased with higher cytological grades. Madhumati *et al.*<sup>6</sup> concluded in their study that p53 could be used as an important marker for low-grade CIN lesions showing high proliferative index and that p53 overexpression can be utilized as a marker to differentiate difficult cases of CIN III from microinvasive SCC.

While correlating histologic type with the p53 score (Table 6) and p53 positivity (Table 7), a statistically significant association was observed in our study indicating that p53 positivity (92.3%) was predominantly seen in SCC. A similar pattern was observed in other studies.<sup>9,10,14</sup> In our study, p53 positivity increased in grade and intensity with the increase in pleomorphism of the nuclei. In the present study, of the 26 cases of SCC, all cases of LCK and 87.5% of LCNK were p53 positive, similar to the study done by Carrilho *et al.*<sup>15</sup> However, this was not statistically significant. In a study done by Jiko *et al.*, p53 mutations were seen in 32% ADC and the incidence of these mutations was higher in cases at advanced clinical stages and with high grades of nuclear and structural atypia.<sup>26</sup> We had a single case of ADC cervix, and it was p53 negative (Figure 4). Although, in various studies low positivity has been seen in ADC, it is difficult for us to comment on p53 positivity pattern in ADC due to fewer cases of this histologic type in our study. In our study, p53 positivity increased as the Broder's grade worsened (Tables 6 and 7), similar to various other studies.<sup>10,16</sup> However, this was not statistically significant ( $P = 0.419$ ) (Table 7).

The aim of this study was to evaluate p53 as a potential biological marker that has been previously investigated for prognostic information in cervical cancer, and it covers a variety of major functions in cervical carcinogenesis. The positive correlation of p53 expression with well-established prognostic factors such as lymphovascular invasion and FIGO stage in cervical cancer has been demonstrated in various studies in the past.<sup>23</sup> Few studies have also showed that p53 accumulation in the tumor was associated with shorter overall patient survival.<sup>10</sup> In our study, p53 positivity increased with age, clinical stage, SCC histologic type, and higher tumor grade. The pattern of positivity was different in normal cervical epithelium, CIN, and invasive SCC with increase in p53 grade and score. This observation could be used to advocate the use of p53 as a screening and prognostic biomarker in cervical carcinoma.

In future, studies with a larger sample size representative of all histologic categories could be performed to evaluate the correlation of p53 positivity with clinico-pathological parameters, prognosis and response to therapy in Indian patients with CIN and invasive cervical carcinomas.

## CONCLUSION

In our study, we observed that p53 expression was associated with SCC in statistically significant manner. Owing to its different pattern of positivity in normal and pre-neoplastic cervical epithelium, p53 could be used as a diagnostic biomarker to correctly diagnose and categorize CIN lesions. The p53 expression could also be used to differentiate CIN III from SCC in difficult situations. Furthermore, p53 grade and p53 score could be used as an adjunct to histological prognostic parameters in assessing the degree of pleomorphism and thus, biological behavior of the tumor.

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# Incisal Show – A Decrease with an Increase in Lines of Life

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## Abstract

**Introduction:** Older subjects usually show less of their upper incisors and more of their lower incisors than younger subjects.

**Objective:** To determine upper and lower central incisor crowns visibility with variability in age and length of lips at rest in Pondicherry subjects.

**Materials and Methods:** A total of 96 random voluntary subjects were chosen and divided into 3 groups. Group 1, 20-40 years of age; Group 2, 41-60 years of age; Group 3, 61 years of age and older. Each group contained 32 subjects. The vertical display of the incisors was measured in millimeters from the midpoints of the incisal edges of the upper and lower central incisors to the borders of the upper and lower lips, respectively, by two methods – manual measurement using vernier caliper and the other using standardized photographic method.

**Results:** The mean maxillary incisor display of Group 1 was 3.33 mm, Group 2 was 2.83 mm, and Group 3 was 1.21 mm and that for mandibular central incisor visibility for Group 1 was 0.17 mm, Group 2 was 0.25 mm, and Group 3 was 1.63 mm. For an increase in lip length from 19 to 22 mm, there was an average decrease of maxillary incisal visibility by 0.2 mm.

**Conclusions:** There was a decrease in the maxillary and an increase in mandibular incisor visibility as the age progresses. Maxillary incisor visibility also decreased as there was an increase in the lip length. No significant difference was there according to sex.

**Key words:** Lip length, Mandibular incisal visibility, Maxillary incisal visibility, Photographs, Vernier caliper

## INTRODUCTION

Facial appearance is an important factor in many cultures, and the mouth and teeth in particular are major factors determining our perceptions of emotion and facial attractiveness.<sup>1</sup> According to Sarver, the smile arc is defined as the relationship of the curvature of the incisal edges of the maxillary incisors and canines to the curvature of the lower lip in the posed smile. The ideal smile arc has the maxillary incisal edge curvature parallel

to the curvature of the lower lip. These factors are quite important in dentures. Tooth placement is very likely the greatest contributor to the denture look. The denture look is “that typical facial appearance common to most denture wearers.”<sup>2,3</sup>

Pound advises placing the teeth back in the original position from which they arose. A great many others have accepted this philosophy, and it is widely advocated in the modern prosthodontic literature. Prothero, Nicholas, Sears, Landa, Schlosser and Gehl and Allen instructed to position the upper central incisor vertically so that 0-2 mm of the incisal edge is visible below the upper lip. However, an attempt to create a more youthful appearance will appear inharmonious with the skin and facial structures for variations in age and will produce a displacing factor in that the denture will be out of balance between the tongue and labial musculature.<sup>4,5</sup>

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Esthetics has become increasingly important in the practice of modern dentistry and is synonymous with a natural harmonious appearance. Esthetics or display zone according to Sachdeva *et al.* is composed of the size, shape, position, and color of the displayed tooth, gingival contour, buccal corridor, and framing of the lips. Lip position and the amount of tooth display during smile and speech are important in prosthodontics. Therefore, the study was done to evaluate the age-related changes of maxillary and mandibular incisor display related to upper lip length at rest.<sup>6</sup>

The aim of the study was to investigate the degree of visibility of maxillary and mandibular central incisor according to age and lip length. The objective was to study the incisal display and lip length.

- By direct manual methods using a vernier caliper (Figure 1).
- By photographs using J-ruler software (Figure 2).

## MATERIALS AND METHODS

This study was conducted in the Department of Prosthodontics, Mahatma Gandhi Postgraduate Institute of Dental Sciences, Puducherry. A sample size of 96 was used for different age groups (Table 1).

### Exclusion Criteria

- Missing anterior teeth
- Traumatized lips

**Table 1: Sample size**

Age group	Sample size
20-40 years	32
41-60 years	32
>60 years	32
Total sample size	96



**Figure 1: Vernier caliper**

- Extreme attrition
- Mobile or extruded anterior teeth
- Prosthetic anterior teeth replacements
- Uncooperative individuals.

Measurements of incisor display were obtained with the lips at rest and mandibular posture unstrained. The following procedure was used: Subjects were asked to sit in front of the examiner in an upright posture with their heads in the natural head position or the esthetic position. The natural head position is defined “as the position of the head in a standing up or an erect sitting individual, with his visual axis oriented horizontally.”<sup>7</sup>

The patients were then instructed to wet their lips with their tongues, open their mouths gently, swallow and articulate the word “Emma.” Each subject’s posture was checked twice to ensure that the lips were at rest and the teeth slightly apart. The amounts of upper and lower central incisor crowns displayed were then measured with a vernier caliper from the midpoints of the incisal edges of right upper central incisors to the lower border of the upper lip and from the midpoints of both lower central incisors to the upper border of the lower lip (Figures 3 and 4). When an incisor could not be seen, the measurement was considered to be zero.

For the photographic method, photographs were taken with the patient in the same position using a single lens reflex camera (Camera Details - Canon 5D Mark II of 24 pixel resolution and with a lens zoom of 24-105 mm using two photopro 23 photographic umbrella lights with 500 W) (Figure 5).

### Methods of Standardization

- Distance from the camera to eye level of the patient is standardized to 5 ft
- All patients were made to sit with the natural head position



**Figure 2: Photographic set up**



- Camera lens aligned to patients' eye level
- Maxillary right central incisor midline (line drawn perpendicular to the incisal edge) is used as a reference for measurement (Figure 6).

During taking a photograph, a reference scale is placed at the level of the maxillary central incisor. A software (J-ruler)

is used. The zoom of the picture is adjusted to match a mm of the reference scale with a mm of the software ruler (Figure 7a and b). The software provides accurate measurement between two points.

### Statistical Analysis

Paired *t*-test was done to compare manual and photographic methods.

One-way ANOVA test was done to analyze the relativity of the maxillary and mandibular incisor visibility to age.

## RESULTS

Using a paired *t*-test, it was found that there was no significant difference in lip length, maxillary and the mandibular incisor visibility between two measures and indicating the existence of reliability. So, both the methods were used to measure the maxillary incisor visibility.

One-way ANOVA test results showed that the maxillary and the mandibular incisor visibility had a significant change according to age, i.e., the maxillary incisor visibility decreases by age and the mandibular incisor visibility



Figure 3: Lip length measurement



Figure 4: Incisal visibility measurement

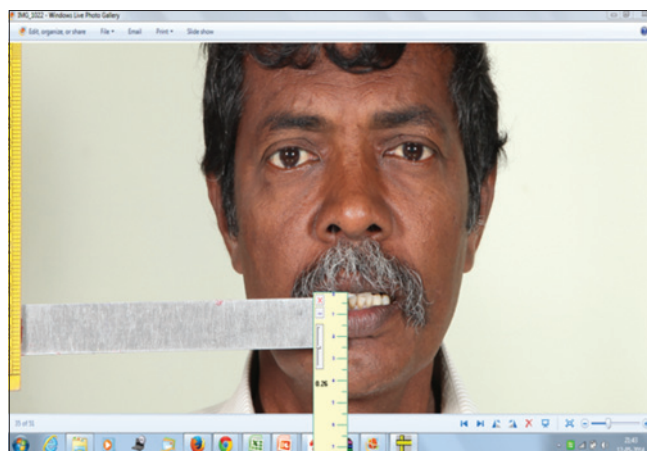


Figure 6: Incisal visibility measurement in the software



Figure 5: The photographic set up



Figures 7: (a and b) Zoomed view of measurement using software

increases by age (Tables 2 and 3). However, results show no significant difference between the incisor visibilities according to sex (Table 4).

## DISCUSSIONS

According to the test results, there was no significant difference in lip length, maxillary and the mandibular incisor visibility between two measures (manual method and the photographic method) and indicating the existence of reliability.

The upper and lower incisor crowns visibility below and above the margins of the lips were measured. When the lips were at rest, the reduction of upper incisor display with age and an increase in the lower incisor display with age in both men and women was found. These findings may have important implications for prosthodontic treatment planning which tend to ignore long-term changes in the incisor - lip relationships. The incisor visibility given in complete dentures have to be modified according to age. If not, the dentures will end up in what is called the “denture look.”<sup>3</sup>

The display of the anterior teeth is relevant not only for dental esthetics but also for facial attractiveness. The shape, alignment, position, and display of the upper

central incisors determine a pleasant smile and should be considered when planning for complete dentures.

The positions of the incisal edges of the upper incisors relative to the relaxed lips are often used as a vertical reference point. The determination of the “relaxed lips position” is reproducible but not easily obtained for all patients or on some occasions.<sup>12</sup> Our findings on the age changes in the display of the upper and lower incisors and, in particular, the reduced display of the upper anterior teeth and increased display of lower anterior teeth with age, agree with previous studies. These results confirm previous reports by Dong *et al.* and de Motta *et al.* that young people display more of their upper incisors than older people. These changes were not determined by changes in the positions of the teeth but rather by age-related changes in the facial tissues and the effect of gravity on the lips. Elongation of the lips continues throughout life and exceeds the age-related increase in lower anterior face height. The positions of the lips also depend on factors such as lip length, lip type, and muscle tonus, but these factors were not assessed.<sup>8,9</sup>

Graph 1 describes the maxillary and the mandibular incisor variation according to age and lip length. The X-axis denotes the increase in age, and the Y-axis denotes the incisor display. The graph shows the three ranges of lip length in three different colors. This indicates that as the lip length increases the incisor display of maxillary central incisor decreases for every age group. Such coordination is not found for mandibular incisor display. The overall graph shows that as the age increases the maxillary incisor display decreases and the mandibular incisor display increases.

The study results are in accordance with the results obtained by Vig and Brundo,<sup>3</sup> who noted that there was a decrease in maxillary incisor exposure of about 3.41 mm

**Table 2: Results of one-way ANOVA comparing maxillary incisor by age**

Age	N	Mean	SD	F value	P value
21-40	32	3.33	1.11	13.43	0.0000
41-60	32	2.81	0.96		
>60	32	1.95	1.21		

P<0.05 - significant (F value is significant), the maxillary incisor visibility decreases by age, SD: Standard deviation

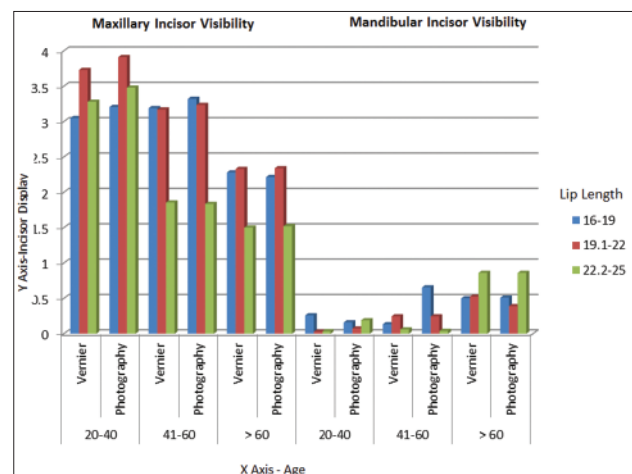
**Table 3: Results of one-way ANOVA comparing mandibular incisor by age**

Age	N	Mean	SD	F value	P value
21-40	32	0.17	0.42	13.46	0.0000
41-60	32	0.14	0.30		
>60	32	0.70	0.68		

P<0.05 - significant (F value is significant), the mandibular incisor visibility increases by age, SD: Standard deviation

**Table 4: Incisor visibility according to sex**

Sex/ Method	Maxillary incisor visibility		Mandibular incisor visibility	
	Vernier	Photography	Vernier	Photography
Female	2.76	2.86	0.29	0.31
Male	2.74	2.8	0.33	0.43



**Graph 1: Comparing the maxillary and mandibular incisal visibility of three different age groups of patients with varying lip length**

when compared with people of age group from 29 years to above 60 years. The findings of Dong *et al.*<sup>8</sup> were that there was a maxillary incisor display of about 2.5 mm at rest and 2 mm at smile when people of 20-29 and above 60 years are compared.

Age-related changes in incisor display can be underestimated if the sample includes subjects from a narrow age band. Subjects between 20 and 60+ years were used. It is important that incisor display is appropriate for the age of the patient. The prosthodontic literature typically recommends that artificial teeth are set up so that 2 mm of the central incisor crowns is visible when the lips are at rest, but patients who want a more youthful appearance will often ask for more of their incisor crowns to be visible.<sup>10</sup> When the display of the anterior teeth is more in older individuals, artificial look is provided. To increase a natural appearance for the patients of age above 60 years, the maxillary incisal visibility can be reduced and mandibular incisal visibility can be increased, thus aiding in a better esthetics for the elderly.

The limitations of this study include the manual errors in making the measurements. To minimize these errors, two techniques of measuring the visibility is followed and both the techniques are found to give the same results. The study helps as a guide to determine the positioning of the incisors in cervico incisal direction. Any guidelines regarding the labiolingual positioning are not provided.

## CONCLUSIONS

1. With increasing age, both genders showed less of their upper incisors and more of their lower incisors
2. No significant difference in visibility according to gender
3. Significant decrease in visibility according to lip length.

The present study concludes that the range of central incisor visibility varies according to age and lip length, and average values cannot be used as a guide for all cases in clinical practice. The average mandibular incisor visibility increases from 0.1 to 0.58 mm as age increases and maxillary incisor visibility decreases to less than 2 from 3.5 mm as age increases.

This study would guide in proper positioning of the incisors considering the age and lip length of the patients. The consequences of incorrect positioning of the maxillary central incisors in relation to the maxillary lip line include both obvious esthetic consequences and other more subtle problems including improper plane of occlusion and occlusal vertical dimension. The result of the present study can be used as a reference according to age, sex, and lip length of the patients to correctly position the maxillary and the mandibular anterior teeth in complete denture, removable and fixed partial and implant supported prosthesis.<sup>11,13</sup>

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# Laboratory Findings and Clinical Correlation in Assessing the Severity of Perinatal Asphyxia

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## Abstract

**Introduction:** Perinatal asphyxia contributes significantly to neonatal morbidity and mortality.

**Objective:** The study was done to investigate the predictive values of various biochemical markers, neurosonographic, and echocardiographic findings in assessing the severity of perinatal asphyxia.

**Materials and Methods:** A prospective observational study conducted on babies admitted to the neonatal intensive care unit (NICU) during the period of January 2012 to January 2016 in Vydehi Institute of Medical Sciences and Research Centre, Bengaluru, Karnataka, India with perinatal asphyxia. About 80 babies were included in the study with perinatal asphyxia. The clinical and neurological examination was done for all the neonates included in the study. Blood samples for different systemic biomarkers were taken from all the babies within 15 min following their admission, then at 48 h and at 72 h of admission to the NICU. The patients with hypoxic-ischemic encephalopathy (HIE) were divided into three groups (Stage 1: Mild, Stage 2: Moderate, and Stage 3: Severe) according to the Sarnat and Sarnat staging system. The predictive values of these biochemical markers in determining the stage of HIE were assessed.

**Results:** Out of 80 babies included in the study 57.5% were male babies. The mean gestational age and birth weight were  $39 \pm 2.0$  weeks and  $2907 \pm 420$  g, respectively. The cesarean section rate was 38.75%. According to the classification of Sarnat and Sarnat, 37 (46.25%) patients had Stage 1, 23 (28.75%) had Stage 2, and 20 (25%) had Stage 3 HIE. About 10 babies died during and after the study period. There was statistically significant increase in cardiac markers (creatinine kinase BB [CK-BB], troponin I, CK-MB), hepatic markers (alanine aminotransferase, prothrombin time/international normalized ratio) and increase in lactate in the cases of severe HIE stage.

**Conclusion:** HIE is the most severe manifestation of perinatal asphyxia which can be predicted by early laboratory evaluation of biomarkers so as that early treatment can be initiated.

**Key words:** Hypoxic-ischemic encephalopathy, Perinatal asphyxia, Sarnat and Sarnat staging

## INTRODUCTION

Perinatal asphyxia is a condition wherein there is an impairment of transfer of the respiratory gasses resulting in hypoxemia and hypercapnia, accompanied by metabolic acidosis. The WHO defines perinatal asphyxia as "Failure to initiate or sustain breathing at birth."<sup>1</sup> Perinatal asphyxia

is a third most common cause of neonatal death (23%) after preterm birth (28%) and sepsis (26%). The asphyxial injury may involve virtually every organ system of the body, but hypoxic-ischemic encephalopathy (HIE) is the most common sequelae.<sup>1</sup>

HIE characterized mainly by abnormal muscle tone and reflexes, an altered level of consciousness, and commonly by convulsions is an outcome of perinatal asphyxia.<sup>2</sup> HIE is a cause of death in newborns, and who survive are prone to serious neurological disorders such as cerebral palsy.<sup>2</sup>

## Clinical Manifestations

Neonatal encephalopathy is defined as "A clinically defined syndrome of disturbed neurological function in the earliest

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days of life in the term infant, manifested by difficulty with initiating and maintaining respiration, depression of tone and reflexes, subnormal level of consciousness, and often by seizures.”<sup>3</sup>

Sarnat and Sarnat classified HIE into three clinical stages: Mild (Stage 1), moderate (Stage 2), and severe (Stage 3) encephalopathy. HIE infants have various levels of consciousness and the behavioral changes ranging from irritability to stupor or coma.<sup>4</sup> In most cases, systemic hypoxia-ischemia results in multiorgan dysfunction. The lungs of asphyxiated newborns can be injured by hypoxia, as a result of inhaled meconium, secondary to cardiac dysfunction, or compromised due to pulmonary hypertension. Accordingly, gas exchange is impaired and assisted ventilation may be needed.<sup>4</sup>

The Apgar score is used to describe the newborn's physical condition at birth. Any hypoxic insult may cause depression of the Apgar score. A prolonged depression of the Apgar score is associated with death or severe neurodevelopmental outcome.<sup>3</sup> Hypoxia-ischemia causes direct damage to the myocardium reacted by the increase of cardiac enzymes.<sup>4</sup> The other multisystem effects regard kidneys, liver, and bone marrow. Fluid retention and hyponatremia may occur due to inappropriate secretion of antidiuretic hormone.<sup>5</sup> Bone marrow depression causes an increase in release of nucleated red blood cells (NRBC) and thrombocytopenia. Alteration in blood glucose levels may be observed, hypoglycemia being most common.<sup>4</sup>

### Diagnosis

Clinical evaluation and laboratory values are used to assess and manage the asphyxiated babies. The best indicator for intrapartum asphyxia is severe metabolic acidosis (pH <7.0 and base deficit  $\geq 12$  mmol/L) in umbilical cord arterial blood at delivery.<sup>6</sup> Cranial and doppler ultrasonography, computerized tomography, and magnetic resonance imaging are the most used brain imaging techniques.

### Biochemical Markers

Neonatal asphyxia causes multiorgan failure involving mainly the kidney, liver, brain, and heart which is associated with poor prognosis.<sup>6</sup> The kidney is one of the most important organs commonly involved in the multiple organ dysfunction caused by perinatal asphyxia. Evaluations of blood urea and serum creatinine levels are the tests most frequently used to assess renal injury caused by perinatal asphyxia.<sup>6</sup> Accordingly, markers of tubular dysfunction, such as urinary  $\beta 2$  microglobulin, have been found to be better indicators of early renal injury.<sup>8</sup> Myocardial injury normally develops when this compensation

mechanism fails. Electrocardiogram, echocardiography, and measurement of cardiac enzymes are used to assess myocardial dysfunction.<sup>7</sup>

## MATERIALS AND METHODS

A prospective observational study was conducted on babies admitted to the neonatal intensive care unit (NICU) from Vydehi Institute of Medical Sciences and Research Centre, Bengaluru, from January 2012 to January 2016 with perinatal asphyxia. During this 4-year period, we analyzed about 97 cases and as per our inclusion criteria of which 17 cases were excluded for various reasons. 80 neonates fulfilling the following criteria were finally analyzed after approval from the Ethical Committee for the study and written consent from the parents.

### Inclusion Criteria

1. All newborns with perinatal asphyxia were included if at least one of the three were present:
  - A. Intrapartum signs of fetal distress, as indicated by non-reassuring non-stress test on continuous electronic fetal monitoring and by meconium staining of the amniotic fluid
  - B. Apgar score of <1 at 1 min or <7 at 5 min of life
  - C. The requirement of positive pressure ventilation
  - D. Profound metabolic or mixed acidemia (pH < 7.10) in an umbilical artery blood sample, if obtained
  - E. Mild, moderate, or severe HIE, as defined by Sarnat and Sarnat staging.<sup>5</sup>

### Exclusion Criteria

1. Preterms with gestation <36 weeks or weight less than 1800 g,
2. Major congenital malformation, chromosomal abnormalities, or any metabolic disorders,
3. Birth trauma,
4. Septic shock,
5. Neonates born to mothers who have received magnesium sulfate or opioids within 4 h before delivery.

Babies included in the study as per criteria were studied for demographic details, such as gestational age, birth weight, and risk factors for perinatal asphyxia, were also recorded. Gestational age was assessed from last menstrual period and New Ballard score. Arterial blood gas (ABG) analysis was done from the umbilical arterial blood. Thorough clinical and neurological examination was done for all the neonates included in the study. Blood samples are taken from all the patients in these three groups within 15 min following their admission, then at 48 h and at 72 h of admission to the NICU. Blood samples are analyzed for

ABG, HCO<sub>3</sub>, base deficit levels, whole blood cell (WBC) count parameters (hemoglobin [Hb], total leukocyte count [TLC], platelet count), renal parameters (blood urea nitrogen [BUN], creatinine, and urinary micro globulins), liver parameters (aspartate aminotransferase, alanine aminotransferase, fibrinogen levels, prothrombin time/international normalized ratio [PT/INR]), cardiac enzymes (creatine kinase BB [CK-MB], CK-BB, troponin levels) lactate dehydrogenase (LDH), C-reactive protein (CRP), lactate, uric acid (UA) and electrolyte levels. The patients with HIE were divided into three groups (Stage 1: Mild, Stage 2: Moderate, and Stage 3: Severe) according to the Sarnat and Sarnat staging system within 48-72 h following their admission to the NICU. The predictive values of these biochemical markers in determining the stage of HIE were assessed. All the babies looked for any cerebral edema, any intracranial bleeds, cardiac activity (ventricular contraction, persistent pulmonary hypertension of the newborn [PPHN], left ventricular output), and corticomedullary differentiation of the kidney on ultrasound.<sup>9</sup>

Blood lactate levels analyzed by a gas analyzer Gem Premier 3000; reference values 0.3-3 mmol/L; serum level of troponin I determined along with other biomarkers (CK-MB and CRP) by enzyme-linked immunosorbent method on enzyme-linked fluorescent assay (cTnI reference range is from 0.01 to 2.8 µg/L.<sup>10</sup> The following variables were analyzed along with the 1<sup>st</sup> and 5<sup>th</sup> min Apgar score.

CK-MB fraction level was determined by a biochemical analyzer Beckman Coulter. Serum concentration of CRP was determined by the biochemical analyzer Beckman Coulter. The reference value in the clinical lab of Vydehi Hospital was irrespective of age is <0.35 ng/mL.<sup>11</sup>

### Statistical Analysis

Descriptive statistics (mean and standard deviation) are calculated. To display the mean values of biochemical markers descriptive statistics – median and quartiles. To compare the mean values of variables two populations were used: Mann–Whitney test and ANOVA. The correlation of two numerical characteristics was examined using Spearman's and Pearson's correlation coefficient. The suitability of numeric variables was tested using receiver operating characteristic curves.

## RESULTS

Out of 80 babies included in the study, 57.5% were male. The mean gestational age and birth weight were 39±2.0 weeks and 2907 ± 420 g, respectively. The cesarean section rate was 38.75%. According to the classification of Sarnat and Sarnat, 37 (46.25%) patients had Stage 1, 23 (28.75%) had Stage 2, and 20 (25%) had Stage 3 HIE (Table 1).

There was a total of 25% of preterm, 44% were term neonates, and 31% were postterm admitted in the study

**Table 1: Demographic data of the patients**

Demographic data	Staging according to Sarnat and Sarnat staging (staging done at 48 h of life)			P value
	Stage 1 n=37 (%)	Stage 2 n=37 (%)	Stage 3 n=37 (%)	
Preterm babies n=20 (25%)	13 (35)	3 (14)	4 (20)	0.176
Term babies n=35 (44%)	20 (54)	10 (43)	5 (25)	0.135
Post term babies n=25 (31%)	4 (11)	10 (43)	11 (55)	0.001
SGA/IUGR n=30 (37.5%)	6 (16)	10 (43)	14 (55)	0.154
Gestational age (in weeks)	38.4 (37.1-39.5)	39.1 (38.2-40.5)	39.5 (38.6-41.6)	0.284
Male n=46 (57.5%)	16 (43)	16 (70)	14 (70)	0.112
Female n=34 (42.5%)	21 (57)	7 (30)	6 (30)	
Apgar score (mean)	7	6	5	0.101
Mode of delivery				
Vaginal n=37 (46.25%)	19 (52)	9 (40)	9 (45)	1.212
LSCS n=31 (38.75%)	17 (46)	10 (43)	4 (20)	
Assisted n=12 (15%)	1 (2)	4 (17)	7 (35)	
Materno fetal factors				
No antenatal checkups n=10 (12.5%)	6 (16)	2 (8)	2 (10)	0.001
PROM/PPROM n=12 (15%)	8 (22)	3 (14)	1 (5)	0.001
Fetal distress n=13 (16%)	3 (8)	5 (21)	5 (25)	1.121
Meconium stained liquor n=15 (18%)	3 (8)	5 (21)	7 (35)	0.001
Prolonged labor n=8 (10%)	4 (11)	2 (8)	2 (10)	1.116
Antepartum hemorrhage n=8 (10%)	3 (9)	3 (14)	2 (10)	1.241
Eclampsia n=4 (5%)	0	3 (14)	1 (5)	1.023
Without any risk factors n=10 (12.5%)	10 (27)	0	0	0.001

PROM: Premature rupture of membranes, PPROM: Preterm premature rupture of membranes, LSCS: Lower segment caesarean section, SGA: Small for gestational age, IUGR: Intrauterine growth restriction

group with perinatal asphyxia. There were statistically significant higher number of babies of postterm in Stage 3 then those with Stage 1 and 2 HIE ( $P = 0.001$ ); there was no difference between Stage 1 and 2 HIE between preterm, term, and postterm babies (Table 1). Around 18% of the babies with meconium stained liquor had asphyxia of which 35% had Stage 3 HIE.

No statistically significant difference was detected among the three groups with regard to Hb and WBC levels. However, platelet count was the lowest in the patients with Stage 3 HIE, more so for the blood levels taken at the time of admission. Among the biochemical renal parameters, there was no difference in BUN values whereas creatinine levels were high in Stage 3 HIE compared to that of Stage 1 and 2 (Table 2).

The levels of serum glutamic oxaloacetic transaminase and serum glutamic pyruvic transaminase are significantly higher in Stage 3 HIE done at 48 h and 72 h compared to that Stage 1 and 2 and at admission levels of Stage 3. Fibrinogen levels are lowest in Stage 3 HIE compared to that Stage 1 and 2 HIE. There were significant higher PT/INR levels in Stage 3 babies compared to that of Stage 1 and 2. There was no difference in glucose levels in all the stages of HIE (Table 2).

There is a statistically significant elevation in cardiac enzyme levels (CK-MB and CK-BB) and LDH in children in Stage 3 HIE compared to babies from Stage 1 and 2. There was statistically significant low pH,  $\text{HCO}_3$  and increase in the base deficit and lactate levels in Stage 3 HIE babies compared to that of Stage 1 and 2 (Table 3).

There is a statistically significant increased levels of CRP in Stage 2 and 3 compared to Stage 1 HIE. There is a significant decrease in sodium levels in babies of Stage 3 HIE compared to that Stage 1 and 2.

In the study out of 80 babies, 10 babies died, seven died at the end of 48 h, and three after 72 h. There were statistically significant high levels of CK-BB, troponin I, CRP, lactate and a very low levels pH at admission in non-survivors (Table 3).

A higher number of Stage 3 HIE babies had diffuse cerebral edema with intracranial bleeds and higher resistive index. Stage 3 babies had poor ventricular contraction with decreased ventricular output and increased PPHN. Higher number of Stage 3 babies had poorly differentiated corticomedullary differentiation in ultrasound of kidneys compared to that of Stage 1 and 2 (Table 4).

## DISCUSSION

Perinatal asphyxia causes multiorgan dysfunction mainly the nervous system leading to encephalopathy, which may take 72 h for neurological manifestations to appear. As it requires nearly 3 days for the systemic manifestations and categorization into different stages, early laboratory analysis will be helpful so that initiation of the treatment is started, as treatment is effective only when it is administered in the first 6 h of life.

In a study done by Vishnu *et al.*, there was an increase in NRBC and TLC in Stage 2 and 3 of HIE, whereas a decrease in platelet count in Stage 3. In our study, there was no difference in Hb and TLC count among different stages of HIE. Whereas, decreased platelet count and increase in NRBCs were seen in babies with Stage 3 HIE.<sup>9</sup>

As per literature, there is an increase in tubular proteins (notably in beta-2 microglobulins and myoglobulins) along with an increase in BUN and creatinine in the early stages of renal failure secondary to perinatal asphyxia. The study done by Banerjee *et al.* revealed that an elevated levels of urinary  $\beta 2$  microglobulin with HIE babies, irrespective of clinical staging; conversely, serum creatinine and blood urea were shown to be increased only in newborns with severe HIE (Sarnat Stage 3). Furthermore, a recent study highlighted that the increase of urinary  $\beta 2$  microglobulin is directly related both to asphyxia grading (Apgar score) and to Sarnat and Sarnat staging of HIE.<sup>7</sup> In our study, BUN was normal, whereas creatinine and urinary beta-2 microglobulins in urine were elevated in HIE Stage 3 babies.<sup>10</sup>

Increase in liver enzymes is observed due to effect of hypoxia on liver and other multi organs. The effect increases as the level of hypoxia increases. In our study, we observed a significant worsening in the results of liver and kidney function tests as the stage of HIE progressed.<sup>11</sup>

In study done by Fernandez *et al.* measured the serum CK-BB (brain isoenzyme) activities of 33 full-term newborns in the 4<sup>th</sup> and 10<sup>th</sup> h of life and discovered that babies who died of severe HIE or developed neurologic sequelae had significantly higher serum CK-BB activities than babies who did not have neurological abnormalities. Based on this observation, they claimed that a high serum CK-BB activity is a sensitive marker of brain injury. In our study, the babies with HIE Stage 3 had higher CK-BB levels compared to that of the children in Stage 1 and 2.<sup>12</sup>

Holzmann *et al.* showed that fetal scalp blood sampling is an early marker of intrapartum hypoxia, and they claimed

Table 2: Laboratory data of the cases as per stages of HIE

Laboratory data	Stage 1		Stage 2		Stage 3		P value (within groups)	P value (Bet groups)		
	At admitted	48 h	72 h	At admitted	48 h	72 h			At admitted	48 h
Hb	17.2±2.8	16.8±2.6	16.6±2.2	16.8±2.6	16.7±2.1	18.2±3.2	17.9±2.9	17.2±2.2	18.2±3.2	P1-2: 0.621 P2-3: 0.546 P3-1: 0.462
WBC count	22608±4408	19201±3324	18213±2126	26212±6218	22163±4312	23121±5120	26149±6129	25129±6145	24121±8120	P1-2: 0.254 P2-3: 0.126 P3-1: 0.193
Platelet count	286012±44123	261212±36145	254162±32132	192183±52412	184782±48149	141213±46121	112141±36129	108941±49213	141213±46121	P1-2: 0.326 P2-3: 0.001 P3-1: 0.001
BUN	18±3	17±4	18±2	18±3	17±4	17±5	22±4	21±3	17±5	P1-2: 0.764 P2-3: 0.675 P3-1: 0.365
Cr	0.5±2	0.4±1	0.4±1	0.5±2	0.6±1	0.6±1	0.9±3	0.8±2	0.8±1	P1-2: 0.231 P2-3: 0.001 P3-1: 0.001
UA	6.8±0.4	6.7±0.3	6.7±0.2	6.8±0.4	6.7±0.3	8.4±0.2	9.2±0.3	10.4±0.3	9.6±0.2	P1-2: 0.321 P2-3: 0.001 P3-1: 0.001
Urinary macroglobulin	1.81±0.21	1.73±0.15	1.69±0.19	2.9±0.21	3.1±0.12	2.8±0.20	4.2±0.19	4.4±0.24	4.8±0.23	P1-2: 0.621 P2-3: 0.001 P3-1: 0.001
SGOT	62	64	62	62	64	76	84	102	121	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
SGPT	44	42	41	44	42	72	89	96	72	P1-2: 0.367 P2-3: 0.001 P3-1: 0.001
Fibrinogen	196	184	181	196	184	154	142	138	144	P1-2: 0.531 P2-3: 0.001 P3-1: 0.001
PT	1.2	1.15	1.12	1.32	1.28	2.2	2.4	2.6	2.2	P1-2: 0.219 P2-3: 0.001 P3-1: 0.001
Glucose	56±10	64±6	66±8	52±8	61±4	62±5	61±4	64±5	66±3	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
CPK-MB	340±126	412±184	422±182	618±218	1212±136	1180±148	2812±464	2612±512	2182±412	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001

(Contd)...



Table 2: (Continued)

Laboratory data	Stage 1		Stage 2		Stage 3		P value (within groups)	P value (Bet groups)			
	At admitted	48 h	72 h	At admitted	48 h	72 h					
CK-BB	14.4±2.1	15.1±1.9	15.4±2.1	18.8±2.6	18.7±2.1	18.2±1.9	26.2±2.3	31±1.9	29.7±2.6	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
	0.19±0.05	0.21±0.06	0.24±0.04	0.34±0.11	0.38±0.13	0.44±0.15	0.77±0.21	0.84±0.25	0.96±0.15	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
	762±92	482±86	562±96	1121±121	1098±102	1114±106	772±282	2142±302	2784±482	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
LDH	7.32±0.07	7.36±0.04	7.39±0.03	7.2±0.12	7.3±0.04	7.32±0.03	7.14±0.12	7.21±0.09	7.28±0.04	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
	18.2±3.2	19.1±2.8	19.6±2.1	18±3	17±4	18±2	13.6±4.1	14.1±3.2	15.2±2.8	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
	-8.1±4.1	-7.9±3.8	-7.2±2.4	0.6±2	0.7±1	0.7±1	-16.2±2.1	-12.8±1.8	-9.1±2.1	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
BE	3.6	4.2	3.9	6.8±0.4	6.7±0.3	6.7±0.2	6.8	11.2	10.4	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
	0.32±0.11	0.36±0.16	0.31±0.10	0.45±0.21	0.42±0.18	0.40±0.16	2.49±1.22	2.32±0.96	1.32±1.11	0.001	P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
	136±4.02	135±4.3	136±4.12	196	184	181	130±4.8	127±5.1			P1-2: 0.453 P2-3: 0.001 P3-1: 0.001
Na	8.2±0.2	8.3±0.1	8.3±0.1	7.8±0.3	7.9±0.2	7.9±0.1	7.6±0.2	7.8±0.1			P1-2: 0.301 P2-3: 0.311 P3-1: 0.231

Hb: Hemoglobin, WBC: Whole blood cell, BUN: Blood urea nitrogen, Cr: Creatinine, UA: Uric acid, SGOT: Serum glutamic oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase, PT: Prothrombin time, CPK-MB: Creatine phosphokinase-MB, CK-BB: Creatine kinase-BB, LDH: Lactate dehydrogenase, CRP: C-reactive protein

that lactate levels might be an earlier marker than the pH value when a hypoxic process is present. In our study, the mortality is high in babies with high lactate levels and babies of Stage 3 HIE.<sup>13,14</sup>

In our study, the levels of serum lactate and LDH levels are high in Stage 3 of HIE and, as the stage of HIE progressed, the results of the two tests used in measuring serum lactate and LDH levels showed a statistically significant increase.<sup>15</sup> Basu *et al.* showed that the newborns with asphyxia had significantly higher plasma UA levels than healthy newborns and that there was a positive correlation between UA levels, HIE stage, and APGAR score. In our study, the levels in Stage 3 HIE babies had significantly higher UA levels.<sup>16,17</sup>

**Table 3: Biomarkers in children between asphyxiated survivors and non-survivors**

Biomarkers	Asphyxiated survivors (n=70)	Asphyxiated non survivors (n=10)	P value
pH	7.14±0.08	7.08±0.11	<0.001
CK-BB	18.1±3.1	29.32±2.8	<0.001
Lactate	6.2±1.4	9.1±3.1	<0.001
Troponin I	0.46±0.12	0.84±0.09	<0.001
CRP	1.2±0.32	2.6±1.1	<0.001

CRP: C-reactive protein, CK-BB: Creatine kinase BB

Based on the results of our study, we can claim that the troponin I, pH, CK-BB, lactate and CRP which were done at admission had higher prognostic factors in predicting the mortality before the clinical determination of the HIE stage in newborns with perinatal asphyxia according to the Sarnat and Sarnat scoring system. Further, determining the cutoff values for these biochemical markers would help clinicians to differentiate Stage 1 HIE from the advanced stages so that therapeutic hypothermia treatment can be initiated.

## CONCLUSION

- HIE is predominant cause of mortality and morbidity neonates with perinatal asphyxia.
- Sarnat and Sarnat staging can be used for clinical staging of newborns with perinatal asphyxia and as a predictor of prognosis.
- Renal, cardiac, and hepatic biomarkers can be used as early predictors for morbidity and mortality for the asphyxiated neonates.
- Neurosonographic and echocardiographic findings in 48-72 h of life also can be used as prognostic factors of severity of asphyxia.
- Early prediction of the severity of asphyxia is used for treatment and intervention for better survival and outcome.

**Table 4: Radiological and echocardiographic findings of the cases according to the stages of HIE**

USG/ECHO parameters	Stage 1			Stage 2			Stage 3			P value (within groups)	P value (bet groups)
	At admitted	48 h	72 h	At admitted	48 h	72 h	At admitted	48 h	72 h		
Brain edema	No edema	No edema	No edema	No edema	10 minimal edema	14 minimal edema	5 diffuse edema	12 diffuse edema	10 diffuse edema	0.001	P1-2: 0.212 P2-3: 0.001 P3-1: 0.001
IVH	No	No	No	No	2 (grade 2)	4 (grade 3)	1	3	4	0.001	P1-2: 0.121 P2-3: 0.001 P3-1: 0.001
Intracranial bleed	No	No	No	No	1 baby	1 baby	1 baby	2 babies	4 babies	0.001	P1-2: 0.326 P2-3: 0.001 P3-1: 0.001
Doppler of ACA-RI	0.8	0.8	0.8	0.8	0.6	0.9	0.8	0.6	0.55	0.632	P1-2: 0.764 P2-3: 0.675 P3-1: 0.365
ECHO ventricular contraction	Good	Good	Good	Not good	Good	Good	Not good	Not good	Not good	0.001	P1-2: 0.231 P2-3: 0.001 P3-1: 0.001
PPHN	40	28	20	50	32	28	52	34	36	0.112	P1-2: 0.321 P2-3: 0.102 P3-1: 0.119
Left ventricular output	260	260	280	170	200	260	110	140	170	0.001	P1-2: 0.621 P2-3: 0.001 P3-1: 0.001
Abdominal ultrasound	Normal study			Minimally lost (hyper echogenicity increased but able to differentiate minimally)			Completely lost (complete hyper echogenicity)			0.001	P1-2: 0.621 P2-3: 0.001 P3-1: 0.001

IVH: Intraventricular hemorrhage, ACA RI: Anterior cerebral artery resistance index, ECHO: Echocardiography, PPHN: Persistent pulmonary hypertension of the newborn

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# Intraocular Pressure Control in Post Trabeculectomy Patients with Pseudoexfoliation Syndrome: A Prospective Study

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## Abstract

**Introduction:** Eyes with pseudoexfoliation syndrome have a greater frequency of glaucoma. There are high frequency and severity of optic nerve damage at the time of presentation, poor response to medical treatment, worse field damage, and the more frequent necessity for surgical intervention.

**Purpose:** The prime aim was to study the analysis of the effectiveness of trabeculectomy in controlling intraocular pressure (IOP) (defined as an IOP <21 mmHg) in patients of exfoliative glaucoma and comparison of success rate of trabeculectomy in controlling IOP with or without additional post-operative medication in patients of exfoliative glaucoma.

**Materials and Methods:** The prospective study was conducted in the postgraduate, Department of Ophthalmology, Government Medical College Srinagar. About 50 cases of exfoliative glaucoma underwent primary trabeculectomy. Patients with a history of trauma, uveitis, and previous ocular surgery were excluded from the study. Post-operative follow-up was done on 1<sup>st</sup>, 2<sup>nd</sup>, and 4<sup>th</sup> week and then at 2, 6, and 12 months in terms of visual acuity, IOP, slit-lamp examination (for bleb status), visual field, and fundus examination.

**Result:** The study showed that average post-operative fall of IOP from initial level was 14.14 mmHg at 6 months (49.15%) ( $P < 0.000$ ) in comparison to pre-operative mean IOP of 28.26 mmHg. The percentage of patients with controlled IOP without additional medical therapy at 6 months was 92% and percentage of patients requiring post-operative medical therapy (only one drug) for IOP control was 6% making an overall percentage of patients with controlled IOP (with or without additional treatment as 98%).

**Conclusion:** Our study concludes that trabeculectomy is an effective modality for controlling IOP in patients with pseudoexfoliative glaucoma.

**Key words:** Glaucoma, Intraocular pressure, Pseudoexfoliation, Trabeculectomy

## INTRODUCTION

Glaucoma is a leading cause of irreversible blindness throughout the world and refers to a group of diseases

that have a common characteristics of optic neuropathy with associated field loss for which elevated intraocular pressure (IOP) may be one of the risk factors.<sup>1</sup> Glaucoma based on initial event is classified as an open angle, angle closure, developmental, or associated with other ocular and systematic disorders.<sup>2</sup> Pseudoexfoliation syndrome (XFS) belongs to the last group and eyes with XFS have a greater frequency of glaucoma.<sup>3</sup> There is high frequency and severity of optic nerve damage at the time of diagnosis, worse field damage, poorer response, more severe clinical course, and more frequent necessity for surgical intervention.<sup>4</sup> XFS usually effects one eye, or one

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eye in advance and usually involves age more than 50 years. Deposits of white material (exfoliation) can be seen on lens (three zones), iris, cornea (Sampaulesi's line), ciliary processes, zonules, and above all trabecular meshwork.<sup>5</sup> Exfoliation glaucoma has to be treated even in absence of field damage, if left untreated can lead to it. Glaucoma in XFS is to be treated on same lines as primary open angle (POAG) but it responds less than POAG but it responds well to filtering surgery (trabeculectomy) than POAG.<sup>6</sup>

## MATERIALS AND METHODS

This study was conducted in 50 diagnosed cases of exfoliative glaucoma who were operated with primary trabeculectomy and followed up for 6 months to 1 year (in some cases). Indications for trabeculectomy were uncontrolled IOP despite maximum tolerated medication and disease progression. Criteria for inclusion was patients with exfoliation, 6 months F/U minimum, if both eyes were involved first eye was taken and no surgery being done before trabeculectomy. Pre-operative assessment included visual acuity, slit-lamp examination (SLE), gonioscopy, fundus examination, and visual field assessment. Patients were operated by the senior staff of the Department of Ophthalmology for trabeculectomy. Post-operative F/U was done on 1<sup>st</sup>, 2<sup>nd</sup>, and 4th week and then after 3<sup>rd</sup>, 6th and if possible 12 months postoperatively in terms of visual acuity, IOP, SLE (for status of bleb), fundus and field of vision.

## OBSERVATIONS

The study revealed demographic data about age in years -  $60.26 \pm 7.38$  and about gender male:female (32:18). The observations that were made from the study as shown in Tables 1-7.

Post-operative cup disc ratio remained same in 84% of cases, whereas it deteriorated in 16% of cases and improved in none.

Post-operative visual field status at 6 months when compared with pre-operative visual field showed same status in 84% of cases, improvement in 2% and deterioration in 14%.

## DISCUSSION

Trabeculectomy has proved itself a safe and simple filtering procedure.<sup>7</sup> As per our study, its pressure reducing effect in exfoliative glaucoma is striking (92% without medication) and 98% with medication, as far as can be judged (6 months mainly). The results are close to results published by Jerndal and Kriisa (96%).<sup>8</sup> The mean IOP of all cases in our study

**Table 1: Pre-operative visual acuity (Snellen chart)**

Visual acuity (Snellen chart)	Number of cases (%)
6/12 or better	7 (14)
6/18 to 6/36	19 (38)
6/60 or less	24 (50)
Total	50 (100)

**Table 2: Pre-operative IOP (applanation tonometry)**

IOP (mmHg)	Number of cases (%)
>15-20	12 (24)
21-30	20 (40)
31-40	14 (28)
41-50	3 (6)
51-60	1 (2)
Total	50 (100)

**Table 3: Distribution of cases according to post-operative IOP**

IOP (mmHg)	Number of cases			
	1 <sup>st</sup> week	1 <sup>st</sup> month	3 months	6 months
>21	2 (4)	1 (2)	3 (6)	1 (2)
10-20	44 (88)	48 (96)	46 (92)	49 (98)
<10	4 (8)	1 (2)	1 (2)	0 (0)
Total	50 (100)	50 (100)	50 (100)	50 (100)

IOP: Intraocular pressure

**Table 4: Success of trabeculectomy in relations to post-operative IOP at 6 months**

Post-operative IOP	Number of cases (%)
Control without treatment	46 (92)
Control with additional treatment	3 (6)
Total controlled with and without additional treatment	49 (98)
Failure (IOP not controlled)	1 (2)

IOP controlled=IOP<21 mmHg at 6 months, IOP: Intraocular pressure

**Table 5: Changes in mean IOP from pre-operative level at different follow-up of all cases**

Mean pre-operative IOP	Mean post-operative IOP			
	1 <sup>st</sup> week	1 <sup>st</sup> month	3 months	6 months
28.26±8.72	14.10±3.59	13.68±3.11	13.95±3.52	14.12±3.19

IOP: Intraocular pressure

was  $14.12 \pm 3.19$  mmHg at 6 months which is close to results given by Popovic and Sjöstrand in whose study the mean post-operative IOP at last F/U visit (46.2 months) was 15.3 (5.1) in exfoliation glaucoma.<sup>6</sup> Our mean pre-operative IOP was  $28.26 \pm 8.72$  mmHg which is in accordance with study conducted by Popovic and Sjöstrand were mean IOP at operation was 28.2 mmHg in exfoliation glaucoma.<sup>6</sup> The mean age of the patients in our study is 60.26 years for both males and females, and this coincides with the mean

**Table 6: Changes in mean IOP from pre-operative levels at different follow ups along with their significance level**

A				
Pre-operative IOP (mean±SD)	Post IOP at 1 <sup>st</sup> week (mean±SD)	Change in IOP (mmHg)	t value	Significance (2-tailed)
28.26±8.72	14.10±3.59	14.16	12.097	0.000
B				
Pre-operative IOP (mean±SD)	Post IOP at 1 <sup>st</sup> month (mean±SD)	Change in IOP (mmHg)	t value	Significance (2-tailed)
28.26±8.72	13.68±3.11	14.58	11.858	0.000
C				
Pre-operative IOP (mean±SD)	Post IOP at 3 months (mean±SD)	Change in IOP (mmHg)	t value	Significance (2-tailed)
28.26±8.72	13.95±3.52	14.31	11.434	0.000
D				
Pre-operative IOP (mean±SD)	Post IOP at 6 months (mean±SD)	Change in IOP (mmHg)	t value	Significance (2-tailed)
28.26±8.72	14.12±3.19	14.14	11.426	0.000

IOP: Intraocular pressure, SD: Standard deviation

**Table 7: Distribution of cases according to post-operative visual acuity at 6 months**

Visual acuity	Number of cases (%)
Improved	2 (4)
Remained same	32 (64)
Deteriorated	16 (32)

age of 52 years in study by Jerndal and Kriisa.<sup>8</sup> Our study also showed increased susceptibility of males to exfoliative glaucoma (64% vs. 36%) as by Konstas *et al.*<sup>9</sup> Post-operative visual acuity in our study remained same at 6 months in about 64% of cases, however, it deteriorated in 32% of cases which is higher as by Jerndal and Kriisa, cause being our patients have advanced cupping and low vision so less chances of improvement.

In our study, 42 cases, no changes in visual field at 6 months, 7 cases showed deterioration while 1 case showed improvement. Similarly, in 52 cases by Jerndal and Krussu, 42 were same at 2 years, 9 deteriorated, and 1 showed improvement.

## CONCLUSION

Our study conclusively proves that trabeculectomy is a very effective modality in controlling IOP in pseudoexfoliative

glaucoma cases. This assumes a more significance given that XFS glaucoma is associated with the early field loss, poorer response to medical therapy, advanced cupping at presentation and aggressive nature of the disease as compared to other types of glaucoma. A lasting control of IOP is obtained by primary trabeculectomy and thus preserving the vision the patients and improving the quality of life of these patients.

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# Evaluation of Shade Differences between Natural Anterior Teeth in Patients of Different Age Groups, Skin Tone, and Gender: A Computerized Cross-sectional Study

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## Abstract

**Introduction:** Tooth shade is one of the most significant factors affecting esthetics. It is general misconception in people that white bright teeth are more attractive than yellow teeth. However, we as dentists are aware of the fact that teeth shade vary with skin color, age, and gender.

**Purpose:** The purpose of this scientific paper is to evaluate shade differences between natural anterior teeth in patients of different age groups, gender and skin tone of Puducherry population using a digital camera and to subsequently feed the data into software to determine the shade.

**Materials and Methods:** A total of 100 individuals aged above 16 years were divided into four age groups: Group 1 - 16-25 years; Group 2 - 26-35 years; Group 3 - 36-45 years; Group 4 - >46 years participated in this study. Photographs of all the individuals were taken using Canon 5D Mark II camera of 24 pixel resolution with lens zoom of 24-105 mm using two Photopro 23 photographic umbrella lights with 500 W under standardized conditions. Later, they were fed into Adobe Photoshop software to obtain the values of hue, saturation, and brightness of the middle third of maxillary central incisor. Tooth shades were divided into four categories according to value, and skin tones were divided into three categories (fair, medium, and dark) using Revlon makeup shades as a guide. These data were analyzed using Kruskal-Wallis ANOVA  $H$  value test.

**Results:** Significant tooth shade differences were discovered among the subjects with skin colors ( $P < 0.001$ ). Persons with medium to dark skin tones were more likely to have teeth with higher values (lighter), whereas with lighter skin tones have lower values (darker). A higher incidence of males with darker teeth as compared to females was evident, and significant darkening of teeth was found to occur with advancing age irrespective of gender predilection.

**Conclusion:** Within the limitation of the study, tooth shade value, skin color, gender, and age were significantly correlated.

**Key words:** Age, Digital camera, Gender, Skin color, Tooth color

## INTRODUCTION

Prosthodontists have always been faced with the challenge of harmonizing tooth shade with a facial appearance in

fully edentulous patients. They suggest that the color of the teeth must harmonize with the surrounding environment such as skin, hair, eye color, and age all with the aim of enhancing facial esthetics. It is also suggested that the hue of artificial teeth should harmonize with the patient's complexion (Boucher *et al.*, 1975; Winkler, 1979). These authors also advocated the use of the color of the facial skin as one basic guide in selecting color for artificial teeth in Caucasians. The knowledge of human tooth color and its distribution are a very important in understanding of matching in esthetic dentistry (O'Brien *et al.*, 1997). He also

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reported statistically significant color difference between the gingival to the incisal regions of teeth and that these differences are clinically significant. The illusion of greater contrast between skin color and tooth shade explains the perception among prosthodontists and restorative dentists that individuals with darker skin colors have lighter shades of teeth (Richardson, 2001).

A smile is the most visible record of a dentist's care. The significance of tooth shade in one's perception of smile attractiveness cannot be underestimated. In today's beauty conscious society, the demand for esthetic dentistry has increased a lot in last few years. Tooth shade is one of the most significant factors affecting esthetics.<sup>1</sup> It is general misconception in people that white bright teeth are more attractive than yellow teeth. However, we as dentists are aware of the fact that teeth shade vary with skin color, age, and gender. Tooth color has a strong correlation with age, generally becoming darker and yellower with time. As the age advances, the pulp chamber which is large during young age becomes smaller as a result of deposition of secondary dentin, making tooth more opaque. Many studies have shown that women have lighter and less yellow teeth than men. The color of the facial skin serves as the basic guides to tooth shade. The face is the frame into which the portrait (the teeth) will fit. Therefore, the shade of the teeth should harmonize with the color of the skin of the face.<sup>2</sup>

In past, various studies and surveys were conducted investigating the relationship of skin color to tooth shade. Some of these found inverse relationship between skin color and tooth shade while others found no relationship. These varying results can be attributed to the differences in the ethnic origin of the population studied. Bearing this view in mind, a study was planned to evaluate the shade differences of the natural anterior teeth in different skin color, age groups, and gender using digital method.<sup>3</sup>

## MATERIALS AND METHODS

This study was conducted to investigate the relationship between tooth shade value, age, gender, and skin color in the population of Puducherry, India. A total of 100 subjects belonging to different age groups, of equal distribution visiting the Department of Prosthodontics and Implantology, Mahatma Gandhi Post Graduate Institute of Dental Sciences, Puducherry were selected. In this study, subjects with a full complement of maxillary and mandibular anterior teeth without any endodontic therapy or restorations, developmental defects or disease were selected, to determine the skin color and shade of teeth.

Subjects who had a history of bleaching procedures, intrinsic, extrinsic or tetracycline staining, xerostomia, radiation therapy, smoking, or abnormalities in tooth development were excluded. Female subjects were specially asked not to wear any make-up, lipstick, or lip gloss.

### Determination of Shade of Teeth

The subject was positioned upright with the mouth at the camera lens level and the camera's position at four feet distance from the subject (Figure 1). The camera used was Canon 5D Mark II of 24 pixel resolution with lens zoom of 24-105 mm using two Photopro 23 photographic umbrella lights with 500 W (Figure 2). Clinicians were screened for color vision deficiency with Ishihara test for color blindness, and no color vision deficiencies were found. Photographs were clicked and were fed into Adobe Photoshop software to obtain the values of hue, saturation, and brightness of the middle third of maxillary central incisor which was matched to the nearest values of Vita 3D master guide to obtain the tooth shade (Figure 3).



Figure 1: Standardization of lighting conditions and patient position



Figure 2: Canon 5D Mark II



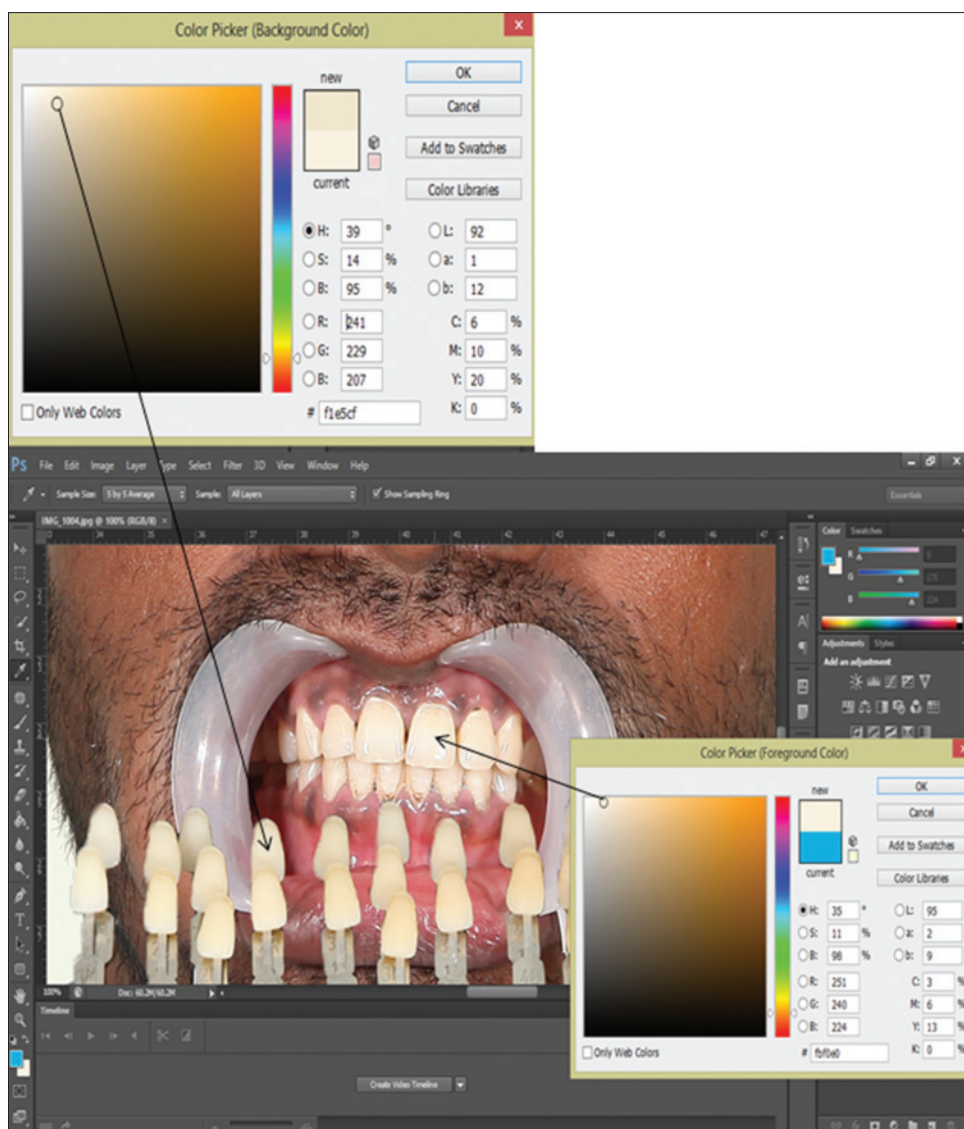


Figure 3: Tooth shade matching using Adobe Photoshop software

### Determination of Skin Color

Skin tones were divided into three categories: Shade 1, fair; Shade 2, medium; Shade 3, dark with the use of Revlon foundation makeup shade guide. The vanilla, shell and nude shade groups of the Revlon compacts corresponded to the fair skin group; the natural beige, medium beige, and cool beige shades of the compact corresponded to the medium skin group, and the golden beige, rich ginger shades of the compact corresponded to the dark skin group. Shades beyond the deeper shades of the compact were categorized in the dark skin group (Figure 4).

### RESULTS

Variations in shades of permanent maxillary central incisor were determined in relation to gender, age and



Figure 4: Revlon makeup shade guide for skin tone categorization

also on the basis of skin tone, by applying Kruskal–Wallis ANOVA *H* value test. Our study comprised 100 patients, out of which 65 were males and 35 were females. They were equally distributed into four age groups of 25 each on the basis of chronological age (Table 1). A total of 26 different shades are represented in Vita 3D Master shade guide. Out of these, only 15 shades were recorded in our study sample. Overall, the most common shade recorded was 2R1.5 (14.0%) followed by 2R2.5 (12%), and 1M2 (12%) and LR1.5 (9.0%) (Table 2). In comparison to females, males had higher values (darker) (Table 3). When considering the value groups of the shade guide in relation to age groups, interesting results were found (Table 4). In Groups I and II, “Value 2” shades were the most common, whereas in Groups III and IV, “Value 3” shades were the most common. Relation to gender, the “medium” skin tone was most common among males, whereas the “light” skin tone was most common among females. When considering these skin tones in relation to the value groups, similar trends regarding tooth shades were seen in both “light” and “medium” skin tones, whereby “Value 2” shades were most common.

## DISCUSSION

This study tried to establish a relationship between shades of teeth and skin color of the individuals according to their age and gender. The importance of esthetics in dentistry has shown marked increase owing to new interest and public awareness. Tooth color was found to be one of the important factors affecting esthetics. Color is complex and encompasses both subjective and objective phenomena. The most popular method for describing color was the Munsell system (3,11-13).<sup>4</sup> It had been widely used in dentistry. The three attributes of color in this system were hue, value, and chroma. Hue was defined as the particular variety of a color, shade, or tint produced by a specific wavelength of light acting on the retina. Chroma was defined as the intensity of a hue that is amount of color saturating per unit area of an object. The value was defined as the relative lightness or darkness of a color or the brightness of an object. Value is considered to be of greater importance.

For tooth shade determination, we used the middle third site of the tooth because there was a color gradation in natural teeth from the incisal to the cervical areas. The middle site of the teeth was said to be best representative of its color because the incisal site was most often translucent and was affected by its background while the cervical color was modified by scattered light from the gingiva.

The color of the facial skin served as basic guide in shade selection of teeth. Specifically, it is suggested that the value

**Table 1: Distribution of patient's by age and gender**

Age	n (%)		
	Male	Female	Total
16-25	16 (24.6)	9 (25.7)	25 (25.0)
26-35	16 (24.6)	8 (22.9)	25 (25.0)
36-45	17 (26.2)	9 (25.7)	25 (25.0)
≥46	16 (24.6)	9 (25.7)	25 (25.0)
Total	65 (65.0)	35 (35.0)	100 (100.0)

**Table 2: Distribution of patient's by shade selected and gender**

Shade selected	n (%)		
	Male	Female	Total
1M1	1 (1.5)	1 (2.9)	2 (2.0)
1M2	6 (9.2)	6 (17.1)	12 (12.0)
2L1.5	7 (10.8)	3 (8.6)	10 (10.0)
2L2.5	1 (1.5)	0 (0.0)	1 (1.0)
2M1	4 (6.2)	6 (17.1)	10 (10.0)
2M2	4 (6.2)	4 (11.4)	8 (8.0)
2R1.5	8 (12.3)	6 (17.1)	14 (14.0)
2R2.5	9 (13.9)	3 (8.6)	12 (12.0)
3L1.5	5 (7.7)	1 (2.9)	6 (6.0)
3L2.5	7 (10.8)	2 (5.7)	9 (9.0)
3M1	3 (4.6)	0 (0.0)	3 (3.0)
3M2	6 (9.2)	3 (8.6)	9 (9.0)
3R1.5	1 (1.5)	0 (0.0)	1 (1.0)
4L2.5	1 (1.5)	0 (0.0)	1 (1.0)
4M2	2 (3.1)	0 (0.0)	2 (2.0)
Total	65 (65.0)	35 (35.0)	100 (100.0)

Kruskal–Wallis ANOVA *H* value=5.19, *P*=0.0228, *P*<0.05 (Significant at 5% level)

**Table 3: Distribution of patient's by value group and gender**

Value group	n (%)		
	Male	Female	Total
Value 1	7 (10.8)	7 (20.0)	14 (14.0)
Value 2	33 (50.8)	22 (62.9)	55 (55.0)
Value 3	22 (33.9)	6 (17.1)	28 (28.0)
Value 3	3 (4.6)	0 (0.0)	3 (3.0)
Total	65 (65.0)	35 (35.0)	100 (100.0)

Kruskal–Wallis ANOVA *H* value=5.14, *P*=0.0198, *P*<0.05 (Significant at 5% level)

**Table 4: Distribution of patient's by value group and skin tone**

Value group	Skin tone, n (%)			Total n (%)
	Light	Medium	Dark	
Value 1	6 (14.0)	6 (12.8)	2 (20.0)	14 (14)
Value 2	23 (53.5)	27 (57.5)	5 (50.0)	55 (55)
Value 3	13 (30.2)	12 (25.5)	3 (30.0)	28 (28)
Value 3	1 (2.3)	2 (4.3)	0 (0.0)	3 (3)
Total	43 (43.0)	47 (47.0)	10 (10.0)	100 (100)

of the teeth must correspond to darkness or lightness of the facial skin tone. Persons with medium and dark skin were more likely to have teeth in high-value category than

persons with fair skin color. These results are similar to the findings of Jahangiri *et al.*<sup>5</sup> who found inverse relationship between tooth shade and skin color in their study on multiracial population.

The results of this study showed that there was a significant relationship between shades of teeth and the age-groups selected. It was noted that with increasing age, there was a tendency for the teeth to be of darker shades, which was in accordance with other studies on the subject. In his study conducted in Baghdad, Hassan *et al.*<sup>6</sup> found that the number of patients exhibiting colors of gray and red-gray increased with increasing age and thereby supporting the findings of our study on the whole.

When considering the shades of teeth in relation to gender, we found that males exhibited darker shades than females of the same age group. This finding was supported by studies conducted by Esan *et al.*<sup>7</sup> and Guo *et al.* Their studies have found that gender was significantly associated with tooth shades, in that men were more likely to present with darker tooth shades, whereas women of the same age group were more likely to show lighter tooth shades.

In light of our findings, it is suggested that when dealing with the task of fabricating a complete denture, certain factors must always be borne in mind while selecting a suitable shade for use in their prostheses. The parameters included were age, gender and skin complexion of the patient. Thus, it is our impression that if all details are considered during tooth shade selection, a more life-like prosthesis can be provided to the patient.<sup>8</sup>

## CONCLUSION

Within the limitations of this study, the following conclusions were drawn:

1. Tooth shade is significantly associated with age of the

individuals, in that teeth tend to darken in color with advancing age which happens due to enamel wear and subsequent dentin exposure.

2. Tooth shade is also significantly associated with gender, in that males have relatively darker shade than females of the same age group.
3. Tooth shade is also significantly associated with color of the skin, in that people with lighter skin tones tend to have teeth with darker colors while those with darker skin tones possess teeth of lighter colors.<sup>9</sup>

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The authors would like to thank Mr. Raja Raja Chozhan, MPR stills for his technical support.

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# Comparative Study between Kocher's Method and External Rotation Method in Acute Anterior Dislocations and Fracture-dislocations of Shoulder

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## Abstract

**Background:** Traditional technique-like Kocher's method to reduce dislocation of the shoulder is painful to patient and associated with complications.

**Aim:** Aim of the present study is to compare external rotation reduction method with Kocher's method in anterior dislocation shoulder.

**Materials and Methods:** A total sample 22 patients of anterior dislocations of the shoulder were treated in emergency department. Among 22 patients, on 12 patients Kocher's method was tried. In 10 patients, external rotation method tried.

**Results:** Out of 12 patients in Kocher's method, 9 patients were reduced under short general anesthesia (GA) and 3 patients were reduced in casualty without anesthesia. However, in external rotation method, 8 patients were reduced without anesthesia and 2 patients were reduced under short GA.

**Conclusion:** External rotation method is a safe and reliable method in acute dislocations of the shoulder that can be performed painlessly.

**Key words:** Dislocation, Rotation, Shoulder

## INTRODUCTION

Traditional technique-like Kocher's method to reduce dislocation of the shoulder is painful to patient and associated with complications.<sup>1-3</sup>

The new technique is a relatively safe and reliable. The aim of this study to compare pros and cons of new external rotation reduction method with old Kocher's method in acute anterior dislocations and fracture-dislocations.<sup>4-9</sup>

## MATERIALS AND METHODS

This study was conducted in the emergency department of the hospital during 24 months from September 2013

to September 2015, Kocher's method tried in 12 patients and external rotation method in 10 patients.

### Inclusion Criteria

Acute anterior dislocations and greater tuberosity fracture-dislocations of shoulder.

### Exclusion Criteria

Polytrauma, hemodynamic instability, three- and four-part proximal humerus fractures, and glenoid fracture-dislocations. Delayed dislocation more than 24 h were excluded from the study.

History of patients was recorded. Previous attempts of reduction were noted. Comorbid data recorded. Written informed consent obtained. Preanesthetic evaluation was done in every patient. Method of reduction was planned, and short GA was needed if there was any difficulty in reduction in both methods.

Pain tolerance was recorded, and complications such as axillary nerve, vascular injury, and iatrogenic fracture were noted.

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**Table 1: Patients details using Kocher's method or external rotation method**

Name	Age/sex	Diagnosis	Anesthesia	Method	Admission date
Pankajam	76/F	Anterior Dislocation With#	No	Kocher's	17/9/13
Subburam	49/M	Anterior Dislocation	GA	Kocher's	20/9/13
Anwartheen	25/M	Anterior Dislocation	GA	Kocher's	31/3/14
Indhrani	65/F	Anterior Dislocation With#	GA	ER	18/4/13
Karuvammal	40/F	Anterior Dislocation	No	ER	14/5/14
Senthilkumar	20/M	Anterior Dislocation	No	ER	29/5/14
Manikalai	32/M	Anterior Dislocation	GA	Kocher's	12/6/14
Kaliappan	36/M	Anterior Dislocation	No	ER	19/7/14
Pradeep	29/M	Anterior Dislocation	No	ER	28/7/14
Sundarapandi	23/M	Anterior Dislocation	GA	Kocher's	14/8/14
Subramani	66/M	Anterior Dislocation With#	No	ER	22/9/14
Perisamy	31/M	Anterior Dislocation	No	ER	28/9/14
Saraswathy	45/F	Anterior Dislocation	No	Kocher's	31/10/14
Sreenivasan	46/M	Anterior Dislocation	GA	Kocher's	13/11/14
Suresh	21/M	Anterior Dislocation With#	GA	Kocher's	30/11/14
Tamilselvam	23/M	Anterior Dislocation	No	ER	22/12/14
Karnan	40/M	Anterior Dislocation With#	No	ER	12/1/15
Sankaran	46/M	Anterior Dislocation	GA	Kocher's	28/1/15
Subramani	57/M	Anterior Dislocation	GA	ER	20/2/15
Chitra	34/F	Anterior Dislocation	GA	Kocher's	12/3/15
Mohammed	54/M	Anterior Dislocation With#	GA	Kocher's	24/5/15
Marimuthu	38/M	Anterior Dislocation	GA	Kocher's	22/6/15

GA: General anesthesia

**Technique**

The diagnosis was confirmed by clinical examination and radiographic evaluation.

**External Rotation Method**

In supine patient, without any traction, the elbow was flexed 90° and arm was abducted to side of the chest. With shoulder in 10-20° forward flexion with grasped wrist, the shoulder was rotated externally until forearm in coronal plane.

Minimal force was given. Patients were given injection diclofenac 3 cc intramuscularly. Once reduced the arm rotated internally and kept across the chest.

**Kocher's Method**

In supine patients, the arm was abducted and externally rotated. Traction was given. Once reduced arm was rotated internally and kept across the shoulder.

If reduction was difficult, short GA was administered in both methods.

Reduction was checked in post-reduction X-ray. Patients were immobilized in arm sling.<sup>10-11</sup>

**RESULTS**

About 22 patients were treated in period of 24 months from September 2013 to September 2015 in the emergency department.

Among 22, 12 patients were reduced using Kocher's method, and 10 patients were reduced using external rotation method (Table 1).

Among 22 patients, 18 patients were male and 4 patients were female.

The case sheets of 22 patients who were treated with either of these two methods in the period between September 2013 and September 2015 were evaluated. The mechanism of injury was a simple fall, a fall from height, and road traffic accident. There were 18 male and 4 female patients. The mean age was 40 years (range, 20-60 years). 12 right shoulders and 10 left shoulders were involved. Among 22, in 20 patients, this was first dislocation of affected shoulder. Greater tuberosity fracture was associated with dislocation in 6 patients.

Closed reduction was achieved with the use of Kocher's method in 12 patients (10 male + 2 female), and external rotation method in 10 patients (8 male + 2 female).

In Kocher's method, 9 among 12 dislocations were reduced under short GA.

In external rotation method, 2 among 10 patients needed anesthesia for reduction. Totally, 5 patients had moderate pain.

Two patients had a history of recurrent dislocation of the shoulder which was reduced using Kocher's method. The mean duration of hospitalization of 22 patients was

2 days. No short-term complications were noted in this study.

## DISCUSSION

This study demonstrated the advantage of external rotation method of reduction in acute shoulder dislocation. This is reliable and safe while causing minimum patient discomfort and not requiring anesthesia in most of the patients. In Kocher's method, the used traction increased muscle spasm and made reduction difficult without anesthesia.

So, this external rotation method is a rational, simple, and relatively pain-free method to reduce an anterior dislocation of the shoulder when compared to Kocher's method.<sup>12-16</sup>

## CONCLUSION

External rotation method is a safe and reliable method in acute dislocations of the shoulder that can be performed painlessly.

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# Role of Multiplanar Reconstruction Imaging and Three-dimensional Computed Tomography Imaging in Diagnosing Cranial and Facial Fractures

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## Abstract

**Introduction:** Skull fractures can occur in road traffic accidents, assaults, sports, and any other injuries. Fractures to the skull can occur in any region of the skull. The role of plain radiographs in assessing facial traumas has declined over the years. The use of multiplanar reconstruction (MPR) and three-dimensional (3D) recon images of multiple detector computed tomography (MDCT) in the musculoskeletal system is of tremendous advantage in traumatic injuries when the results of plain radiography fail to answer the doubts of the surgeons regarding satisfactory alignment of complex fractures.

**Objective:** To assess the accuracy of MDCT with MPR and 3D reconstruction sequences in imaging cranial and facial fractures.

**Materials and Methods:** A total of 100 patients fulfilling the criteria were included in the study, the average age taken was from 22 to 44 with appropriate brain and facial protocols with bone and soft tissue reconstruction. Inclusion criteria: Traumatic cranial and facial fractures. Exclusion criteria: Pregnant and lactating women. Nontraumatic.

**Results:** The results of the present study revealed that compared to the four types of fractures, simple undisplaced was found to be the most frequently occurring one, wherein MPR technique was found to be more detective for fractures compared to MRP and 3D, MPR, axial and 3D, MPR and axial.

**Conclusions:** Thus, this study has high lightened the usefulness of MPR technique as an imaging tool in enabling accurate localization of free bone fragments and assessing the degree of their displacement, thus helping reduce recurrent exposures.

**Key words:** Cranial, Fractures, Reconstruction

## INTRODUCTION

The various injuries that are caused by ferocity lead to the head and facial regions being most commonly affected. Involvement of these regions may lead to life-threatening situations, which include profuse blood loss, soft tissue

swelling, lacerations, and pain.<sup>1</sup> Skull fractures (also known as cranial fractures) can occur in road traffic accidents, assaults, sports, and any other injuries. Fractures to the skull can occur in any region on the skull. All brain injuries including traumatic brain injury, subdural hematoma, epidural or extradural hematoma or traumatic intracerebral hematoma/contusion.<sup>2,3</sup> The role of plain radiographs in assessing facial traumas has declined over the years since X-rays are sensitive to cranial vault fractures but insensitive to skull base fractures as it does not provide sufficient information regarding the anatomic details.<sup>4,5</sup> The role of magnetic resonance imaging (MRI) in trauma is to assess soft tissue injuries since it has good soft tissue contrast, and it also aids in assessing patients with neurological

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**Table 1: Parameters**

kVp	mAs	Slice thickness	Increment	Fov	Scan length	DLP mGy*cm	CTDI vol mGy*cm
100-120	300-350	5 mm	2.5 mm	18-22	250-300 mm	1095	45.0

DLP: Dose-length product, Fov: Field of view, CTDI: Computed tomography dose index

deficits but is not useful as compared to computed tomography (CT) in the evaluation of bony pathologies. The use of multiplanar reconstruction (MPR) and three-dimensional (3D) recon images of multiple detector computed tomography (MDCT) in the musculoskeletal system is of tremendous advantage in traumatic injuries when the results of plain radiography fail to answer the doubts of the surgeons regarding satisfactory alignment of complex fractures. Small structures that are not well seen with conventional CT imaging can be clearly depicted using MPR and 3D overlapping reconstruction at small intervals. Reformatted images also provide complementary information about various conditions including congenital malformation, vascular anomalies, and trauma involving the cranial and facial bones. The added advantage of MDCT is 3D technology which is very helpful in assessing large comminuted, displaced, and complex fractures involving multiple planes hence providing a road map for surgeons to initiate appropriate management.<sup>6-8</sup> These data obtained improve communications between the interpreting radiologist and the referring clinician and between the referring clinician and patients, since multiplanar and 3D reformations, give a real-time view of exam data in any plane with the ability to screen-capture the images for the permanent digital archive. MPR and 3D images are usually generated from the original two-dimensional data, and all reformatted images are obtained with the help of a neuroradiology fellow or a post processing technologist. During CT examinations, radiation exposure should be minimized for sensitive organs as prescribed by “ICRP” therefore, the radiologic technologists and radiologists must recognize the risks of patient doses during CT examinations and suggest appropriate protocols to reduce the doses.<sup>9,10</sup>

## MATERIALS AND METHODS

A total of 100 patients with clinical history and examination findings of cranial and facial fractures from Chettinad Hospital and Research Institute who were referred for CT imaging to the Department of Radiology were included in the study. The study was initiated after the approval of Institutional Human Ethics Committee. Informed consent was obtained from the participating conscious subjects/subjects attenders, before the study related procedure. 100 patients fulfilling the criteria were included in the study; the average age taken was from

22 to 44. Patients were scanned in a Philips Ingenuity Core 128 Slice CT Machine with appropriate brain and facial protocols with bone and soft tissue reconstruction. During the study, proper instructions were given to the patient and protective measures, such as lead aprons, were used to cover the patient’s body and to minimize the radiation dose to the patient. Throughout the procedure vitals were monitored. Fractures that were assessed include hairline, simple undisplaced, comminuted, and simple displaced. The images obtained were subjected to radiological analysis and interpretation (Table 1).

## Selection Criteria

Inclusion criteria: Traumatic cranial and facial fractures.

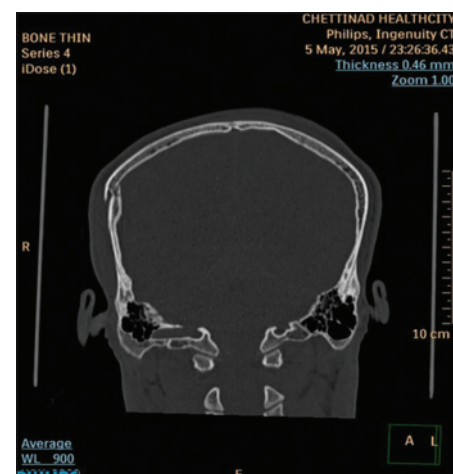
Exclusion criteria: Pregnant and lactating women. Nontraumatic.

## RESULTS

The results of the present study revealed that compared to the four types of fractures, simple undisplaced was found to be the most frequently occurring one, wherein MPR technique was found to be more detective for fractures compared to (Figures 1-4 and Graphs 1-3):

1. MRP and 3D
2. MPR, axial, and 3D
3. MPR and axial.

Statically analysis was carried out using formula and software *t*-test.



**Figure 1: Minimally displaced fracture in right parietal and right temporal bones , well depicted in coronal reformatted CT image**



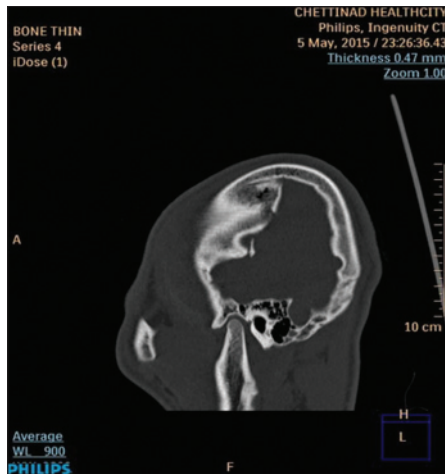


Figure 2: Sagittal reformatted CT image showing the fracture line



Figure 4: 3D CT image is very well demonstrating depressed fracture in right parietal and temporal bones and full extent of the fracture

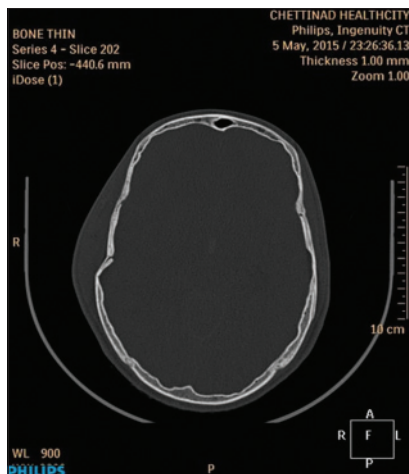


Figure 3: Axial CT image showing depressed fracture

## DISCUSSION

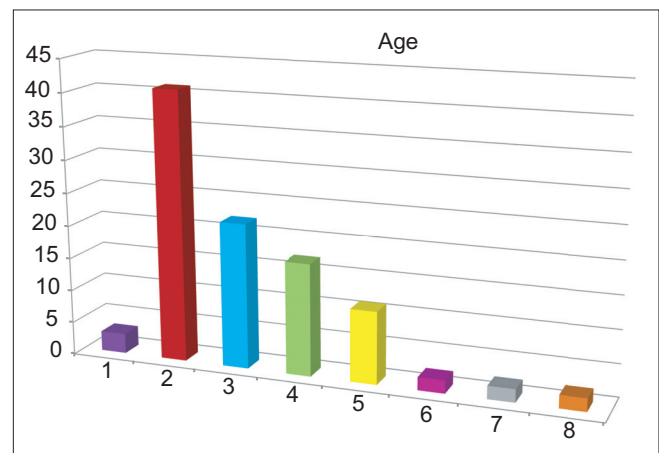
### Plain Radiography

Plain radiography is the initial imaging modality in trauma patients but since it cannot provide adequate information regarding the internal and skull base anatomy its significance in assessing cranial and facial fractures trauma has declined, moreover in patients with multiple traumas especially involving cranial and facial injuries, there may be life-threatening consequences while positioning the patients, hence its role is limited.<sup>11,12</sup>

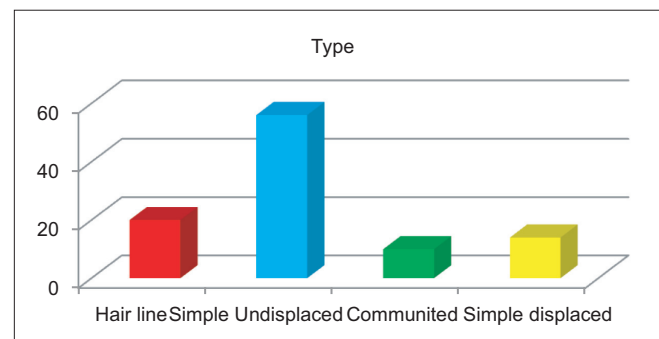
Depressed fracture noted in right parietal bone impinging on underlying brain parenchyma.

Segmental fracture noted in the inner table of right frontal sinus resulting in a large defect.

In the evaluation of fractures, MPR and 3D sequences are widely used for successful, identification of fracture sites. This is especially true for fractures of the cranial and

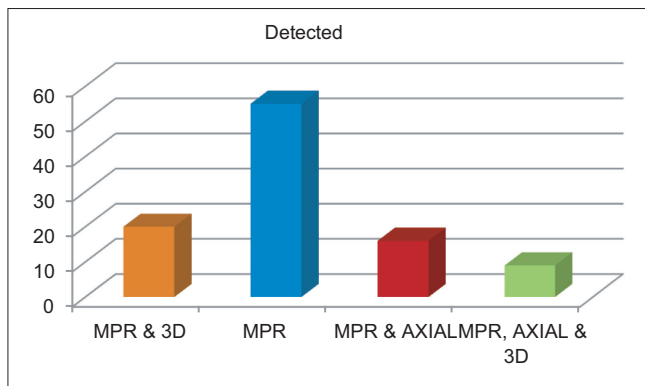


Graph 1: The above bar graph shows that in my study fractures were seen to occur more commonly in the age groups pertaining to 20-40 years



Graph 2: The above bar graph shows that in my study simple undisplaced fractures were the most common ones sustained

facial region. This is because these structures are located and run in the transverse plane, but trauma images can produce false-positive images since adjacent regions easily overlap. Hence, this produces a false image thereby making diagnosis difficult. However, in a wider context, transverse



**Graph 3: The above bar graph shows that in my study multiplanar reconstruction images were the most accurate means of detecting cranial and facial fractures**

imaging is useful as a method of visualization of anatomical elements perpendicular to the examined plane.<sup>13-16</sup> A good example would be the evaluation of anterior and lateral walls of the maxillary sinus and orbital bones.

The highest sensitivity in diagnosing fractures of the maxilla, frontal, and nasal bone was revealed by MPR. It was noted that in imaging of thin and delicate bone structures (such as cribriform plate of the ethmoid bone) and orbital floor; and in some cases also the anterior wall of the maxillary sinus, 3D reconstructions were less useful than MPR. The use of 3D reconstructions in these areas often produces false-positive images suggestive of nonexistent holes that are difficult or impossible to differentiate from fractures. Hence, 3D reconstructions cannot be used as the only imaging method in visualization of fractures.<sup>17-20</sup>

When comparing the results of imaging with the use of direct acquisition of raw data, with 3D reconstructions, it is also worth noticing their susceptibility to artifacts, i.e., the occurrence of false image elements that do not exist in real.<sup>21,22</sup> They may follow from the study protocol only. For example, if the slice is too thick during MPR, a “stair-step” artifact appears.

Hoeffner *et al.* conducted a study, in which it was proved that acquisition of MDCT, with slice thickness of 2.5 mm and slice distance of less than 1.5 mm, is enough to avoid “stair-step” artifacts in MPR reconstructions.

Furthermore, in the visualization of free, dislocated fracture fragments, MPR reconstructions turned out to be more successful in the assessment of post-traumatic lesions involving the orbits and maxillary sinuses.

3D reconstructions have also turned out to be of limited utility not only in the above-discussed group of symptoms but also in imaging of the ethmoid bones. However, it was

successful in visualizing free bone chips within the condylar process, branches and body of the mandible, anterior wall of the frontal sinus, zygomatic arch, zygomatic bones, and nasal bones. It has also proved useful in imaging of “tripod fractures.”<sup>23,24</sup>

The technique of 3D reconstruction also turned out to be useful also in the evaluation of fractures, with a high number and extent of dislocations of bone chips. Moreover, from among all applied techniques of presentation and reconstruction of CT images, the 3D option allows for a very precise reconstruction of post-traumatic anatomical relations in contrast to transverse and multiplanar imaging.<sup>25</sup>

## CONCLUSIONS

Thus, this study has high lightened the usefulness of MPR technique as an imaging tool in enabling accurate localization of free bone fragments and assessing the degree of their displacement, thus helping reduce recurrent exposures.

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# Clinicopathological Study of Lichen Planus in a Tertiary Care Center

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## Abstract

**Background:** Lichen planus (LP) is an idiopathic papulosquamous disease of the skin and mucous membranes. The classical lesions are violaceous, flat-topped polygonal papules associated with intense itching. It is worldwide in distribution with a variable incidence between 0.14% and 0.80%.

**Aims:** The objective of the study was to find out the clinicopathological profile of LP cases seen among patients attending the dermatology out-patient department in a tertiary care center.

**Materials and Methods:** A total of 90 patients were clinically diagnosed as LP during the study period. A detailed clinical history was elicited, and clinical examination was done for all the patients, and the findings were meticulously recorded. Relevant lab investigations and skin biopsy of the lesional sites were done.

**Results:** LP constituted 0.16% of the total patients diagnosed during the period of study. 51% of patients were between 31 and 50 years of age. Papules were present in 79%, and plaques were present in 14% of the patients. 21% of patients had oral mucosal involvement, and nail involvement was seen in 17%. The diseases, which were found to be associated with LP, were diabetes mellitus, hypertension, hypothyroidism, vitiligo, and alopecia areata. The malignant change was observed in a case of long-standing hypertrophic LP.

**Conclusion:** In our study, the majority of patients fall in the 31-50 years age group. Various studies show that childhood involvement is uncommon. In our study, childhood LP accounted for about 9% of cases. There was a complete correlation between clinical types and histopathological features in all the patients.

**Key words:** Lichen planus, Papulosquamous, Violaceous

## INTRODUCTION

Lichen planus (LP) is an idiopathic papulosquamous disease of the skin, mucous membranes, and nails. The exact incidence and prevalence of LP are unknown, but the overall prevalence is believed to be less than 1% of the general population.<sup>1</sup> LP commonly affects middle-aged adults though any age can be affected. About 2/3<sup>rd</sup> cases occur between 30 and 60 years of age.<sup>2</sup> A slight female preponderance has been reported. Males have an earlier age of onset (4<sup>th</sup> decade) than females (5<sup>th</sup> decade). No

racial predilection has been noted. Exact etiology is not known. It is considered to be due to the cell-mediated immune response to an epidermal antigen in genetically predisposed persons.<sup>3</sup> Infections, drugs, dental amalgam materials, and stress are known to be triggering factors. The classical lesions of cutaneous LP are violaceous, polygonal flat-topped papules and plaques associated with intense itching. The sites of predilection are flexor surface of wrists, trunk, and thighs. Lesions can appear along sites of trauma. This is known as Koebner's phenomenon. This study was done to document and analyze the clinicopathological profile of LP in Indian population.

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## MATERIALS AND METHODS

The study was conducted in the Department of Dermatology, Government Rajaji Hospital, Madurai, Tamil Nadu, India. A total of 90 patients clinically

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diagnosed as LP during a study period of one year were taken for the study. A detailed clinical history, including duration, site of onset, symptoms, drug history, and family history, was elicited. A complete general examination, systemic examination, and dermatological examination were made. Digital photographs were taken. The morphology and distribution of skin lesions, presence of any other associated diseases were noted. The concomitant affection of mucosa, hair, nails, palms, soles, and genital involvement was recorded. Laboratory investigations such as urine examination, blood sugar, liver function tests, blood venereal disease research laboratory, and complete hemogram were done. Skin biopsy was done in all the patients after obtaining informed consent. Sections stained with hematoxylin and eosin was used to study the histological features of LP.

## OBSERVATIONS AND RESULTS

The following observations were made from the study. Out of 90 cases of LP studied, 60 (66.66%) were of LP classical type. Other types of LP encountered were hypertrophic, eruptive, linear, annular, follicular, actinic, LP pigmentosus, lupus erythematosus (LE)/LP overlap, and isolated oral LP (Table 1). The majority of patients were in the age group of 31-50 years (Table 2).

About 46/90 patients were females and 44/90 were males (Table 3). The initial site of onset was limbs in 63% (Figure 1), trunk in 21%, face in 8%, oral mucosa in 6%, and genital mucosa in 2%. Papules were seen in 79%, and plaques were seen in 14% of the patients. Koebner's phenomenon was seen in 33% of the patients. The presenting symptoms of the patients were itching in 73% and pain in 7% and 20% were asymptomatic. Childhood LP was seen in 9% (8 patients). Oral mucosal involvement was noted in 19 patients. Reticular, plaque type, and erosive patterns were seen in oral lesions of 11, 5, and 3 patients, respectively. Genital lesions were observed in 9 male patients (10%). Nail changes were seen in 16 patients (18%). Pterygium was found in 3 of the patients. Other nail changes noted were longitudinal ridging, onychomadesis, trachyonychia, nail plate thinning, longitudinal melanonychia, onychoschizia, and punctate leukonychia. Palmoplantar lesions were associated in 20% of cases. Mucosal and palmoplantar involvement were not seen in children. The diseases which were found in the association were diabetes mellitus in 6 patients (6.6%), hypertension in 2 patients, and hypothyroidism in 2 patients. Vitiligo was seen in a patient and alopecia areata was observed in a patient. Squamous cell carcinoma was found in a case of long-standing hypertrophic LP.

**Table 1: Clinical types of LP**

Clinical types of LP	Number of patients (%)
Classical	60 (66.66)
Hypertrophic	10 (11.11)
Linear	5 (5.55)
Eruptive	4 (4.44)
LP pigmentosus	3 (3.33)
Oral	2 (2.22)
Annular	2 (2.22)
Follicular	2 (2.22)
Actinic	1 (1.11)
LE/LP overlap	1 (1.11)

LP: Lichen planus, LE: Lupus erythematosus

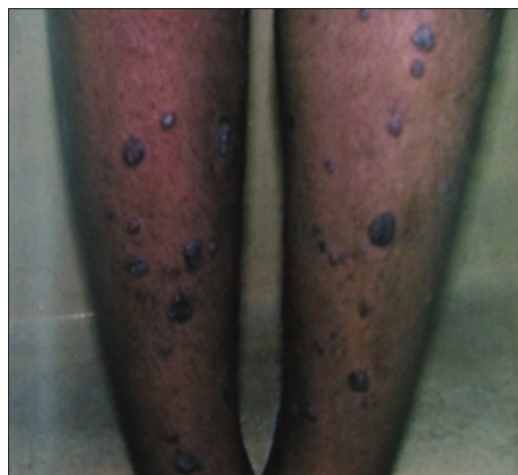
**Table 2: Age distribution**

Age group in years	Number of patients (%)
0-10	6 (6.67)
11-20	8 (8.88)
21-30	16 (17.77)
31-40	24 (26.66)
41-50	22 (24.44)
51-60	10 (11.11)
61-70	4 (4.44)

**Table 3: Sex distribution**

Clinical type of LP	Number of male patients	Number of female patients
Classical	27	33
Eruptive	3	1
LP pigmentosus	1	2
Oral LP	-	2
Annular	2	-
Hypertrophic	7	3
Linear	3	2
Actinic	-	1
Follicular	1	1
LE/LP overlap	-	1

LP: Lichen planus, LE: Lupus erythematosus



**Figure 1: Violaceous papules of lichen planus**

### Histopathological Features

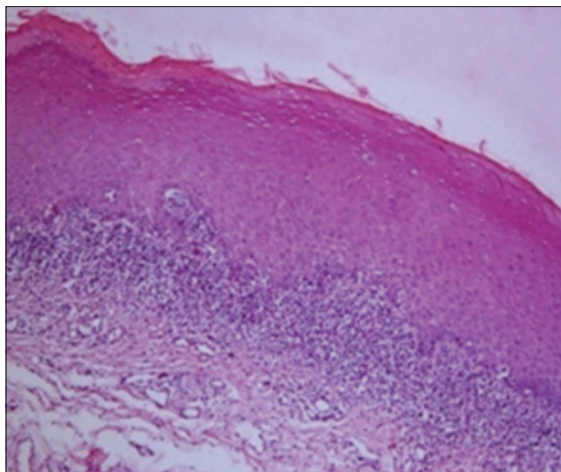
All of the sections examined showed classical histopathological changes of LP. Epidermal changes were characterized by orthohyperkeratosis (seen in 84%), focal hypergranulosis (80%), irregular acanthosis (78%), toothing of rete ridges (78%), and basal cell liquefaction degeneration (100%). Epidermal thinning was observed in the case of LP actinicus. Hypertrophic LP had more marked hyperkeratosis and acanthosis and follicular plugging was present in lichen planopilaris.

Dermal changes were characterized by a band-like inflammatory infiltrate predominantly of lymphocytes intermingled with a few macrophages in the dermo-epidermal junction in most of the cases (Figure 2). In lichen planopilaris, perifollicular involvement was present. A prominent perivascular infiltrate was observed in the case of LE/LP overlap. Civatte bodies or necrotic keratinocytes were present in only 46% of cases in the lower epidermis and the papillary dermis. They were observed in large numbers in the case of actinic LP and LP pigmentosus. Pigment incontinence in the form of melanophages was seen in the superficial dermis in all the cases. Both linear LP and eruptive LP showed classical histological features.

Two cases of classical LP lesions showed parakeratosis and prominent eosinophilic infiltrate in addition to the lymphocytic infiltrate. Both had history of drug intake, one patient was taking captopril, another one was on chlorpromazine. A diagnosis of drug-induced LP was made based on the findings. Features of squamous cell carcinoma were seen in the biopsy of warty growth in a case of hypertrophic LP.

### DISCUSSION

This study describes the clinical and histopathological characteristics of patients with LP. In our study, the majority



**Figure 2: Band-like infiltrate on histopathology**

of patients fall in the 31-50 years age group which is similar to studies done by Singh *et al.* and Bhattacharya *et al.*<sup>2</sup> We observed that classical LP was the most common, constituting 67% of total cases which is in concordance with the literature.<sup>2</sup> This was followed by hypertrophic type (11%), linear variant (5.5%), eruptive type (4%), and LP pigmentosus (3%). Oral LP was seen in 2%. Annular LP was present in 2% and lichen planopilaris was present in 2%. 1 patient had features of LE/LP overlap and 1 patient presented with actinic LP. Classical, linear, and eruptive types were seen in children. Linear variant, which is reported to be relatively rare, was the third common type in this study. In our study, we found that there was no predominant gender predilection. In the literature, there has been no consistency regarding any sexual predilection of LP, but most of the studies have shown that females are more commonly affected than males.<sup>4</sup> In our study, we found that lower limbs (63%) were the most common site to be affected in classical LP (Figure 1). A similar observation has been reported in various studies, and venous stasis has been offered as a likely explanation.<sup>2</sup> Oral mucosal involvement was seen in the form of reticular pattern, plaques, or erosions in 21% of patients. The reticular type was the most prevalent and the buccal mucosa was the most common site affected, an observation supported by the literature. Palmoplantar lesions (20%) and nail changes (18%) were common. Association of other immune-mediated diseases was noted. Neoplastic transformation of LP is a rare event.<sup>5</sup> In our patient with hypertrophic LP of 8 years duration, squamous cell carcinoma developed. Most of the characteristic histopathologic features of LP were observed in our study. The frequently seen features were orthohyperkeratosis, basal layer liquefaction degeneration, pigment incontinence, focal hypergranulosis, band-like infiltrate, and irregular acanthosis.

### CONCLUSION

LP was seen mostly in patients in the 4<sup>th</sup> and 5<sup>th</sup> decades. Classical lesions were the most common followed by hypertrophic and linear variants in our study. Limbs were the most frequent site of onset. Association of other autoimmune diseases was noted. All the patients showed a complete correlation between clinical types and histopathological features.

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# Comparative Study of Intrathecal Dexmedetomidine and Buprenorphine as Adjuvant to Bupivacaine in Spinal Anaesthesia: A Randomized Controlled Trail

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## Abstract

**Background:** Various adjuvants were used with local anesthetic in subarachnoid blocks to improve the quality and efficacy. Nowadays, non-opioids like dexmedetomidine had also been introduced in neuraxial blocks and to be investigated as a useful and effective adjuvant.

**Aim:** The aim of this study is to evaluate and compare intrathecal dexmedetomidine and intrathecal buprenorphine as an adjuvant to 0.5% hyperbaric bupivacaine for lower abdominal surgeries with respect to sensory and motor blockade, hemodynamic changes, and adverse effects.

**Materials and Methods:** This prospective, randomized, double-blind study was conducted on 60 adult patients of ASA physical status 1 and 2 in the age group of 18-60 years, posted for elective lower abdominal surgeries. The patients were randomly allocated into two groups, namely, Group BB and Group BD of 30 each. Patients in Group BB received 75 mcg of buprenorphine with 0.5% hyperbaric bupivacaine 15 mg intrathecally. Patient in Group BD received 5 mcg of dexmedetomidine with 0.5% bupivacaine 15 mg intrathecally. The following parameters observed were onset and duration of sensory and motor block, time for sensory regression to S1, degree of sedation, hemodynamic stability, and any side effects associated with these drugs. Collected data were analyzed using appropriate statistics.

**Results:** There was no significant difference between groups regarding demographic characteristics and type of surgery. The onsets of sensory and motor blockades were not statistically significant. The duration of sensory blockade was prolonged in dexmedetomidine group (51%) compared to buprenorphine group. Sensory regression to S1 was also got prolonged in dexmedetomidine group. The sedation level was higher in Group BD (dexmedetomidine) compared to Group BB (buprenorphine).

**Conclusion:** Dexmedetomidine as an intrathecal adjuvant with 0.5% hyperbaric bupivacaine prolong the sensory and motor blockade with fewer side effects, and the degree of sedation is better.

**Key words:**  $\alpha_2$  adrenergic agonist, Buprenorphine, Dexmedetomidine, Lower abdominal surgery

## INTRODUCTION

In subarachnoid blocks, local anesthetics are widely used in combination with adjuvants nowadays to shorten the onset of action, increase the quality of block, increase the

duration of anesthesia and analgesia, and decrease the dose of local anesthetics.<sup>1</sup> Dexmedetomidine is a highly selective  $\alpha_2$  agonist and introduced in clinical practice in 1999.

The food and drug administration approved dexmedetomidine use for short-term sedation and analgesia in intensive care unit. Although Food and Drug Administration has not approved dexmedetomidine as an adjuvant in neuraxial blocks. In neuraxial anesthesia, dexmedetomidine mediates its analgesia effects via spinal  $\alpha_2$  receptors by depressing the release of C-fiber neurotransmitters and hyperpolarization of post-synaptic dorsal neuron.<sup>2</sup> Buprenorphine is an opioid used frequently

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as an adjuvant in spinal anesthesia for post-operative pain relief.<sup>3-5</sup> It exhibits analgesic property both at spinal and supraspinal levels.<sup>6,7</sup> It has been used for various surgeries at different doses for the past decades. It has consistently proven to prolong the duration of anesthesia.<sup>3,4,8</sup>

The aim of this study is to evaluate and compare intrathecal dexmedetomidine and intrathecal buprenorphine as an adjuvant to 0.5% hyperbaric bupivacaine for lower abdominal surgeries with respect to sensory and motor blockade, hemodynamic changes, and adverse effects.

## MATERIALS AND METHODS

After approved by the Institutional and Ethical Committee, this study was conducted in 60 ASA I and II patients undergoing elective lower abdominal surgeries under subarachnoid block, and all patients are explained about the procedure and written informed consent was obtained in the age group of 18-60 years.

The detailed pre-anesthetic check-up was done on all patients and relevant hematological, biochemical, and radiological investigations were carried out for all patients as per surgical requirements. Patients with known contraindication for spinal anesthesia or with coagulation disorders or on anticoagulation therapy or with cardiac illness were excluded from this study.

The patients were randomly allocated into two groups to each using closed cover technique. BD group patient received 3 ml 0.5% bupivacaine (15 mg) and dexmedetomidine (5 µg) in 0.5 ml normal saline. BB group patient received 3 ml or 0.5% bupivacaine (15 mg) and 0.5 ml by buprenorphine (75 µg). A total volume of the injected solution was 3.5 ml in both groups.

### Anesthetic Procedures

In the operating room, appropriate equipment for the airway management and emergency drugs were kept ready. Non-invasive blood pressure monitor, pulse oximeter, and electrocardiogram (ECG) leads were connected to the patient. Pre-operative baseline systolic and diastolic blood pressure recorded and intravenous line were secured. Patients are preloaded with 10 ml/kg of ringer lactate infusion 10 min before the subarachnoid block.

On sitting position, the skin over the back was prepared with antiseptic solution and draped with sterile towel. After skin infiltration lignocaine 2%, 26G Quinke needle was inserted at L3-4 intervertebral space after confirmation of free flow of cerebrospinal fluid, the prepared solution was injected. The patients were made lie after the injection immediately and time was noted.

The follow-up parameters noted are as follows: (a) Time of injection of subarachnoid block, (b) time of onset and duration of the block, (c) time of onset and duration of motor block, (d) degree of sedation, (e) time for surgery regression to S1 dermatome and (f) duration of surgical procedure, and (g) systolic and diastolic blood pressure, mean arterial blood pressure, pulse rate and oxygen saturation were recorded at 0, 3, and 5 min and there after every 5 min up to 45 min of the procedure.

### Adverse Effects

1. Hypotension was said to have occurred mean arterial pressure fell less than 60 mmHg
2. Bradycardia was defined if heart rate <50/min
3. Respiratory depression if respiratory rate <8/min or SpO<sub>2</sub> <90%
4. Any discomfort such as nausea, vomiting shivering, pruritus, and ECG changes was noted
5. Vomiting was planned to manage with ondansetron 4 mg intravenously
6. Ramsay sedation score was used to assess the degree sedation
7. In completion of surgery patient was shifted to post-anesthesia care unit for observation
8. Injection diclofenac sodium 75 mg was given as rescue analgesic when patient complained of pain in post-operative period.

## RESULTS

Patient demographic data that includes age, sex and duration of surgery between groups were comparable (Tables 1 and 2, Graphs 1 and 2). The time of onset of surgery block was slower in group PB ( $3.47 \pm 0.507$ ) when compared with Group BD ( $2.57 \pm 0.504$ ), and the p value was statistically not significant ( $0.629 > 0.05$ ) (Table 3 and Graph 3). The average time taken for the onset of motor block was 3.38 min in Group BB and 4.13 min in Group BD. It was statistically not significant ( $P = 0.775 > 0.05$ ) (Table 4 and Graph 4).

The mean duration of sensory block was shorter in Group BB ( $332 \pm 18.81$  min) when compared with Group BD ( $502.13 \pm 12.27$  min) and statistically significant ( $P < 0.05$ ). The mean duration of sensory block in Group BD is 51% longer than Group BB (Table 5 and Graph 5). The mean duration of motor block was shorter in Group BB ( $298.63 \pm 35.79$  min) when compared with Group BD ( $432.33 \pm 12.74$  min) and statistically significant ( $P < 0.05$ ). The mean duration of motor block in Group BD is about approximately 44% longer than Group BB (Table 6 and Graph 6). The time of surgery regression to S1 was shorter in Group BB ( $272.27 \pm 15.39$  min) when compared

**Table 1: Age distribution**

Age group	N (%)	
	Group BB	Group BD
Age in years		
Below 30	6 (20)	8 (26.7)
31-40	9 (30)	6 (20)
41-50	6 (20)	9 (30)
Above 50	9 (30)	7 (23.3)
Total	30 (100)	30 (100)
Range	19-60 years	18-60 years
Mean±SD	42.33±12.88	40.57±13.22
P value	0.875 not significant	

SD: Standard deviation

**Table 2: Sex distribution**

Sex	N (%)	
	Group BB	Group BD
Male	25 (83.3)	23 (76.7)
Female	5 (16.7)	7 (23.3)
Total	30 (100)	30 (100)
P value	0.752 not significant	

**Table 3: Time of onset of sensory block**

Parameter	Time of on set of sensory block (in minutes)	
	Group BB	Group BD
Range	3-4	2-3
Mean±SD	3.47±0.507	2.57±0.504
P value	0.629 not Significant	

SD: Standard deviation

**Table 4: Time of onset of motor block**

Parameter	Time of onset of motor block (in minutes)	
	Group BB	Group BD
Range	3-5	3-5
Mean±SD	3.83±0.817	4.13±0.78
P value	0.775 not significant	

SD: Standard deviation

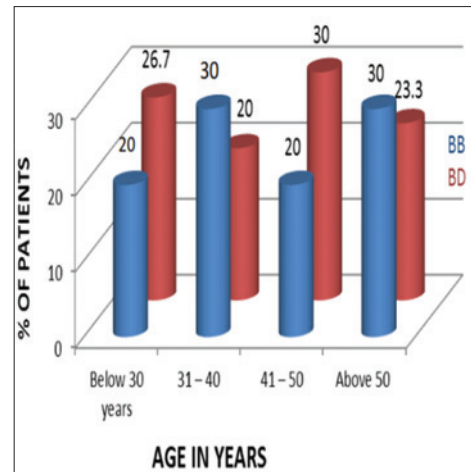
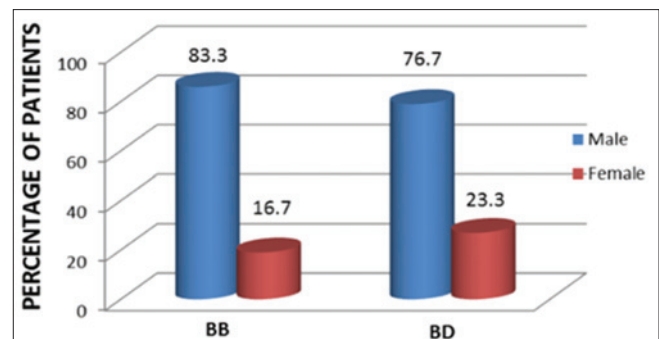
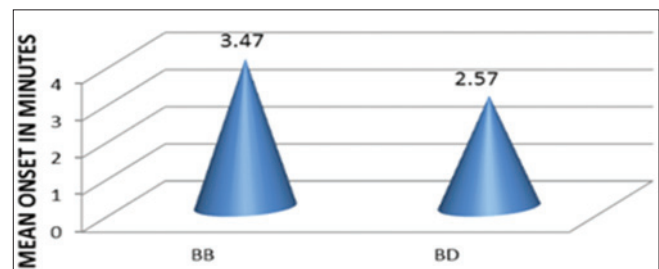
**Table 5: Duration of sensory block**

Parameter	Duration of sensory block (in minutes)	
	Group BB	Group BD
Range	303-360	480-520
Mean±SD	332±18.81	502.13±12.27
P value	0.005 significant	

SD: Standard deviation

to with Group BD ( $398.1 \pm 6.50$  min) and statistically significant ( $P < 0.05$ ) (Table 7 and Graph 7).

The mean arterial pressure was monitored from preoperative basal to 45 min of procedure (11 intervals) none of the

**Graph 1: Age distribution****Graph 2: Sex distribution****Graph 3: Onset of sensory block**

intervals had statistically significant (Table 8 and Graph 8). Heart rate was recorded in 11 intervals out of which only 2 intervals (0 and 3<sup>rd</sup> min) was statistically significant (Table 9 and Graph 9). The degree of sedation by using Ramsay sedation scale, better in Group BD when compared to Group BB (Table 10).

## DISCUSSION

It has been found recently that prolonged duration of action of buprenorphine is due to its local anesthetic action.<sup>9</sup> The lesser side effects in the post-operative period were due to its high lipid solubility.<sup>10</sup>

**Table 6: Duration of motor block**

Parameter	Duration of motor block (in minutes)	
	Group BB	Group BD
Range	293-360	413-460
Mean±SD	298.63±35.79	432.33±12.74
P value	<0.05 significant	

**Table 7: Time of sensory regression to S1**

Parameter	Time of sensory regression to S1 (in minutes)	
	Group BB	Group BD
Range	250-299	389-409
Mean±SD	272.27±15.39	398.1±6.50
P value	0.001, <0.05 significant	

**Table 8: Mean arterial pressure**

Time interval (min)	Mean±SD		P value
	BB Group	BD Group	
0	81.23±10.45	80.17±10.45	0.963
3	80.57±13.35	80.90±10.47	0.089
5	75.63±14.47	80.33±13.79	0.854
10	78.60±13.71	83.20±12.63	0.897
15	75.07±11.96	78.97±12.75	0.337
20	81.17±13.09	79.53±13.21	0.780
25	79.60±10.83	79.60±10.61	0.958
30	74.50±10.86	76.97±11.53	0.406
35	82.13±12.96	83.47±11.56	0.222
40	77.60±10.93	76.43±11.08	0.663
45	78.43±11.50	77.57±12.10	0.503

SD: Standard deviation

**Table 9: Heart rate**

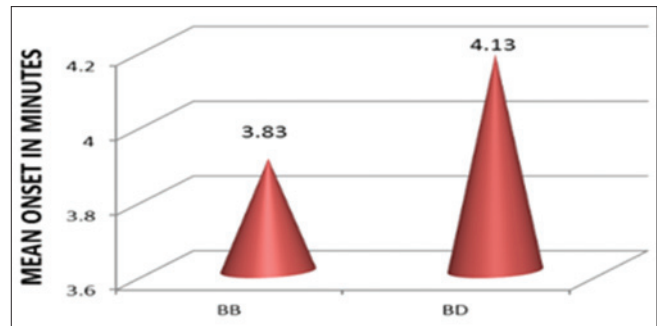
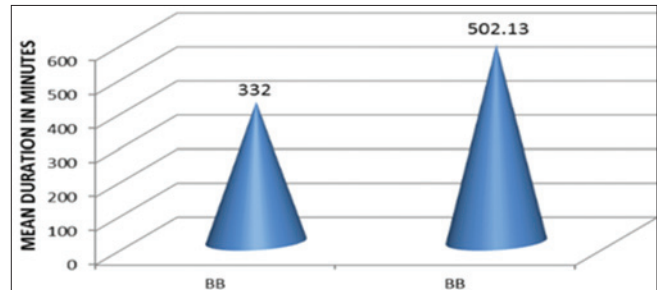
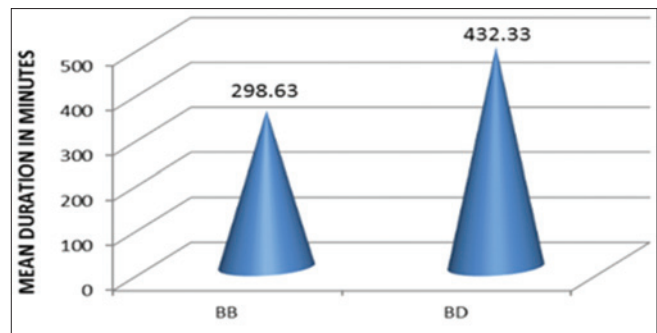
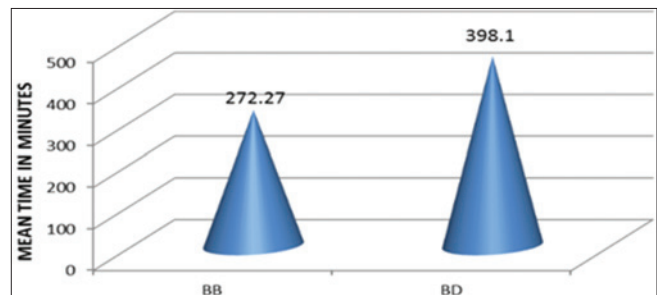
Time interval (min)	Mean±SD		P value
	BB Group	BD Group	
0	78.93±12.21	77.43±9.16	0.035*
3	81.47±13.37	74.27±9.13	0.000*
5	80.63±12.79	81.07±11.55	0.360
10	78.37±13.96	80.33±11.89	0.769
15	77.73±15.92	77.80±12.18	0.083
20	79.23±13.13	82.40±13.49	0.806
25	79.77±12.05	78.57±12.43	0.668
30	80.93±12.50	79.87±12.58	0.684
35	79.90±11.72	78.17±11.21	0.584
40	79.70±12.15	80.73±11.36	0.442

SD: Standard deviation

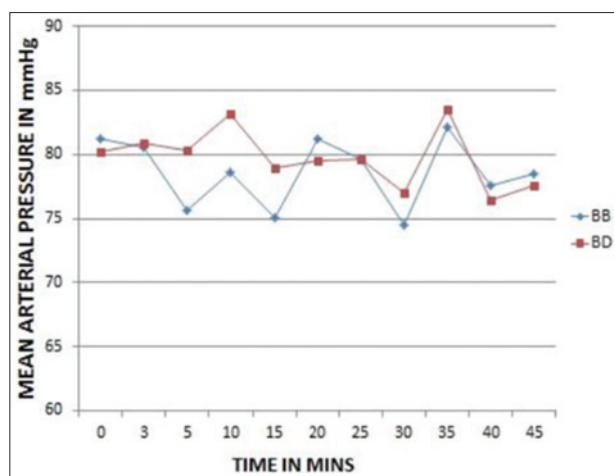
**Table 10: SpO<sub>2</sub>**

Parameter	SpO <sub>2</sub>	
	Group BB	Group BD
Range (%)	97-100	97-100
Mean±SD	98.53±1.008	98.43±1.006
P value	0.972 not significant	

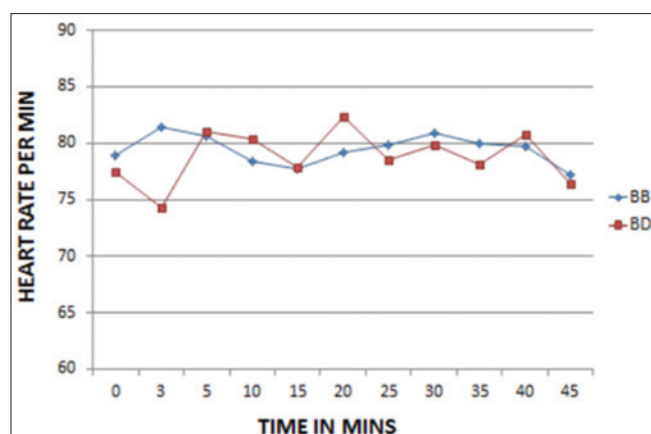
SD: Standard deviation

**Graph 4: Onset of motor block****Graph 5: Duration of sensory block****Graph 6: Duration of motor block****Graph 7: Time of sensory regression to S1**

Dexmedetomidine as an additive to intrathecal hyperbaric bupivacaine to prolong the quality and duration of action is not clearly known.<sup>11</sup> It is attributed that it acts by binding to post-synaptic dorsal horn neurons and to the c-fibers in the presynaptic region and decreasing the release of c-fiber neurotransmitters producing hyperpolarization of neurons in the post-synaptic region.<sup>12</sup>



Graph 8: Comparison of mean arterial pressure



Graph 9: Comparison of heart rate

Kanazi *et al.*<sup>13</sup> have used 3 mg of dexmedetomidine and said to have equipotent effect with clonidine. Eid *et al.*<sup>14</sup> studied the effects of dexmedetomidine on dose related manner (10 mcg and 15 mcg) and confirmed the prolongation of duration of analgesia. Many studies have chosen 5 mg of dexmedetomidine as an additive to buprenorphine and proven efficiency.<sup>15</sup> Hence, in our study, we choose 5 µg dexmedetomidine as an additive.

In this study, dexmedetomidine group prolonged duration of analgesia compared to buprenorphine group which has 51% higher than later. Gupta *et al.*<sup>16</sup> had shown similar results. In our study itself, motor blockade in dexmedetomidine group was about 45% prolonged and this could be explained by increased dosage used comparing with Gupta *et al.*<sup>16</sup> study.

It was noted that 2 cases of bradycardia and nil cases of hypotension in dexmedetomidine group where on 6 cases of bradycardia and 8 cases of hypotension in buprenorphine group and they were managed successfully with the use of atropine 0.6 mg intravenously and

ephedrine in incremental doses of 6 mg. Gupta *et al.*<sup>16</sup> study, the incidence of bradycardia was more in dexmedetomidine group. Dexmedetomidine causes bradycardia but the effect is more prominent when administered intravenously with higher doses.<sup>17</sup> The sedation score (Ramsay sedation scale) was higher in patients belonging to dexmedetomidine group as compared to buprenorphine group and it is statistically significant.

## LIMITATION

The absence of control group to compare the effect of drugs separately is lacking in our study.

## CONCLUSION

Dexmedetomidine as intrathecal adjuvant with 0.5% hyperbaric bupivacaine prolong the sensory and motor blockade with fewer side effects and the degree of sedation is better.

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# Estimating the Height of an Individual from the Length of Ulna in Tamil Nadu Population and its Clinical Significance

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## Abstract

**Introduction:** The height of an individual is a very important parameter for establishing the identification. The height can be indirectly estimated from different parts of the skeleton. Such estimations are of great use in anthropometry, forensic science, and anatomy. Ulna bone has been chosen because it is subcutaneous and can be used for measurements.

**Objective:** The objective of this study is to estimate the height of an individual from the length of ulna using a derived equation and to compare the results with other studies done in different populations.

**Materials and Methods:** The study was done on 300 subjects who were patients and the attenders visiting the out patient Department of Sri Muthukumaran Medical College Hospital and Research Institute, Chennai, Tamil Nadu, India. The age of the subjects ranged from 20 to 50 years and was healthy without any skeletal deformity. The Institutional Ethics Committee clearance was obtained. After getting written consent from the subject, the height of the individual was measured from vertex to heel, and the length of both right and left ulna bones was measured from olecranon process to styloid process. The data were tabulated and analyzed statistically.

**Results:** In this study, the mean height of male was 164.4 cm and female was 153.7 cm. The mean length of the right ulna was 27.7 cm (males) and 25.6 cm (females). The mean length of the left ulna was 27.6 cm (males) and 25.4 cm (females). Pearson's correlation interpreted a very high significant ( $P < 0.001$ ) relation between the length of the ulna and the height. The regression equation was derived to estimate the height of an individual from the length of the ulna in males and females.

**Conclusion:** The ulna bone length is a reliable and accurate parameter which is used in estimating the height of an individual. The regression equation, which was derived in this study, can be of great help to anatomists, clinicians, anthropologists, and forensic scientists.

**Key words:** Estimation of height, Height of individual, Length of ulna bone, Stature of individual, Ulna bone

## INTRODUCTION

The height of an individual is one of the important parameters for establishing the identification. In bedridden, old or individuals with skeletal deformity the height can be indirectly estimated from different parts of skeleton.<sup>1</sup> Such estimations are of great use in anthropometry, forensic

science, and anatomy.<sup>1,2</sup> Previous studies in this regard have been done on cadavers. The measurements taken on a cadaver may not be accurate because of the positioning of cadaver, age factor or due to debilitating diseases.<sup>3</sup> Hence, measurement on live subjects gives an accurate data for deriving the regression equation to correlate the height of an individual with length of the ulna.

This study used ulna bone as it is subcutaneous and hence surface landmarks such as olecranon and styloid process are easily identifiable and can be used for measurements.<sup>4</sup> Ossification of ulna starts at the 8<sup>th</sup> week of fetal life and the proximal epiphysis fuses with the shaft at the 14<sup>th</sup> year in females and 15<sup>th</sup> year in males. The distal epiphysis fuses at the 17<sup>th</sup> year in females and 18<sup>th</sup> year in males. After

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50 years, there will be some degenerative changes in joints and cartilages and also spinal cord shrinkage affecting the height of an individual.<sup>4</sup> Hence, the age group considered for the study ranged from 20 and 50 years.

Factors, such as race, gender, and nutrition, determine the height of an individual. Hence, a population and gender specific formula are necessary for estimating the height of an individual. The objective of this study is to estimate the height of an individual from the length of ulna using a derived equation for Tamil Nadu population and to compare the results of our study with other studies done in different populations.

## MATERIALS AND METHODS

This study was done on 300 subjects (119 males and 181 females) who were the patients and the attenders visiting the Outpatient Department of General Medicine of Sri Muthukumaran Medical College Hospital and Research Institute, Chennai, Tamil Nadu, India. The Institutional Ethics Committee clearance was obtained. Subject information sheet was given to the patients and written informed consent was obtained from them. Following are the inclusion criteria for the study: (1) The age of the subjects ranged from 20 to 50 years and (2) The subjects were healthy without any skeletal deformity. The exclusion criteria for the study were: (1) Bedridden patients and (2) Patients who did not know their age.

The subjects were made to stand erect in anatomical position. The height of the individual subject was measured from vertex to heel in centimeters using a standard height measuring scale. The subjects were asked to fully flex the elbow with palms spread over opposite shoulder. The length of both right and left ulna bone was measured in centimeters from tip of olecranon process to tip of styloid process using a measuring tape. The data thus obtained were tabulated separately for male and female and were analyzed statistically.

### Statistical Analysis

IBM SPSS Statistics Version 20 was used. Mean, standard deviation, and range were calculated for height of the subjects and length of the ulna bone (on both sides

separately). The above statistics were interpreted by Student's *t*-test.

Pearson's correlation was used for comparing the relationship between the height of the individual and length of the ulna bone of the study subjects. Simple regression equation was derived for both sides in male and female separately. *P* values ( $P \leq 0.05$ ) were treated as statistically significant.

## RESULTS

The study subjects were analyzed according to their height and length of ulna as follows Table 1.

In Table 1, the comparison between the height of the individual and length of ulna of male and female has been done. The mean height of male was  $164.4 \pm 6.4$  cm (range: 147.4-179 cm) and female was  $153.7 \pm 7.0$  cm (range: 138.7-173 cm). The difference between the mean heights of male and female was statistically very highly significant ( $P < 0.001$ ). The mean length of right ulna bone in male was  $27.7 \pm 1.3$  cm (range: 24.4-31 cm) and in female was  $25.6 \pm 1.3$  cm (range: 23-29.5 cm). The difference between the mean length of the right ulna of male and female was statistically very highly significant ( $P < 0.001$ ). The mean length of left ulna bone in male was  $27.6 \pm 1.4$  cm (range: 24-31 cm) and in female was  $25.4 \pm 1.3$  cm (range: 22.9-29.4 cm). The difference between the mean length of left ulna of male and female was statistically very highly significant ( $P < 0.001$ ).

The mean length of the right ulna was  $27.7 \pm 1.3$  cm and left ulna was  $27.6 \pm 1.3$  cm in males. In females, the mean length of the right ulna was  $25.6 \pm 1.3$  cm, and left ulna was  $25.4 \pm 1.3$  cm. The difference between the mean length of right and left ulna was not statistically significant in both male and female as per Student's *t*-test interpretation ( $P > 0.05$ ) as shown in Table 2.

Pearson's correlation was used to interpret the relationship between the length of ulna and height of the individual. In this study, the coefficient correlation (*r*) was 0.754 (right ulna) and 0.745 (left ulna) in males; 0.691 (right ulna) and 0.701 (left ulna)

**Table 1: Comparison of height of the individual and ulna bone length between the male and female**

Variable	Mean $\pm$ SD		Difference between the mean	<i>t</i>	d.f	Significance
	Male <i>n</i> =119	Female <i>n</i> =181				
Height (cm)	164.4 $\pm$ 6.4	153.7 $\pm$ 7.0	10.7	13.293	298	<i>P</i> <0.001
Right ulna (cm)	27.7 $\pm$ 1.3	25.6 $\pm$ 1.3	2.1	13.525	298	<i>P</i> <0.001
Left ulna (cm)	27.6 $\pm$ 1.4	25.4 $\pm$ 1.3	2.2	14.243	298	<i>P</i> <0.001

SD: Standard deviation

in females. This value of  $r$  shows a positive correlation. This indicates a very high significant ( $P < 0.001$ ) relation between the length of the ulna and the height. The % of determination which was derived from correlation coefficient ( $r$ ) showed that the male right ulna determined the height of the individual by 56.85% ( $r^2$ ) and left ulna determined the height by 55.5% ( $r^2$ ). Similarly, the female right ulna determined the height of the individual by 47.7% ( $r^2$ ) and left ulna determined the height by 49.1% ( $r^2$ ) as shown in Table 3.

The above respective regression equation may be used for estimation of the individual height. The estimated height of male using either right or left side length of ulna may be equal. Similarly, in female estimated height may be equal using either right or left side length of the ulna.

## DISCUSSION

This study was done to observe the relationship of length of ulna bone with the height of the individual. With the acquired data, a regression equation was derived to estimate the height of an individual from the length of the ulna.

Height depends on age, gender, and race hence varies in various populations. This study is a population-specific study, which was done in Tamil Nadu population. The mean height of males were higher than females (males: 164.3 cm, female: 153.7 cm) in this study, which was also observed in other studies done in Eastern India population<sup>5</sup> (males: 167.5 cm, females: 152.5 cm), Gujarat population<sup>2</sup> (males: 169.8 cm, females: 155.2 cm), Maharashtra population<sup>1</sup> (males: 171.9 cm, female: 165.4 cm), West Bengal population<sup>3,6</sup> (males: 164.3 cm, females: 153.8 cm), and Sri Lanka population<sup>7</sup> (males: 170.1 cm, females: 157.6 cm).

The age group for this study was 20-50 years. Ossification of ulna begins at the 8<sup>th</sup> week of fetal life. The proximal

epiphysis fuses with shaft at 16<sup>th</sup> year and distal epiphysis fuses at the 18<sup>th</sup> year in females and 20<sup>th</sup> year in males. After 50 years, some degenerative changes in joints and cartilage will affect the height.<sup>4</sup>

Ulna bone was used in this study because it is subcutaneous and the surface landmarks were easily measurable. The estimation of height from the length of the ulna was more accurate and reliable when compared to other studies done using foot,<sup>8</sup> tibia,<sup>9</sup> skull,<sup>10</sup> and radius<sup>11</sup> length. Ulna bone length can be advantageous, especially when there is a lower trunk and lower extremity deformity.<sup>12</sup>

Pearson's correlation was used to predict the significant relationship between the height and length of ulna of the subjects. In this study, the coefficient correlation ( $r$ ) was 0.754 (right ulna) and 0.745 (left ulna) in males; 0.691 (right ulna) and 0.701 (left ulna) in females. This value of  $r$  shows a positive correlation. This indicates a very high significant ( $P < 0.001$ ) relation between the length of the ulna and the height.

This was also similar to Mondal *et al.*,<sup>3,6</sup> who also observed that coefficient correlation ( $r$ ) was 0.786 (right ulna) and 0.687 (left ulna) in males; 0.67 (right ulna) and 0.82 (left ulna) in females. Prasad *et al.*<sup>1</sup> calculated the coefficient correlation ( $r$ ) as 0.65 in males and 0.68 in females. Hence, confirming this study's observation that length of ulna bone can give a correct estimation of height because of a very high significant relation between the length of ulna and height.

The simple regression analysis was done to know the strength of the relation between length of ulna and height. According to Lal and Lala,<sup>13</sup> regression coefficient ( $b$ ) is a better guide for calculation of height of an individual

**Table 2: Comparison of ulna length between right and left in male and female**

Sex	Mean±SD		Difference between the mean	t	d.f	Significance
	Right ulna length (cm)	Left ulna length (cm)				
Male	27.7±1.3	27.6±1.4	0.1	0.068	236	$P>0.05$
Female	25.6±1.3	25.4±1.3	0.2	0.866	360	$P>0.05$

SD: Standard deviation

**Table 3: Estimation of height of male and female from length of ulna**

Sex	Side	Correlation coefficient ( $r$ )	$r^2$	% of determination	Regression equation ( $Y=a+bX$ )
Male	Right	0.754	0.5685	56.85	$Y=63.984+3.631X$
	Left	0.745	0.555	55.5	$Y=66.232+3.551X$
Female	Right	0.691	0.477	47.7	$Y=57.995+3.745X$
	Left	0.701	0.491	49.1	$Y=56.048+3.839X$

Y: Height of an individual, a: Constant, b: Regression coefficient of X, X: Length of ulna



**Table 4: Regression coefficient in different populations**

Study	Region	Male		Female	
		Right	Left	Right	Left
Present study	Tamil Nadu	3.631	3.551	3.745	3.839
Thummar <i>et al.</i> <sup>2</sup>	Gujarat	3.117	3.667	5.314	5.335
Prasad <i>et al.</i> <sup>1</sup>	Maharashtra	2.92	2.92	2.37	2.37
Mondal <i>et al.</i> <sup>3,6</sup>	West Bengal	4.19	3.26	3.89	4.39
Mehta <i>et al.</i> <sup>14</sup>	Madhya Pradesh	3.562	3.285	3.562	3.285
Allbrook <sup>15</sup>	British	3.06	3.06	3.06	3.06
Illayaperumal <i>et al.</i> <sup>7</sup>	Sri Lanka	2.645	2.645	3.536	3.536

when the identity of the individual is not known. In this study, it was 3.631 (right ulna) and 3.551 (left ulna) in males; 3.745 (right ulna) and 3.839 (left ulna) in females. Following is the comparison of regression coefficient of our study with other studies in different populations, as given in Table 4.

In this study, the regression equations derived for Tamil Nadu population will help in estimating the height of an individual from the length of ulna bone. This equation will serve as an alternative for prediction of height, which can be used for nutritional assessment in bedridden patients, old patients, or patients with skeletal deformity.<sup>16</sup> It can be used in forensic science to predict the stature from incomplete or decomposed skeletal remains which help to establish the identity of an unknown individual.<sup>1,2,17</sup> Anthropometry uses various scientific methods and the techniques for estimating the various measurements on the living as well as the skeleton of man.<sup>2</sup> For biological anthropologists, it is important to update their researches on diverse population groups residing in different geographic zones.<sup>8</sup> Hence, this study will help the anthropologists in their further researches.

## CONCLUSION

The length of the ulna bone is a reliable and accurate parameter, which is used in estimating the height of an individual. The regression equation, which was derived in this study, can be of great help to anatomists, clinicians, anthropologists, and forensic scientists.

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# Usefulness of Bolus Intravenous Sodium Bicarbonate in Prevention of Contrast-Induced Nephropathy in Patients Undergoing Percutaneous Cardiac Interventions

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## Abstract

**Introduction:** Contrast-induced nephropathy (CIN) is the third most common cause for acute kidney injury and occurs in 13-20% of patients undergoing catheter procedures.

**Materials and Methods:** A study was conducted to assess the effectiveness of an additional intravenous bolus sodium bicarbonate to the standard regimen which was followed in our institution (i.e., 12 h hydration and 3 days of N-acetyl cysteine).

**Results:** In this study of 185 patients, the incidence of CIN was not statistically different, but there was a trend toward lower serum creatinine levels and higher estimated glomerular filtration rate (eGFR) in the test group which could suggest a lower incidence of CIN if the sample size was larger.

**Conclusion:** Significant improvement in eGFR was seen in patients who received sodium bicarbonate in addition to the standard treatment.

**Key words:** Contrast induced nephropathy, Estimated glomerular filtration rate, Intravenous sodium bicarbonate, N acetyl cysteine

## INTRODUCTION

Contrast-induced nephropathy (CIN) is estimated to occur in up to 13-20% of patients with chronic renal impairment undergoing cardiac catheterization. 0.5-12% of these patients require hemodialysis and longer hospitalization. Therapeutic measures available for decreasing CIN includes (1) Hydration with saline, (2) N-acetyl cysteine (NAC), and (3) intravenous (IV) sodium bicarbonate. Recent studies have suggested that a single bolus IV administration of sodium bicarbonate is more protective

than plain hydration alone in the prevention of CIN. This finding has to be validated in the South Indian population and compared with the previous data from studies done in other populations.

## Aim and Objectives

1. To estimate the burden of CIN in South Indian population undergoing cardiac interventions
2. To compare the efficacy of IV sodium bicarbonate with isotonic saline and NAC versus isotonic saline and NAC to prevent CIN in patients with renal dysfunction undergoing cardiac interventions.

## MATERIALS AND METHODS

Patients with mild to moderate renal dysfunction undergoing cath procedures were randomised to test and control groups according to randomisation table. 105

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patients were randomised to test group ( Group A ) and 80 patients to control group ( Group B ).

Group A (sodium bicarbonate + hydration + NAC)

Or

Group B (hydration + NAC)

Patients in the Group A received single bolus IV administration of sodium bicarbonate (25 ml of 7.5% NaHCO<sub>3</sub> = 22.5 meq) 5 min before the contrast exposure in addition to standard hydration and NAC.

Standard hydration consisted of 0.9% NaCl at 1 ml/kg/h (0.5 ml/kg/h for patients with left ventricular ejection fraction [LVEF] <40%) for 12 h. Diuretics were withheld for the day of the procedure. NAC was given at 1200 mg twice daily 1 day before the procedure and 2 days after the procedure.

Non-ionic contrast agent was used for all patients. Elective procedures were done using the radial/femoral approach. Serum creatinine and S.K+ levels were measured at baseline and on day three after the procedure.

The primary endpoint was the development of CIN defined as an increase in the creatinine of >25% or >0.5 mg/dl within the first 3 days after the procedure compared to baseline.

#### Inclusion Criteria

1. Age >18 years
2. eGFR between 30 and 90 ml/m
3. Elective coronary angiograms/percutaneous coronary interventions/cardiac catheterizations/peripheral angiograms.

#### Exclusion Criteria

1. Allergy to contrast medium
2. Pregnancy
3. Dialysis dependency
4. Exposure to contrast agent within the preceding 48 h of the study
5. Class 4 NYHA heart failure
6. LVEF <20%
7. Single functioning kidney
8. Use of concomitant nephrotoxic agents.

## RESULTS

The baseline characteristics were similar in the test group and control group. The mean amount of contrast used was also similar (Table 1).

The majority of procedures done in the test group were coronary angiograms (Group A) (Graph 1).

The majority of procedures done in the test group were also coronary angiograms (Group B) (Graph 2).

Table 2 shows that there was a statistically significant improvement in eGFR in the test group. There was an improvement in creatinine values also which did not reach statistical significance (Table 2).

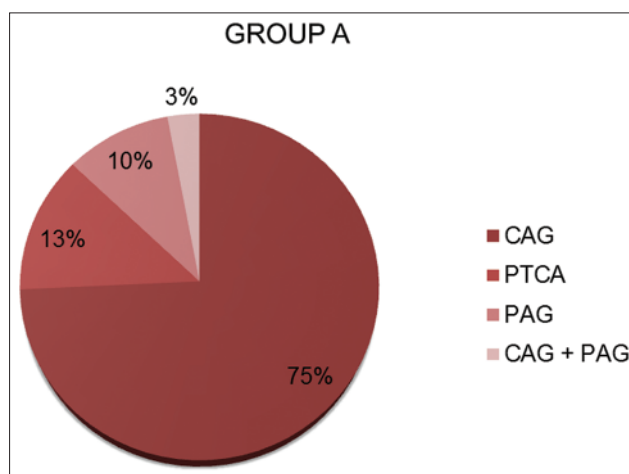
Table 3 shows that there was no statistically significant difference of baseline creatinine or day 3 creatinine between the test and control groups.

Graph 3 depicts in a bar diagram format the baseline and day 3 creatinine of Group A (test group) and baseline and day 3 creatinine of Group B (control group). There is a decrease in the serum creatinine on day 3 in the test group but it was not statistically significant (Graph 3).

Table 4 compares the baseline eGFR of test versus control groups and day 3 eGFR of test versus control groups. A statistically significant improvement in eGFR was observed in the test group on day 3 with  $P = 0.01$  (Table 4).

**Table 1: Baseline characteristics of the test group (Group A) versus the control group (Group B)**

Characteristics	Group A -105 (test)	Group B - 80 (control)	P value
Mean age	57.60 years	59.60 years	-
Males (%)	45 (71.4)	48 (76.2)	0.69
Diabetes (%)	37 (58.73)	35 (55.55)	0.86
Hypertension (%)	46 (73)	43 (68.25)	0.70
Dyslipidemia (%)	34 (53.97)	40 (63.49)	0.37
Smoking (%)	33 (52.38)	36 (57.14)	0.72
Contrast volume	58 ml	61 ml	0.69



**Graph 1: The cath procedures done in Group A**

**Table 2: A comparison of baseline creatinine versus day 3 creatinine and baseline eGFR versus day 3 eGFR in Group A and B**

Groups	P value
Group A	
Creat baseline versus creat D3 (1.26 vs. 1.21)	0.11
eGFR baseline versus eGFR D3 (58.19 vs. 62.49)	0.02
Group B	
Creat baseline versus creat D3 (1.26 vs. 1.29)	0.17
eGFR baseline versus eGFR D3 (56.37 vs. 54.86)	0.19
Group A versus Group B	
Creat baseline Group A versus Group B (1.257 vs. 1.263)	0.87
Creat D3 Group A versus Group B (1.211 vs. 1.294)	0.12

eGFR: Estimated glomerular filtration rate

**Table 3: A comparison of baseline creatinine values of test and control group and day 3 creatinine values of test and control group**

Group A versus Group B	P value
Creat baseline	0.87
Group A versus Group B (1.257 vs. 1.263)	
Creat D3	0.12
Group A versus Group B (1.211 vs. 1.294)	

**Table 4: A comparison of baseline eGFR values of test versus control group and day 3 eGFR values of test versus control group**

Group A versus Group B	P value
eGFR baseline Group A versus Group B	0.40
eGFR D3 Group A versus Group B	0.01

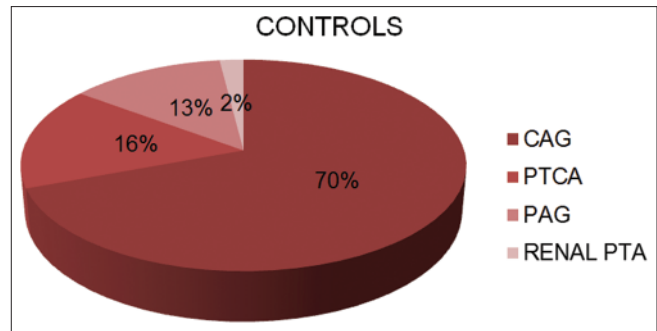
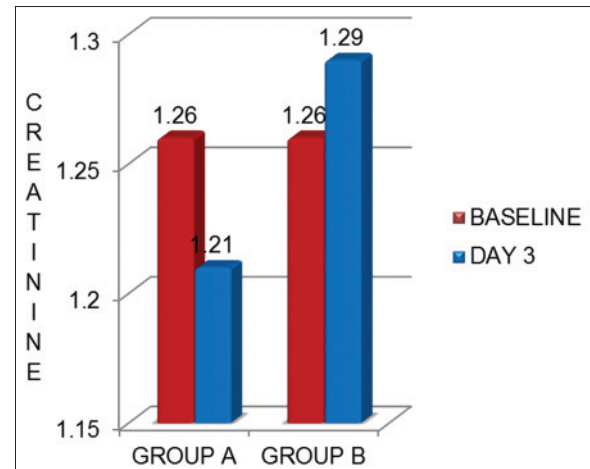
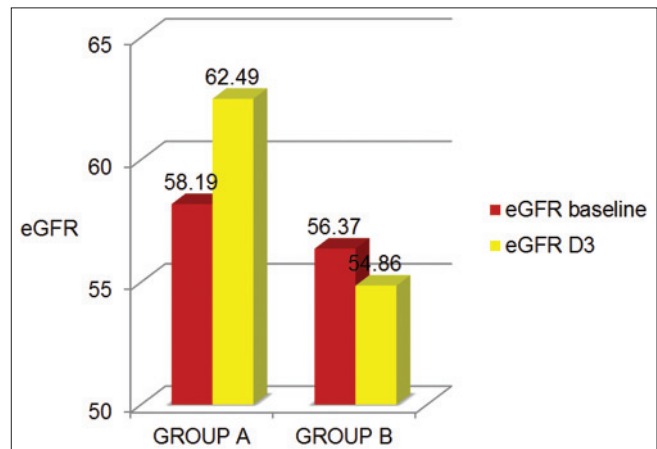
eGFR: Estimated glomerular filtration rate

Graph 4 depicts in a bar diagram format the baseline and day 3 eGFR of Group A (test group) and baseline and day 3 eGFR of Group B (control group). There is an increase in the eGFR on day 3 in the test group, whereas in the control group there was a decrease of eGFR (Graph 4).

The incidence of primary endpoint – CIN was 3.78% (7 patients) in the study 3.81% (4 patients) in the Group A and 4.76% (3 patients) in the Group B ( $P = 0.65$ ). There was no statistically significant difference in the primary endpoint CIN between the test and control groups. The majority of patients who developed CIN had a percutaneous transluminal coronary angioplasty as the cath procedure, which may be due to the higher amount of contrast used (Graph 5).

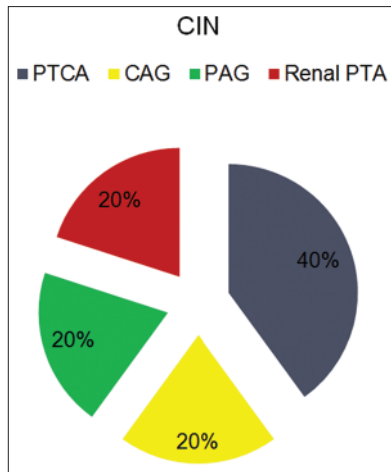
## DISCUSSION

CIN occurs in 13-20% patients following IV contact administration. It is defined as an increase in serum

**Graph 2: The cath procedures done in Group B****Graph 3: A graph comparing baseline creatinine values of test and control group and day 3 creatinine values of test and control group****Graph 4: A graph comparing baseline estimated glomerular filtration rate (eGFR) values of test and control group and day 3 eGFR values of test and control group**

creatinine by 25% from baseline or an increase in absolute value by 0.5 mg/dl within 48-72 h of exposure to contrast material. The incidence is more in patients with prior kidney disease, diabetes mellitus, dehydration, congestive heart failure, larger volumes of contrast used, and in patients with recent exposure to contrast material (<48 h).<sup>1</sup>





**Graph 5: The procedures done for 7 patients who developed contrast induced nephropathy expressed in percentage**

There are various mechanisms by which contrast agents cause kidney damage. They are:

1. Direct cytotoxic effect on the renal proximal tubular cells
2. Increased cellular damage by reactive O<sub>2</sub> species
3. Increased resistance to blood flow
4. Renal vasoconstriction particularly in deeper portions of outer medulla:
  - a. By direct action on V.S.M.C
  - b. From metabolites such as adenosine and endothelin
  - c. Osmotic contrast agents decrease water reabsorption leading to increased interstitial pressures:
    - Decreases GFR and causes local compression of vasa recta.
5. Contrast agents increase resistance to blood flow by increasing blood viscosity and increasing red cell deformability:
  - This sludging generates local ischemia
  - Activate reactive oxygen species that result in tubular damage at a cellular level.<sup>2,3</sup>

The cornerstone for prevention of CIN is hydration. The renal blood flow is compromised for about 20 h following a contrast administration. Intravascular volume expansion maintains renal blood flow, preserves NO production, prevents hypoxemia, and increases contrast elimination.<sup>4-7</sup>

A number of other strategies are also investigated including statins, IV soda bicarbonate, NAC, vitamin C, theophylline, aminophylline, and even hemodialysis.

IV sodium bicarbonate has many proposed mechanisms of action.<sup>8,9</sup> NaHCO<sub>3</sub> makes urine more alkaline and thus increases free radical and peroxide-mediated injury as they are generated more in an acidic environment.<sup>10</sup>

Most of the previous systematic reviews and relevant meta-analyses demonstrated that IV NaHCO<sub>3</sub> could decrease the incidence of CIN.<sup>11-21</sup> However, secondary endpoints like RRT and mortality were not improved with soda bicarbonate therapy. The result of this study did not show any significant differences in the incidence of CIN among patients who received IV saline plus NAC versus those who received additional NaHCO<sub>3</sub> as a single IV bolus. The overall incidence of CIN was very low which was probably due to the aggressive hydration protocol. There was even one study from Mayo clinic wherein they found that NaHCO<sub>3</sub> was associated with an increase in incidence of CIN.<sup>22</sup>

Although it was not statistically significant, there was a trend which could suggest an added benefit of NaHCO<sub>3</sub> and NAC, when the changes in creatinine values were analyzed. The reason for not reaching a statistically meaning conclusion may be the smaller size of the study group. With more patients trend might have reached statistical significance. The patients needed for a statistically significant study was much higher than our initial calculation. The remedial trial, with a much larger sample size, was an adequately powered study and it demonstrated a significant benefit from addition of IV NaHCO<sub>3</sub> to the existing therapies.<sup>23</sup>

A number of trials and meta-analyses have found that a combination of NAC and NaHCO<sub>3</sub> is superior to either agent used alone in the prevention of CIN. Three studies on patients who got NAC in both groups and additional NaHCO<sub>3</sub> for the test group favored the NaHCO<sub>3</sub> group.<sup>23-25</sup>

In a study hydration with NaHCO<sub>3</sub> in addition to NAC high dose was associated with lesser incidence of CIN in the setting of urgent percutaneous coronary intervention for ST-elevation myocardial infarction.<sup>26</sup> However, in studies done by Yang *et al.* and Thayssen *et al.*, they could not derive any additional benefit by addition of IV NaHCO<sub>3</sub>.<sup>27,28</sup> Our study was in mild to moderate renal dysfunction patients and probably the incidence of CIN was too low in this group of patients with intense hydration. Hence, a large-scale well designed randomized controlled trials is required to determine whether NaHCO<sub>3</sub> in addition to hydration and NAC is more useful.

## CONCLUSIONS

1. Intensive hydration is the cornerstone for prevention of CIN and it can reduce the incidence of CIN to very low levels
2. Addition of sodium bicarbonate was not more effective to reduce the incidence of CIN in our patients with mild to moderate renal dysfunction

3. Significant improvement in eGFR was seen in patients who received sodium bicarbonate in addition to the standard treatment.

## LIMITATIONS

The incidence of primary endpoint was very low in the study. Studies in larger subset of patients will be required to derive a conclusion.

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# Enteropathogenic Infections in Human Immunodeficiency Virus Positive Patients in a Tertiary Care Center: A Clinicomicrobial Study

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## Abstract

**Background:** Since the beginning of the human immunodeficiency virus (HIV) epidemic, opportunistic infections have been recognized as common complications of HIV infection. Intestinal opportunistic infections present commonly as diarrhea. Several species of protozoa and other bacterial infections have been associated with acute and chronic diarrhea in HIV-infected patients.

**Aims:** The objective of this study was to find out the prevalence and presentation of enteropathogenic infections in HIV-positive patients and to study the correlation between CD4 cell count and the prevalence of intestinal parasites.

**Materials and Methods:** A total of 100 consecutive HIV-positive patients were included in the study. All patients above 15 years of age who were positive for HIV by two rapid tests and ELISA were taken for the study. Stool samples were sent for the evaluation of parasites using wet saline method, wet iodine method, floatation technique, sedimentation technique, modified acid-fast staining, and stool culture.

**Results:** Out of 100 HIV positive cases, 72% were below the age group of 40. The age range varied from 25 to 55 years. Enteric pathogens were recovered from 65% of patients. *Cryptosporidium* was the most common pathogen isolated which was found in 50.76% of the patients. The other pathogens isolated were *Isospora belli* (4.62%), *Microsporidia* (1.54%), *Entamoeba histolytica* (4.62%), *Ancylostoma duodenale*, and *Escherichia coli* seen in 1.54% each. Mixed infections were seen in 35.38% of the patients. The prevalence of infections was high in patients with CD4 count <200/mm<sup>3</sup>. Most of the patients with a lower CD4 count were symptomatic.

**Conclusion:** In our study, coccidian parasites were the most common gastrointestinal pathogens isolated. About 80% of the patients who harbored enteropathogens were symptomatic. Mixed infections were commonly seen in profoundly immunosuppressed patients. Patients with advanced illness were more symptomatic than those in the early stages.

**Key words:** *Cryptosporidium*, Enteropathogens, Human immunodeficiency virus

## INTRODUCTION

Human immunodeficiency virus (HIV) infection is a major threat to the human population across the world though the incidence of HIV infection is falling globally. These

patients suffer from various opportunistic infections, most commonly encountered being tuberculosis, candidiasis, *Pneumocystis jiroveci* pneumonia, and diarrhea due to various pathogens.<sup>1</sup> Studies indicate that diarrhea due to enteropathogenic infections occurs in 30-60% of HIV/acquired immune deficiency syndrome (AIDS) patients. Chronic diarrhea is responsible for considerable morbidity and mortality in such patients. Only few studies regarding the prevalence of intestinal opportunistic infections in HIV-infected patients are done in South India. This study was done to evaluate the prevalence of such infections in HIV patients in our setup and to ascertain the importance of stool examination for the detection of enteropathogens

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that AIDS in treatment, thereby decreasing the morbidity and mortality due to opportunistic gastrointestinal infections.

## MATERIALS AND METHODS

The study was conducted in the Department of Dermatology-Venereology, Government Rajaji Hospital, Madurai, Tamil Nadu, India. A total of 100 patients were included in the study irrespective of the symptomatology, CD4 count, and anti-retroviral therapy status. Patients older than 15 years of age who were positive for HIV by two rapid tests and ELISA were taken for the study. Socio-demographic and clinical data were collected. Routine blood, urine investigations, and CD4 count were done in all patients. Stool samples were collected in two containers, one containing glycerol phosphate buffer and other containing formol saline. The following methods were done for the evaluation of parasites – wet saline method, wet iodine method, floatation technique, sedimentation technique, modified acid-fast staining, and stool culture. Two smear preparations, one unstained preparation and another stained with Lugol's Iodine were made. Unstained preparation is specially useful for demonstration of actively motile forms of parasites like *Entamoeba histolytica*. Wet iodine mount helps in the visualization of the cysts of protozoa. Modified acid-fast staining was done to detect *Cryptosporidium* and *Isospora*. Staining for *Microsporidia* was done using strong trichrome stain. For enteric bacterial pathogens stool culture was done on nutrient agar and MacConkey agar plates.

## OBSERVATIONS AND RESULTS

The following observations were made from the study. Out of the 100 patients 54 were males and 46 were females. Out of the male patients 66% were symptomatic and out of the female patients 54% were symptomatic (Table 1). The symptoms included diarrhea, vomiting, abdominal pain, flatulence, and dyspepsia. 72% of the patients were below the age group of 40. The age range was from 25 to 55 years (Table 2). In our study, we observed that 65% of the patients harbored enteric pathogens. *Cryptosporidium* was isolated in 50.76% of the patients, *Isospora belli* in 4.62%, *Microsporidia* in 1.54%, *E. histolytica* in 4.62%, *Ancylostoma duodenale* in 1.54%, and *Escherichia coli* in 1.54% of the patients. 35.38% of the patients had mixed infections (Table 3). The majority of enteric infections were observed in patients with CD4 < 200 and most of them were symptomatic (Table 4).

## DISCUSSION

Enteric pathogens are common opportunistic infections and are a major cause of morbidity and mortality in HIV-infected people. The prevalence of enteric pathogens shows wide geographic variations and their isolation carries importance while treating HIV patients especially in advanced stage of immunosuppression. In this study, enteric pathogens were isolated from 65% of patients. A study conducted by Mohandas *et al.*<sup>2</sup> showed only 30% prevalence of enteropathogens. The prevalence in relation to CD4 count or stage of the disease has not been mentioned in their study. The majority of our patients were in Stage III and IV of the disease, which account for the increased prevalence of enteric pathogens in our patients. Variations in socioeconomic status, personal hygiene, quality of water supply may also have a role in the disparity. The study conducted by Kumar *et al.*<sup>3</sup> at Chennai in 152 HIV-positive patients showed 34.21% of enteric parasites, which is also very low compared to our study. About 80% of our patients who harbored enteric pathogens had symptoms such as diarrhea, vomiting, nausea, belching, flatulence, and colicky abdominal pain. Diarrhea was the predominant symptom seen in all patients, a finding also recorded in other studies.

**Table 1: Symptomatology and sex distribution**

Gender	With symptoms	Without symptoms	Total
Males	36	18	54
Females	25	21	46
Total	61	39	100

**Table 2: Age distribution**

Age	Male	Female	Total
<30	6	12	18
31-40	27	26	53
41-50	20	6	26
>50	1	2	3

**Table 3: Enteric pathogens in relation to symptoms**

Enteropathogen	With gastrointestinal symptoms (%)	Without gastrointestinal symptoms (%)	Total in percentage
<i>Cryptosporidium</i>	27 (41.53)	6 (9.23)	50.76
<i>Isospora</i>	2 (3.08)	1 (1.54)	4.62
<i>Microsporidia</i>	1 (1.54)	-	1.54
<i>Entamoeba histolytica</i>	1 (1.54)	2 (3.08)	4.62
<i>Ancylostoma duodenale</i>	1 (1.54)	-	1.54
<i>Escherichia coli</i>	1 (1.54)	-	1.54
Mixed infections	19 (29.23)	4 (6.15)	35.38
Total	52 (80)	13 (20)	100



**Table 4: Enteropathogens in relation to CD4 count**

Pathogen	CD4<200		CD4=201-499		CD4>500	
	Symptomatic (%)	Asymptomatic (%)	Symptomatic (%)	Asymptomatic (%)	Symptomatic (%)	Asymptomatic (%)
<i>Cryptosporidium</i>	25 (38.45)	1 (1.54)	1 (1.54)	5 (7.69)	-	1 (1.54)
<i>Isospora</i>	2 (3.08)	-	-	1 (1.54)	-	-
<i>Microsporidia</i>	1 (1.54)	-	-	-	-	-
<i>Entamoeba histolytica</i>	1 (1.54)	1 (1.54)	-	-	-	1 (1.54)
<i>Ancylostoma duodenale</i>	1 (1.54)	-	-	-	-	-
<i>Escherichia coli</i>	1 (1.54)	-	-	-	-	-
Mixed infections	17 (26.14)	1 (1.54)	2 (3.08)	-	-	3 (4.62)

Gupta *et al.* showed in their study that 55.8% of patients were symptomatic, comparatively lower than that in our study. Out of the 100 patients screened, *Cryptosporidium* was the sole pathogen isolated in 33 patients, and in 21 patients, it was seen as a mixed infection. The prevalence as a sole isolate was 50.76%. The study done by Chakraborty *et al.*<sup>4</sup> showed a prevalence of 43% of cryptosporidial diarrhea in a sample size of 125. *Isospora* was found in only 4.62% of the patients, comparable with Mohandas *et al.* study but study done by Kumar *et al.* revealed a higher percentage (13.7%).<sup>3</sup> *E. coli* was the most common bacterial isolate and *Klebsiella* was seen in 2 patients of mixed infection. Mixed infections were noted in 23 (35.38%) patients. *Cryptosporidium* was the predominant pathogen isolated in the mixed infections. Out of these 23 patients, 18 (78.2%) had CD4 count <200. 82.6% of patients with mixed infections were symptomatic. These features signify the importance of immune system in clearing the enteric infections and that advanced immunosuppression provides a favorable environment for mixed infections. The majority of enteric infections were observed in patients with CD4 <200 and most of them were symptomatic.

## CONCLUSION

There are wide geographic variations in the prevalence of enteropathogenic infections in HIV-infected people due to variations in socioeconomic conditions, literacy rates, hygiene practices, and availability of safe drinking water. In our study, 65% of our study population harbored an enteropathogen and coccidian parasites were the most common pathogens isolated.

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# Comparative Study of the Diagnostic Ability of Ultrasonography and Magnetic Resonance Imaging in the Evaluation of Chronic Shoulder Pain

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## Abstract

**Introduction:** Shoulder pain is recognized as a disabling problem. The most common causes of shoulder pain in primary care are reported to be rotator cuff disorders, acromioclavicular joint diseases, and glenohumeral joint disorders. The final diagnosis in case of chronic shoulder pain is based on a collective clinical as well as radiological evaluation which includes radiographs, ultrasonography (USG), and magnetic resonance imaging (MRI).

**Materials and Methods:** After obtaining ethical clearance, 85 cases of chronic shoulder pain were enrolled for the study. A detailed history with clinical examination was done. Patients were subjected to X-ray anterior-posterior and axial as initial investigation. On viewing, the X-ray next modality was decided. All those cases where no obvious bony lesion was seen were further evaluated by USG and MRI. The diagnosis was confirmed by arthroscopy.

**Result:** For partial thickness tear of supraspinatus, USG had a sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of 60%, 97.6%, 95.5%, 74.1%, and 80.3%, respectively, as compared to 88.6%, 96.0%, 93.9%, 92.3%, and 92.9%, respectively, for the same parameters on MRI. For full thickness tear of supraspinatus, USG had a sensitivity, specificity, PPV, NPV, and accuracy of 95.2%, 90.6%, 76.9%, 98.3%, and 91.8%, respectively, as compared to 95.2%, 98.4%, 95.2%, 98.4%, and 97.6%, respectively, for the same parameters on MRI.

**Conclusion:** As far as comparative evaluation of USG and MRI, except for full thickness tear where both the modalities had equal sensitivity, for all the other diagnoses MRI showed a higher sensitivity. However, for partial thickness tear, USG had a higher specificity as compared to MRI; for all the other diagnoses, MRI showed a higher specificity. In terms of overall accuracy, MRI had a higher accuracy as compared to USG, for all the diagnoses except for full thickness tears.

**Key words:** Arthroscopy, Chronic shoulder pain, Full thickness tear, Partial thickness tear, Tendinosis, Ultrasonography

## INTRODUCTION

Shoulder pain is recognized as a disabling problem and is one of the most common reasons for visit to a general practitioner with nearly 1% of the adult population reporting with new episodes of shoulder pain.<sup>1</sup>

Shoulder pain is defined as chronic when it has been present for longer than 6 months. Compromised shoulder movement due to pain, stiffness, or weakness can cause substantial disability and affect a person's ability to carry out daily activities (eating, dressing, personal hygiene) and work.

Thus, it is a severe disability and results in a heavy loss of working days and disability. Shoulder complaints may have an unfavorable outcome, with only about 50% of all new episodes of shoulder complaints presenting in medical practice showing a complete recovery within 6 months.<sup>1,2</sup> After 1 year, this proportion increases to 60%.<sup>2</sup>

Although community data on shoulder pain is limited, the prevalence of shoulder pain among in urban and rural

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populations of India has been reported to be 2% and 7.4%, respectively.<sup>3,4</sup>

The most common causes of shoulder pain in primary care are reported to be rotator cuff disorders, acromioclavicular joint disease, and glenohumeral joint disorders,<sup>5</sup> with classification of these disorders based primarily on results of clinical tests.<sup>6-9</sup> However, inconsistent diagnostic terminology,<sup>10</sup> lack of universally accepted diagnostic classification criteria,<sup>11,12</sup> and poor specificity of many physical examination tests,<sup>13,14</sup> hamper confidence in classification systems that use clinical test criteria alone.

The final diagnosis in case of chronic shoulder pain is based on a collective clinical as well as radiological evaluation. The clinical evaluation includes both medical history as well as physical assessment. The role of occupational history in the causation of chronic shoulder pain is also important and makes an essential part of history taking. Diagnostic imaging remains to be the next in the algorithm of achieving a final diagnosis. These include radiographs, magnetic resonance imaging (MRI), arthrography, computed tomography, and ultrasonography (USG). However, use of appropriate imaging technique depends mainly on the findings of clinical evaluation and suspected pathology. For example, for suspected diagnosis of rotator cuff disorders, MRI is preferred; whereas for suspected labral pathology, MRI arthrography is suggested.<sup>15</sup> Each of these diagnostic modalities has its own economic and financial implications as well as limitation of accuracy. Techniques such as USG are cost-effective, yet they are highly technician dependent and, therefore, have not yet gained widespread acceptance.<sup>15</sup> The vast differences in the responsible pathologies of chronic shoulder pain make it difficult to adopt a single, cost-effective diagnostic test for the final diagnosis. Thus, the diagnostic process often becomes prolonged and leads to prolongation of the quality of life of affected patient which has physical, financial, social, and psychological repercussions too.

In this research study, we made an attempt to carry out a clinico-radiological evaluation of chronic shoulder pain and comparing the diagnostic findings of two different modalities USG and MRI with arthroscopically/surgically confirmed the diagnosis to come up with a more valuable and clinically relevant algorithm for the efficient diagnosis of chronic shoulder pain.

## MATERIALS AND METHODS

### Study Design

The present study was carried out as a prospective observational study.

### Settings

The study was carried out at the Department of Radiodiagnosis, Era's Lucknow Medical College, Lucknow, Uttar Pradesh, India.

### Duration of Study

About 18 months starting from January 2014 to June 2015.

### Sampling Frame

Patients presenting with the complaints of shoulder pain were selected for the purpose of the study. The sampling frame of the study was bound by the following inclusion and exclusion criteria:

#### Inclusion criteria:

- Either gender, aged 21-60 years
- Presenting with shoulder pain for last 6 months or more.

#### Exclusion criteria:

- Patients not providing consent to participate in the study
- Having shoulder pain for less than 6 months
- History of any congenital deformity of shoulder
- Contraindication of MRI: Pacemakers and metallic implants.

### Clearance and Approvals

Clearance for carrying out the study was obtained from the Institutional Ethical Committee, Era's Lucknow Medical College, Lucknow, Uttar Pradesh, India. Informed consent was obtained from all the patients.

### Sample Size

Sample size is 85.

### Methodology

All the patients falling in the sampling frame were invited to participate in the study.

After obtaining informed consent, demographic information was noted. An elaborate history was taken from all the patients which was followed by a thorough clinical evaluation, in which duration of symptoms, affected side, dominant hand, range of movement was noted. A thorough medical history, nature of complaints, symptoms, and signs were noted. In case of an injury being the cause of shoulder pain, cause of injury was also noted.

Patients were subjected to X-ray anterior-posterior (AP) and axial as initial investigation. On viewing, the X-ray next modality was decided. All those cases where no obvious bony lesion was seen were further evaluated by USG and MRI. The diagnosis was confirmed by arthroscopy.

**X-ray machine**

In plain radiography, AP view (kv - 55 mAs - 12) and axial view (kv - 50 mAs - 9) were taken on 800 mA Siemens machine and in few cases under fluoroscopy using collimation where ever required.

**Ultrasound machine**

USG was done with a high-frequency 7.5-12 MHz broadband linear transducer on GE, Voluson P8 machine.

**MRI machine**

0.4 TESLA HITACHI APERTO.

**Statistical Analysis**

The statistical analysis was done using Statistical Package for Social Sciences Version 15.0 statistical analysis software. The values were represented in number (%) and mean.

**RESULTS**

According to arthroscopic findings, partial thickness tear of supraspinatus ( $n = 35$ ; 41.2%) was the most common diagnoses followed by full thickness of supraspinatus ( $n = 21$ ; 24.7%) and tendinosis of supraspinatus ( $n = 16$ ; 18.8%). Among other diagnoses ( $n = 13$ ; 15.3%) – labral tear was most common ( $n = 4$ ; 4.7%) subacromial-subdeltoid bursitis; partial thickness tear of subscapularis, full thickness tear of infraspinatus, and adhesive capsulitis was diagnosed in 2 (2.4%) patients each; and full thickness tear of long head of biceps in 1 (1.2%) patient (Table 1).

On USG, in a total of 16 (18.8%) patients, all the findings were found to be normal. Maximum number of patients were diagnosed as full thickness tear of supraspinatus ( $n = 26$ ; 30.6%) followed by partial thickness tear of supraspinatus ( $n = 22$ ; 25.9%) and tendinosis of supraspinatus ( $n = 11$ ; 12.9%). A total of 10 (11.8%) patients were collectively placed under diagnosis “others” – these included 2 (3.5%) cases each of partial thickness tear of subscapularis, full thickness tear of infraspinatus, adhesive capsulitis, and labral tears; and 1 (1.2%) case each was diagnosed as subacromial deltoid bursitis and full thickness tear of long head of biceps (Table 2).

As per MRI diagnosis, maximum number of cases had partial thickness tear of supraspinatus ( $n = 33$ ; 38.8%) followed by full thickness tear of supraspinatus ( $n = 21$ ; 24.7%) and tendinosis of supraspinatus ( $n = 16$ ; 18.8%). There were 12 cases (14.1%) placed under ‘others’ category that included – 3 (3.5%) labral tear, 2 (3.5%) each as subacromial deltoid bursitis, partial thickness tear of subscapularis, full thickness tear of infraspinatus, adhesive capsulitis, and 1 (1.2%) full thickness tear of long head of biceps. On MRI, 3 (3.5%) cases were diagnosed as normal (Table 3).

For partial thickness tear of supraspinatus, USG had a sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of 60%, 97.6%, 95.5%, 74.1%, and 80.3%, respectively, as compared to 88.6%, 96.0%, 93.9%, 92.3%, and 92.9%, respectively for the same parameters on MRI.

For full thickness tear of supraspinatus, USG had a sensitivity, specificity, PPV, NPV, and accuracy of 95.2%, 90.6%, 76.9%, 98.3%, and 91.8%, respectively, as compared to 95.2%, 98.4%, 95.2%, 98.4%, and 97.6%, respectively, for the same parameters on MRI.

**Table 1: Distribution according to final diagnosis based on arthroscopy**

Group	Final diagnosis	N (%)
I	Partial thickness tear of supraspinatus	35 (41.2)
II	Full thickness tear of supraspinatus	21 (24.7)
III	Tendinosis of supraspinatus	16 (18.8)
IV	Others	13 (15.3)
	Subacromial subdeltoid bursitis	2 (2.4)
	Partial thickness tear of subscapularis	2 (2.4)
	Full thickness tear of infraspinatus	2 (2.4)
	Adhesive capsulitis	2 (2.4)
	Full thickness tear of long head of biceps	1 (1.2)
	Labral tear	4 (4.7)

**Table 2: Correlation between final diagnosis and USG diagnosis**

Characteristic	N (%)			
	Group I (n=35)	Group II (n=21)	Group III (n=16)	Group IV (n=13)
Normal	7 (20.0)	0 (0.0)	6 (37.5)	3 (23.1)
Partial thickness tear of supraspinatus	21 (60.0)	1 (4.8)	0 (0.0)	0 (0.0)
Full thickness tear of supraspinatus	6 (17.1)	20 (95.2)	0 (0.0)	0 (0.0)
Tendinosis of supraspinatus	1 (2.9)	0 (0.0)	10 (62.5)	0 (0.0)
Others	0 (0.0)	0 (0.0)	0 (0.0)	10 (76.9)

USG: Ultrasonography.  $\chi^2=166.47$  (df=12);  $P<0.001$

**Table 3: Correlation between final diagnosis and MRI diagnosis**

Characteristic	N (%)			
	Group I (n=35)	Group II (n=21)	Group III (n=16)	Group IV (n=13)
Normal	1 (2.9)	0 (0)	1 (6.3)	1 (7.7)
Partial thickness tear of supraspinatus	31 (88.6)	1 (4.8)	1 (6.3)	0 (0.0)
Full thickness tear of supraspinatus	1 (2.9)	20 (95.2)	0 (0.0)	0 (0.0)
Tendinosis of supraspinatus	2 (5.70)	0 (0.0)	14 (87.50)	0 (0.0)
Others	0 (0.0)	0 (0.0)	0 (0.0)	12 (92.3)

MRI: Magnetic resonance imaging.  $\chi^2=217.77$  (df=12);  $P<0.001$



For tendinosis of supraspinatus, USG had a sensitivity, specificity, PPV, NPV, and accuracy of 62.5%, 91.3%, 62.5%, 91.3%, and 85.9%, respectively, as compared to 87.5%, 97.1%, 87.5%, 97.1%, and 95.3%, respectively, for the same parameters on MRI.

For “other” diagnoses, USG had a sensitivity, specificity, PPV, NPV, and accuracy of 76.9%, 100%, 100%, 96.0%, and 96.5%, respectively, as compared to 100%, 100%, 100%, 100%, and 100%, respectively, for the same parameters on MRI (Table 4).

## DISCUSSION

In this study, an attempt was made to compare the role of high-resolution USG and magnetic resonance imaging in the evaluation of chronic shoulder pain with follow-up to ascertain the accuracy of clinical and radiological findings.

For this purpose, a total of 85 patients with complaints of chronic shoulder pain were enrolled in the study. The mean age of patients was 45.21 years, majority of them were males. Similar to results of present study Shrestha and Alam<sup>16</sup> and Vijayvargiya *et al.*<sup>17</sup>

In this study, chronic shoulder pain was defined as the presence of shoulder pain for more than 6 months and majority of patients had shoulder pain over 6-9 months (56.5%). There were 32 (37.6%) with shoulder pain over 9-12 months and 5 (5.9%) with shoulder pain for more than a year. This study showed a high predominance of the right side (76.5%) as compared to the left side (23.5%). In this study, a total of 17 (20%) cases had a history of diabetes.

History of trauma was reported in 48 (56.5%) cases. This is in consistence with the observation of Donovan and Paulos,<sup>18</sup> who observed that overuse and traumatic injuries make up most of the causes features such as tenderness (34.1%) and complaints such as night pain (65.9%) were also common. As far as range of motion was concerned, it was normal to >45° in 50/85 (58.8%) patients, thus indicating that in general the patients were able to perform

their routine tasks – and this might be the reason for the chronic condition. In resource-poor settings such as our people often tend to ignore their medical needs until it leads to restriction of their routine functions which leads to the development of a chronic condition.

In this study, clinically a total of 56 (65.9%) were diagnosed as rotator cuff-tear followed by supraspinatus impingement ( $n = 15$ ; 17.6%), calcific tendinitis ( $n = 8$ ; 9.4%), subacromial-subdeltoid bursitis ( $n = 4$ ; 4.7%), and adhesive capsulitis ( $n = 2$ ; 2.4%), respectively. Clinical diagnosis is often based on the outcome of a host of clinical tests which have a varying efficacy.<sup>19,20</sup>

The final diagnosis was based on the arthroscopic evaluation. Partial thickness tear of supraspinatus ( $n = 35$ ; 41.2%) was the most common diagnoses followed by full thickness of supraspinatus ( $n = 21$ ; 24.7%) and tendinosis of supraspinatus ( $n = 16$ ; 18.8%). Among other diagnoses ( $n = 13$ ; 15.3%) – labral tear was most common ( $n = 4$ ; 4.7%) subacromial-subdeltoid bursitis, partial thickness tear of subscapularis, full thickness tear of infraspinatus, and adhesive capsulitis was diagnosed in 2 (2.4%) patients each, and full thickness tear of long head of biceps in 1 (1.2%) patient.

The arthroscopic findings, in turn, showed the varying underlying pathologies for different clinical diagnoses and as indicated above showed the need of inclusion of more refined diagnostic modalities to avoid chronicity.

On correlating the clinical findings with arthroscopic findings, it was seen that for almost all the arthroscopic diagnoses majority number of patients showed rotator cuff tear as the clinical diagnosis. Similarly, clinical diagnosis of supraspinatus impingement coincided with a large proportion of patients with varying arthroscopic findings. The arthroscopic findings in such a condition provide a much better pathological condition than the generalized clinical diagnosis vis-à-vis a generalized rehabilitation/treatment approach which failed to provide a substantial clinical improvement and in turn resulted in the evolution of a chronic condition.

**Table 4: Comparative evaluation of diagnostic efficacy of USG and MRI for different causes of chronic shoulder pain**

Confirmed cause	USG					MRI				
	Sensitivity	Specificity	PPV	NPV	Accuracy	Sensitivity	Specificity	PPV	NPV	Accuracy
Partial thickness tear of supraspinatus	60.0	97.6	95.5	74.1	80.3	88.6	96.0	93.9	92.3	92.9
Full thickness tear of supraspinatus	95.2	90.6	76.9	98.3	91.8	95.2	98.4	95.2	98.4	97.6
Tendinosis of supraspinatus	62.5	91.3	62.5	91.3	85.9	87.5	97.1	87.5	97.1	95.3
Others	76.9	100.0	100.0	96.0	96.5	92.7	100.0	100.0	98.6	98.8

PPV: Positive predictive value, NPV: Negative predictive value, USG: Ultrasonography, MRI: Magnetic resonance imaging

Shoulder injuries are difficult to differentiate pathologically merely on the basis of demography. No doubt, they mostly affect the younger age groups and males – practically owing to their relatively heavier activity profile. In fact, almost all the age groups can be victims of different types of shoulder injuries; they are more dependent on the activity level of an individual and etiology.

In this study, for different arthroscopically diagnosed types of shoulder injuries, statistically no significant association of age, gender, duration of complaints, affected side, dominant side, and history of diabetes could be seen. However, history of trauma was less common for the tendinosis and more common for partial and full thickness tear. Tendinosis is a chronic degeneration of tendon's collagen related with overuse. When overuse is continued without giving the tendon time to heal and rest such as with repetitive strain injury, tendinosis results. Even tiny movements, such as clicking a mouse, can cause tendinosis when done repeatedly.<sup>21</sup> Owing to association with traumatic etiology, partial, and full thickness tears are often accompanied with tenderness. Clinical examination of tendinosis is often accompanied with localization of tear guided by tenderness.<sup>22</sup> The findings of this study also highlighted the relevance of this clinical finding in differentiating rotator cuff tears and tendinosis.

In this study, night pain was significantly higher in all the arthroscopic diagnosis except tendinosis. Thus, this study showed a high prevalence of night pain in full and partial tears.

In this study, both MRI as well as USG had more than 90% sensitivity for full thickness tears which is in agreement with the reported comparative efficacy of USG and MRI. According to Dinnes *et al.*,<sup>23</sup> for full-thickness tears, overall sensitivities and specificities are high with MRI Ultrasound is considered to be accurate when used for the detection of full thickness tears; although sensitivity is lower for detection of partial thickness tear, specificity remained high.<sup>23</sup> The findings of this study supported this point of view. In this study, USG showed a poor sensitivity toward partial thickness tears, whereas MRI showed a high sensitivity for both partial ( $n = 32/37$ ; 86.5%) as well as full thickness tears ( $n = 21/23$ ; 91.3%). Kenn *et al.*<sup>24</sup> in their study also showed a high sensitivity of MRI for both partial as well as full thickness tears. In this study, USG had a slight edge over MRI in the diagnosis of full thickness tear ( $n = 22/23$ ; 95.7%).

In this study, both USG as well as MRI showed a better efficacy for full thickness tears as compared to partial thickness tears. Observation to a similar effect regarding the performance of USG was also made by Cullen *et al.*;<sup>25</sup>

de Jesus *et al.*<sup>26</sup> In our study, MRI had a higher efficacy for both full thickness as well as partial thickness tears, whereas USG had a higher efficacy for full thickness tears only.

This study shows MRI to be a highly sensitive as well as specific technique for differentiation among different shoulder pathologies.

As far as comparative evaluation of USG and MRI, except for full thickness tear where both the modalities had equal sensitivity; for all the other diagnoses; MRI showed a higher sensitivity. However, for partial thickness tear, USG had a higher specificity as compared to MRI; for all the other diagnoses, MRI showed a higher specificity. In terms of overall accuracy, MRI had a higher accuracy as compared to USG for all the diagnoses except for full thickness tears.

Correlation of USG and MRI with clinical diagnosis showed that clinical diagnosis failed to diagnose the tears, especially clinical diagnosis of supraspinatus impingement which was later on diagnosed as full/partial thickness tear and tendinosis by MRI and USG. Thus, these imaging techniques helped to identify the underlying shoulder pathologies more clearly.

However, of the two techniques being used, MRI diagnosed shoulder pathologies in relatively more number of cases (78/80; 97.5%) as compared to USG (74/80; 92.5%). Ultimately, MRI was both more sensitive as well as specific for most of the underlying pathologies as compared to USG.

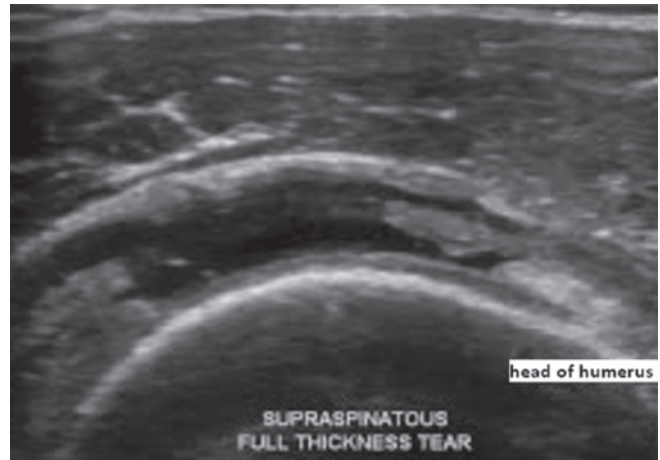
The findings in this study helped to understand various underlying pathologies of chronic shoulder pain and showed that reliance on clinical diagnosis only delays the management and hence the development of chronicity. A high efficacy of both the techniques was observed for all the underlying pathologies except for partial thickness tears where MRI had a definitive upper edge over USG. Because diagnosis of full thickness tear is more crucial from the point of view of surgical management, where both the techniques were almost equally efficient, in low-resource settings, USG is the diagnostic modality of choice, whereas in a well-equipped setting, MRI should be the preferred mode of diagnosis. This study was one of the pioneering studies with respect to the evaluation of diagnostic techniques for chronic shoulder pain owing to different etiologies, a problem less explored; hence, further studies are recommended to substantiate the findings of present study (Figures 1-6).

## CONCLUSION

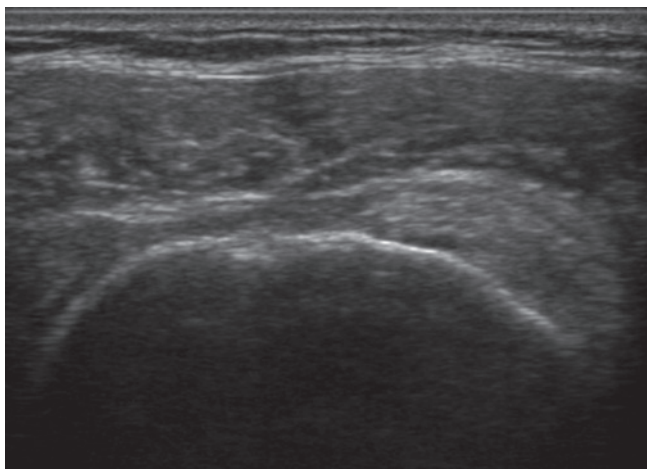
On the basis of observations made during study and their analysis, the following conclusions have been drawn:



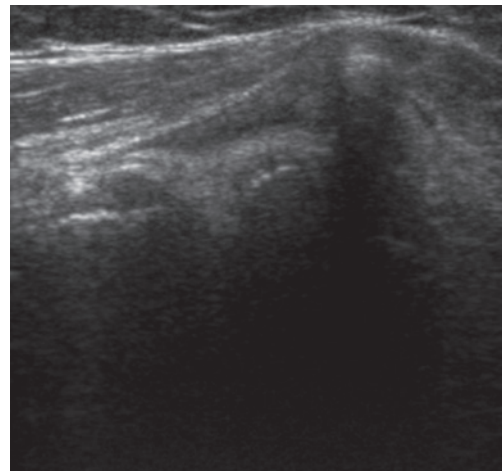
**Figure 1:** Anterior-posterior X-ray showing calcification of supraspinatus tendon in case of chronic tear



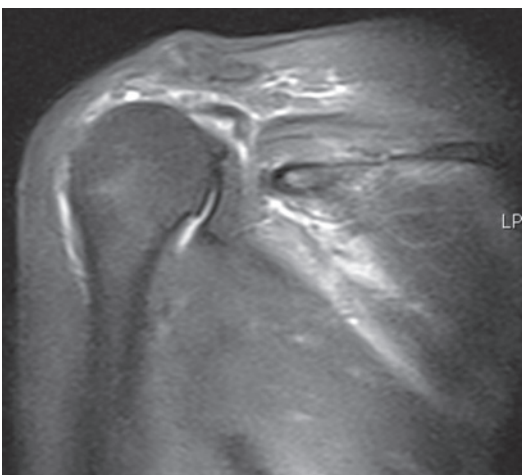
**Figure 3:** Full thickness supraspinatus tear as seen on high-resolution ultrasonography



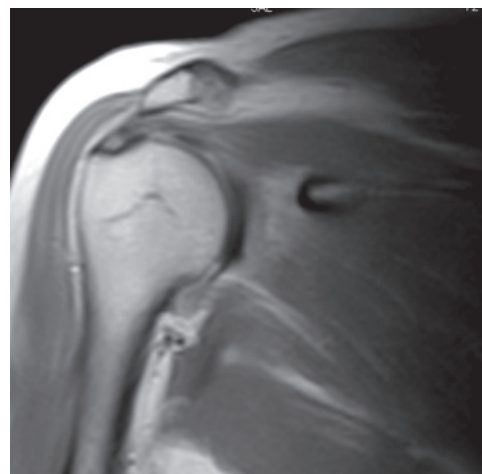
**Figure 2:** Partial tear of supraspinatus on high-resolution ultrasonography



**Figure 4:** Calcification of tendon of supraspinatus as seen on ultrasonography



**Figure 5:** Coronal sagittal short tau inversion recovery image demonstrating full thickness supraspinatus tendon tear



**Figure 6:** Coronal proton-density image showing focal altered signal intensity in supraspinatus tendon with no obvious disruption of fibers suggesting - tendinosis of supraspinatus

1. For partial thickness tear of supraspinatus, USG had a sensitivity, specificity, PPV, NPV, and diagnostic

accuracy of 60%, 97.6%, 95.5%, 74.1%, and 80.3%, respectively, as compared to 88.6%, 96.0%, 93.9%,



92.3%, and 92.9%, respectively, for the same parameters on MRI.

2. For full thickness tear of supraspinatus, USG had a sensitivity, specificity, PPV, NPV, and diagnostic accuracy of 95.2%, 90.6%, 76.9%, 98.3%, and 91.8%, respectively, as compared to 95.2%, 98.4%, 95.2%, 98.4%, and 97.6%, respectively, for the same parameters on MRI.
3. For tendinosis of supraspinatus, USG had a sensitivity, specificity, PPV, NPV, and diagnostic accuracy of 62.5%, 91.3%, 62.5%, 91.3%, and 85.9%, respectively, as compared to 87.5%, 97.1%, 87.5%, 97.1%, and 95.3%, respectively, for the same parameters on MRI.
4. For other diagnoses, USG had a sensitivity, specificity, PPV, NPV, and diagnostic accuracy of 76.9%, 100%, 100%, 96.0%, and 96.5%, respectively, as compared to 92.3%, 100%, 100%, 98.6%, and 98.8%, respectively, for the same parameters on MRI.
5. In others, category labral tear was the most common ( $n = 4$ ; 4.7%); however, it was diagnosed correctly only in 2 cases on USG and in 3 cases in MRI. Subacromial-subdeltoid bursitis, partial thickness tear of the subscapularis, full thickness tear of infraspinatus, and adhesive capsulitis were seen in 2 (2.4%) cases each, among these subacromial-subdeltoid bursitis was missed in 1 case on USG however in MRI all these were matched accurately. Full thickness tear of the long head of biceps was seen in 1 (1.2%) and both the techniques detected it accurately.
6. Confirmation of cause of chronic pain was more precise in MRI as compared to USG. Considering the diagnostic supremacy of MRI, it is therefore recommended to be used as a non-invasive diagnostic tool of choice as an aid to clinical assessment.

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# Comparison of the Accuracy of Spot Urinary Protein/Creatinine Ratio and Urinary Dipstick with the 24-h Urine Protein Estimation in Children with Nephrotic Syndrome

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## Abstract

**Introduction:** Nephrotic syndrome is a common renal disease. 24-h urinary protein (HUP) excretion, which is commonly accepted method for quantification of proteinuria, is time-consuming and inconvenient. A spot urine examination would be more acceptable and less time consuming. A simple, easy and precise method is necessary for proteinuria detection.

**Aim:** To compare the accuracy of spot urinary protein/creatinine ratio and urinary dipstick with the 24-HUP estimation in children with nephrotic syndrome.

**Materials and Methods:** An observational study was conducted on 102 children with all types of nephrotic syndrome under the age of 12 years in the Government Madurai Medical College Hospital, Madurai, for 1 year.

**Results:** The correlation between spot protein creatinine ratio (PCR) and 24-h proteinuria is statistically significant irrespective of the degree of proteinuria ( $P \leq 0.001$ ). Dipstick correlates well with 24-HUP in all ranges of proteinuria ( $P \leq 0.001$ ).

**Conclusion:** Spot PCR can be used as a reliable test to detect proteinuria even on an outpatient basis. The dipstick can be used to give an instant reliable test for proteinuria detection. Nephrotic syndrome is a chronic disease and having multiple relapses. Parents can be trained for earlier detection of proteinuria using the dipstick, so it can be helpful in management.

**Key words:** 24-h urine protein, Dipstick, Nephrotic syndrome, Proteinuria, Spot protein/creatinine ratio

## INTRODUCTION

In Nephrotic syndrome, proteinuria detection is used diagnostically. A common accepted method for quantification of proteinuria is 24-h urinary protein (HUP) excretion. However, it is time consuming, cumbersome, and imprecise due to collection error. A spot urine examination would be more acceptable and less time consuming.<sup>1-3</sup>

Recent studies have shown that the correlation between spot urinary protein/creatinine ratio (UPr:UCr), urinary dipstick, and 24-HUP estimation was statistically highly significant for all levels of proteinuria.

The most widely used screening test is urine dipstick test.<sup>1</sup> It is usually highly specific, but sensitivity is not always high enough as in quantitative methods. False positive and false negative results may occur in some situations. A simple, convenient and accurate method is crucial for proteinuria detection.<sup>4-6</sup>

This study is done to compare the accuracy of spot UPr:UCr and urinary dipstick method with the 24-h protein estimation in children with nephrotic syndrome.

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## MATERIALS AND METHODS

This is an observational study conducted in the Government Madurai Medical College Hospital, Madurai, for 1 year. The study population includes children with all types of nephrotic syndrome under age of 12 years. The study excludes proteinuria with alkaline urine (pH>8), diluted urine (specific gravity <1.002), gross hematuria, and pyuria since it may give false positive or false negative results with dipstick.

Informed consent was obtained from the parent/guardian for the study. Data were collected about the age and sex. Height and weight were measured. Body surface area was arrived using Mosteller formula. Patients were asked to collect urine for 24 h. Collection time starts from 7.00 am on the 1<sup>st</sup> day and completed by 7.00 am the next day. The 24-HUP was determined. The next random urine sample should be subjected to spot protein creatinine ratio (PCR) and dipstick tests. The results of the spot PCR, dipstick, and 24-HUP were recorded as normal, abnormal, and nephrotic proteinuria. The accuracy of spot UPr:UCr and urinary dipstick were compared with the 24-HUP estimation. For the determination of 24-HUP excretion, measure the urine volume and calculate the result as follows:

$$24 \text{ h urine protein} = \frac{\text{Urine protein in mg/dl} \times \text{total volume of urine excreted in 24 h}}{100}$$

Result reported as<sup>2</sup> normal range of proteinuria - <4 mg/m<sup>2</sup>/h, abnormal proteinuria - 4-40 mg/m<sup>2</sup>/h, nephrotic proteinuria - >40 mg/m<sup>2</sup>/h.

The next random urine sample should be subjected to following tests.

### Spot UPr:UCr

UPr can be estimated by the sulfosalicylic acid method. UCr can be estimated by the Jaffe's method (picric acid method).<sup>4,5</sup>

Spot UPr:UCr is arrived by dividing UPr concentration (mg/dl) by UCr concentration (mg/dl).

Results reported as

- Normal protein excretion - <0.5 in children <2 years of age
- <0.2 in children ≥2 years of age
- Abnormal proteinuria - 0.5-2 in children <2 years of age
- 0.2-2 in children ≥2 years of age
- Nephrotic proteinuria - >2.

### Dipstick Test

Using DIP 'N' READ, a 10 reagent strip, proteinuria was measured. 5-10 ml of urine was taken in a test tube. The strip was immersed completely in the urine and withdrawn immediately. Prolonged immersion will produce a false positive result due to leak of buffer. Specific gravity, pH, leukocytes, and blood were also determined using this A-10 reagent strip. The study excludes proteinuria with alkaline urine (pH>8) since it may give false positive results; diluted urine (specific gravity >1.010)<sup>3</sup> since it may give false negative. Gross hematuria was excluded by detecting red blood cells in the dipstick. By detecting leukocytes, pyuria was excluded.

The result was reported as<sup>2,3</sup> negative no protein, trace - 10-20 mg/dl, 1±30 mg/dl, 2±100 mg/dl, 3±300 mg/dl, 4±1000-2000 mg/dl.

The results of the spot PCR, dipstick, and 24-HUP were depicted as normal, abnormal, and nephrotic proteinuria, respectively (Table 1).

## RESULTS

In this study, 1% of the case was an infant, 46.1% of cases belonged to 6-12 years age group, and 52.9% of cases belonged to children more than 6 years. Mean age is 6.87 years. Standard deviation is -3.4418. Out of the 102 cases, 61 cases (59.8%) were males and 41 cases (40.2%) were females (Table 2).

Results of dipstick are shown in Table 3. Out of the 102 cases, 29.4% of spot PCR results were <0.5/<0.2 in children <2 years or more than 2 years, respectively. 33.3% were 0.5-2/0.2-2 in children <2 years of age or more than 2 years of age, respectively. 37.3% of spot PCR results were >2 (Table 4).

Out of the 102 cases, 29.4% of 24-HUP results were <4 mg/m<sup>2</sup>/h. 35.3% were 4-40 mg/m<sup>2</sup>/h. 35.3% of 24-HUP results were <4 mg/m<sup>2</sup>/h (Table 5).

### Comparison between the Three Groups

The following comparisons were done

- Comparison between urine spot protein/creatinine ratio and 24-HUP
- Comparison between urine dipstick and 24-HUP.

### Comparison of Spot PCR and 24-HUP (Table 6)

When spot PCR was compared with 24-HUP, 86.7% (26/30) of samples with spot PCR <0.5/<0.2 had a protein excretion of <4 mg/m<sup>2</sup>/h. 82.4% (28/34) of samples with spot PCR 0.5-2/0.2-2 had a protein excretion of 4-40 mg/m<sup>2</sup>/h.

**Table 1: The results of the spot PCR, dipstick, and 24-HUP**

Proteinuria	Dipstick	Spot PCR	24-HUP
Normal proteinuria	Negative Trace 1+	<2 year <0.5 ≥2 year <0.2	<4 mg/m <sup>2</sup> /hr
Abnormal proteinuria	2+	<2 year 0.5-2 ≥2 year 0.2-2	4-40 mg/m <sup>2</sup> /hr
Nephrotic proteinuria	3+ 4+	>2	>40 mg/m <sup>2</sup> /hr

Spot PCR: Spot protein creatinine ratio, 24-HUP: 24-hour urine protein, PCR: Polymerase chain reaction

**Table 2: Age and wise distribution (n=102)**

Age in years	N (%)		Total N
	Male	Female	
0-1	1 (1)	-	1
1-6	29 (28.4)	18 (17.6)	47
>6	31 (30.4)	23 (22.6)	54
Total	61 (59.8)	41 (40.2)	102

**Table 3: Results of dipstick**

Results	N (%)
Negative	19 (18.6)
Trace	6 (5.9)
1+	9 (8.8)
2+	32 (31.4)
3+	10 (9.8)
4+	26 (25.5)
Total	102 (100)

**Table 4: Results of spot PCR**

Results	N (%)
<0.5/<0.2	30 (29.4)
0.5-2.0/0.2-2.0	34 (33.3)
>2	38 (37.3)
Total	102 (100)

PCR: Polymerase chain reaction

**Table 5: Results of 24-HUP**

Results	N (%)
<4 mg/m <sup>2</sup> /hr	30 (29.4)
4-40 mg/m <sup>2</sup> /hr	36 (35.3)
>40 mg/m <sup>2</sup> /hr	36 (35.3)
Total	102 (100)

24-HUP: 24-hour urine protein

89.5% (34/38) of samples with spot PCR >2 had a protein excretion of >40 mg/m<sup>2</sup>/h. This was statistically significant ( $P \leq 0.001$ ) in all ranges of proteinuria.

#### Comparison of Dipstick and 24-HUP (Table 7)

When dipstick was compared with 24-HUP, 82.4% (28/34) of samples with dipstick negative/trace/1+ had a protein

**Table 6: Comparison of spot PCR and 24-HUP**

Spot PCR	24-HUP, N (%)			Total N
	<4 mg/m <sup>2</sup> /hr	4-40 mg/m <sup>2</sup> /hr	>40 mg/m <sup>2</sup> /hr	
<0.5/<0.2	26 (86.7)	4 (13.3)	-	30
0.5-2.0/0.2-2.0	4 (11.8)	28 (82.4)	2 (5.9)	34
>2	-	4 (10.5)	34 (89.5)	38
Total	30 (29.4)	36 (35.3)	36 (35.3)	102

24-HUP: 24-hour urine protein, PCR: Polymerase chain reaction

**Table 7: Comparison of dipstick and 24-HUP**

Dipstick	24-HUP, N (%)			Total N
	<4 mg/m <sup>2</sup> /hr	4-40 mg/m <sup>2</sup> /hr	>40 mg/m <sup>2</sup> /hr	
Negative/trace/1+	28 (82.4)	6 (17.6)	-	34
2+	2 (6.3)	24 (75)	6 (18.8)	32
3+/4+	-	6 (16.7)	30 (83.3)	36
Total	30 (29.4)	36 (35.3)	36 (35.3)	102

24-HUP: 24-hour urine protein, PCR: Polymerase chain reaction

excretion of <4 mg/m<sup>2</sup>/h. 75% (24/32) of samples with dipstick positivity of 2+ had a protein excretion of 4-40 mg/m<sup>2</sup>/h. 83.3% (30/36) of samples with dipstick positivity of 3+/4+ had a protein excretion of >40 mg/m<sup>2</sup>/h. This was statistically significant ( $P \leq 0.001$ ) in all ranges.

## DISCUSSION

Mean age in our study was 6.871 years. This is similar to Shastri *et al.*<sup>6</sup>, study and Chahar *et al.*<sup>7</sup> study, in which the mean age were 6.7 years and 7.3 years, respectively. Out of the 102 cases, 61 cases (59.8%) were males and 41 cases (40.2%) were females. This is similar to Shastri *et al.*<sup>6</sup> study, in which 58.2% were males and 41.7% were females.

In this study, the range of values observed urine spot PCR was 0.12-50 with the mean value of 4.96. In Iyer *et al.*<sup>8</sup> study, the range of observed value of UP/UC 1.7-9.6 with the mean value of  $5.5 \pm 2$ .

When spot PCR was compared with 24-HUP, the result was statistically significant ( $P \leq 0.001$ ) in all ranges. This is similar to Shastri *et al.*,<sup>6</sup> Chahar *et al.*,<sup>7</sup> Indira Agarwal *et al.*,<sup>9</sup> Biswas *et al.*,<sup>10</sup> Mustafa *et al.*,<sup>11</sup> Mir *et al.*,<sup>12</sup> and Ginsberg *et al.*<sup>13</sup> studies where spot PCR correlates well with 24-HUP irrespective of the degree of proteinuria.

When dipstick was compared with 24-HUP, the result was statistically significant ( $P \leq 0.001$ ) in all ranges of proteinuria. This is similar to Indira Agarwal *et al.*<sup>9</sup> and Biswas *et al.*<sup>10</sup> studies where dipstick correlates well with 24-HUP irrespective of the degree of proteinuria.

## CONCLUSION

- Nephrotic syndrome is more common in males than females
- There is statistically significant correlation between spot PCR and 24-h proteinuria irrespective of the degree of proteinuria. So, spot PCR, which is a quantitative method can be used as a reliable test to detect proteinuria even on outpatient basis
- Dipstick correlates well with 24-HUP. So, dipstick can be used to give an instant reliable test for proteinuria detection.

Nephrotic syndrome is a chronic disease and having multiple relapses. Since earlier detection prevents relapse, parents can be trained for earlier detection of proteinuria using the dipstick.

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# Analysis of the Profile and Outcome of Children those Received Oxygen Support through High-flow Nasal Cannula in a Rural Medical College Hospital

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## Abstract

**Background:** Oxygen therapy remains the first-line intervention for children admitted with respiratory distress. Heated humidified high-flow nasal cannula (HHHFNC) oxygen therapy represents a new alternative to conventional oxygen therapy. HFNC generates flows up to 60 L/min, yet using a nasal cannula as an interface to the patient. Heating and humidification of gas mixtures allow comfortable delivery of flow rates that match or exceed the patient's inspiratory flow rate.

**Materials and Methods:** Children with moderate to severe respiratory distress admitted over a period of 1-year from January 2014 to December 2014.

**Results:** Out of 52 children, who received humidified high-flow oxygen therapy, 40 (76.92%) were infants below 1 year of age. 31 (59.62%) children were males. The major cause for respiratory distress needing initiation of oxygen therapy with high-flow nasal cannula is respiratory cause contributing to 69.23% followed by cardiac causes which contribute 13.46% of cases who received humidified high-flow nasal oxygen. Among the respiratory system diseases, bronchopneumonia is the leading cause which makes 52.78%. Moreover, 28 children (53.85%) received humidified high-flow nasal oxygen therapy for a total duration of 1-4 days. 40 (76.92%) children recovered completely and did not need any further intervention in the form of ventilation or referral to higher center. 9 (17.31) failed therapy and required intubation.

**Conclusion:** Use of HHHFNC for oxygen administration is feasible for infants with moderate-severe bronchiolitis in a general pediatric ward. HHHFNC therapy provided efficient respiratory support and oxygen delivery in infants with respiratory distress in our Paediatric Intensive Care Unit, and its introduction coincided with a significant reduction in the need for intubation of infants with viral bronchiolitis.

**Key words:** Children, Heated humidified high-flow nasal cannula, Oxygen, Respiratory distress, Rural medical college hospital

## INTRODUCTION

Administration of supplementary oxygen forms an essential part of the management of respiratory distress. Nasal cannulae are a well-established mode of delivery of oxygen therapy, but the amount of oxygen that can be

delivered has traditionally been limited by poor tolerance of flow rates  $>2$  L/min in children. The heating (to body temperature) and humidification (to  $>99\%$  relative humidity) of oxygen and air mixtures allow comfortable delivery at flow rates which match or exceed the patient's inspiratory flow rate, thus limiting entrainment of room air. This is known as heated humidified high-flow nasal cannula (HHHFNC) therapy.

In addition to improving oxygenation, HHHFNC therapy may improve the efficiency of ventilation, reduce work of breathing, and avoid the need for intubation.<sup>1-3</sup> Furthermore, the inspired oxygen concentration can be titrated to the patient's need; anecdotally, it is better

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tolerated by the patient; and potentially, continuous positive airway pressure can be delivered.<sup>1,4-6</sup>

There is currently no single, simple definition of high flow. In infants, it usually refers to the delivery of oxygen or an oxygen/room air blend at flow rates  $>2$  L/min.<sup>7</sup> Some authors adjust the flow rates on body weight and recommend using 2 L/kg/min, which provides a degree of distending pressure<sup>8-10</sup> and reduces the work of breathing.<sup>11</sup> In children, flow rates  $>6$  L/min are generally considered high flow.<sup>12</sup> High flow presents several advantages over conventional “low-flow” oxygen therapy in terms of humidification, oxygenation, gas exchange, and breathing pattern.

It is proposed that HHHFNC therapy reduces work of breathing and improves efficiency of ventilation through several mechanisms as follows:<sup>1</sup>

- Washout of nasopharyngeal dead space leading to improved alveolar ventilation
- Reduction in the inspiratory resistance associated with the nasopharynx
- Improvement in conductance and pulmonary compliance by supplying adequately warmed and humidified gas
- Reduction in metabolic work associated with gas conditioning
- May provide positive distending pressure for lung recruitment.

Despite the advantages of this technique, the quality of the literature dealing with a pediatric population remains poor. The Cochrane Library deemed that no study was able to provide indications and guidelines for HHHFNC therapy in pediatric patients with a high level of evidence.<sup>8</sup> Similar conclusions were expressed about the use of HHHFNC in the specific situation of infants with acute viral bronchiolitis.<sup>13</sup> In 2014, recommendations are still based on extrapolations from observational or physiological studies but not on evidence. For clinical practice, HHHFNC seems feasible in most of the populations currently managed with noninvasive ventilation, and sometimes, it appears to be better tolerated.

The objective of this study was to analyze the profile and outcome of children who were given high-flow humidified oxygen therapy as the first line therapy in a rural medical college hospital.

## MATERIALS AND METHODS

### Study Center

This study was conducted in the Paediatric Intensive Care Unit (PICU) of a Rural Medical College Hospital, which

is equipped with a high-flow heated humidified nasal cannula machine and 2 ventilators with 24 h monitoring by 1 Assistant Professor, 1 Senior Resident, 1 Junior Resident, and 2 Staff Nurses.

### Sampling

This was a retrospective study conducted for 1-year from January 2014 to December 2014. The data were compiled from the information entered in the high-flow nasal cannula utility register and nominal registers. All the children who were given initiation of oxygen therapy with humidified high-flow nasal cannula for moderate to severe respiratory distress were included in the study. The method of assessment of severity of respiratory distress was adapted from the World Health Organization management of acute respiratory tract infections in children (Table 1). The parameters analyzed were age and sex of the children who received HHHFNC therapy, etiology of respiratory distress, duration of oxygen therapy through high-flow nasal cannula, and outcome of the intervention. The results were analyzed by tabular columns.

## RESULTS

A total of 52 children had received humidified high-flow nasal oxygen therapy as the initial method of oxygen supplement for treating respiratory distress during the study period of 1-year. Out of them, 40 were infants that make 76.92% and 12% children were more than or equal to 1 year of age making 23.08% of the children received HHHFNC therapy (Table 2).

Among these 52 children, 31 were males and 21 were females contributing 59.62 and 40.38, respectively (Table 3).

On analyzing the etiology for the respiratory distress, we found 36, out of 52 cases, were respiratory system disorders. So, 69.23% of the cases received HHHFNC therapy because of respiratory system pathologies. 7 cases (13.46%) were having cardiac diseases. 6 babies with neurologic diseases and 3 cases of miscellaneous causes received HHHFNC oxygen therapy contributing to 11.54% and 5.77% of the total recipients (Table 4).

The leading respiratory system cause was bronchopneumonia. 22 children had bronchopneumonia that made 61.12% of the respiratory causes and 42.31% of the total cases with the need for HHHFNC therapy. Out of 22 children with bronchopneumonia, 1 had associated parapharyngeal abscess and 2 had associated stridor. The second common respiratory cause was bronchiolitis ( $n = 8$ ) which contributed to 22.22% of the respiratory causes and 15.38% of total cases. Then, 2 children had empyema which was 5.56% of respiratory causes. Rest of the respiratory system disorders treated with

**Table 1: Assessment of breathing difficulty adapted from who management of acute respiratory infections in children (Who, Geneva,1995)**

Assessment of severity (breathing difficulty)			
Respiratory distress	Mild	Moderate	Severe
Oxygen saturation in room air(%)	>95	92-95	< 92
Chest wall in-drawing	None/mild	Moderate	Severe
Nasal flaring	Absent	May be present	Present
Grunting	Absent	Absent	Present
Apnea	None	Absent	Present
Feeding difficulty	Normal	Approximately half of normal intake	Less than half normal intake
Behavior	Normal	Irritable	Lethargic Unresponsive Flaccid Decreased level of consciousness Inconsolable

**Table 2: Age-wise distribution of children given oxygen through high-flow nasal cannula**

Total no of children given oxygen through high-flow cannula	<1 year of age	≥1 year of age
52	40 (76.92)	12 (23.08)

**Table 3: Gender-wise distribution of children given oxygen through high-flow nasal cannula**

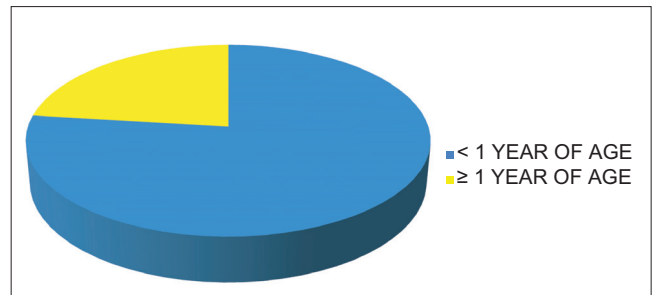
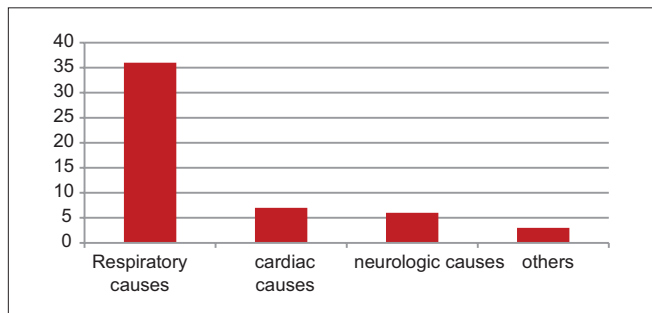
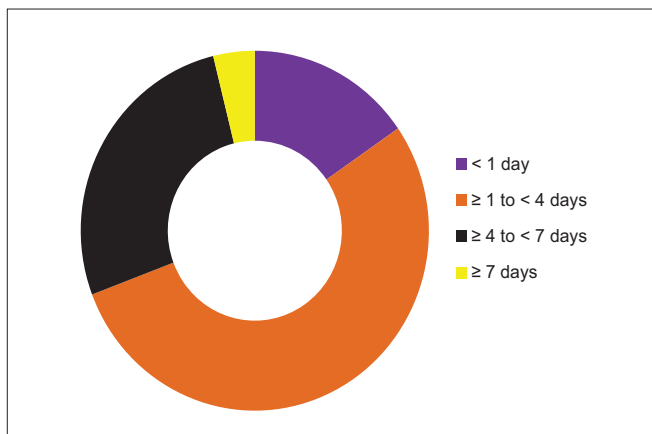
Total no of children given oxygen through high-flow cannula	Male	Female
52	31 (59.62)	21 (40.38)

**Table 4: Etiological break up of children given high-flow oxygen therapy**

Etiology	N (%)
Respiratory causes	36 (69.23)
Cardiac causes	7 (13.46)
Neurologic causes	6 (11.54)
Miscellaneous	3 (5.77)
Total	52 (100)

high-flow therapy were one case each of consolidation, collapse with consolidation, acute laryngotracheobronchitis and pneumothorax, each being 2.78% (Table 5).

A total of 7 children with heart diseases were treated with HHFNC therapy for respiratory distress. 6 children had congenital heart diseases and 1 child had rheumatic heart disease. Out of 6 congenital heart disease cases, 2 were ventricular septal defect with atrial septal defect with

**Figure 1: Age-wise distribution of children received oxygen through high-flow nasal cannula****Figure 2: Gender-wise distribution of children given oxygen through high-flow nasal cannula****Figure 3: Etiological break up of children given high-flow oxygen therapy****Figure 4: Break up according to duration of high-flow oxygen therapy**

congestive cardiac failure and two children had isolated ventricular septal defect each group making 33.33% of cardiac cases who received HHHFNC. One child with cyanotic spell and one child with large atrial septal defect with congestive cardiac failure too were benefitted with high flow (Table 6).

There were 6 children with central nervous system (CNS) diseases who were supported with HHHFNC therapy. 2 children with cerebral palsy with seizures, 2 children with acute CNS infections, and 2 children with idiopathic status epilepticus were treated, each group being 33.33% of the total neurological causes (Table 7).

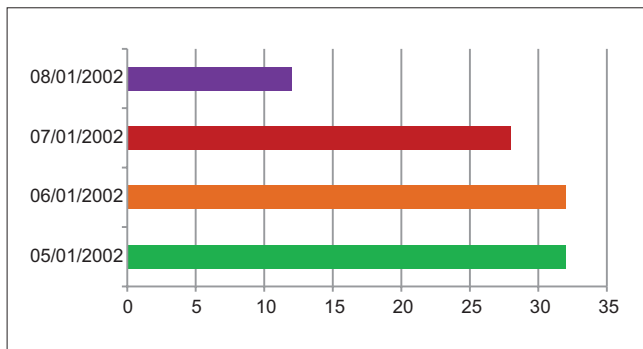
About 2 children with acute diarrheal disease had been received in a state of shock and had been given HHHFNC and 1 child with septic shock also was benefitted (Table 8).

Out of the total 52 children, 8 (15.38%) had received HHHFNC oxygen therapy for <1 day, 28 children (53.85%) received for 1-4 days, 14 children (26.92) for 4-7 days, and 2 children (3.85%) received for more than 7 days (Table 9).

Among the 52 recipients of HHHFNC oxygen therapy, 40 children recovered completely. This made 76.92% recovery during the study period. 9 children required further intubation and mechanical ventilation and among them 3 babies recovered and 6 succumbed to the illness. The mortality percentage was 11.54% (Table 10).

About 9 children needed intubation and assisted mechanical ventilation. Failure of HHHFNC is need for intubation for further management. The therapy failure was noted in 17.31% of children.

Among them, 3 children were extubated and discharged, but 6 children expired. The children who recovered with ventilation were a case of empyema, a case of bronchiolitis with subglottic stenosis and a case of acute CNS infection.



**Figure 5: Break up according to outcome of children given high-flow oxygen therapy**

The 6 children who could not be revived were as follows. A 7-month-old and a 10-month-old male infants with idiopathic status epilepticus; a 75-day-old female child with severe bronchiolitis; a 2-month-old male infant with bronchopneumonia; a 5-year-old male child with

**Table 5: Breakup of respiratory causes**

Disease	N (%)	Percentage
Acute laryngotracheobronchitis	1 (2.78)	
Bronchiolitis	7 (19.44)	22.22
Bronchiolitis with seizures	1 (2.78)	
Bronchopneumonia	19 (52.78)	61.12
Bronchopneumonia with parapharyngeal abscess	1 (2.78)	
Bronchopneumonia with stridor	2 (5.56)	
Collapse consolidation	1 (2.78)	
Consolidation	1 (2.78)	
Empyema	2 (5.56)	
Pneumothorax	1 (2.78)	
Total	36 (100)	

**Table 6: Breakup of cardiac causes**

Disease	N (%)
Cyanotic spell	1 (16.67)
Rheumatic heart disease with congestive cardiac failure	1 (16.67)
VSD/congestive cardiac failure	2 (33.33)
VSD/ASD/congestive cardiac failure	2 (33.33)
Atrial septal defect/congestive cardiac failure	1 (16.67)
Total	7 (100)

**Table 7: Breakup of neurological causes**

Disease	N (%)
Cerebral palsy with seizures	2 (33.33)
Acute CNS infections	2 (33.33)
Idiopathic status epilepticus	2 (33.33)
Total	6 (100)

CNS: Central nervous system

**Table 8: Breakup of miscellaneous causes**

Disease	N (%)
Acute diarrheal disease with shock	2 (66.66)
Septicemia with shock	1 (33.33)
Total	3 (100)

**Table 9: Break up according to duration of high-flow oxygen therapy**

Duration	N (%)
<1 day	8 (15.38)
≥1 to <4 days	28 (53.85)
≥4 to <7 days	14 (26.92)
≥7 days	2 (3.85)
Total	52 (100)



**Table 10: Break up according to outcome of children given high-flow oxygen therapy**

Outcome	N (%)	Percentage
Recovered	40 (76.92)	17.31
Ventilated and recovered	3 (5.77)	
Ventilated and expired	6 (11.54)	
Referred to higher center	3 (5.77)	
Total	52 (100)	

consolidation who was a known case of Type I diabetes mellitus; and a 7-year-old female child with acute rheumatic carditis with congestive cardiac failure.

Out of the 3 children who were referred to the higher center for further expert management, 2 had septicemia with shock, and one child had empyema. They all survived (Figures 1-5).

## DISCUSSION

In our study, the most common final diagnosis was bronchopneumonia ( $n = 22$ , 42.31) and the second common being bronchiolitis ( $n = 8$ , 15.38%).<sup>14</sup>

Kelly *et al.* reported a similar case study, which included 498 cases. The most common final diagnosis was acute bronchiolitis ( $n = 231$ , 46%), followed by pneumonia ( $n = 138$ , 28%) and asthma ( $n = 38$ , 8%).<sup>14</sup>

Two observational studies have shown improvement in physiological parameters in children receiving HHHFNC therapy. Respiratory distress scores significantly improved as HHHFNC therapy flow rates increased in infants with bronchiolitis and older children requiring oxygen therapy.<sup>6,8</sup> In another cohort of pediatric patients (median age 6.5 months) receiving HHHFNC therapy on a PICU, measured work of breathing significantly decreased as HHHFNC therapy increased from 2 to 8 L/min.<sup>15</sup>

In the study by Schibler *et al.*, out of the 298 cases, the most common diagnosis was bronchiolitis ( $n = 167$ ). 11 cases were cardiac cases, and 7 were neurometabolic cases. All were given HHHFNC therapy as the initial mode of oxygen support.<sup>3</sup>

In our study, the failure rate was 17.31% ( $n = 9$ ). Out of 52 children, 9 needed escalation to invasive ventilation.

In the study by Kelly *et al.*, of the 498 patients, 42 (8%) of patients failed therapy and required intubation following HFNC trial.<sup>14</sup>

Schibler *et al.* reported that, overall, 56 (19%) infants receiving HHHFNC therapy needed escalation to other noninvasive and 36 (12%) to invasive ventilation.<sup>3</sup>

In our study, the common cause for escalation to invasive ventilation was respiratory system disorder ( $n = 5$ ), followed by neurological cause ( $n = 3$ ) 55.56% and 50%, respectively. 2 out of 8 cases of bronchiolitis required ventilator support. Therefore, 25% of bronchiolitis cases required ventilatory support in our study.

Kelly *et al.* conclude that a final diagnosis of bronchiolitis was observed to be protective with respect to intubation (odds ratio, 0.40; 95% confidence interval, 0.17–0.96).<sup>14</sup>

In the study by Schibler *et al.*, of the infants with a primary diagnosis of viral bronchiolitis, only 6 (4%) required escalation to invasive ventilation. There was a significantly greater incidence of invasive ventilation in the cardiac ( $n = 12$ , 50%) and other ( $n = 7$ , 41%) groups compared with the bronchiolitis ( $n = 6$ , 4%) and lung disease without peripheral airway obstruction ( $n = 8$ , 12%) groups ( $P = 0.05$ ). Most of the cardiac infants needed intubation for a cardiac surgical procedure or cardiac failure.<sup>3</sup>

Bressan *et al.* reported that out of 27 infants with bronchiolitis who were included in the study no escalation to other forms of respiratory support was recorded.<sup>16</sup>

## CONCLUSION

Use of HHHFNC for oxygen administration is feasible for infants with moderate-severe bronchiolitis in a general pediatric ward. HHHFNC therapy provided efficient respiratory support and oxygen delivery in infants with respiratory distress in our PICU, and its introduction coincided with a significant reduction in the need for intubation of infants with viral bronchiolitis. Further, research is required to establish safety and efficacy of HHHFNC definitively.

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# Serum Zinc Level in Children Admitted with Pneumonia at Tertiary Care Children's Hospital

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## Abstract

**Introduction:** Zinc is an essential micronutrient in humans. Worldwide, pneumonia accounts for 18% of under-five mortality and it is the leading infectious cause of childhood mortality. There is greater risk of diarrhea, pneumonia, and growth failure in zinc-deficient population.

**Purpose:** The purpose of this study is to compare serum zinc level in children with severe pneumonia with age, sex, and nutritional matched controls.

**Materials and Methods:** Serum zinc level in 50 children admitted with severe pneumonia was compared with the matched controls.

**Results:** The mean serum zinc level in children with pneumonia (60.98) is significantly lower than that of controls (73.124) with ( $P = 0.001$ ).

**Conclusion:** Serum zinc levels are significantly low in children with severe pneumonia compared with age, sex, and nutritionally matched controls.

**Key words:** Children, Micronutrient, Pneumonia, Under-five, Zinc

## INTRODUCTION

Zinc is an essential micronutrient in humans. In human being, zinc is 2<sup>nd</sup> only to iron in quantity.<sup>1-3</sup> There are more than 70 zinc-containing enzymes in human being. Zinc is critical for functioning of biomembranes. Zinc protects from the oxidative damage by competing for binding sites with redox metals. Zinc has both acute and chronic antioxidant action.<sup>4-7</sup> Zinc is needed for thymulin, and it is possible zinc is involved in the genesis of hematopoietic stem cells in the thymus microenvironment. Zinc deficiency increasing the inflammatory pathology in the respiratory tract with increasing damage to the cells is a proposed mechanism.<sup>8</sup>

Zinc also prevents the recruitment of white blood cells and release of cytokines from them and effectiveness of zinc said to increase with increase in the severity of pneumonia.<sup>9</sup>

Studies suggest that there is greater risk of diarrhea, pneumonia, and growth failure in zinc-deficient population.<sup>10-12</sup> The effectiveness of zinc supplementation in early recovery and reduction of severity of pneumonia has been shown by a number of studies. Effectiveness of zinc supplementation in early recovery and reduction of severity of pneumonia has been shown by number of studies.<sup>13,14</sup>

Although zinc supplementation is specifically recommended for developing countries,<sup>3</sup> there is no study available demonstrating the serum zinc level in children with pneumonia in South India. There is a need to demonstrate the zinc level in children with pneumonia for further recommendations. This study is designed to compare the serum zinc level in children admitted with pneumonia to the matched controls.

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## MATERIALS AND METHODS

This study was done at a tertiary care children's hospital in South India. The study population included children admitted with severe pneumonia according to the World Health Organization (WHO) classification clinically and showing radiological evidence of pneumonia. The age group included was between 3 months and 5 years. Any child on zinc supplementation, children with aspiration pneumonia, chemical pneumonia, persistent pneumonia, severe acute malnutrition, and coexisting illness were excluded.

All children admitted with pneumonia are examined and recruited as per inclusion and exclusion criteria. 50 such children were recruited to the study after obtaining informed consent from the parents. Weight for length/weight for height was calculated. According to the WHO chart, the nutritional status classified. Children having Z-score between  $-3$  and  $-2$  were classified as moderate acute malnutrition and having Z-score more than  $-2$  were classified as normal nutrition.

Controls with similar age (adjusted for 2 months), sex, and nutritional status were recruited equal number for cases.

For both cases and control group, 2 ml of blood drawn. Serum separated after centrifuging the clotted sample. In the separated serum, zinc level is obtained using photometry. The mean serum zinc level between two groups is compared using independent *t*-test.

## RESULTS

The study population consists of 100 children with 50 cases and 50 controls. The age distribution was as per Table 1. Of the 50 children recruited with pneumonia, there are 36 male children and 24 female children. Nutritional status in the total study group is given in Table 2. Mean serum zinc level in children with pneumonia is compared with that of the control group. There is a significant difference between children with pneumonia and controls in serum zinc levels. Mean serum zinc level in children with pneumonia is 60.982 mg/dl. The mean serum zinc level in age, sex, and nutrition matched controls is 73.124 mg/dl. Mean serum zinc level is significantly lower in children with pneumonia than their matched controls ( $P = 0.001$ ) Table 3.

## DISCUSSION

There is no significant difference between the mean serum zinc levels between the different age groups of children admitted with pneumonia ( $P = 0.826$ ). Studies done in

**Table 1: Age distribution**

Age	Case	Control	Total frequency
≤12 months	18	18	36
13-24 months	20	20	40
25-60 months	12	12	24
Total	50	50	100

**Table 2: Nutritional status**

Status	Case	Control	Frequency	Percent	Valid percent	Cumulative percent
Normal	34	34	68	68.0	68.0	68.0
MAM*	16	16	32	32.0	32.0	100.0
Total	50	50	100	100.0	100.0	

\*MAM: Moderate acute malnutrition

**Table 3: Zinc level in cases and control**

Type	N	Mean zinc level*	Standard deviation	P value
Case	50	60.982	18.8926	0.001
Control	50	73.124	17.1420	

\*Mean serum zinc level expressed in mg/dl

serum zinc level in pneumonia, diarrhea showed similar results that age is not a confounding factor in serum zinc in pneumonia.<sup>15,16</sup> Comparison of mean serum zinc level between male and female children recruited in this study does not show any significant difference like other published data.<sup>15-17</sup> Analysis within pneumonia group also shows that the mean serum zinc level in children with moderate acute malnutrition is significantly low than children with normal nutrition ( $P = 0.02$ ). Low mean serum zinc level in children in moderate acute malnutrition may be due to poor intake leading to zinc deficiency associated with other micronutrient deficiency. Similar finding was found in study done by Kumar *et al.*<sup>15</sup>

Mean serum zinc level is significantly lower in children with severe pneumonia than the matched controls ( $P = 0.001$ ). This is similar to the finding of the Kumar *et al.*,<sup>15</sup> Arica *et al.*,<sup>16</sup> and Pushpa and Memon.<sup>17</sup> Main proposed cause for having low mean serum zinc level is already existing zinc deficiency which increases the susceptibility of the child to get pneumonia by impairing child's immunity.<sup>18</sup> Other explanation for low serum zinc level is a shift of zinc from plasma to liver.

Deficiency of zinc, due to inadequate intake of food-containing zinc or decreased absorption, is more commonly seen in developing countries.<sup>19</sup> It is one of the 10 important factors leading to increased illness in children in developing countries.<sup>20</sup>

Supplementation of zinc in children decreasing the morbidity and fatality in infections was shown by trials.<sup>9,13</sup>



Pneumonia being the leading killer infectious disease in children, effect of zinc supplementation has been extensively studied in pneumonia.<sup>13,14</sup>

The benefit of zinc supplement to prevent and decrease the severity of pneumonia is mainly due to correction of zinc deficiency. The finding of low mean serum zinc level in children with severe pneumonia favors this. There is need for further studies to recommend routine supplementation of zinc for children to prevent pneumonia and for the therapeutic use of zinc in severe pneumonia. The main limitation of this study is follow-up with zinc supplementation, and its effectiveness is not demonstrated.

## CONCLUSION

Serum zinc levels are significantly low in children with severe pneumonia compared with age, sex, and nutritionally matched controls. Low serum zinc level found in children with pneumonia probably due to zinc deficiency highlights the importance of inclusion of food item-containing good qualitative (absorbable) and quantitative amount of zinc in children's diet.

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# Magnitude of Preterm Admissions in Neonatal Intensive Care Unit of Rural Medical College Hospital

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## Abstract

**Introduction:** Of late, the incidence of preterm births is increasing worldwide, and Asia and Africa are the major contributors of global preterm burden. Preterm babies have increased the risk of morbidity and mortality which is inversely related to both gestational age and birth weight. In spite of the advancements in therapeutics and improvements in the infrastructure and manpower, if preterm births are increasing, goal of reducing infant mortality rate (IMR) will be more difficult.

**Objectives:** To determine the magnitude of preterm admissions in a special care baby unit of a rural medical college hospital.

**Materials and Methods:** All preterm admissions admitted from January 2015 to December 2015 were retrospectively studied.

**Results:** Preterm babies contribute 31.06% of the total admissions, 10.18% of the total admissions were preterm babies <34 weeks of gestational age, and 20.88% of total admissions were preterm babies of gestational age between 34 and 37 weeks.

**Conclusions:** Preterm babies contribute a significant percentage of the total newborn admissions in a tertiary care center of a rural medical college hospital. Without improving the preterm care reduction of neonatal mortality rate and thereby IMR will be a dream unaccomplished.

**Key words:** Admissions, Magnitude, Preterm, Rural medical college hospital

## INTRODUCTION

Preterm birth has been defined by the World Health Organization (WHO) as any live birth before 37 completed weeks of gestation or fewer than 259 days since the 1<sup>st</sup> day of a woman's last menstrual period.

Preterm birth occurs for a variety of reasons. Most preterm births happen spontaneously, but some are due to early induction of labor or cesarean birth, whether for medical or non-medical reasons.

Common causes of preterm birth include multiple pregnancies, infections, and chronic conditions such as diabetes and high blood pressure; however, often no cause is identified. There could also be a genetic influence. A better understanding of the causes and mechanisms will advance the development of solutions to prevent preterm birth.

Recent global estimates suggest that more than 1 in 10 or estimated 15 million babies born in 2010 were preterm, of which more than 1 million died as a result of preterm birth and related complications.<sup>1</sup> Although neonatal mortality rates (NMRs) have fallen globally between 1990 and 2009,<sup>2</sup> the absolute numbers and rates of preterm birth have increased during this period.<sup>3</sup> More than 1 million infants die every year because they are born preterm, according to the report. Those who survive have an increased risk of morbidities such as cerebral palsy, blindness, and hearing loss.

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In fact, the global concern about the burden of preterm birth has resulted in November 7<sup>th</sup> being earmarked as World Prematurity Day.<sup>4</sup> Increasing preterm birth could significantly militate against the achievement of Millennium Development Goal 4.<sup>5</sup> Perhaps, in response to this threat, a goal to reduce preterm-specific mortality by 50% by 2025 has been set in the WHO's "born too soon" report.<sup>6</sup>

Approximately one-third of preterm survivors suffers from severe long-term neurological disabilities such as cerebral palsy or mental retardation.<sup>6</sup> Even late preterm births (34-36 weeks' gestation) have a higher rate of disabilities, jaundice, and delayed brain development. Preterm birth affects not only infants but also their families who may have to spend substantial time and financial resources to ensure care for their preterm infants; thus, preterm birth has increasing cost implications for families and health services.<sup>7</sup>

Improved care of preterm babies has resulted in reduced mortality in developed countries. This is not so in developing countries where the management of preterm birth babies is fraught with difficulties arising from scarcity of resources typified by poorly-equipped specialized newborn care units. Consequently, the burden of the complications and mortality from preterm births remains a significant potential challenge to newborn health in resource-poor settings. Currently, there is scant literature on the epidemiology of preterm births to guide efforts at preventing and/or managing preterm births. The aims of this study were to determine the magnitude of preterm admissions and to ascertain the need for improved facility in the care of the preterm babies.

## MATERIALS AND METHODS

### Study Center

The study was carried out at a neonatal intensive care unit (NICU) in a rural medical college hospital. It has 11 warmers, 2 continuous positive airway pressure units, 7 ventilators, and 8 infusion pumps. It is manned by 1 Professor, 4 Pediatricians, 1 Junior Residents, 2 Interns, and 18 Staff Nurses.

### Sampling

This was a retrospective descriptive study. Using the nominal registers, all preterm admissions for 1-year period from January to December 2015 were obtained. All preterm babies <37 weeks admitted to NICU were included in the study while those born at or after 37 completed weeks were excluded. The gestational ages at birth were calculated using the mother's last menstrual period or early pregnancy ultrasound scan or modified Ballard scoring.

The birth weights were taken as the first recorded weight at birth for the inborns or the weight on admission for those born outside the hospital and presented within the first 24 h of life.

The preterms were classified into 2 main categories according to gestational age at birth as those with gestational age <34 weeks and those with gestational age between 34 and 37 weeks.

## RESULTS

During the study period, a total of 2375 babies were admitted. Out of these, 1719 babies were inborn babies and remaining 656 babies were delivered in the nearby Primary Health Centers, Government Hospitals or private hospitals or at home and had been referred or brought to our hospital for NICU care (Table 1). Out of 2375 babies, 735 babies were preterm babies contributing 30.95% of the total admissions (Table 2). The highest percentage of preterm admissions was noted during January and lowest during June. Among the 735 preterm babies admitted, 534 babies were inborn babies and 201 babies were outborn babies. This makes 72.65% of preterm admissions from Inborn and 27.35% of preterm admissions from outborn ward (Table 3). Most of the preterm admissions were inborn. With this data, we infer that most of the anticipated preterm deliveries were recognized, and the babies were transported in utero. Both the spontaneous preterm labor and also the non-spontaneous preterm labor where there might be maternal complications were referred to higher centers where facilities for expert maternal care and expert preterm care are available round the clock. Out of the total 735 preterm babies admitted, 225 babies were of gestational age <34 weeks contributing to 9.47% of the total newborn admissions (Table 4) and 30.61% of total preterm admissions (Table 5). The number of late preterm babies with gestational age between 34 and 37 weeks was 510 which made 21.47% of the total newborn admissions in NICU for the year 2015 (Table 6) and 69.39% of the total preterm admissions in NICU for the year 2015 (Table 5). Major proportion of the preterm babies admitted was of late preterm babies as per the results.

## DISCUSSION

The preterm admission rate in this NICU is 30.95%. A previous Indian study from Assam published before 17 years in the year 1998 had estimated a preterm admissions rate of 21.2%.<sup>8</sup> A South African study, which was published in the year 1999, reported a much higher rate of 54% as preterm admission rate.<sup>9</sup>

**Table 1: Total and month-wise admissions in NICU\***

Month	Inborn admissions	Outborn admissions	Total admissions
January	148	38	186
February	113	48	161
March	197	70	267
April	165	60	225
May	149	55	204
June	154	53	207
July	139	58	197
August	123	55	178
September	139	58	197
October	139	54	193
November	134	58	192
December	119	49	168
Total	1719 (72.38)	656 (27.62)	2375

\*Percentage in parentheses, NICU: Neonatal intensive care unit

**Table 2: Total and month-wise preterm admissions in NICU**

Month	No of preterm admissions	Percentage of preterm admissions
January	82	44.09
February	77	47.83
March	104	38.95
April	76	33.78
May	56	27.45
June	38	18.36
July	57	28.93
August	50	28.09
September	46	23.35
October	47	24.35
November	56	29.17
December	46	27.38
Total	735	30.95

NICU: Neonatal intensive care unit

**Table 3: Month-wise preterm admissions in inborn and outborn wards of NICU\***

Month	Inborn preterm admissions	Outborn preterm admissions	Total preterm admissions
January	72	10	82
February	54	23	77
March	75	29	104
April	29	47	76
May	40	16	56
June	27	11	38
July	46	11	57
August	39	11	50
September	35	11	46
October	40	7	47
November	43	13	56
December	34	12	46
Total	534 (72.65)	201 (27.35)	735

\*Percentage in parentheses, NICU: Neonatal intensive care unit

The estimated prevalence of preterm admissions in a tertiary health center in South Nigeria is 24%.<sup>10</sup> In this study conducted by Kunle-Olowu *et al.*, out of the 634 babies admitted to the Special Care Baby Unit during

**Table 4: Month-wise admissions of preterm babies of gestational age <34 weeks**

Month	No of preterm babies of gestational age <34 weeks admitted in NICU	Percentage of preterm babies of gestational age <34 weeks admitted in NICU
January	11	5.91
February	8	4.97
March	19	7.12
April	10	4.44
May	20	9.8
June	17	8.21
July	21	10.66
August	29	16.29
September	22	11.17
October	24	12.44
November	24	12.5
December	20	11.9
Total	225	9.47

NICU: Neonatal intensive care unit

**Table 5: Analysis of preterm admissions based on gestational age\***

Total preterm admissions in the year 2015	Preterm of gestational age <34 weeks admitted in the year 2015	Preterm of gestational age 34-37 weeks admitted in the year 2015
735	225 (30.61)	510 (69.39)

\*Percentage in parentheses

**Table 6: Month-wise admissions of preterm babies of gestational age 34-37 weeks**

Month	No of preterm babies of gestational age 34-37 weeks admitted in NICU	Percentage of preterm babies of gestational age 34-37 weeks admitted in NICU
January	71	38.17
February	69	42.86
March	85	31.84
April	66	29.33
May	36	17.65
June	21	10.14
July	36	18.27
August	21	11.8
September	24	12.18
October	23	11.92
November	32	16.67
December	26	15.48
Total	510	21.47

NICU: Neonatal intensive care unit

the study period of 3 years from January 2010 to October 2012, 152 (24%) were preterm. The unit has 6 cots and 3 incubators and is manned by 2 Pediatricians, Residents, and Nursing staff with an average ratio of one nurse to 6 patients.

Ugochukwu *et al.* from a special care baby unit of Nnewi reported a preterm admission rate of 18% over a total



**Table 7: Comparison of our study with other 2 studies from tertiary care centers**

Parameters	Our study	Kunle-Olowu <i>et al.</i>	Ugochukwu <i>et al.</i>
Study period	12 months	3 years	29 months
Total admissions	2375	634	699
Total preterm admissions	735	152	133
Percentage of preterm admissions	30.95	24	19

period of 29 months from May 1998 to October 2000.<sup>11</sup> This unit consists of three wards designated for inborn babies, outborn babies, and isolation. There are 17 cots, 1 infant warmer, 5 incubators, 2 oxygen cylinders, 5 phototherapy units, 1 apnea monitor, and 4 resuscitation kits.

Our study has reported a higher case load and higher preterm admission rate than the tertiary health center in South Nigeria (Table 7).

## CONCLUSIONS

Preterm babies contribute a significant percentage of the total newborn admissions in a tertiary care center of a rural medical college hospital. Without improving the preterm care reduction of NMR and thereby infant mortality rate will be a dream unaccomplished. Augmentation of the existing infrastructure, therapeutic facilities, manpower

and periodic training and review of the staff nurses is the need of the hour.

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# Hand Preference in Cerebral Palsy with Special Reference to Prematurity

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## Abstract

**Introduction:** Cerebral palsy (CP) is a static encephalopathy primarily causing impairment of movement and of posture. Handedness may be defined as the preferential use of one hand for performing unimanual tasks. Patients with CP develop early hand preference.

**Purpose:** To determine if the incidence of left handedness is high in children with CP and to investigate the association between prematurity, CP and hand preference.

**Design:** Case-control study.

**Materials and Methods:** A total of 129 children aged 6-15 years with CP and 516 age and gender matched controls were enrolled for the study. The handedness was assessed based on responses to questions on hand preference for writing/drawing, feeding, and throwing a ball. The data were analyzed by conditional logistical regression and calculating the odds ratio (OR) and 95% confidence intervals (CI) for left handedness.

**Result:** The mean age of cases was 9.1 years (standard deviation [SD] = 2.58) and that of controls was 9.6 years (SD = 2.72). Male female ratio was 1.22:1 for cases and 1.3:1 for controls. Spastic diplegia (79.07%) was the most common type of CP followed by hemiplegia (13.18%), quadriplegia (6.97%), and extrapyramidal CP (0.77%). Of the 129 children with CP, 49 (37.98%) were left-handed, while 21 (4.06%) of the 516 normal controls were left handed. The OR for left handedness in children with CP as compared with normal children was 14.43 (95% CI = 8.22-25.35). Nearly one-fifth (20.16%) of the study cases were preterm and out of these 57.69% cases were found to have left hand preference ( $P = 0.0204$ ).

**Conclusion:** The study shows that left handedness is very frequently encountered in children with CP. A significant association exists between preterm CP children and left handedness.

**Key words:** Cerebral palsy, Left handedness, Preterm

## INTRODUCTION

Cerebral palsy (CP) is a static encephalopathy and comprises a heterogeneous group of non-progressive motor impairment syndromes primarily causing impairment of movement and of posture. The cause is a brain insult occurring either prenatally, perinatally or postnatally and affecting areas of the brain which control muscle tone, power and coordination.<sup>1</sup>

Spastic diplegia is bilateral spasticity of lower extremity which is greater than the upper extremity. Periventricular leukomalacia (PVL) and prematurity are the most common associations with spastic diplegia.<sup>2</sup>

Handedness may be defined as preferential use of one hand for performing uni-manual tasks.<sup>3</sup> About 90% of humans are right handed.<sup>4</sup> Most left-handers are males.<sup>5-7</sup> Prematurity has been associated with left handedness.<sup>8</sup> Normally, infants do not show hand preference. Babies with hemiparetic CP may develop hand preference, using the unaffected arm to reach out for toys even when they are closure to the opposite affected hand. Even though, there is no clear-cut consensus as to the age at which adult-like handedness is achieved, it is only after age of 6 years that a clear hand preference can be observed.<sup>9</sup>

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The aim of this study was to ascertain the correlation between left handedness and various types of CP. The objective was to study the prevalence of left handedness among patients with CP and also to investigate the correlation between prematurity-related CP and hand preference.

## MATERIALS AND METHODS

This case-control study was conducted in the Department of Pediatrics, Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh, India. The duration of the study was from September 2014 to December 2015. About 129 children with CP, attending the pediatric outdoor, between the ages 6-15 years were selected by convenience sampling. Detailed birth history, past history, family history, and relevant demographic information were taken. Each child was evaluated by a trained physiotherapist who classified each child's handedness on the basis of parental interview regarding which hand the child preferred while writing/drawing, feeding and throwing a ball. The handedness was also confirmed by direct visualization.

Age and gender matched controls ( $n = 516$ ), in the ratio of four control per patient, were selected from the outdoor patients who had no apparent congenital or neurological anomaly affecting the upper or lower extremities. The parents of the control subjects were asked to fill out a questionnaire in which the same three hand performance activities were asked.

### Statistical Methods

The SPSS Statistics 17.0 (SPSS Inc., Chicago, IL, USA) was used. Power calculations before the study (with a  $\beta$  of 0.10 and a two-sided  $\alpha$  of 0.05) showed that it would be possible to detect a three-fold higher prevalence of left handedness among cases than controls (assumed to be 8-10%). The association between diplegic CP and left handedness was assessed by odds ratio (OR) as a measure of relative risk. The precision of OR was taken as 95% confidence interval (CI), calculated from Mantel-Haenszel Chi-square test.

## RESULTS

The mean age of both cases and controls was 9.1 years (standard deviation [SD] = 2.58) and 9.6 years (SD = 2.72), respectively. Male female ratio was 1.22:1 (cases) and 1.3:1 (controls). Of the 129 children with CP, 37.98% ( $n = 49$ ) were left handed, while 4.06% ( $n = 21$ ) of the 516 controls were left handed. Table 1 shows the frequency of hand preference among the cases and the controls documenting a propensity of male CP children toward left handedness.

The OR for left handedness in children with CP as compared with normal children was 14.43 (95% CI = 8.22-25.35).

Out of 129 cases, 102 (79.07%) were diplegic, 9 (6.97%) were quadriplegic, 17 (13.18%) were hemiplegic, and one (0.77%) was ataxic. Among the different types of CP, left handedness was noticed in 53.92% cases of spastic diplegia, 52.94% of hemiplegic CP, and 33.33% of quadriplegic CP patients (Figure 1).

In the study group, 20.16% ( $n = 26$ ) cases were delivered preterm. Among the preterms, a significant percentage 57.69% ( $n = 15$ ) ( $P = 0.0204$ ) demonstrated a left hand preference whereas 33% ( $n = 34$ ) of term CP children showed a left hand preference (Figure 2).

In the control group, 3.29% ( $n = 17$ ) cases were delivered prematurely. In these normal preterm babies, 17.65% ( $n = 3$ ) showed left hand preference, whereas only 3.61% ( $n = 18$ ) of term CP children showed a left hand preference (Figure 3).

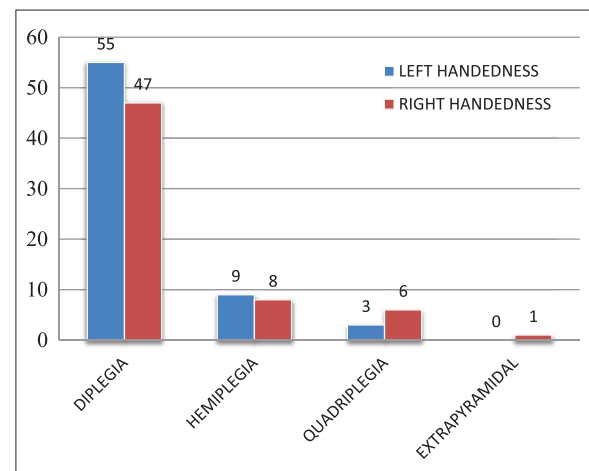
## DISCUSSION

In this study, handedness was judged by assessing three functions (writing/drawing, feeding and throwing

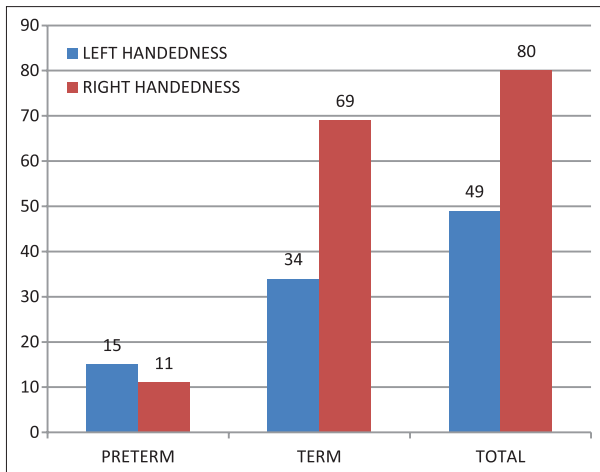
**Table 1: Frequency of left hand and right dominance among children with cerebral palsy and controls**

Gender	Hand dominance	Normal control $n=516$ (%)	Cerebral palsy cases $n=129$ (%)
Female	Left	6 (2.68)	16 (27.59)*
	Right	218 (97.32)	42 (72.49)
Male	Left	15 (5.14)	33 (46.48) <sup>§</sup>
	Right	277 (94.86)	38 (53.52)

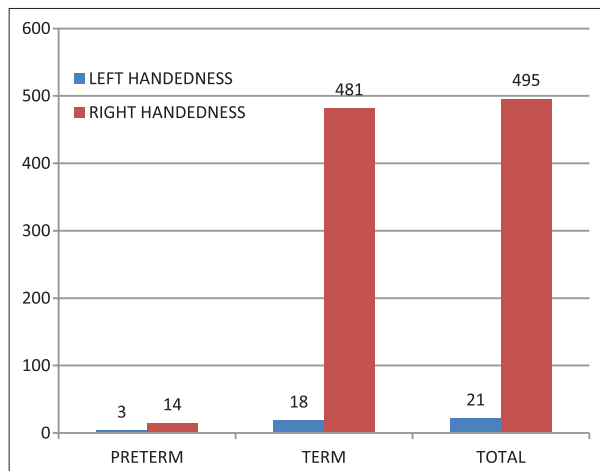
\* $P=0.0330$ ,  $^{\S}P=0.0094$



**Figure 1: Handedness among different types of cerebral palsy**



**Figure 2: Handedness and gestational age in cerebral palsy cases**



**Figure 3: Handedness and gestational age in control cases**

a ball). Interviewing and handedness questionnaire (e.g., Edinburgh inventory) are the two common methods for assessing hand preference.<sup>7,10-12</sup> Interviewing is done by asking the individual/parent which hand they prefer to use to perform a task; whereas, questionnaires inquire as to how frequently one hand is preferentially employed to perform a given set of activities. Since quite a few of these activities are not performed by normal Indian children, on account of cultural differences, hence, using the inventory would have necessitated several modifications.<sup>13,14</sup> Furthermore, a proportion of study cases may not have been able to understand or cooperate appropriately tasks included in these inventories. Although such inventory could have been given to normal controls, this was not done for the sake of uniformity. In spite of this limitation, it is very unlikely that the significant differences in handedness between normal and children with CP are due to inaccuracies in ascertaining the handedness. Similar results have reported in the previous studies from this country.<sup>15,16</sup> Lin *et al.* reported a high prevalence of left handedness in children

with diplegia.<sup>13</sup> Yokochi *et al.*<sup>17</sup> noted high prevalence of left handedness in athetoid CP patients and Dubey *et al.* reported high proportion of left handers among CP patients.<sup>18</sup>

This study reflects that a large number of children with CP are left handed. The study shows that approximately one-fifth of the patients with CP were born prematurely. Out of these a significant proportion of children demonstrated left hand preference. These findings are in agreement with the previous study by Dubey *et al.*<sup>18</sup> The reason is unclear. An explanation could be that damage to the dominant left cerebral hemisphere causes a mild hypofunction of the right hand leading the child to switch to left hand for daily activities.<sup>19</sup> The extent and site of brain damage differs on the basis of timing of insult (gestational age) and the cause of insult. Subcortical white matter damage and PVL are the more common in preterm babies.<sup>20,21</sup> Further *in vivo* studies including the use of magnetic resonance imaging is suggested to evaluate this propensity toward left handedness.

In several ethnic groups and cultures, forced hand conversion is practiced as it is considered socially inappropriate to use left hand for eating, accepting gifts or performing rituals.<sup>22-24</sup> Studies show that forced change in handedness leads to cortical re-organization in normal children<sup>25,26</sup> but no such studies have been reported in children with CP.

Knowledge of the fact that a child with CP has a high likelihood of being left handed will help the pediatrician counsel the parents to refrain from forcing the child to perform routine activities with the right hand. Furthermore, functions performed by non-dominant hemisphere such as visuo-spatial information, and music should be reinforced by vocational training.

## CONCLUSION

The study shows that left handedness is very frequently encountered in children with CP. A significant association exists between preterm CP children and left handedness.

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# Treatment of Multiple Impacted Canines - Maxillary Left Canine and Both Mandibular Canines: A Case Report

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## Abstract

Impaction is the total or partial lack of eruption of a tooth well after the normal age of eruption. In the mandibular arch, the canine impaction can occur due to over-retained deciduous tooth or crowding in the anterior region because of the arch length-tooth material discrepancy. This case report describes the orthodontic treatment of an 18-year-old girl, who had 3 impacted canines (maxillary left and both mandibular canines). The treatment protocol involved leveling and alignment of both upper and lower arches followed by sequential traction of the 3 impacted canines. All the impacted canines were brought to their correct position in maxillary and mandibular arch. The patients smile dramatically improved after orthodontic treatment. A stable occlusion was achieved.

**Key words:** Extrusion, Guidance of impacted teeth, Impaction, Mesiodens, Mucoperiosteal flap, Over-retained deciduous teeth, Periodontium, Supernumerary teeth

## INTRODUCTION

Impaction is the total or partial lack of eruption of a tooth well after the normal age of eruption. The most commonly impacted maxillary tooth is the canine, occurring in less than 2% of the general population,<sup>1</sup> followed by the central incisor with a frequency of 0.06-0.2%.<sup>2</sup> According to Kokich and Mathews,<sup>3</sup> the cause of labial impaction of canines probably is related to either a retained deciduous tooth, diversion of canine tooth bud, or idiopathic failure of eruption of unknown origin. The labial impaction of a maxillary central incisor can occur because of an unerupted mesiodens or supernumerary tooth.<sup>4</sup> In the mandibular arch, the canine impaction can occur due to over-retained deciduous tooth or crowding in the anterior region because of the arch length-tooth material discrepancy.

This case report describes the sequential management of 3 impacted canines (one maxillary and two mandibular). Treatment is done with an interdisciplinary approach, in which an orthodontist and an oral surgeon were involved. The treatment success was the result of the combined efforts of the orthodontist, the oral surgeon, and the patient.

## CASE REPORT

An 18-year-old girl came to the Department of Orthodontics at Nair Hospital Dental College, Mumbai, Maharashtra, India, with a chief complaint of an unesthetic smile due to missing teeth in maxillary and mandibular anterior region. The patient was physically healthy and had no history of medical or dental trauma. No signs or symptoms of temporomandibular joint dysfunction were noted at the initial examination.

The extra-oral examination showed a convex profile due to the retrusive chin. The intra-oral examination showed an Angle's class I malocclusion with spacing in upper left and lower right and left canine region and partially erupted

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mandibular left first premolar. Three teeth were missing, one maxillary left canine and both mandibular canines. There was no sufficient space for the accommodation of canines in the arch. Overbite was 50-60% with slightly increased curve of spee.

Cephalometrically, the patient had a class II skeletal relationship with slight retrognathism of the mandible (ANB angle, 4°). The panoramic radiograph showed all permanent teeth including the maxillary and mandibular third molar buds. The maxillary left canine and both mandibular canines were impacted. Periapical radiographs were taken with the Clark's tube-shift technique to confirm the labial position of the impacted teeth.

### Treatment Objectives

Ideally, the treatment objectives would include full resolution of the malocclusion of the all 3 impacted canines and partially erupted left mandibular first premolar in the dental arch. Alternative treatment plans with less ambitious objectives were presented to the patient for consideration.

### Treatment Alternatives

The following treatment alternatives were considered.

1. Forced eruption and alignment with surgical intervention of the impacted teeth in the dental arch, which would be the ideal treatment option for this case.
2. Extraction of all impacted teeth and replacement with conventional prosthesis or implants. However, the loss of alveolar bone after several extractions could be detrimental to the esthetics of the future prosthesis.

### Treatment Progress

Finally, it was decided to attempt forced eruption and alignment of the impacted teeth. Both a periodontist and an oral surgeon were consulted to formulate the treatment plan. The patient was asked to sign the consent form.

The maxillary and mandibular molars were banded, and the remaining teeth were bonded with a  $0.022 \times 0.025$  in pre-adjusted appliance. After the initial leveling and alignment, a  $0.019 \times 0.025$  stainless steel archwire was inserted in the maxillary and mandibular arch with an open coil spring in the position of the impacted teeth to hold, and if necessary, create space for its eruption.

After gaining sufficient space for the impacted canines, the patient was referred to the oral surgeon for the surgical procedures of the initial treatment plan. A wide mucoperiosteal flap, similar to that described in closed-eruption technique was raised over the impacted canines.<sup>3</sup> A Begg bracket was bonded on the labial surface of all the impacted canines. The flap was returned to the same position and sutured, living a tied 0.010-in ligature wire protruding through the mucosa and attached to the base arch wire. After a week, a light force of 60-90 g was applied by an elastomeric chain from the ligature wire to the impacted canines. Later, during final alignment, pre-adjusted edgewise brackets were bonded on the erupted canines. After final leveling and alignment, debonding done and removable retainers were given to the patient.

### RESULTS

The overall active treatment duration was 24 months. All the impacted canines were brought into their correct position in the dental arch. The partially erupted mandibular left first premolar was also corrected. The final occlusion was good and stable, except for the mandibular right canine, which finished toward an end-to-end relationship. Periodontal examination showed that there was mild to moderate gingival recession with respect to a mandibular left canine with slight root exposure. However, still there was a dramatic improvement in patient's smile. The pre-treatment and post-treatment extra-oral and intra-oral photographs are shown in Figures 1 and 2, respectively.

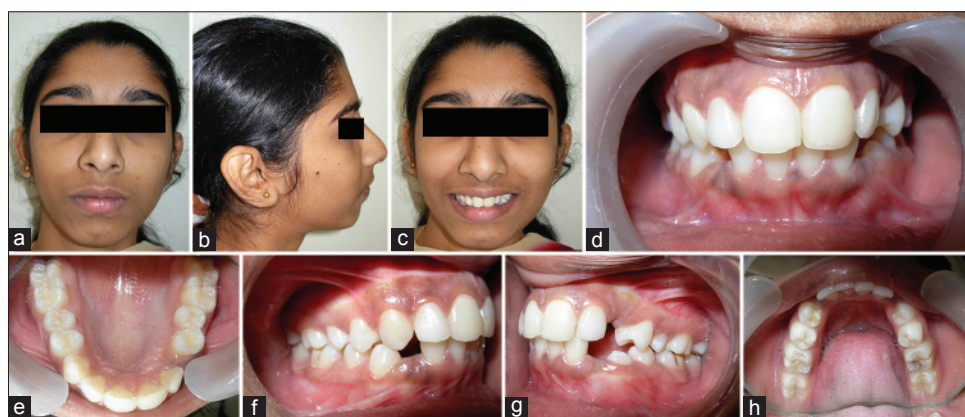


Figure 1: (a-h) Pre-treatment facial and intraoral photographs

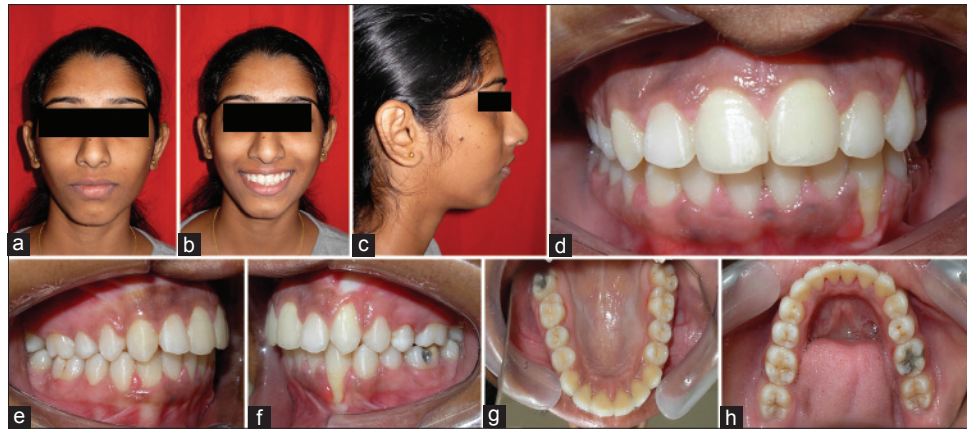


Figure 2: (a-h) Post-treatment facial and intraoral photographs

## DISCUSSION

Several reports have indicated that the impacted teeth can be brought to proper alignment in the dental arch,<sup>5,6</sup> however, only a few have dealt with as many impacted canines as seen in this patient.<sup>7,8</sup> It has been suggested that, in up to 75% of patients, impacted teeth erupt spontaneously after removal of over-retained or supernumerary teeth. Most commonly, supernumerary teeth occur in the anterior midline, and because of their additional tooth bulk, frequently cause malposition of adjacent teeth or prevent their eruption.<sup>9</sup> When spontaneous eruption does not occur, surgical exposure is indicated.<sup>10</sup> Power and Short<sup>11</sup> showed that, of 22 impacted maxillary canines that overlapped the lateral incisors up to half the root width, 16 normalized into a normal eruptive position after removal of the deciduous canines. The surgical exposure for the orthodontic guidance of impacted teeth must be well planned to prevent any harmful effects on the periodontium. The patients post-treatment periodontal status showed satisfactory gingival contours and oral hygiene, except for the mandibular left canine, where there was mild to moderate gingival recession, which may be attributed to trauma from occlusion or improper positioning of the mucoperiosteal flap during surgical exposure.

## CONCLUSION

1. The treatment of multiple impacted teeth was a clinical challenge. The prosthodontic option was less

time-consuming but less attractive than the purely orthodontic solution. A conservative flap design, coupled with sequential extrusion of impacted teeth with a light force, helped us to achieve the desired results.

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# Pneumobilia with Cholangitic Abscess: A Case Report

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## Abstract

Pneumobilia or aerobilia is an accumulation of air in the biliary tree. Pneumobilia is considered as a serious pathology, requiring urgent surgical intervention. Most cases are iatrogenic in origin, occurring post-surgeries for sphincterotomy or hepaticojejunostomy, or choledochojejunostomy. We report here a case of 32-year-old woman presenting with high fever and abdominal pain with air in the biliary tree and cholangitic abscess, which did not subside in spite of being on full dose higher antibiotics. Eosophagogastroduodenoscopy revealed multiple choledochoduodenal fistulas. Magnetic resonance cholangiopancreatography confirmed pneumobilia. The patient was advised 4-weeks rest, after which surgical intervention would be contemplated and followed up with ultrasonography scan weekly.

**Key words:** Aerobilia, Biliary tree, Cholangitic abscess, Choledochoduodenal fistula, Pneumobilia

## INTRODUCTION

Pneumobilia or aerobilia is an accumulation of air in the biliary tree.<sup>1</sup> The most common conditions associated with pneumobilia include: (1) A biliary-enteric surgical anastomosis, (2) an incompetent sphincter of Oddi, or (3) a spontaneous biliary-enteric fistula, and rarely. (4) Biliary bronchopleural fistula.<sup>2</sup> Most cases of pneumobilia are related to gallstone disease. Pneumobilia is considered as a serious pathology, requiring urgent surgical intervention.

We report here a case of 32-year-old woman presenting with high fever and abdominal pain with air in the biliary tree and cholangitic abscess.

## CASE REPORT

The 32-year-old woman was brought by her husband with a history of fever, bilious vomiting, and mild abdominal pain since 5 days. Fever was high grade associated with chills. The patient had also had nausea with 2-3 episodes of bilious vomiting, and mild abdominal pain. The patient

had undergone cholecystectomy 20 years back in view of congenital choledochal cyst of the common biliary duct (CBD); the post-operative period until now was uneventful. No other significant past medical/surgical history was elicited. Her abdominal examination revealed severe tenderness in the right hypochondriac region. Other systemic examination revealed no abnormality.

Abdominal ultrasound showed mild fullness of intrahepatic biliary radicals (IHBR) in the right lobe of the liver with few echogenic foci within. Computed tomography scan of the abdomen was performed which showed dilatation of the central and peripheral IHBR with pneumobilia, and multiple calculi in these IHBR. Few round cystic lesions, likely cholangitic abscesses, could be seen in the peripheral aspects of segment VII of the right lobe of liver communicating with the biliary radicals. Eosophagogastroduodenoscopy (OGDscopy) showed multiple fistulous openings at D1-D2 junction, considered to be choledochoduodenal fistulas. Magnetic resonance cholangiopancreatography (MRCP) was advised for further confirmation. The MRCP confirmed the presence of air foci in the proximal CBD, representing choledochoduodenal fistula, with dilatation of central and peripheral IHBR, with pneumobilia, with multiple calculi in the dilated IHBR (Figures 1-4).

## Management

The patients' blood was investigated and revealed her hemoglobin (Hb) to be 10.8 mg/dl, total leukocyte count - 14000/ $\mu$ l, and platelets of 314 $\times$ 10<sup>3</sup>/ $\mu$ l.

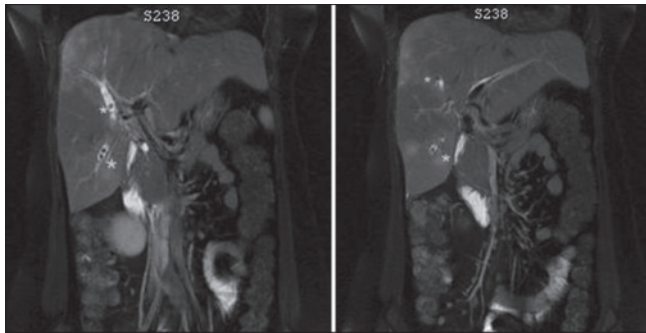
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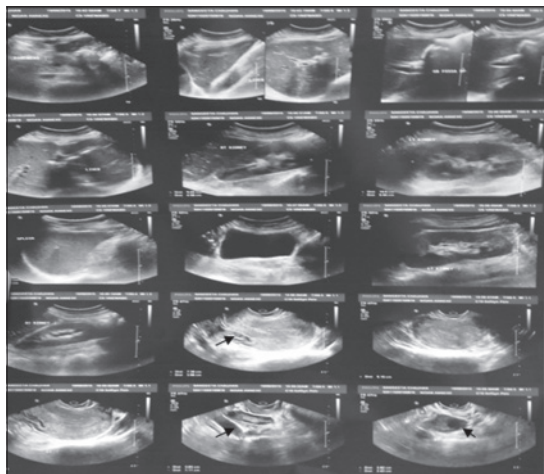
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**Figure 1: Coronal T2-weighted (T2W) magnetic resonance (MR) image reveals that the suspected stones are air bubbles (\*) within the right hepatic biliary radical. MR cholangiopancreatography images may be misinterpreted therefore T2W images are most significant in identifying the pneumobilia**

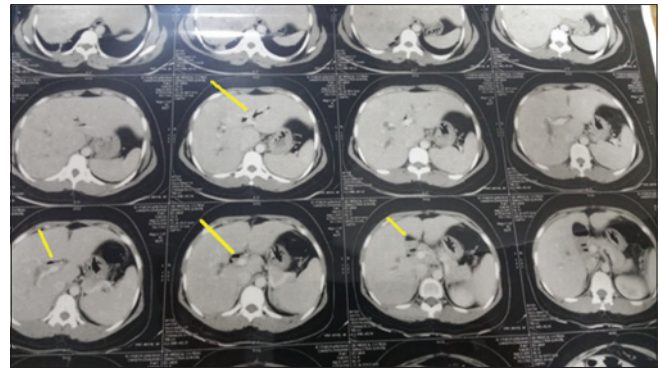


**Figure 2: Abdominal ultrasound. Arrows represent mild fullness of intrahepatic biliary radicals in the right lobe of liver with few echogenic foci within**

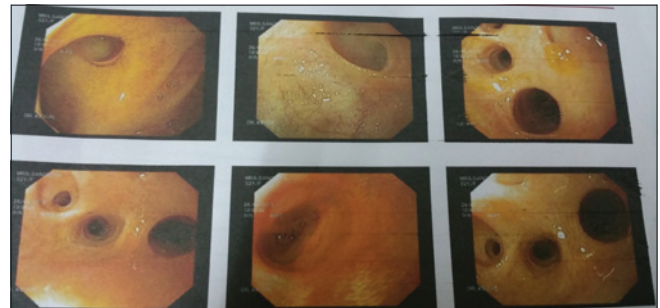
In spite of starting the patient on higher antibiotics in full doses - injection piperacillin, injection metronidazole, the fever and abdominal pain did not subside. OGDscopy was done; which revealed multiple choledochoduodenal fistulas and was advised MRCP for further evaluation. The presence of pneumobilia was confirmed by MRCP, after which she was advised rest for 4 weeks till sepsis settled, after which surgical intervention would be contemplated and was asked to follow-up with ultrasonography scan weekly.

## DISCUSSION

Pneumobilia is the presence of air in the biliary tree. Most cases are iatrogenic in origin, occurring post-surgeries for sphincterotomy or hepaticojejunostomy, or choledochojejunostomy. In the absence of a history of these procedures, other causes should be looked for. Mostly,



**Figure 3: Abdominal computed tomography-scan. Dilatation of central and peripheral intrahepatic biliary radicals (IHBR) with pneumobilia, and multiple calculi in these IHBR. Few round cystic lesions, likely cholangitic abscesses could be seen in the peripheral aspects of segment vii of right lobe of liver communicating with the biliary radicals**



**Figure 4: Oesophagogastroduodenoscopy. Fistulous openings at D1-D2 junction, considered to be choledocho-duodenal fistulas**

such patients do have enterobiliary fistula of some origin, or more ominous, cholangitis. Spontaneous pneumobilia may occur due to gallstone erosion in the biliary tree to an adjacent viscus.<sup>3</sup>

Our patient was a 32-year-old woman with a history of congenital choledochal cyst of CBD, followed by cholecystectomy, 20 years ago. Her post-operative period was uneventful. However, her present imaging investigations revealed multiple calculi in the IHBDs, air foci in the proximal CBD, and intrahepatic cholangitic abscesses.

Pneumobilia has been reported to have a presentation similar to that of cholelithiasis. A long-standing history of biliary stones, recurrent biliary tract infections, and the presence of CBD stones do predispose the occurrence of choledochoduodenal fistula when seen with cholelithiasis.<sup>4</sup> Previous biliary surgery is a lesser contributing factor, as seems to be the case in our report. Choledochoduodenal fistula leads to exposure of biliary tract to gut flora. This not only complicates the case by the occurrence of

cholangitic abscess, but also leads to biliary diarrhea, fluid and electrolyte wasting, and malabsorption.

Abdominal computed tomography (CT) is a valuable diagnostic method as fistulas, air in biliary tree, in addition to contraction of the gallbladder, can be visualized. Although our patient was cholecystectomized, CT imaging of a biliary enteric fistula is also useful for differentiating between a gall bladder enteric fistula and a common bile duct-enteric fistula.<sup>5</sup>

Proximal choledochoduodenal fistulae are managed surgically. Two main surgical approaches, one-stage procedure (comprising enterotomy, cholecystectomy, and fistula repair) and two-stage procedure (enterotomy with or without subsequent cholecystectomy and fistula repair) are available.<sup>6</sup> There is no consensus on which is better. In our case, the patient being previously cholecystectomized was managed with high dose antibiotics and OGDscopy done initially on presentation and revealed multiple choledochoduodenal fistulas. CT-abdomen was done which was suggestive of dilatation of central and peripheral IHBR with pneumobilia and findings of the cholangitic abscess. MRCP was advised which confirmed the presence of air foci in the proximal CBD, representing

choledochoduodenal fistula, with dilatation of central and peripheral IHBR, with pneumobilia, with multiple calculi in the dilated IHBR.

## CONCLUSION

Pneumobilia is a rare entity. Occurring with cholangitic abscess in a patient with an uneventful cholecystectomy, it presents a challenging case for determining the diagnosis as well as the management.

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# Synchronous Bilateral Breast Benign Phyllodes Tumors in an Adolescent Female along with Depression: A Case Report

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## Abstract

Cystosarcoma phyllodes or phyllodes tumors are a rare neoplasm of the breast and present as painless breast mass. It accounts for 1% of all breast tumors. Whether benign, borderline or malignant, they have a high potential of recurrence. The bilateral occurrence of these biphasic tumors is rare. According to the literature, most of them are malignant and asynchronous. Synchronous bilateral benign presentation in a young nulliparous female is extremely rare. The definitive treatment of the benign entity is either wide local excision or mastectomy depending on size and age of the patient. We report a case of synchronous bilateral benign phyllodes tumors in a 22-year-old female associated with depressive features. Bilateral breast biopsy revealed benign phyllodes tumors. The case under report finds rarity due to its synchronous bilateral benign presentation in an unmarried adolescent female where the decision making regarding its management with surgical procedure becomes difficult and the significance of treating the associated depression in such a patient.

**Key words:** Adolescent female, Bilateral benign tumors, Breast, Depression, Phyllodes tumor, Synchronous

## INTRODUCTION

Phyllodes tumor is a rare fibroepithelial neoplasm of the breast in children and adolescents. In most of the cases, it presents as a rapidly growing, clinically benign breast mass. These tumors usually present as unilateral painless, well-circumscribed, mobile breast masses.<sup>1</sup> Bilateral tumors are rare entity and usually malignant and asynchronous in nature.<sup>2</sup> These tumors are locally aggressive and have high recurrence rate. Surgery is the mainstay of treatment.<sup>1</sup> We report a case of synchronous bilateral benign phyllodes tumors in a 22-year-old woman associated with depressive features. Local excision performed for the right side tumor and mastectomy with breast reconstruction performed for the left side tumor. There was an improvement in depressive features that was analyzed with Hamilton

depression rating scale (HDRS) with decrease in score after surgery and with appropriate pharmacotherapy.

## CASE REPORT

The 22 years young adolescent nulliparous female presented with bilateral breast lumps since 18 months. The patient developed features of depression during that period. Bilateral breast examination revealed lump on both the breasts without any axillary lymph node enlargement. Right breast examination showed a lump of size 6 cm × 6 cm, non-tender in nature, firm to hard in consistency, with lobulated appearance and normal intact nipple-areolar complex without any skin or chest wall fixity. Left breast examination revealed a lump of size 10 cm × 10 cm, non-tender in nature, firm to hard in consistency, with lobulated appearance and normal intact nipple-areolar complex without any skin or chest wall fixity. Contrast enhanced computed tomography scan of neck, chest, abdomen, and pelvis revealed lobulated well defined minimally enhancing bilateral breast masses (Figure 1). Careful examination ruled out other possible sites of lesion. Tru-cut biopsy from both the breast revealed

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features of benign phyllodes tumors (Figure 2). The patient was referred for psychiatric evaluation as at the time of presenting she was having low mood, crying spells and failed to carry out routine activities effortlessly. She was growing more aloof, and her HDRS score was calculated at first interview to assess the severity of the symptoms. The patient's score was HDRS 16 at the first interview. Surgery was performed on both the breast. A wide local excision with clear surgical margins was performed for right side benign phyllodes, whereas mastectomy with breast reconstruction was performed for left side benign phyllodes due to larger size of the tumor. Following surgery, the patient's general condition had markedly improved; she had gained appetite and weight. She was advised sertraline 50 mg at morning and clonazepam 0.25 mg once after dinner if required at the time of discharge. After 2 months of follow-up, the patient's HDRS score became drop to 3.

## DISCUSSION

Johannes Muller (1838) first used the term cystosarcoma phyllodes.<sup>3</sup> In 1982, the World Health Organization declared the "phyllodes tumor" as the most appropriate term among many synonyms. Phyllodes tumors account for

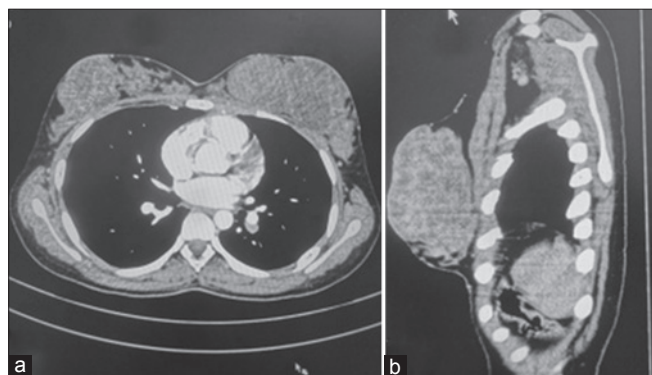
<0.5% of all breast malignancies.<sup>4</sup> The vast majority occur in women, in whom the median age at presentation is 42-45 (range 10-82 years).<sup>5</sup> This case is a 15 years female which is unusual. Synchronous bilateral multifocal phyllodes tumors are seen in a limited number of case reports.<sup>2</sup> Most of these reported have malignant form of the disease, at least, one side of the breast. The synchronous bilateral benign presentation is an extremely rare entity.

Phyllodes tumors are classified as benign, borderline and malignant basing on microscopic findings including stromal cellularity, cellular pleomorphism, mitotic activity, margins appearance, and stromal distribution.<sup>6</sup> Benign and malignant variants constitute 35-64% and 25%, respectively, and the rest are borderline.<sup>4</sup> All the subtypes of phyllodes tumors have a high propensity for recurrence. This case had synchronous bilateral presentation and met all the criteria for benign phyllodes tumor of both the sides.

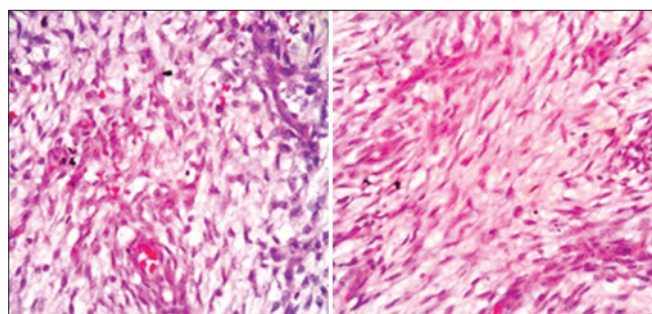
Phyllodes tumors are usually rapidly growing. The size varies from 1 to 41 cm with an average of 7 cm.<sup>4</sup> About 20% of the cases grow beyond 10 cm (giant phyllodes tumor) and rarely attain size of 40 cm when it is a unique challenge to the surgeon with respect to treatment options. Among children and adolescents, most phyllodes tumors exhibit a benign behavior.<sup>7</sup> The present case is a bilateral benign phyllodes tumor in an adolescent female. There are no standard etiologic or predisposing factors available for phyllodes tumors, except Li-Fraumeni syndrome, a rare autosomal dominant condition which is characterized by the development of multiple tumors.<sup>8</sup> Most bilateral phyllodes tumors in young women are associated with pregnancy or lactation.<sup>2</sup> Lactation is a precipitating factor in the metamorphosis of bilateral phyllodes tumor.<sup>2</sup> However, the role of female hormone still remains unclear. The present case is without pregnancy and lactation.

Phyllodes tumors present as a nonpalpable mass in 20% of cases and are identified on screening mammography.<sup>9</sup> Mammographically, phyllodes tumors are well defined with a smooth and occasionally lobulated border.<sup>10</sup> On ultrasound examination, phyllodes tumors often show smooth contours with low level homogeneous internal echoes and the absence of posterior acoustic enhancement.<sup>11</sup> There are no reliable mammographic or ultrasonic indicators available to differentiate between benign and malignant lesions.<sup>10,12</sup> Magnetic resonance imaging (MRI) provides more accurate extent of the disease prior to surgery, but, few data support the routine use of it.<sup>13</sup> MRI gives a better idea regarding the achievement of adequate margins when mastectomy to be performed.

Both phyllodes tumors and fibroadenomas are a spectrum of fibroepithelial lesions. It is difficult to distinguish



**Figure 1: (a and b) Contrast enhanced computed tomography scan of thorax showing bilateral minimally enhancing lobulated breast masses (left side mass [8 cm × 10 cm] larger than right side [6 cm × 6 cm])**



**Figure 2: Microsection shows presence of stromal hypercellularity with proliferation of stromal cells only with normal glandular elements (H and E, ×400)**

diagnosis of fibroadenoma and phyllodes tumors by fine needle aspiration cytology and core biopsy.<sup>14</sup> An accurate pre-operative diagnosis needs imaging studies or biopsy, and the intraoperative frozen section. Microscopically, phyllodes tumors are characterized by epithelial lined cystic spaces with a hypercellular stromal projection. The stromal elements are a key component for differentiation of phyllodes tumor from fibroadenoma, and distinguishing between benign and malignant variants. An epithelial component with stromal components differentiates the phyllodes tumor from other stromal sarcomas.<sup>4</sup> There is no standard diagnostic protocol for pre-operative diagnosis of this rare disease. The present case on pre-operative tru-cut biopsy revealed findings consistent with bilateral benign phyllodes tumor of the breast.

Phyllodes tumor is best treated with wide excision when the size of the tumor is small. Surgical management is the mainstay of treatment in all types of phyllodes. Depending on the size of the breast, and size, location, and number of tumors; complete surgical excision with clear margins, mastectomy with or without breast reconstruction are the few treatment options for benign phyllodes tumors. Each subsequent recurrence converts tumor into a more aggressive one.<sup>15</sup> In the case of giant phyllodes tumor, excision with required margins is not possible. Mastectomy should be the treatment of choice in such patients including recurrent disease.<sup>16</sup> Like ipsilateral phyllodes tumor, surgery is the mainstay of treatment for bilateral presentation. Radical surgery does not have any survival advantage.<sup>17</sup> Mastectomy has better results than breast-conserving surgery in borderline and malignant cases.<sup>18</sup> There is controversy regarding the role of chemotherapy and radiotherapy.<sup>19</sup>

Phyllodes tumors have favorable prognosis with 5 years disease-free survival rates of 96%, 74% and 66% after surgery for benign, borderline and malignant phyllodes tumors, respectively.<sup>4</sup> There is no correlation about risk factors between tumor size and local recurrence.<sup>20</sup> Tumor size in relation to the breast is important for the extent of surgery and pathological resection margins. The most important factor for local control is excision with clear margins.<sup>18</sup> Wider margins (>1 cm) have the lowest risk of recurrence.<sup>21</sup> The possibility of local recurrence is 6-10% in benign, 25-30% in borderline and over 25% in malignant variants. Distant metastasis occurs in 3-13% of cases and lung is the most common site of distance metastasis.<sup>22</sup>

Depressive clinical features may develop in young women with breast phyllodes tumor. HDRS is the most widely used clinician-administered depression assessment scale.<sup>23</sup> It has 17 questions on mood and other symptoms which are scored. It consists of a set of 17 questions on depressed

mood, feelings of guilt, suicide, insomnia in early and middle of night, insomnia early in the morning, work and activities, retardation, agitation, anxiety psychic, anxiety somatic, somatic symptoms of gastrointestinal, general somatic, genital symptoms, hypochondrias, loss of weight, and insight which are given scores. This provides with an objective score which is done before and after treatment to quantify the improvement in depressive symptoms.

The present case is treated with surgery. Left side breast phyllodes treated with mastectomy and breast reconstruction due to larger size of the tumor, whereas wide local excision with clear surgical margins was performed for right side breast phyllodes. There was a significant improvement in depressive features.

## CONCLUSION

A differential diagnosis of phyllodes tumor should be considered in a rapidly growing but clinically benign breast lump, especially in young women. A thorough pre-operative diagnosis of this rare disease is important to determine the surgical approach.

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# Giant Vesical Calculus: A Rare Case Report

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## Abstract

A vesical calculus weighing more than 100 g is considered to be a giant vesical calculus. Male preponderance for vesical calculi is well-known. Here, we report a 48-year-old male patient who presented to us with a giant vesical calculus of 700 g, which is quite rare. The stone was removed by open cystolithotomy. Although vesical stones are not rare but finding such a large vesical stone causing bladder outlet obstruction is extremely rare and causes a diagnostic dilemma. The purpose of presenting this case is that there are still rural places in India where basic medical facilities like ultrasound are not available leading to a delay in diagnosis and treatment of the patient.

**Key words:** Cystolithotomy, Urinary bladder, Vesical calculus

## INTRODUCTION

Bladder stones are the most common manifestation of lower urinary tract lithiasis, currently accounting for 5% of all urinary stone disease and approximately 1.5% of urologic hospital admissions. Bladder calculi in non-endemic areas are typically found in adults and almost always in association with other disease processes resulting in urinary stasis or the introduction of a foreign body. Primary bladder calculi are more common in children exposed to low protein, low phosphate diets. Primary bladder calculi rarely recur after treatment. Secondary bladder calculi are generally associated with bladder outlet obstruction.

## CASE REPORT

A 48-year-old male patient residing at Karjat presented with complaints of dull aching pain in hypogastrium, with obstructive voiding symptoms such as poor stream, poor caliber of micturition, hesitancy and sense of incomplete evacuation, storage symptoms such as severe dysuria, urgency and frequency since 1 year, terminal painful

hematuria with clots on and off since 6 months, and fever with chills since 2 days. The patient was investigated at a nursing home in the periphery, where ultrasonography (USG) abdomen revealed prostatomegaly likely to be a prostatic malignancy. So, the patient was referred from there to Tata Memorial Cancer Hospital. There on transrectal ultrasound revealed a large pelvic lesion with hyperechoic lesion measuring 10 cm × 8 cm, which was pushing urinary bladder anteriorly and with echoes within the bladder suggestive of cystitis, prostate appeared normal without any hypoechoic lesion of 26 g. Grayscale USG abdomen showed a 10 cm × 7 cm calculus in the bladder with changes of cystitis with left renal staghorn calculus (4.7 cm × 0.8 cm) with bilateral moderate hydronephrosis. MRI pelvis showed a large intravesical calculus measuring 12 cm × 9 cm × 7 cm with mildly thickened bladder wall, with compression of the bilateral vesicoureteric junction and bilateral hydronephrosis. Prostate and seminal vesicle were normal. So, the patient came to MGM Hospital, Kamothe where on examination there was an 11 cm × 7 cm hard fixed immobile lump palpable in hypogastrium. On per rectal examination, there was hard nodular mass above prostate with firm grade 2 prostate. On routine investigation, hemoglobin - 12; thin layer chromatography - 11,740, urine routine showed occult blood 3+, protein 1+, 10-12 red blood cells, and 2-4 pus cells; creatinine - 1.8, sodium - 137; potassium - 5.2, serum calcium of 8 mg/dl. Urine culture was sterile. X-ray kidney, ureter, and bladder (KUB) (Figure 1)

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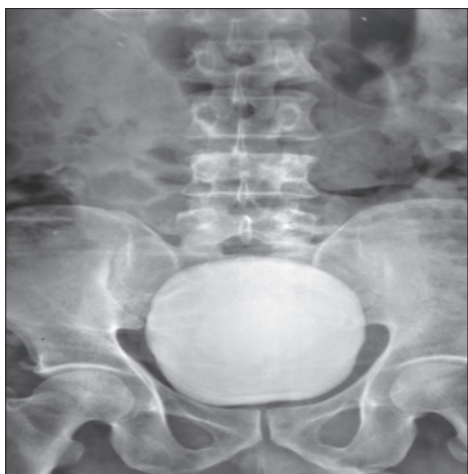


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**Figure 1: X-ray kidney ureter bladder showing giant vesical calculus**



**Figure 2: Vesical calculus gross view**

revealed a large bladder stone with left renal staghorn calculus. Computed tomography-KUB was suggestive of 11 cm × 7 cm vesical calculus with left renal 4.8 cm staghorn calculus with bilateral moderate hydronephrosis with grade 2 prostatomegaly.

The patient was catheterized to relieve his symptoms and was started on IV broad spectrum antibiotics as he had a fever with chills before surgery. In view of giant vesical calculus, suprapubic cystolithotomy was planned. A combined intra- and extra-peritoneal approach was taken as there were gross adhesions of the fundus with peritoneum due to repeated attacks of cystitis, through lower midline vertical incision. On exploration bladder was inflamed, stretched, and thin walled with gross adhesions to surrounding structures. After doing anterior cystostomy, there was a 13 cm × 10 cm × 8 cm yellowish-white hard bladder stone. Bladder stone was removed (Figure 2), wash given and bladder was closed in two layers after putting a 22 F suprapubic, 18 F per urethral catheter and a pelvic drain. Weight of the stone



**Figure 3: Vesical stone weighing 700 g**

was 700 gms. (Figure 3) Post-operative period was uneventful, and the patient was discharged on 7<sup>th</sup> post-operative day. Per urethral catheter was removed on the 10<sup>th</sup> day, suprapubic catheter was clamped and removed on the 12<sup>th</sup> day after checking his urine flow rate. Stone analysis revealed uric acid, triple phosphate, and calcium oxalate indicative of primary stone formation.

## DISCUSSION

A giant vesical calculus more than 100 g is an unusual finding in urological practice.<sup>1-4</sup> Giant vesical calculus are universally uncommon, and there are only a few case reports of stone weighing more than 500 g.<sup>2</sup> Urinary bladder stone can be either primary or secondary. Most common causes include urinary tract infection due to bladder outlet obstruction leading to stasis, encrustation around a foreign body, neurogenic bladder, bladder diverticulum, and long-term catheterization.<sup>3</sup> Urinary bladder stone constitute of 5% of all urolithiasis. Bladder stone are more common in males. Most vesical calculus is composed of triple phosphate, calcium carbonate, and calcium oxalate. It is thought that a giant vesical calculus develops from a nidus of infection or a single ureteric stone with progressive layerwise deposition of calcified matrix. Bladder stones are often multilayered. Studies have shown that the bladder stone nucleus often does not contain struvite or calcium phosphate; however, subsequent concentric layers contain these substances only in large amount. Schwartz and Stoller indicated that infection may not be the inciting factor in stone formation but may also play a major role in further stone crystallization.<sup>3</sup> In the era of laparoscopic and robotic surgery, the purpose of presenting this case is that there are still rural places in India where basic medical facilities such as ultrasound are not available leading to a delay in diagnosis and treatment of the patient.

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# Laparoscopic Distal Pancreatectomy for Serous Cystadenoma with Anomalous Vasculature

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Pancreatic cystic neoplasms account for 2% of all pancreatic neoplasms of which only 1% are malignant.<sup>1</sup> They are usually picked up as incidental findings in imaging investigations. Pre-operative diagnosis still remains challenging. Imaging and fluid analysis often seems non-specific. Fine-needle aspiration cytology does not always yield diagnostic cells.

A 50-year old female presents with chronic abdominal pain for 5 years. Ultrasound abdomen revealed a pancreatic mass with features suggestive of cystadenoma. Contrast-enhanced computed tomography (CT) was done which showed an anomalous course of the splenic artery. A three-dimensional CT reconstruction (Figure 1) was used to trace the exact course and lie of the splenic artery, which showed it to be posterior and inferior to the pancreas, lying behind the course of the splenic vein. The patient was planned for laparoscopic distal pancreatectomy with the aid of the reconstructed image and underwent the same using high energy tissue sealing device (Figure 2). The spleen-preserving procedure could not be performed due to the posteroinferior and adherent course of the splenic artery. Post-operative period was uneventful. Histopathology confirmed the mass (Figure 3) as serous cystadenoma of the pancreas with margins free. Subsequent follow-up was uneventful. This case is highlighted to show that laparoscopic distal pancreatectomy can be performed safely even in tricky situations providing careful evaluation, especially of vascular anomalies is done.



Figure 1: Computed tomography three-dimensional reconstruction of anomalous anatomy

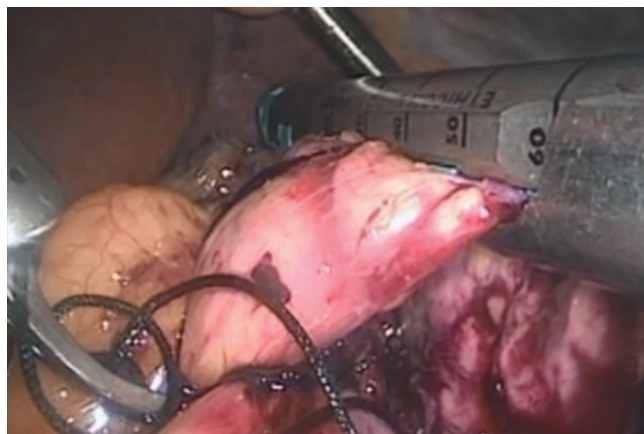


Figure 2: Distal pancreatectomy with high energy tissue sealers

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## Points to Ponder

1. Rare reports of invasive growth<sup>2</sup> and mass lesion causing obstructive jaundice<sup>3</sup> have been reported in serous cystadenoma of the pancreas and hence should be thought to have malignant potential and hence must be resected. Spleen-preserving distal pancreatectomy

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**Figure 3: Specimen picture**

should be the surgery of choice in ideal cases.

2. Laparoscopic distal pancreatectomy is now being done in advanced centers for its excellent patient acceptability, decreased hospital stay time, less

bleeding, more chance of splenic preservation, and overall less morbidity.<sup>4</sup> Moreover, it provides better access to deeper reaches of the abdomen and in such cases having anomalous splenic artery, better visualization, and access are available to ideally tackle the tumor.

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