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## Contents

### ORIGINAL ARTICLES

- Canal Shaping with ProTaper Next: An *Ex Vivo* Study  
*Annil Dhingra, Satyabrat Banerjee, Neha Aggarwal, Vikrant Yadav* 1
- Dermal Sensitivity to Common Allergens and Effect of Allergens Avoidance in Patients of Allergic Rhinitis and Bronchial Asthma in Malwa Region: A Hospital Based Study  
*Kallol Sinha, H G Varudkar, Arti Julka, J C Agrawat, Mustafa Singapurwala, Piyush Gupta, Abhisheka Kumar* 5
- Study of Carotid Intima-Media Thickness in Patients with Coronary Artery Disease and Stroke  
*Mayank Sarawag, Manju Bhaskar, Rajinderpal Singh, Sameer Saharan, Kuldeep Singh Yadav* 10
- Usage of Over the Counter Drugs – The Counterintuitive Exploitation  
*Saranya Nagalingam, Geetha Chella Krishnan, Balaji Arumugam* 16
- Cheiloscopy: The Study of Lip Prints in Relation to Gender and Geographic Distribution  
*Sneha C Khanapure, Jithesh Jain, S R Ananda, S Supreetha, K N Abhishek, M Shilpa* 21
- Assessment of Proteinuria by the Determination of Micro Total Protein and Estimated Glomerular Filtration Rate in Type 2 Diabetes Mellitus Patients  
*Sangeeta Kapoor, Keerti Rastogi, Anjali Verma, Manoj Kumar, Indu Saxena* 27
- Isolated Oligohydramnios – Is it an Indication for Induction of Labor?  
*Fatima Anis, S Haseena, Jamila Hameed, Ramya Ramadoss, Madhumitha Sekaran, S Radhika* 32
- Prevalence and Etiological Factors Causing Hearing Loss in School Going Children of Vizianagaram District  
*Ramachandra Rao Vengala, Visweswara Rao Suraneni, Sadhana Osuri, Pruthviraju Uppalapati, Ayyappa Amara* 36
- A Study of Malignant Ovarian Tumors with Special Emphasis on Malignant Epithelial Tumors  
*Neelu Gupta, Saroj Ola, Dharm Chand Kothari, Sanjeev Chahar* 41



Computed Tomography Evaluation of Intracranial Space Occupying Lesions in Adults <i>Aarti Anand, Bhawana Sonawane, Prashant Titare, Pradip Rathod</i>	47
Hepatic Biochemical Parameters Changes in <i>Plasmodium falciparum</i> malaria <i>M S Shwetha</i>	53
Safety and Efficacy of Low Dose Continuous Graded Epidural Anesthesia in Patients with Left Ventricle Dysfunction, Scheduled for Elective Below Umbilical Surgeries: Clinical Study <i>Naveen Kumar Avvaru, S Jagadeesa Charlu</i>	56
Evaluation of Dry Powder Inhaler-Emitted Aerosol of Budesonide and Formoterol demonstrated by Andersen Cascade Impactor Using Respirable Fraction: An <i>In-Vitro</i> Study <i>Krishnaprasad K, Sobti V, Bhargava A</i>	61
Prospective Evaluation of Outcome of Pregnancy of Unknown Location <i>Lekshmi Pillai, S Haseena, N Narmadha, Jamila Hameed, Madhumitha Sekaran, S Radhika</i>	65
Magnitude and Risk Factors for Physical Domestic Violence during Pregnancy <i>Pankaj Salvi, Geeta Pardeshi, Ramesh Bhosale, Ajay Chandanwale</i>	69
Prevalence and Characteristics of Molar Incisor Hypomineralization in Children Residing in South Bangalore, India <i>Venkatesh Babu, Smriti Jha</i>	74
Computer Aided Photogrammetric Analysis of the Dental and Facial Midline Relationship: A Clinical Study <i>Ravi Shankar Yadav, Tanu Mahajan, Rajashekar Sangur, Niyati Singh, Preshit Sahare, Mahinder Chauhan, Chandan Matsyapal, Rishibha Bhardwaj</i>	79
Clinical, Radiographic and Histopathologic Features of Ameloblastoma: A Retrospective Analysis of 21 Cases <i>Hitesh Shoor, Keerthilatha M. Pai, Shaloo Gupta, Anuj Garg, Himanshu Sharma, Naresh Kumar</i>	83
Closure versus Non-closure of Peritoneum in Cesarean Section and Evaluation of Post-operative Pain: A Hospital Based Study <i>H K Cheema, Chanjiv Singh, Sanwal Singh Mehta, Simrat Suri</i>	89

- Evaluation of Patient Satisfaction in Two Different Skin Closure Techniques: Subcuticular Sutures versus Staples: A Hospital Based Study  
*H K Cheema, Chanjiv Singh, Sanwal Singh Mehta, Simrat Suri* 93

## CASE REPORTS

- Post Traumatic Lower Lid Reconstruction by Wolfe Graft: A Case Report  
*H R Padmini, Venita Juliet Noronha* 97

- A Rare Case Report on Unilateral Optic Nerve Sheath Meningioma  
*H R Padmini, Pranitha Prabhu* 100

- Sudden Onset of Loculated Hemothorax: An Uncommon Complication of Anticoagulant Therapy in Stroke  
*Trilok C Rao, Aanchal Teotia, Jaimin Mansuriya, Ritesh Kamal, Krittibus Samui* 103

- Infiltrating Angiolipoma: A Rare Benign Soft Tissue Neoplasm with Malignant Potential  
*Chetan Rajput, Hemant Chaudhary* 106

- Orbital Reconstruction of a Severely Contracted Socket Using Autogenous Derma-Fat Graft: A Case Report  
*H R Padmini, Venita Juliet Noronha* 109

- Spinal Myoclonus Following Intrathecal Anesthesia with Bupivacaine for Elective Appendicectomy  
*Ankur Khandelwal, Deba Gopal Pathak, Rupankar Nath, Prasanta Sonowal, Chandni Pasari, Shrikant Subhash Kote* 112

- Total Dystrophic Onychomycosis Caused by *Syncephalastrum recemosum*: A Case Report  
*Ramya Kumaran, K G Rudramurthy* 115

- Imaging of Nasopharyngeal Carcinoma with Intracranial Extension  
*P Shereen Chidhara, A Venkateshwaran* 117

- Invasive Pituitary Macroadenoma: A Rare Case Report  
*Shruti Patil, Tanvi Choubey Dixit* 121

# Canal Shaping with ProTaper Next: An *Ex Vivo* Study

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## Abstract

**Introduction:** The use of nickel-titanium rotary files have changed the way root canals are prepared leading to few procedural errors in more complicated root canal systems. Advanced instrument designs with noncutting tips, radial lands, different cross-sections, superior resistance to torsional fracture and varying tapers have been developed to improve the efficacy of the file systems.

**Aim:** The aim of this study was to provide an overview and evaluate the efficiency of the recently introduced rotary file system ProTaper Next.

**Materials and Methods:** A total of 50 mandibular first molars were taken. Glide path was established up to the working length using PathFiles no 13 and 16 (Dentsply Maillefer). Canals were prepared using the ProTaper Next multiple file system (Dentsply Maillefer, Ballaigues, Switzerland)(PTN). Pre- and post-instrumented scans were taken using cone-beam computed tomography and superimposed to evaluate canal shaping using CS 3D imaging software v.3.2.9 (Carestream Dental, US). Working time was also recorded. Statistical analysis was performed using Student's *t*-test.

**Results:** PTN (Dentsply Maillefer, Ballaigues, Switzerland) exhibited negligible transportation with more centered preparations. Working time was less when compared to many other systems. No instrument breakage was reported.

**Conclusion:** PTN (Dentsply Maillefer, Ballaigues, Switzerland) is optimally designed to prepare the majority of the root canal configurations. It is one of the few systems available for efficient and safe root canal preparations.

**Keywords:** Canal shaping, Glide path, Path file, Protaper Next

## INTRODUCTION

Successful endodontic treatment includes proper root canal shaping and effective debridement of the root canal system (Schilder 1974, Sjogren *et al.* 1990). Tapered preparations with chemical debridement and preservation of the root canal anatomy are the primary requisites for better endodontic outcomes. Root canal shaping aims to remove the root canal contents, mainly the microorganisms, vital and necrotic pulp so as to create space for the irrigant for canal disinfection. It also aims

to preserve the integrity and location of the canal and the apical anatomy.<sup>1</sup>

In severely curved canals, traditional stainless steel instruments often fail to achieve the tapered root canal configurations and there is greater risk of instrument separation.<sup>2</sup> The use of nickel titanium (Ni-Ti) rotary files have changed the way root canals are prepared leading to few procedural errors in more complicated root canal systems.<sup>3</sup> Maintaining the canal curvature with less straightening of the root canals are the basis of efficient canal preparation.<sup>2</sup> Advanced instrument designs with noncutting tips, radial lands, different cross-sections, superior resistance to torsional fracture and varying tapers have been developed to improve the efficacy of the file systems.<sup>4</sup>

Out of the many systems available, very few have been able to achieve these goals. This study aims to present an

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overview of the recently introduced Ni-Ti rotary system PTN (Dentsply Maillefer, Ballaigues, Switzerland) and evaluate its canal shaping using cone-beam computed tomography (CBCT).

The various parameters evaluated were root canal curvature, canal transportation, centric ability and working time.

## MATERIALS AND METHODS

The ethical approval for conducting this study was obtained from the Institutional Ethical Clearance Committee. The permission to conduct this study in the respective colleges was obtained from the head of these institutions.

### Sample Preparation

Fifty extracted human mandibular first molars with mature apices and similar root shape were taken. The teeth were sectioned through the furcation, and the samples were mounted on an acrylic block. Mesio buccal roots were considered for this study. Working length was determined, and patency established using a 10 No. K File (Dentsply Maillefer, Ballaigues, Switzerland). Seven small grooves were made on the external surface of the root using a HiDi 520 round diamond bur and filled with composite (Z250, 3M ESPE, St. Paul, MN, USA). These composite-filled grooves acted as reference points from the apex of the tooth at levels 0 mm, 1 mm, 2 mm, 3 mm, 5 mm and 7 mm, for the superimposition of the CBCT images obtained before and after instrumentation. Pre-instrumented CBCT scans were taken. The specimens were then prepared using the PTN (Dentsply Maillefer, Ballaigues, Switzerland) rotary file system. Recapitulation and irrigation were carried out after each instrumentation using 2.5% sodium hypochlorite (NaOCl). Post instrumented scans were taken after the canal shaping was completed. The various parameters were analyzed using the On Demand 3D software (Carestream, India) and calculated using the following methods.

### Working Time

Working time was evaluated as the time elapsed until the last instrument reached the working length. It included the time for instrument change and irrigation. This was measured with a stopwatch by two different observers at the same time.

### Root Canal Curvature

Root canal curvature was measured as angles of curvature on sagittal sections of the CBCT scans (Schneider *et al.*, 1971). Straight lines were drawn from the apex to the point of maximum curvature and from this point to the coronal orifice. The angle formed by these lines was subtracted from 180° and that gave the angle of curvature.<sup>5</sup>

### Canal Transportation and Centric Ability

Pre- and post-operative CBCT scans were superimposed and the transportation in the mesiodistal direction, was calculated. The horizontal sections were used and the dimensions were measured by calculating the shortest distance from the periphery of the uninstrumented canal to the periphery of the tooth in both mesial and distal directions and then compared with the values measured from the prepared canals. The following formula was used:

$$\text{Transportation} = (X1-X2) - (Y1-Y2)$$

X1 is the shortest distance from the periphery of the unprepared canal to the distal aspect of the root. X2 represents the shortest distance from the periphery of the prepared canal to the distal aspect of the root. Y1 represents the shortest distance from the periphery of the unprepared canal to the mesial aspect of the root. Y2 represents the shortest distance from the periphery of the prepared canal to the mesial aspect of the root.

Centric ability is the ability of an instrument to remain centered in the canal, thus preserving the canal anatomy. It was calculated by using following formula.

$$\text{centric Ratio} = (X1-X2)/(Y1-2) \text{ or } (Y1-Y2)/(X1-X2)$$

The numerator taken was the smaller of the two numbers (X1-X2) or (Y1-Y2), provided these numbers were unequal. A result of one indicates that the instrument exhibits good centric ability.<sup>6</sup>

Difference in cross-sectional area was measured by measuring the radius of the canal before and after instrumentation. The following formula was used:

$$A = \mu (R2 - R1)^2$$

Paired Student's *t*-test was used to compare the difference at various intervals.

## RESULTS

The mean time taken to prepare root canals with PTN up to X2 is 183 s and 245 s up to X5 (Figure 1). The canal transportation was negligible and was more in the mesial direction apically and in the distal direction coronally. Centric ratio was nearer to one exhibiting centered preparations (Table 1). There were a statistically significant difference in the cross-sectional area before and after instrumentation at all levels (Table 2). The mean of change in angle of curvature was 2.11° (Table 3).

## DISCUSSION

Many rotary instrument systems have been introduced so far with the aim to prepare root canals efficiently by preserving the original root canal anatomy of the tooth.<sup>8</sup> PTN (Dentsply Maillefer, Ballaigues, Switzerland) has recently been introduced by Dentsply Maillefer, Ballaigues, Switzerland. It consists of five files (X1, X2, X3, X4 and X5) with color coded identification ring of yellow, red, blue, double black, and double yellow on their handles respectively. The X1 and X2 are the shaping and finishing files and X3, X4 and X5 are optional. It is made up of the m-wire Ni-Ti technology that is formed by the characteristic thermo mechanical processing. It consists of the three crystalline phases, which are the deformed and micro twinned martensite, R-phase, and austenite phase. The instrument is flexible, and there is

increased resistance to cyclic fatigue. Hence, there are less chances of instrument separation. Taper of PTN (Dentsply Maillefer, Ballaigues, Switzerland) rotary file system varies on a different part of this file. Therefore, contact between dentin and PTN (Dentsply Maillefer, Ballaigues, Switzerland) file is reduced, which reduces the taper lock. In the study, one set of instrument was used to prepare 4-5 canals, and there was no incidence of instrument breakage. The results of the study proved that there are very less chances of instrument separation while using PTN (Dentsply Maillefer, Ballaigues, Switzerland).

Ideal canal preparation requires negligible canal transportation and perfectly centered preparations. It is seen that manual hand files produce less transportation when compared to rotary files. The search for efficient rotary systems that produce less transportation is in

**Table 1: CR and CT after instrumentation at apical, middle and coronal third**

	Mean SD		
	Apical third	Middle third	Coronal third
CR	0.67±0.04	0.50±0.02	0.55±0.04
CT	-0.02±0.02	0.00±0.00	0.12±0.03

CR: Centric ratio, CT: Canal transportation, SD: Standard deviation. CR: A result of one indicates perfect centering ability; the closer the result is to zero, the worse the ability is of the instrument to remain centered

**Table 2: Mean of difference in cross-sectional area, pre- and post-operatively at various levels**

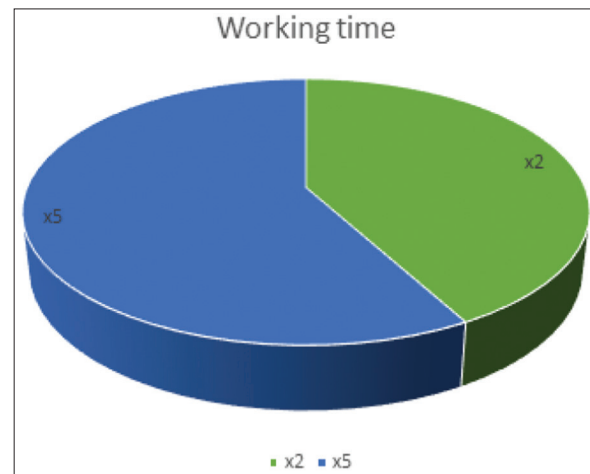
Level (in mm)	Group	N	Mean (mm <sup>2</sup> )	SD (mm <sup>2</sup> )	Sig. (2-tailed)
Zero	1	30	0.5390	0.26046	0.004
	2	30	1.767	1.096	
One	1	30	0.8775	0.43796	0.003
	2	30	2.2381	1.0518	
Two	1	30	3.121	1.8385	0.004
	2	30	6.234	2.456	
Three	1	30	4.308	1.740	0.001
	2	30	6.234	2.456	
Five	1	30	4.308	1.704	0.002
	2	30	8.443	1.790	
Seven	1	30	6.234	2.456	0.003
	2	30	11.409	2.463	
Nine	1	30	11.409	2.463	0.003
	2	30	12.453	2.543	

Statistically significant difference is observed in the difference of the cross-sectional area of the prepared and the unprepared canals ( $P < 0.005$ ). SD: Standard deviation, Group 1: Pre-instrumentation, Group 2: Post-instrumentation

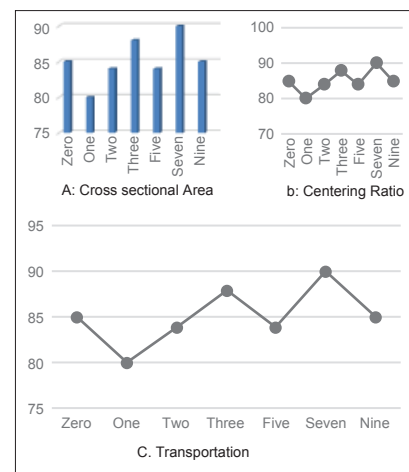
**Table 3: Mean and SD of root canal curvature of each specimen before and after instrumentation**

Group	N	Mean (degree)	SD (degree)	Sig. (2-tailed)
1	30	40.56	1.235	0.001
2	30	38.45	1.126	

Group 1: Pre-instrumentation; Group 2: Post-instrumentation, SD: Standard deviation. Difference in mean of root canal curvature is approximately  $2^\circ$  that shows less straightening of the root canals



**Figure 1: Working Time: Mean time taken to prepare root canals with PTN upto X2 is 183 seconds and 245 seconds upto X5**



**Figure 2: (a) There was significant constant change in the cross-sectional area. (b) More than 80% of the specimens gave the ratio 1 indicating centered preparation. (c) The value of X as calculated by the formula came out to be zero for more than 80% of the samples at various intervals<sup>7</sup>**



progress. PTN (Dentsply Maillefer, Ballaigues, Switzerland) produce negligible or very less transportation. Apically canal transportation was more in the mesial direction and coronally more in the distal direction. The cross-section of PTN (Dentsply Maillefer, Ballaigues, Switzerland) is rectangular in shape. The asymmetric motion, which is because only two edges are in contact with canal wall at time, leads to an efficient canal preparation. The rotation of the off-centered cross-section creates an enlarged space for debris removal, optimizes the canal tracking and reduces binding.

The shaft size of the PTN (Dentsply Maillefer, Ballaigues, Switzerland) is small, therefore providing better access to the posterior teeth. The speed was set at the recommended rotation of 350 rpm with a torque of 2.5 N/cm.

The main aim of biomechanical preparation is to preserve the root canal morphology.<sup>8</sup> Lesser the straightening of the canals, more efficiently the canal is prepared. The difference in the angle of curvature was used to evaluate the efficiency of the file (Schneider and Weine). PTN (Dentsply Maillefer, Ballaigues, Switzerland) exhibited a negligible or slight change in the angle of curvature showing that it produced less straightening and preserved the canal curvature. If the time required for preparing the root canal is less, the operator gets more time for proper irrigation and recapitulation. This leads to a better and successful root canal treatment. As preparing a canal with PTN (Dentsply Maillefer, Ballaigues, Switzerland) requires the use of two files, i.e. X1 and X2 in most of the cases, the other files being optional, therefore the

working time is less as compared to many other multiple rotary file system. The high cutting efficiency also reduces the shaping time.

## CONCLUSION

The study concluded that PTN (Dentsply Maillefer, Ballaigues, Switzerland) is an optimal rotary system for root canal preparations and is successful in preserving the root canal anatomy with less incidence of instrument separation. It is one of the few rotary systems that provides quick and safe endodontic treatment.

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# Dermal Sensitivity to Common Allergens and Effect of Allergens Avoidance in Patients of Allergic Rhinitis and Bronchial Asthma in Malwa Region: A Hospital Based Study

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## Abstract

**Background:** There has been a significant increase in the prevalence of allergy, mainly associated to IgE-mediated disorders such as asthma and rhinitis. The identification and avoidance of causative allergens in allergic rhinitis and asthmatic patients can help to reduce the frequency of symptoms. The objective of this work was to evaluate the prevalence of common allergens and effect of allergens avoidance among patients of allergic rhinitis and bronchial asthma in Malwa region.

**Methods:** Skin prick tests were performed with 220 different allergens including pollens, fungi, house dust mite (HDM), inhalants and contactants, dander, insects and food in 60 patients with allergic rhinitis and bronchial asthma at C. R. Gardi Hospital from 2012 to 2014.

**Results:** About 60% of all patients were predominantly asthmatics, and forty percent were cases of rhinitis. 43% of patients were sensitized to HDM. 42% and 40% of the population were sensitized to spider web dust and ants, respectively. Statistical analysis identified the dust mite and spider web dust as the most common allergens influencing the development and expression of allergic rhinitis and asthma in the studied population. 50% patients of allergic rhinitis became asymptomatic after avoidance of all relevant positive allergens, 21% showed reduced symptoms. 36% patients of bronchial asthma had reduced symptoms and 17% of allergic rhinitis patients became asymptomatic after avoidance of only causative food allergens.

**Conclusions:** The dust mite and spider web dust were the most relevant allergen sources in the asthmatic and allergic rhinitis population. This emphasizes the importance of identifying sensitization and avoiding the relevant allergens can be remedy for allergic rhinitis patients and reduced the frequency of symptoms in asthmatics.

**Keywords:** Allergen avoidance, Allergic rhinitis, Bronchial asthma, Dermal sensitivity test

## INTRODUCTION

Allergic rhinitis and asthma are the most common atopic diseases with an increasing prevalence during the last few

decades. Allergic rhinitis is an IgE-mediated inflammation of the nasal mucosa and of the airways and can manifest either as allergic rhinitis, asthma, or both. However, the vast majority of patients with asthma have rhinitis, and rhinitis is a major independent risk factor for asthma in cross-sectional and longitudinal studies.<sup>1</sup>

There has been a significant exponential growth in the prevalence of atopy, including IgE-mediated allergic diseases such as asthma and rhinitis. It is estimated that 30% of the world population is now affected by one or more allergic conditions and is capable of developing

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specific IgE antibodies to different allergenic proteins from various sources.<sup>2</sup>

Environment in which we breathe contain aeroallergens; these include a number of inorganic and organic contaminants airborne bioparticles such as microorganism, pollen grains, fungal spore, hyphae or fungi, spore of mosses and fern, insects debris, animal dander, mite etc. which are known to be the chief causative agents of allergic disorders such as Bronchial asthma, allergic rhinitis etc. Exposure to an allergen is an important risk factor for the development of atopic sensitization to a specific allergen and exposure to the allergens in sensitized individuals is a risk factor for asthma.<sup>3-6</sup>

Asthma is a worldwide problem, with an estimated 300 million affected individuals. The global prevalence of asthma ranges from 1% to 18% of the population, depending on the country. Indoor and outdoor allergens are important environmental factors that influence the development and expression of asthma. The identification of atopy through specific IgE determination can help to identify the triggers able to cause symptoms of allergic asthma in atopic patients.<sup>7</sup> Geographical variation in the prevalence of sensitization to common aeroallergens is commonly observed across different geographical sources.<sup>8</sup>

Allergic diseases are less common in Asia than in the Western World, which, however, is rapidly catching up. In India, about 15-20% people are estimated to suffering from major allergic disorders. Allergic rhinitis is the most common disease in clinical practice and constitutes more than 50% of allergic disease.<sup>9</sup>

The present study is, therefore, undertaken with a view to evaluation of the allergens involved in patients with allergic rhinitis and bronchial asthma using skin prick test. For the diagnosis of allergy and its effective treatment, it is very important to know about the common causative allergens, which are responsible for bronchial asthma and allergic rhinitis. This may be a great move toward a better understanding of etiopathology and better management of these disorders as avoidance or desensitization with responsible allergens.

## METHODS

This study comprised of 60 patients (aged 10-55 years) of bronchial asthma and allergic rhinitis attending the Pulmonary Medicine OPD, C. R. Gardi Hospital, Ujjain, Madhya Pradesh.

A prospective, observational, hospital-based study to evaluate patients with bronchial asthma and allergic rhinitis

(according to GINA and ARIA guidelines and history base) by allergy testing for role of allergens in the disease excluding uncooperative, unwilling, patients with skin diseases or skin reaction like urticaria or dermatographism, HIV or HbsAg positive, in acute (acute asthma or rhinitis) or co-morbid conditions, bleeding disorders and steroid-dependent asthma.

Preceding dermal sensitivity test, the following investigations such as total leukocyte count, differential leukocyte count, absolute eosinophil count, spirometry, and chest X-ray were done.

### Dermal Sensitivity Test

Allergens for the study were obtained from Creative Diagnostic Medicare Private Limited, Mumbai, India. The concentration of allergen was used for pollen, fungi, dust, epithelia 5000 protein nitrogen units (PNU)/ml; mite (D-farina) and blomia sp. 1000 PNU/ml; mite (*Dermatophagoides pteronyssinus*) and insects 1000 PNU/ml; food 1% w/v. In each patient 218 skin prick were done, using following 35 type of pollen allergen, 15 types of fungus, 3 types of mites, 11 types of dust allergens, 8 types of epithelial allergen, 12 types of insects, 133 types of food allergen and 1 miscellaneous allergen. These allergens are commonly used in India for skin prick test to find out commonest causative allergens.

The following precautions were taken during dermal sensitivity test (a) the test to be performed was explained to the patient before starting the test to allay apprehension. (b) Avoid antihistamine and steroid 48-72 h prior to the test. The patients are instructed to avoid bronchodilator for at least 12 h before the test.

Negative control: Glycerinated buffered saline

Positive control: Histamine acid phosphate 10 mg/ml in glycerinated buffered saline

### Reading and Grading of Reaction

The dermal reaction was read after 15-20 min. The largest diameter was measured to obtain the dimension of the wheal and the surrounding erythema or "flare" response (Figure 2). The "flare" response was achieved by outlining the area of the erythema and wheal diameter using a pen. Various methods have been used to interpret skin test results. Most reactions indicative of clinical allergy are wheals <3 mm in diameter.<sup>10</sup>

## RESULTS

Of 60 individuals, 12,480 skin prick test were performed, 1935 were positive reaction of various allergens, accounting

for 15.07% of study group (Table 1). The ages of the patients who had positive skin test results ranged between 09 and 55 years and 32 (53%) were female. Maximum patients were from the rural area 77%. Most of the patients with allergic rhinitis and bronchial asthma had developed symptoms between ages 21 and 30 years. The prevalence of positive skin reactivity and wheal size was highest in mite *Dermatophagoides farinae* 43.3%, followed by spider web dust 41.7% (Table. 2). It was observed that 40% patients showed an allergic reaction to ants, 38.3% of them showed a hypersensitive reaction to alternaria alternata and House dust each (Figure 1). In our present study, among the allergic population, maximum numbers of patients were hypersensitive to corn and tendi (33.3% each) among food allergens (Table 2)

## DISCUSSION

Our predominantly sedentary indoor lifestyle has been identified as one of the probable causes for increases in the prevalence of allergic rhinitis and asthma. This indoor lifestyle may have led to either an increased exposure to

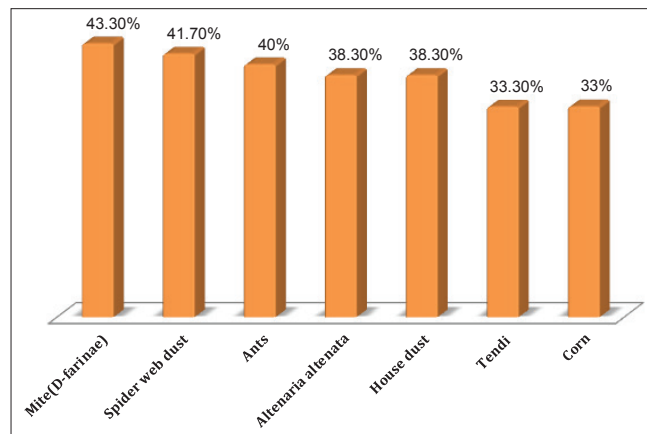


Figure 1: Commonest allergens in study population



Figure 2: Erythema or "flare"

allergens or an increase in factors that enhance the lungs' response to foreign proteins.<sup>11</sup> Clearly, exposure to allergens can provoke acute asthma attacks as well as chronic allergic symptoms.<sup>12</sup>

Sensitization to the species of house dust mite (HDM) was the predominant indoor allergen sensitization in more than 40% of the allergic patients. Conditions for mite growth are a temperature between 22° and 28°C and a relative humidity >55%, but *D. farinae* survives better in somewhat drier climates. Modern houses are characterized by wall-to-wall carpeting, box mattresses, and optimal temperatures for the growth of HDM. Worldwide; there is evidence to suggest that HDM are the most common indoor allergens associated with asthma.<sup>11,13</sup>

Saha (1995) conducted a study to analyze HDM content in allergic rhinitis and asthmatic patients' indoor environments in Calcutta where 80% patients reacted to *D. farinae* and 46% to *D. pteronyssinus* and 43 % to both species.<sup>14</sup>

In this study, sensitization to spider web dust was evident in nearly 42% of the patients with positive skin test results, and sensitization to ants' allergen was evident in 40% of them. Spider web dust is responsible for the rapid onset of respiratory symptoms in persons entering an indoor environment that contains spider web and may constitute a relevant risk factor for exacerbations.

The prevalence of fungal sensitization found in this work was 38.3% of the total allergic population with alternaria alternata

Table 1: Total number of positive skin prick test in study patients

Group of allergies	Number of test performed	Number of positive reaction	Percentage
Pollens	2100	381	18.1
Fungi	900	136	15.1
House dust mite	180	47	26.1
Inhalants	660	116	17.6
Dander's	480	70	11.7
Insects	720	108	15
Foods	7800	1077	13.8
Total	12840	1935	15.07

Table 2: Commonest allergens in study population

Allergen	Type of allergen	Total	Percentage
Mite ( <i>D. farinae</i> )	HDM	26	43.3
Spider web dust	Inhalants	25	41.7
Ants	Insects	24	40.0
Alternaria alternata	Fungi	23	38.3
House dust	Inhalants	23	38.3
Tendi	Food	20	33.3
Corn	Food	20	33.3

HDM: House dust mite, *D. farinae*: *Dermatophagoides farinae*



**Table 3: Case distribution with avoidance of positive allergens**

Allergens prevented	No. (%)					
	Allergic rhinitis (n=24)			Bronchial asthma (n=36)		
	Asymptomatic	Reduced symptoms	Number Improvement	Asymptomatic	Reduced symptoms	Number Improvement
Foods only	4 (17)	0 (0)	0 (0)	0 (0)	5 (14)	0 (0)
Food+HDM	3 (12)	1 (4)	0 (0)	1 (3)	0 (0)	0 (0)
Food+HDM+Inhalant	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)	0 (0)
Food+HDM+Inhalant+Dander's	4 (17)	0 (0)	0 (0)	1 (3)	2 (5)	0 (0)
Food+HDM+Inhalant+Dander's+Insects	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Food+HDM+Inhalant+Dander's+Insects+Fungi	1 (4)	4 (17)	0 (0)	0 (0)	4 (12)	0 (0)
All relevant allergens	0 (0)	0 (0)	7 (29)	0 (0)	0 (0)	21 (58)
Total	12 (50)	5 (21)	7 (29)	2 (6)	13 (36)	21 (58)

HDM: House dust mite

**Figure 3: Procedure of skin prick test**

as the most prevalent source. The result given by Sharma *et al.* (1995), *alternaria alternata* (17.6%) was most common offending allergen in Delhi in asthmatic individuals.<sup>15</sup>

## CONCLUSIONS

Modernization and the inherent pollution associated with the industrialization have contributed to the increasing occurrence of the allergic respiratory disorders like allergic rhinitis or bronchial asthma among population. The efforts are not being made to find out the actual cause of rhinitis or asthma leading to increasing in the prevalence of bronchial asthma and to over usage of drugs. As the fast growing world needs the immediate relief for the suffering, there is an urgent need to find out clinically significant allergens, result of avoidance of those to be a keen observer of each case and to tackle it.

House dust mite and inhalants were the the most relevant allergen sources in the allergic population studied herein, with the *D. farina* major allergen serving as the main cause for sensitization in the patients suffering from allergic rhinitis and bronchial asthma.

To the best of our knowledge, this is the first study examining a panel of sensitizing allergens in a population

of allergic patients living in Malwa region for diagnostic purposes. Using this methodology, it was possible to identify common allergens that could sensitize a relevant percentage of this population.

About 50% patients of allergic rhinitis became asymptomatic after avoidance of all relevant positive allergens, 21% showed reduced symptoms. 36% patients of bronchial asthma had reduced symptoms and 17% of allergic rhinitis patients became asymptomatic after avoidance of only causative food allergens (Table 3).

This result of the study conducted obviously highlights the avoidance of relevant positive allergens for strategies in the treatment of allergic rhinitis, bronchial asthma in all age group without medication. Only avoiding the relevant allergens can be a remedy for allergic rhinitis patients and reduced the frequency of symptoms in asthmatics.

Based on this, allergic rhinitis and asthmatics should be offered effective education about the importance of exploring their sensitization and avoiding to relevant allergens. Subsequently, for better symptom control, health care workers must be encouraged to apply individualized educational strategies for the avoidance of allergens that are clinically relevant for their particular asthmatic patients. Eventually, this will be of significant help in the overall management of allergic symptoms.

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# Study of Carotid Intima-Media Thickness in Patients with Coronary Artery Disease and Stroke

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## Abstract

**Background:** Several studies have shown that carotid intima-media thickness (IMT) is strongly associated with cardiovascular risk factors. It possibly reflects the cumulative burden of atherosclerosis of major vessels regardless of underlying risk factors like hypertension and diabetes mellitus (DM).

**Materials and Methods:** This is a case-control cross-sectional study that explored the use of carotid artery IMT (CIMT) as a marker for atherosclerosis. 150 individuals from the inpatient and outpatient departments of the institute were enrolled into three groups for the purpose of CIMT assessment. Group 1 (healthy controls) consisted 50 individuals with no symptoms of stroke or coronary artery disease (CAD), Group 2 included 50 patients with established stroke and in Group 3 50 patients of CAD were included. In the current study, the baseline characteristics of the 3 study groups are same including age groups, male to female ratio, etc. to avoid confounding.

**Results:** Average CIMT in Controls was found 1.0 mm in a stroke group - 1.3 mm and in CAD group was 1.3 mm. CIMT is a marker of atherosclerosis as its value is raised in stroke and CAD groups compared to age and gender matched controls. And raised values of CIMT are statistically associated with Stroke and CAD. Most important determinants for CIMT in our study is age, hypertension, DM, dyslipidemia, smoking and, family history of cardiovascular disease.

**Conclusion:** CIMT is a very simple very useful, noninvasive, cost-effective, reproducible tool of measurement of atherosclerosis burden in patients of stroke and CAD.

**Key words:** Atherosclerosis, Carotid artery intima media thickness, Coronary artery disease, Intima media thickness, Stroke

## INTRODUCTION

Atherosclerosis is and remains the major cause of death and premature disability in developed societies. Current predictions estimate that by the year 2020 cardiovascular diseases (CVD), notably atherosclerosis, will become the major global cause of total disease burden. As though many generalized or systemic risk factors predispose to its development, it affects various regions of the circulation preferentially and

yields distinct clinical manifestations depending on the particular circulatory bed affected. Atherosclerosis of coronary arteries mainly causes myocardial infarction and angina pectoris and of the arteries supplying the central nervous system frequently provokes strokes and transient cerebral ischemia. In the peripheral circulation, atherosclerosis causes intermittent claudication and gangrene and can jeopardize limb viability. Involvement of the splanchnic circulation can cause mesenteric ischemia. Atherosclerosis can affect the kidneys either directly (e.g. renal artery stenosis) or as a frequent site of atheroembolic disease.<sup>1</sup> Of late carotid artery intima media thickness (CIMT) has become the most recent, most sensitive, non-invasive, widely acceptable and reproducible method for assessment of atherosclerosis burden. The conventional risk factors for CVD such as age, hypertension, diabetes, and smoking, etc. correlate well with CIMT. CIMT has also been shown to correlate

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with emerging risk factors such as lipoprotein(a), oxidized low-density lipoprotein (LDL), high-sensitivity C-reactive protein, dysfunctional high-density lipoprotein (HDL), and homocysteine. Many researchers have studied the role of carotid artery intima-media thickness (IMT) as a risk factor for coronary artery disease (CAD) and stroke. Bots *et al.*<sup>2</sup> found that an increased CIMT predicts future cardiovascular and cerebrovascular events. Tsivgoulis *et al.*<sup>3</sup> found that increased common carotid artery (CCA) IMT values are associated with an increased risk of long-term stroke recurrence. Kablak-Ziembicka *et al.*<sup>4</sup> found that with advancing CAD, IMT increase and patient with mean IMT over 1.15 mm have a 94% chances of having CAD. Touboul *et al.*<sup>5</sup> concluded that The CCA-IMT value may help to differentiate between subjects at low or high long term risk of stroke.

Amato *et al.*<sup>6</sup> concluded that carotid atherosclerosis correlates better with coronary atherosclerosis when both circulations are investigated by the same technique and parameter. Hoskote *et al.*<sup>7</sup> found that for atherosclerosis in India, carotid Doppler and CIMT should become routine screening tool. Agarwal *et al.*<sup>8</sup> compared the CIMT in Type 2 diabetics and concluded that a high CIMT is reliable marker of increased risk of CAD among these patients, even in patients without overt CAD.

Takashi *et al.*<sup>9</sup> studied the Ultrasonic correlates of common carotid atherosclerosis in patients with CAD and concluded that increased IMT correlate well with the prevalence of CAD. IMT of at least 1.0 mm in the old-age persons and 0.7 mm in the middle-aged persons was specific and positively predictive of CAD. In the middle-aged persons, intima-media thickness of the CCA was correlated with the severity of coronary atherosclerosis. Conversely, in the old-aged persons, the presence of plaque and calcification at the bifurcation was correlated with the severity of coronary atherosclerosis. Lester *et al.*<sup>10</sup> concluded that subclinical vascular disease can be detected by CIMT evaluation in young to middle-aged patients with a low Framingham risk score and a coronary artery calcium score of zero. They suggested that these findings have important implications for vascular disease screening and the implementation of primary prevention strategies. Nguyen-Thanh *et al.*<sup>11</sup> concluded that in the primary prevention of CAD, CIMT measurement reclassifies patients into higher or lower risk categories, allowing early appropriate management. Bots<sup>12</sup> aimed to substantiate the evidence supporting the use of measurement of CIMT as a surrogate marker for atherosclerosis and cardiovascular risk. He concluded in this review article that, CIMT may be used as a surrogate endpoint in clinical trials to enable the benefits of new therapies or regimens, and it should be rapidly translated into clinical practice.

Nathan *et al.*<sup>13</sup> for The diabetes control and complications trial (DCCT)/Epidemiology of Diabetes Interventions and Complications Research Group studied whether Intensive Diabetes Therapy has any effect on Carotid Intima-Media Thickness in Type 1 diabetes mellitus (DM). They concluded that the intensive therapy during the DCCT resulted in decrease progression of IMT.

### Objectives of the Study

1. Carotid artery IMT thickness (by B-mode ultrasonography [USG] scan) - Its association with CAD and stroke.
2. Comparison of carotid artery IMT with conventional risk factors for atherosclerosis

## MATERIALS AND METHODS

Cases: Patients admitted in Medical Wards of K.S. Hegde Charitable Hospital under Medicine, Cardiology and Neurology and patients in medical intensive care unit and cardiac care unit diagnosed as having stroke and/or CAD.

Controls: Patients are attending outpatient department in Medicine, Cardiology and Neurology.

Duration of study: From November 2008 to June 2010

50 cases of CAD

50 cases of stroke (both ischemic and hemorrhagic)

50 Controls: Healthy adults more than 30 years of age without present and history of CAD, stroke and no risk factors for atherosclerotic disease like DM, hypertension, dyslipidemia, and obesity.

### Inclusion Criteria

1. Age more than 30 years (both male and female).
2. Present or past diagnosis of CAD.
3. Present or past diagnosis of stroke.

### Exclusion Criteria

1. Age <30 years of age.
2. Cases/controls who are not giving consent.

### Diagnosis of CAD

Clinical features, ECG changes, increased cardiac enzymes, ECHO changes and coronary angiography suggesting CAD.

### Diagnosis of Stroke

Clinical features computed tomography brain (plain or contrast) or magnetic resonance imaging brain (plain or contrast) suggesting stroke.

After confirming the diagnosis of CAD and stroke (CVA), cases underwent measurement of IMT of distal CCA at its posterior wall bilaterally. Cases of CAD underwent coronary angiography to see the extent of the disease.

Controls also underwent measurements of IMT of distal CCA at its posterior wall bilaterally. For the measurement of IMT - B-mode USG scan using 7.5 MHz probe is used and whenever required to see plaques, plaque ulceration, lumen stenosis color Doppler scan is used. A written informed consent obtained from all CAD and stroke patients and from controls.

Clinical examinations included blood pressure recording, assessment of cardiovascular status, height and body weight measurements. Biochemical assessment included fasting and postprandial blood sugar, and fasting lipid profile. Patients were evaluated for the presence and duration of conventional cardiovascular risk factors (hypertension, DM, family history of premature CAD, dyslipidemia, and current smoking). Hypertension was defined as systolic blood pressure > 140 mm Hg, or diastolic blood pressure >90 mm Hg, or self-reported use of antihypertensive medications. Diabetes mellitus was defined as a fasting blood glucose >110 mg/dL, or non-fasting blood glucose >200 mg/dL or pharmacological treatment for diabetes. Dyslipidemia was defined as LDL >130 mg/dL, or HDL <40 mg/dL, or triglycerides >200 mg/dL. Positive family history was considered if a coronary event before the age of 55 years in males or 65 years in females in first-degree relatives. Current smoking or tobacco use was also considered as a risk factor.

A high-resolution Sonos 5500 (Hewlett Packard, Inc., Anaheim, CA, USA) with a duplex B-mode scanner and a linear phased array transducer of 7.5 MHz frequency was used for carotid artery scanning. Thickness of intima-media was measured as the distance between the leading edge of the first echogenic line of the far wall of the carotid artery (lumen intima interface) and the leading edge of the second echogenic line (media-adventitia interface). Measurements of IMT were made at end-diastole (peak of the R wave) at three segments on each side: The distal 1 cm of CCA just before the bifurcation, the carotid bifurcation, and the proximal 1 cm of internal carotid artery and then average of all three taken into consideration, both right and left sides are measured like this method. Measurements were taken only on longitudinal scans and not on transverse scans.

Type of study: Case-control study

### Statistics

Multivariate logistic regression analysis was performed with the use of version 16 of SPSS software (IBM).

## RESULTS

There was no significant difference found in three groups with respect to age, gender, history of smoking,

history and duration of DM and hypertension, and family history of CVD risk factors. In dyslipidemia, there was significant difference, however dyslipidemia was found in 34% in stroke and 48% subjects in CAD group respectively. However, there was no significant difference in LDL and triglyceride profile in CAD and stroke groups.

As shown in Table 1, CIMT is more in risk groups (stroke/CAD). There is statistically significant increase in CIMT on either side comparing control group to CAD/Stroke groups. As there is no significant difference in CIMT in stroke and CAD groups, it can be concluded that raised CIMT is a predictor of either stroke or CAD. It is important to note that risk factors for CVD are similar in both stroke and CAD groups, so no confounding.

There is statistically significant increase in CIMT on either side in comparison of control and CAD groups. There is statistically significant increase in CIMT on either side in comparison of control and Stroke groups. There is no significant difference in CIMT on either side in comparison of Stroke and CAD groups (Table 2).

CVD Risk factors are smoking, family history of CVD, dyslipidemia, hypertension, and DM. As shown in Table 3, as the number of risk factors increase CIMT increases in all three groups. Increase in CIMT in all three groups in accordance with the number of risk factors sometimes may not be apparent as the number of patients may be a limiting factor.

**Table 1: Comparison of CIMT of all three groups on left and right sides individually**

	Number of subjects	Mean CIMT in mm	Standard deviation	F	P
Rt. CIMT					
Control	50	1.0700	0.20329		
Stroke	50	1.3000	0.22857		
CAD	50	1.3020	0.17437	21.522	<0.001
Lt. CIMT					
Control	50	1.0540	0.20919		
Stroke	50	1.2900	0.25173		
CAD	50	1.2800	0.20304	18.010	<0.001

CIMT: carotid artery intima media thickness, CAD: Coronary artery disease

**Table 2: Multiple comparisons**

Dependent variable	(I) Group	(J) Group	Mean difference (I-J)	P
Rt. CIMT	Control	Stroke	-0.2300	<0.001
		CAD	-0.2320	<0.001
	Stroke	CAD	-0.0020	0.999
Lt. CIMT	Control	Stroke	-0.2360	<0.001
		CAD	-0.2260	<0.001
	Stroke	CAD	0.0100	0.973

CIMT: carotid artery intima media thickness, CAD: Coronary artery disease

It can be concluded that CIMT of healthy controls with one or two risk factors is significantly less than CIMT of stroke or CAD groups with the similar number of risk factors.

So CIMT depends not only on conventional CV risk factors, but also on other unknown atherosclerotic risk factors. So, CIMT should surrogate more appropriately for atherosclerotic diseases like stroke and CAD rather than conventional CV risk factors such as hypertension, DM, etc.

Table 4 analyses demonstrating individual contribution by multiple variables as CV risk factors for clinical atherosclerotic diseases outcome as stroke and CAD. It takes consideration of each CVD risk factor as independent risk factor for end point, atherosclerosis-related morbidity (Stroke and CAD in our study). Here, we see that most important determinants for end point of Stroke and CAD are age, family history of CVD, dyslipidemia, and average CIMT. But it is important to note that not all of these factors are independent of each other as average CIMT can

be affected by many of these CVD risk factors. Though hypertension, DM are not shown as significant contributors for stroke and CAD, probably this can be explained that these subjects had less CIMT hence did not have a bad outcome. CIMT is dependent on both conventional CV risk factors like hypertension, DM, etc. and unknown risk factors of atherosclerosis. CIMT is regarded to correlate better with stroke and CAD, than conventional CV risk factors like hypertension, DM, etc.

Table 5 shows that most important determinants for end point of CAD are age, dyslipidemia, hypertension, and average CIMT.

Table 6 shows that most important determinants for end point of Stroke are age, dyslipidemia, hypertension, DM and average CIMT.

## DISCUSSION

Carotid IMT is a valid marker of early atherosclerosis and thus has the potential to detect CAD and CVA in its subclinical phase. It possibly reflects the cumulative deleterious effects of various cardiovascular risk factors over time.<sup>7</sup>

**Table 3: Average CIMT with CVD risk factors in all three groups**

Groups	Number of CVD risk factors	Number of subjects	Mean CIMT	Standard deviation	F	P
Control	0	28	0.9911	0.18260	5.225	0.009
	1	18	1.1667	0.17987		
	2	4	1.0875	0.16520		
Stroke	0	2	1.0750	0.17678	3.238	0.031
	1	17	1.2235	0.19374		
	2	22	1.3091	0.15784		
CAD	3	9	1.4444	0.29309	5.865	0.000
	0	6	1.1250	0.14053		
	1	13	1.2308	0.10712		
	2	20	1.2850	0.14699		
	3	9	1.4556	0.17220		
	4	1	1.3500	0.0		
	5	1	1.6500	0.0		

CIMT: Carotid artery intima media thickness, CAD: Coronary artery disease, CVD: Cardiovascular diseases

**Table 4: Multiple regression analysis stroke and CAD groups**

CVD risk factors	Unstandardized coefficients		T	P (for stroke and CAD)
	B	Standard error		
Age	-0.039	0.007	-5.395	0.000vhs
Gender	0.049	0.164	0.299	0.765
Smoking	-0.067	0.171	-0.391	0.696
Family history	0.252	0.128	1.978	0.050sig
dyslipidemia	0.441	0.128	3.456	0.001vhs
HTN	0.071	0.136	0.526	0.600
DM	0.051	0.142	0.361	0.719
Average CIMT	1.976	0.388	5.095	0.000vhs

DM: Diabetes mellitus, HTN: Hypertension, vhs: Very highly significant, sig: Significant, CIMT: Carotid artery intima media thickness, CAD: Coronary artery disease, CVD: Cardiovascular diseases

**Table 5: Multiple regression analysis CAD group**

CVD risk factors	Unstandardized coefficients		T	P (for CAD)
	B	Standard error		
Age	-0.039	0.009	-4.300	0.001vhs
Gender	-0.035	0.224	-0.155	0.878
Smoking	-0.103	0.237	-0.434	0.665
Family history	0.108	0.158	0.685	0.495
Dyslipidemia	0.701	0.189	3.708	0.001vhs
HTN	0.436	0.218	1.999	0.049sig
DM	0.177	0.222	0.799	0.427
Average CIMT	2.094	0.533	3.930	0.001vhs

DM: Diabetes mellitus, HTN: Hypertension, vhs: Very highly significant, sig: Significant, CIMT: Carotid artery intima media thickness, CAD: Coronary artery disease, CVD: Cardiovascular diseases

**Table 6: Multiple regression analysis stroke group**

CVD risk factors	Unstandardized coefficients		T	P (for stroke)
	B	Standard error		
Age	-0.011	0.005	-2.271	0.026sig
Gender	0.113	0.103	1.094	0.277
Smoking	0.080	0.108	0.739	0.462
Family history	0.085	0.089	0.950	0.345
Dyslipidemia	0.231	0.098	2.362	0.02sig
HTN	0.431	0.095	4.542	0.001vhs
DM	0.473	0.095	4.963	0.001vhs
Average CIMT	0.572	0.249	2.300	0.024sig

DM: Diabetes mellitus, HTN: Hypertension, vhs: Very highly significant, sig: Significant, CIMT: Carotid artery intima media thickness, CAD: Coronary artery disease, CVD: Cardiovascular diseases



In the current study, the baseline characteristics of the three study groups are same to avoid confounding.

In our study following are the results:

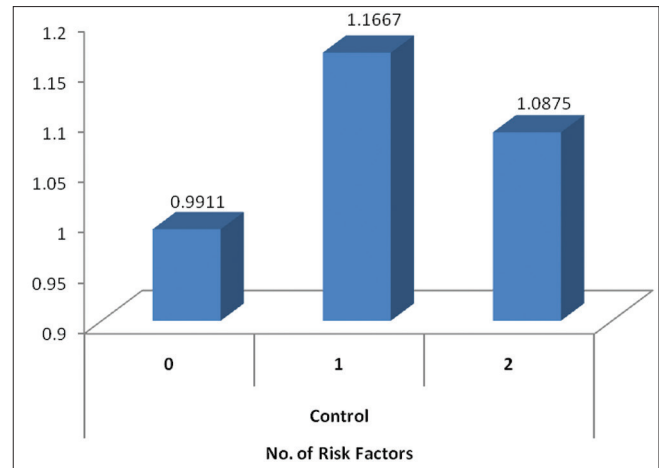
1. CIMA is a marker of atherosclerosis as its value is raised in Stroke and CAD groups compared controls. And raised values of CIMA are strongly associated with Stroke and CAD.
2. As risk factors for atherosclerosis, like age, family history of CVD, dyslipidemia, hypertension, DM, increases value of CIMA increases in a proportional way.
3. Average CIMA:
  - a. Controls: 1.0 mm
  - b. Stroke: 1.3 mm
  - c. CAD: 1.3 mm

As average CIMA goes above 1 mm chances of having atherosclerotic diseases like Stroke and CAD increase.
4. In CAD group when number of vessel involvement (severity of coronary disease) increases average CIMA increases. It concludes that more severe lesions in coronary bed signify severe atherosclerosis that in turn is reflected by more and more increased CIMA. So we can say that CIMA can quantify CAD.
5. In the present study if we consider CIMA as independent variable for atherosclerosis/CVD, it is well comparable with other conventional risk factors for CVD like age, family history of CVD, dyslipidemia, etc. Clinical end points for atherosclerosis like Stroke and CAD, CIMA has statistically significant causal association.

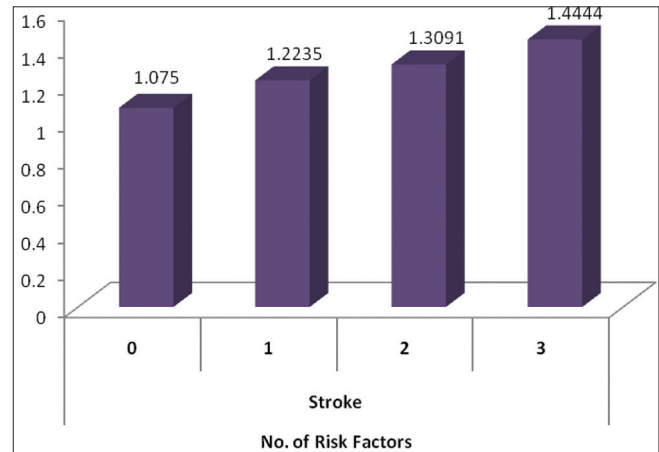
Our study is comparable with previous studies showing a significant association between raised IMT and the presence of significant atherosclerosis/CVD.<sup>2,3</sup> However, numbers of patients in different groups were less to draw any satisfactory conclusion.

In India Gupta *et al.*<sup>1</sup> study was done in 2003 to determine whether CIMA is associated with CAD and cardiovascular risk factors in the Indian population. 101 patients with CAD and 140 control subjects were assessed for CIMA and other conventional CVD risk factors. Results showed that the average IMT was significantly higher in the coronary disease group. Carotid IMT was the most important factor found to be an independent predictor of CAD on multivariate logistic regression analysis. There was a significant association between the number of CVD risk factors and the average IMT values in both control and CAD groups. Similar results are also seen with our study but in our study we had three groups with separate Stroke and CAD groups.

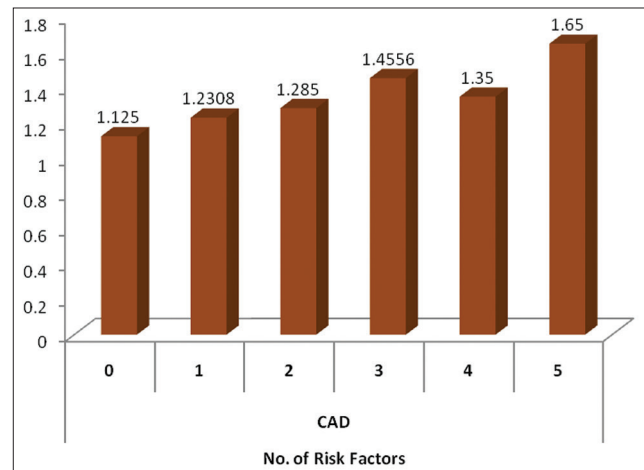
Another study from India, The Chennai Urban Population Study<sup>14</sup> reported significantly raised mean IMT values in diabetic patients compared with non-diabetic subjects. As



**Figure 1: Average carotid artery intima media thickness with cardiovascular diseases risk factors in control group**



**Figure 2: Average carotid artery intima media thickness with cardiovascular diseases risk factors in stroke group**



**Figure 3: Average carotid artery intima media thickness with cardiovascular diseases risk factors in coronary artery disease group**

the diabetes is very strong risk factor for atherosclerosis, we found very strong causal association of DM with stroke in our study. But in case of CAD group strong association of DM

with CAD is not established the reason being small sample size. This can also be explained on the basis of less CIMT.

Among western studies the Atherosclerosis Risk in Communities (ARIC) study<sup>15</sup>, is worth mentioning. In this study, CIMT was significantly higher in individuals with cardiovascular risk factors compared to normal controls. This is a population-based study in which large cohort was followed up for at least 10 years. And in this population-based cohort healthy controls without risk factors for atherosclerosis like family history of CVD, dyslipidemia, hypertension, DM were compared with people with risk factors for atherosclerosis. In our study, we have compared controls with Non-modifiable risk factors for atherosclerosis like age, family history of CVD with Stroke and CAD patients who have both modifiable and Non-modifiable risk factors. We concluded similarly like ARIC study that CIMT increases linearly as the number of risk factors for atherosclerosis increases.

Our study suggests a significant association between IMT and the presence and extends of CAD in the Indian population. However, more data are needed to establish CIMT as a noninvasive tool for the detection of CAD in symptomatic or asymptomatic individuals.

CIMT role in predicting the risk of future cardiovascular events in Western populations has already been established by several large-scale prospective studies. But CIMT role in India for prediction of future CVD has not been done on large randomized prospective studies. Our study was done on the small number of patients with case-control nature, so it difficult to conclude on this aspect of CIMT role.

Finally, it is said that the easy applicability and noninvasive nature of carotid B-mode USG make it suitable for use as a screening tool for atherosclerosis burden. Which group of people should undergo measurement of CIMT is a little controversial issue but those with multiple risk factors for CVD should undergo for CIMT measurement after physician recommendation.

## CONCLUSION

CIMT can be used to assess atherosclerotic diseases burden. It is well-documented tool to see the vascular age of the

person. Large scale studies with randomization are required to establish a cut-off value of average CIMT, according to age, gender and race, above which primary prevention of atherosclerosis can be started. CIMT can be used as monitoring tool for progression and regression of the atherosclerosis process.

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# Usage of Over the Counter Drugs – The Counterintuitive Exploitation

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## Abstract

**Background:** Medicaments bartered directly to a forbearer without a prescription from a healthcare professional, that are harmless when devoured is called as “over the counter (OTC) drugs.” Nowadays, there is an extensive use of non-prescribed drugs that has led to drug resistance that has a major concern in this world of evolution of diseases. This study was conducted as we pre-empt that there would be inflation in usage of OTC drugs.

**Materials and Methods:** This study was carried out as a community-based cross-sectional study at the outskirts of Chennai during October 2014. This study was conducted with the objective of assessing the prevalence of the usage of OTC drugs among the denizens. Pharmacies were randomly chosen and the data's were collected using direct questionnaire method with proper informed consent. The data was entered in MS excel sheet and analysis was performed using SPSS-17 version.

**Results:** A total of 130 study participants were interviewed of which 58% were males with the mean age of 38.6 years. Majority of the study population responded that the main reasons for OTC drugs use were lack of time, less availability of physicians, more number of medical shops, and easy availability of drugs, lack of money and fear of undergoing laboratory investigations. The commonly used OTC drugs were analgesics, antipyretics and antihistamines for the symptoms like fever and the common cold for which they spend INR of Rs. 104 per month.

**Conclusion:** The prevalence of usage of OTC drugs in our study was moderately high and hence interventions should be made to create cognizance among the general population about the risk factors and consequences in consuming non-prescribed drugs.

**Keywords:** Over the counter drugs, Non-prescribed drugs, Self-medication

## INTRODUCTION

Medicaments bartered directly to a forbearer without a prescription from a registered medical practitioner, when devoured is called as “over the counter (OTC) drugs” and self-medication is defined by many authors as the use of medicines by a patient on his own initiative or on the recommendation of a non-professional or a layperson instead of seeking advice from a health care provider.<sup>1,2</sup> Universally, consumption of usage of OTC

drugs by self-medication has become as an ineluctable part of daily lives of the common man in spite of the cognizance of its hazards. In India, there are many factors such as ignorance, lack of awareness, poor socio-economic status, lack accessibility to health care that play a major role in the usage of OTC use of medicines. In addition, advertisements and marketing persuades the general population to buy the medicines without a prescription. The pharmacist plays a predominant role in fostering self-medication among the public. Sometimes, the forebearers confer with the pharmacist or the pharmacy attender for whom the medicines are decided by the pharmacist and some of the medicines are even available in fancy stores, small non-medical shops, etc. Furtherance in the pharmaceutical industry has led to the production of powerful medications of various dosage levels, which when prescribed appropriate acts as a curative agent by enhancing the quality of life. However, inappropriate

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use of medications due to easy availability of the drugs, increased number of pharmacies in the vicinage, and the attitude of self-medication can have a serious health consequence, which is a larger public health issue. Hence, it deserves a revamped scrutiny, especially in developing countries like India to know deep in the site on this public health problem by conducting a community-based qualitative research.

### Aims and Objectives

1. To assess the usage pattern of OTC medicines
2. To find out the rationale with the use of OTC medicines
3. To enlist the common group of drugs consumed without prescription.

## MATERIALS AND METHODS

This study was done as a community-based cross-study among general population residing in and around the areas of North Chennai during the month of October 2014. Around 15 pharmacies were randomly selected from the existing pharmacy shops. The investigator approached the pharmacist and the purpose of the study was completely elucidated to them and authorization was procured. The investigator approached the study participants at the pharmacy shops those who came for buying medicines without prescriptions and they were interviewed after getting the informed consent. Almost all the study participants showed interest in participating in the research except very few. During this research survey, the medical and paramedical personnel came for getting drugs in the pharmacy shops were excluded from the study. Data collection was done by performed pre-tested questionnaire by direct interview method. The questionnaire includes general socio-demographic profile, socio economic status and determinants analogous to OTC drug usage. The data were entered in MS excel sheet and analyzed using SPSS software-17 version (Sun Microsystems Inc., Santa Clara, California, USA).

## RESULTS

### Socio-demographic Profile

The study included a total 130 study participants, of which the males constituted 58.5% (76) and 41.5% (54) were constituted by females. The mean age of the study population was 38.6 years with the mean income of approximately Rs. 19,000 INR. Majority of the study participants 82% (107) were educated up to higher secondary and some degree. The desolate part is that 43.8% (57) of the population were qualified graduates and 58.5% (76) of the study participants belonged to socio economic Class I followed by Class II (21.5%), Class III (13.8%) and

Class IV (6.2%) around 26.2% of the study participants were unemployed.

### Rationale for OTC Usage of Drugs

The world is revolving around an indefinite continued progress of existence exploring every second of life. Thus, lack of time to go to a physician and long hours of waiting at the doctor's clinic plays a major role in self-medication. About 80% (104) of the respondents answered that they used OTC drugs due to insufficient time in getting an appointment to a physician and waiting for the physician. Additionally, increase in the number of medical shops around the neighborhood plays the second basis for the 64% (83) of our study population to seek usage of

**Table 1: Socio-demographic profile of the partakers**

Variable	Number (n=130)	Percentages
Age group		
15-30 years	47	36.2
31-45 years	41	31.5
46 years and above	42	32.3
Gender		
Female	54	41.5
Male	76	58.5
Occupational Group		
Unemployed	34	26.2
Employed	96	76.8
Educational group		
Secondary schooling	50	38.5
Some schooling	23	17.7
Graduates	57	43.8
Socio economic status		
Class I	76	58.5
Class II	28	21.5
Class III	18	13.8
Class IV	8	6.2

**Table 2: Rationale for over the counter usage of drugs**

Variable	Number (130)	Percentages
Lack of time		
Yes	104	80
No	26	20
Lack of money		
Yes	46	35
No	84	65
Accessibility to more shops		
Yes	83	64
No	47	36
Lack of availability of physicians		
Yes	41	31
No	89	69
Easy availability of non-prescribed drugs		
Yes	17	13
No	113	87
Fear of laboratory investigations		
Yes	48	37
No	82	63



OTC drugs (Table 2). The other rationale quoted by the study participants were lack of money, less availability of physicians, easy availability of non-prescribed drugs, fear of laboratory investigations (Figure 1).

### OTC Drug Categories

The investigators were amazed to see patients ask for the drugs with various brand names. We were not able to identify whether this fluency toward the drug names were due to their knowledge or the advertisements or the curse of their extensive use of self-medication. Majority of drugs asked by the patients comes under antipyretic, analgesics and anti-inflammatory, antihistaminic and anti-allergic categories, and such drugs are dispensed by pharmacist without the proper prescription. The various categories of drugs that are sold OTC by pharmacists are shown in Table 3. Approximately, 58% of the study participants use analgesics and antipyretics without prescriptions.

### Symptoms for Which OTC are used

This almost coincide with the group of drugs purchased as OTC with the most common symptom being fever (57%) then followed by common cold (14%), gastrointestinal (GI) disturbances and joint pains. Among the total, eight study participants replied they even buy drugs for hypertension and diabetes without doctor's prescription that is the extreme scenario this study has explored (Figure 2).

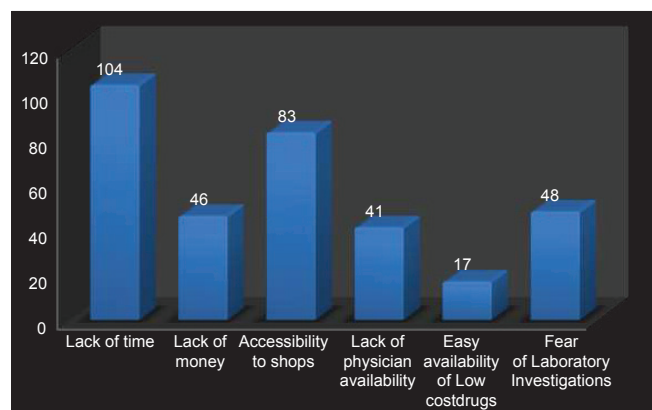


Figure 1: Factors related to use of over the counter drugs

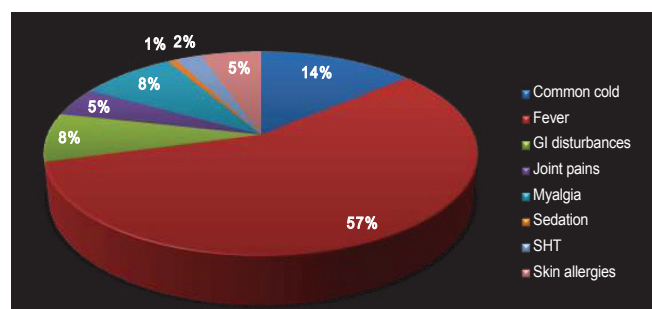


Figure 2: Symptoms for which over the counter drugs are used

### Effects of OTC Usage

The direct and indirect costs spent on buying the OTC medicines per month costs around 104 INR per month ranging from 10 INR to 600 INR. It is surprising that even some of the chronic diseases patients like hypertension, diabetes mellitus get the drugs with the very old doctor's prescriptions of more than 2 or 3 years back and some of the patients buy the drugs by asking the brand names directly. According to the study participants, they use the OTC medicines for cure of illness (51%) and also for at least reduction of severity (46%) in spite of being aware about the side effects. In addition to that, 3% of them experienced some side effects due to the use of OTC drugs.

### DISCUSSION

Our study had dealt with various aspects of OTC drugs usage and the rationale behind its usage is quiet surprising. Study on 130 adults had shown different results the most astonishing result being there was no age difference and gender difference. Almost all the age groups are using the OTC drugs which had become a very common practice it seems and many are aware about the side effects and some of them suffered from the side-effects which may be attributed to over dosage or inappropriate use. Similarly, it is very much surprising that many (58%) belong to Class I socio-economic status, but they state that lack money (35%) is also one of the important factor that they opt for OTC drugs instead of consulting a physician. Lack of accessibility to physician may not be actual fact because the study was done in urban part of Chennai, instead more accessibility to the medical and lack of time may be real reason behind the OTC drug usage. It seems that the money spent on OTC drugs per month was not so high, which may be attributed to the fact the OTC medicines sold are mostly less costly drugs. It has been found out from several studies that internationally the use of OTC drugs has been on the rise.<sup>3,4</sup> A study conducted in USA,<sup>5</sup> showed

Table 3: Drug categories for which the OTC drugs are used

Categories	Number	Percentage
AHT	2	1.5
Analgesics	44	33.8
Anti-cholesterol	1	0.8
Anti-diarrheal	9	6.9
Anti-emetics	3	2.3
Anti-histamines	12	9.2
Anti-pyretics	31	23.8
Anti-ulcer drugs	5	3.8
Antibiotics	4	3.1
OHA	2	1.5
Others	17	13.1
Total	130	100.0

OTC: Over the counter, AHT: Anti hypertensive therapy, OHA: Oral hypoglycemic agents



that 59% reported that having taken OTC drugs in the past 6 months and most commonly they were taken for pain, cough cold and flu, allergy and sinus problems, heartburn, minor infections and skin problems. As far as the symptoms or ailments for which OTC was used, our study also showed similar results with fever, common cold and GI tract disturbances being the common symptoms. Similarly, USA based study reported that 35% of adult Americans use OTC medications on a regular basis, and there was also increasing trend.<sup>6</sup> Shoaib *et al.* from a Pakistan study found out the prevalence of self-medication was high among non-pharmacists (71%) than pharmacists (62%) which shows that the increasing trend of OTC drugs in general population also in developing countries.<sup>7</sup> A study carried out in India by Shrotri *et al.* among pharmacists or shopkeepers had explored that 73.2% of the consumers choose their OTC drugs whereas the remaining 26.3% given the choice to the pharmacists and the study also revealed an important fact that 20.4% of the pharmacists felt that the OTC drugs are unsafe<sup>8</sup> but still they provide the drugs to the consumers without physician prescriptions. Majority (95%) of the Americans<sup>5</sup> read the label on the drugs for possible side-effects when they buy non-prescription medicines but in our study no one interested in knowing the side effects even some of them experienced the side effects. Our study has shown that most of them used analgesics as the common OTC drugs, but the Indore study had revealed that the most common drugs used were analgesics then followed by antibiotics that are very less in our study. Similar evidence was found by Kaufman *et al.*<sup>9</sup> that the commonly used OTC drugs were analgesics then followed by antihistamines and decongestants. In fact, many Indian studies showed that the most commonly used OTC group of drugs are analgesics then antipyretics and antibiotics.<sup>10</sup> Several studies conducted in developed countries had shown there are some benefits and risk associated with the use of OTC drugs. The benefits suggested were direct and rapid access, wide availability, decreased health care system utilization and allowing individuals to be in charge of their own health. The risks associated with OTC drugs are incorrect self-diagnosis, increased risk of drug-drug interactions and adverse events and potential for misuse and abuse.<sup>1,11</sup> Another major threat risk of OTC drugs is the development of antimicrobial resistance worldwide particularly in developing countries where antibiotics are often available without a prescription.<sup>12,13</sup> The aspects which have to be taken care of to reduce this major health problem are to reduce the doctor/patient communication gap and physician's role in reducing the OTC drugs usage. Some of the developed countries studies had reported that only 18% of the physicians educate their patients about safe drug taking and storing while only three-quarters of the physicians report that they ask their patients directly

about OTC drug use.<sup>5,14</sup> As far as the factors related to self-medication or use of OTC drugs Sherazi *et al.* and Jain *et al.* accepts in a systematic review study in Pakistan that ready access to drugs, greater availability, long waiting times, cost of drugs, high cost of private doctor's consultation, quick relief and not serious about the illness were common factors.<sup>15-17</sup> In spite of being the major global health problem, the different aspects of OTC drugs usage and self-medication like consumers attitudes, beliefs, prevalence of OTC drugs use, therapeutic misuse, physician's role, shopkeepers or pharmacists role and effects of chronic OTC drug use are undervalued throughout the world, which needs to be explored.

## CONCLUSION

Growing OTC drug usage is a multi-dimensional global health concern. This unique issue has to be considered desiderata; the government should initiate to take efforts to address the OTC usage of drugs. Legal interventions also should be made to ensure the availability of medications only to the general population with a prescription from a registered medical practitioner. Hence, this study intends to provide an insight into this growing public health problem in our country.

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# Cheiloscopy: The Study of Lip Prints in Relation to Gender and Geographic Distribution

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## Abstract

**Introduction:** Identification of an individual plays a prime role in any forensic investigation. Fingerprints, dental records, and DNA comparisons are some of the techniques that are used commonly. However, there may be certain situations where other supplemental aids like lip print analysis become essential.

**Purpose:** The present study intended to know the uniqueness of lip prints and their relationship with gender and geographical distribution among individuals working in Dental College, Virajpet.

**Materials and Methods:** The study group comprised of 85 subjects working in dental college. The materials used were the dark-colored lipstick, bond paper, cellophane tape, a brush, and a magnifying lens.

**Results:** Study showed that commonly seen lip print patterns among males were Type IV followed Type III and among females, Type II, followed by Type IV. In individuals from Kerala commonly seen lip print patterns were, Type IV, followed by Type II and in individuals from Karnataka, Type II, followed by Type III. Results revealed statistically significant association between gender and lip print patterns whereas, association between geographic location and lip print was not statistically significant.

**Conclusion:** The distribution of lip prints is unique for males and females and the association between geographic location and lip print was not statistically significant. Further studies with larger sample sizes are recommended to substantiate the results.

**Keywords:** Cheiloscopy, Forensic dentistry, Gender identity, Geographic distribution, Identification

## INTRODUCTION

Identity is a set of physical, functional or psychic, normal or pathological characteristics which define an individual. Human identification is one of the most demanding subjects and is based on scientific principles, the object of which is to identify and register individuals for both civil and criminal purposes.<sup>1</sup>

The moral obligation of dental professionals to mankind is not only to serve in clinical examination, diagnosis,

and treatment of oro-facial lesions of local origin, but also to serve in other legal matters as well as community services. Dental surgeon has a dynamic role in a range of objectives of forensic odontology like age and sex determination, participating in disaster management, personal identification of unknown deceased person etc.<sup>2</sup>

In India, as well as all over the world today, crimes of diverse nature are on the rise. Both educated elite of the society and criminals are using sophisticated techniques while committing their crimes, to put the forensic dentist, police, and the public off the scene. Hence, the role of crime detectives has become tough than ever in this sophisticated modern world. As crime scene investigation procedures are becoming more systematic and scientific, criminals are coming up with novel techniques to beat them. Post-mortem reports and finger-prints of late, the DNA fingerprinting methods are being used to take out

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convincing evidence in a court of law. Forensic odontology plays a vital role in the identification of human remains. History shows the use of forensic odontology since 49 A.D. cheiloscopy is a new and less recognized forensic investigation technique that deals with the identification of humans based on lip prints.<sup>3</sup>

The significance of cheiloscopy is linked to the fact that lip prints are inherent, once developed at the 6th month of intrauterine life they are permanent, unalterable even after death, and unique to each person except for monozygotic twins.<sup>1</sup> It has also been confirmed that lip prints recover after undergoing alterations such as inflammation, trauma, and diseases like herpes and that the disposition and form of the furrows does not vary with environmental factors.<sup>4</sup> However, major trauma to lips may lead to pathosis, scarring and the surgical treatment given for lip rectification may alter the shape and size of the lips, thereby altering the pattern and morphology of grooves.<sup>5</sup>

In 1902, Fischer described the system of furrows on the red part of human lips. In 1932, Locard, one of France's greatest criminologists, suggested the use of lip prints in personal identification.<sup>6</sup> In 1950, Synder mentioned in his Textbook of Homicide Investigation that the lip grooves are individually distinct as fingerprints.<sup>7</sup> In 1967, Suzuki made a detailed exploration of the lip measurement, the use and the color of rouge and method of drawing out useful data for forensic application. Later in 1971 Suzuki and Tsuchihashi, carried out a study, and they devised their own classification. McDonell in 1972 conducted a study on lip prints among two identical twins and revealed that two identical twins seemed to be indistinguishable by every other mean but they had different lip prints. Cottone in 1981, reported in his book Outline of Forensic Dentistry, that cheiloscopy is one of the unique techniques used for person identification. In 1990, Kasprzak conducted research for the period of 5 years on 1500 persons to intricate the practical use of lip prints. In 1999, the Federal Bureau of Investigation and the Illinois State Police considered that lip prints are unique like fingerprints and are a useful means of identification.<sup>8</sup>

In the case when the lip prints (lines) are not clear, person identification is possible by examining the matter that constitutes the trace e.g. saliva. The potential for DNA typing from the lip print is also possible. A lip print at the scene of a crime can be a source for conclusions as to the character of the event, how many people involved, sexes, cosmetics used, occupational traits, habits, and the pathological changes of lips. Cheiloscopy can open new horizons in person identification, be it mass disaster or crime scene. Dental identification, DNA comparisons, and fingerprints are probably the most common techniques

used in this context, allowing rapid and secure identification processes. However, since these techniques cannot always be used, sometimes it is essential to apply different and less recognized techniques. Where identification is concerned, the mucosal area of the lip plays most important role.<sup>3</sup>

Hence, the present study was designed with the aim to know the uniqueness of lip prints and their relationship with gender and geographical distribution of an individual and also to determine predominant lip print patterns among study participants.

## MATERIALS AND METHODS

Present cross-sectional survey was conducted in Department of Public Health Dentistry of Coorg Institute of Dental Sciences, Virajpet. The ethical approval for the study was obtained from the Institutional Review Board of Dental College, Virajpet. Informed consent was taken from all the participants.

Sample size was calculated using following formula,

$$n = \frac{N}{1 + Ne^2}$$

Where,  $n$  = Sample size

$N$  = Population size

$e$  = desired level of precision

Total calculated sample size was 85. In the present study dental college is divided into following strata undergraduates, postgraduates, teaching staff and nonteaching staff. A stratified random sample with proportional allocation for each stratum was calculated using the relation

$$n_i = nN_i/N$$

Where,  $n_i$  = sample size for given stratum

$n$  = Total calculated sample size

$N_i$  = Size of given stratum

$N$  = Population size

Subjects above 18 years either of Karnataka or Kerala origin was included, and Individuals with known hypersensitivity to lipsticks and any lip pathology were excluded.

Investigator was trained for recording and analyzing lip prints. Calibration was done by recording lip prints of 10 students from Dental College on 2 successive days. Each



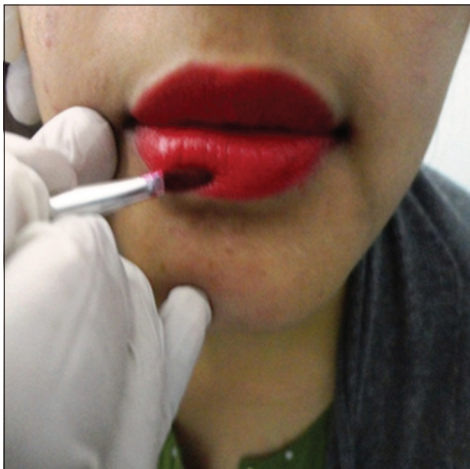
student was examined twice and the results were compared, to know the diagnostic variability agreement. The results so obtained were subjected to assess intra-examiner variability using kappa variability test and the mean kappa co-efficient value was found to be of 0.86, which showed good agreement.

The materials used were the dark-colored lipstick (Street Wear 32), bond paper, cellophane tape, a brush, and a magnifying lens (Picture 1). The subjects were made to sit comfortably in an erect position. Lips of all the subjects were cleaned and wiped dry with tissue paper before the procedure. Dark colored lipstick was applied with a single stroke evenly on the lips using the applicator brush (Picture 2). The subjects were asked to rub both the lips to evenly spread the applied lipstick (Picture 3). A neat strip of transparent cellophane about 15 cm was cut and the glued portion of cellophane tape strip was placed over the lipstick. The lip impression was made in the normal rest position of the lips by dabbing in the center first and then pressing it uniformly toward the corner of the lips

(Picture 4). The subject was asked to relax and then the cellophane strip was removed from the lips in a single stroke and then stuck to a white paper for permanent record purpose (Picture 5). The lip print procured was examined using a magnifying lens to confirm whether the print has been properly reproduced. While studying the lip prints, for overall lip print pattern, the middle part of the lower lip (10 mm wide) was taken as study area, as proposed by Sivapathasundaram *et al.* Since this fragment is almost always visible in any trace, the determination of the pattern depends on numerical superiority of properties of the lines on this study area (Picture 6).<sup>2</sup> These prints were examined using magnifying glass, classified, and analyzed.



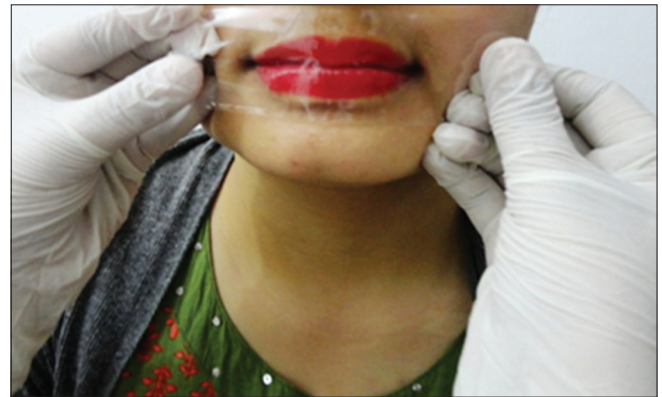
**Picture 1: Materials used**



**Picture 2: Application of lipstick**



**Picture 3: Rolling of lips to spread the lipstick**



**Picture 4: Impression on glued surface of cellophane tape**



**Picture 5: Sticking the cellophane tape on bond paper**





**Picture 6: Analysis of overall lip print pattern**

Each lip print pattern was determined based on following classification by Suzuki and Tsuchihashi 1970.<sup>1</sup>

- Type I: Clear-cut vertical grooves that run across the entire lips.
- Type I': Similar to Type I, but do not cover the entire lip.
- Type II: Branched grooves (branching Y-shaped pattern).
- Type III: Criss-cross pattern.
- Type IV: Reticular, typical checkered pattern, fence like.
- Type V: Undetermined, grooves do not fall into any of the types and cannot be differentiated morphologically.

Study was started in July 2014 and finished in August 2014.

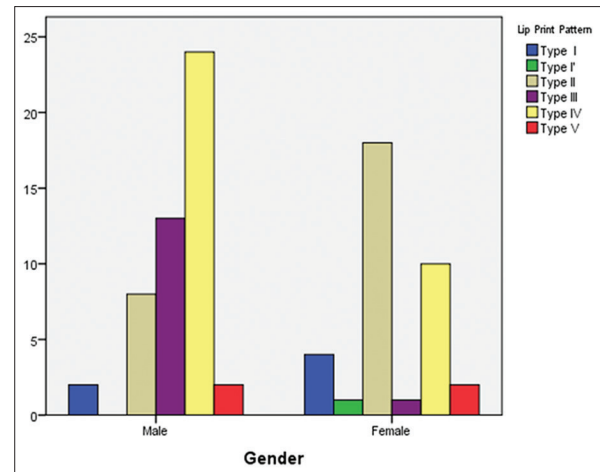
### Statistical Analysis

The collected data were analyzed using SPSS version 16 (SPSS Inc., Chicago) and the statistical test used Chi-square test. As the level of significance used for sample size calculation was 10%, the same level of significance was used for the statistical test.

## RESULTS

Out of 85 individuals included in the study, 49 were males, and 36 were females in the age group of 18-48 years with an average age of 33 years. Geographic location wise 43 were from Kerala and 42 from Karnataka.

As shown in Table 1 and Figure 1 overall predominant lip print patterns among study population were Type IV followed by Type II. Most common lip print patterns seen among males were Type IV followed by Type III and no male had Type I' pattern. Among females, most commonly seen lip print patterns were Type II, followed by Type IV. There was a statistically significant association between gender and distribution of lip print patterns. It was also seen in the present study that no two lip prints matched with each other, thus establishing the uniqueness of lip prints.



**Figure 1: Distribution of overall type of lip print pattern among males and females**

As shown in Table 2 and Figure 2 in individuals from Kerala Type IV was most commonly seen pattern, followed by Type II and in individuals from Karnataka, Type II was commonly seen, followed by Type III lip print pattern. The association between geographic location and lip print was not statistically significant.

## DISCUSSION

Crimes challenge the society in detection, diagnosis and identification of criminals. Establishing a person's identity can be a very difficult process. Hence, the search for various other means of personal identification continues.<sup>3</sup>

Lip prints are very useful in forensic investigation and personal identification. Like finger prints, even lip prints can be instrumental in identifying a person positively.<sup>9</sup> Lip prints are usually left at crime scenes, and can provide a direct link to the suspect. In recent years, lipsticks have been developed that do not leave any visible trace after contact with surfaces such as glass, clothing, cutlery, or cigarette butts. These lip prints are characterized by their permanence and are, therefore, referred to as "persistent" lip prints. Although invisible, these prints can be lifted using materials such as aluminum powder and magnetic powder. Furthermore, the use of lipsticks is not indispensable for leaving lip prints. The edges of the lips have sebaceous glands, with sweat glands in between. Thus, secretions of oil and moisture from these enable development of "latent" lip prints, analogous to latent finger prints.<sup>2</sup>

Even though the lines and furrows are present in both the upper lip and lower lip from one corner of the mouth to the other corner, only the middle portion in the lower lip is always visible in any traces,<sup>2</sup> this was taken into account for determining overall lip print patterns.

**Table 1: Frequency and association of overall lip print patterns in relation to gender**

Lip print patterns	Gender (n (%))		Total n (%)
	Male	Female	
Type I	2 (4.08)	4 (11.1)	6 (7.1)
Type I'	0 (0)	1 (2.78)	1 (1.1)
Type II	8 (16.33)	18 (50)	26 (30.6)
Type III	13 (26.53)	1 (2.78)	14 (16.5)
Type IV	24 (48.98)	10 (27.78)	34 (40)
Type V	2 (4.08)	2 (5.56)	4 (4.7)
Total	49 (100)	36 (100)	85 (100)

$\chi^2$  value=20.044 and P value=0.001\*, \*Statistical significance

**Table 2: Frequency and association of overall lip print patterns in relation to geographic location**

Lip print patterns	Geographic location (n (%))		Total n (%)
	Kerala	Karnataka	
Type I	3 (6.98)	3 (7.14)	6 (7.06)
Type I'	0 (0)	1 (2.38)	1 (1.18)
Type II	10 (23.26)	16 (38.1)	26 (30.59)
Type III	8 (18.6)	6 (14.29)	14 (16.47)
Type IV	20 (46.51)	14 (33.33)	34 (40)
Type V	2 (4.65)	2 (4.76)	4 (4.7)
Total	43 (100)	42 (100)	85 (100)

$\chi^2$  value=3.718 and P value=0.591

In the present study it was seen that no two lip prints matched with each other, thus establishing the uniqueness of lip prints. This is in accordance with the study conducted by Sharma *et al.* in Subharati Dental College, Meerut.<sup>2</sup>

Present study showed that overall predominant lip print pattern among study population was Type IV followed by Type II. Type I' was the rarest lip print pattern among study population. Similarly, study by Verghese *et al.* in Kerala showed that Type IV was the most frequently observed in both the sexes.<sup>10</sup> Other works on Indian subjects have yielded varying results. Study done by Rastogi and Parida in Mangalore showed Type II was the most commonly occurring lip print pattern, and Type V was the rarest.<sup>1</sup> Vahanwalla and Parekh in their study in Mumbai found that Type I was the most frequent. Sivapathasundharam *et al.* studied the lip prints of Indo-Dravidian population and noted that Type III was predominant.<sup>9</sup>

In current study, most commonly seen lip print pattern among males was Type IV followed by Type III and in females, most commonly seen lip print pattern is Type II followed by Type IV. Results showed statistically significant association between gender and lip print pattern. Study done by Sharma *et al.* showed that Type I, I' was most commonly seen in females, whereas Type IV was seen most commonly in males.<sup>2</sup> In contrast to this, study done by Rastogi and Parida showed Type I and Type I' patterns

were more common in males and Type II, Type III, Type IV and Type V patterns were more common in females.<sup>1</sup>

In the current study, it was seen that in participants from Kerala, Type IV was the most commonly seen pattern, followed by Type II lip print pattern and in participants from Karnataka, Type II was the most common lip print pattern, followed by Type III. The association between geographic location and lip print was not statistically significant. Study in Kerala done by Verghese *et al.* showed that Type IV was the most frequently observed in both the sexes.<sup>10</sup> Gupta *et al.* in their study conducted in Karnataka found out that in males frequencies of lip prints: Type I > Type I' > Type III > Type II > Type IV. In females frequencies of lip prints: Type I > Type III > Type I' > Type II > Type IV.<sup>11</sup> In contrast to present study, study done by Rastogi and Parida to know the relationship of lip prints and geographic area showed statistically significant difference in lip print patterns of South Indians and North Indians i.e. there found to be geographic variation in lip print patterns.<sup>1</sup>

Further studies with larger sample size are recommended to determine the relation between lip prints and geographical location.

## CONCLUSION

Study showed that cellophane tape and lipstick can be easily used to retrieve lip prints. Predominant lip print pattern among study population is Type IV followed by Type II. The distribution of lip prints is unique for males and females. Type II is most commonly seen in females followed by Type IV, whereas Type IV followed by Type II was seen most commonly in males. In individuals from Kerala, Type IV was most commonly seen pattern followed by Type II and in individuals from Karnataka, Type II was commonly seen followed by Type III lip print pattern.

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# Assessment of Proteinuria by the Determination of Micro Total Protein and Estimated Glomerular Filtration Rate in Type 2 Diabetes Mellitus Patients

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## Abstract

**Background:** Diabetic nephropathy a leading cause of end stage renal damage, characterized by decreased glomerular filtration rate (GFR) and proteinuria in patients of Type 2 diabetes mellitus (DM). In order to devise a means to protect kidneys at an early stage, the present study has examined micro total protein (MTP) in 24 h urine along with estimated GFR (eGFR) by modification of diet in renal disease (MDRD) and Cockcroft-Gault (CG) prediction equations as predictor of early renal damage in Type 2 DM.

**Aims and Objectives:** The aim was to examine the eGFR and MTP in 24 h urine sample as independent predictors of renal damage in Type 2 DM patients and also to study the additive value of eGFR and MTP in diagnosing incipient diabetic nephropathy.

**Materials and Methods:** Urinary 24 h proteinuria was assessed by pyrogallol red dye method and GFR estimated using MDRD and CG prediction equations.

**Results:** The mean  $\pm$  standard deviation of MTP was compared between diabetic patients ( $1913.3 \pm 2084.15$  mg/24 h) and non-diabetic controls ( $189.5 \pm 66.72$  mg/24 h), found significant proteinuria in diabetic patients. The eGFR estimated by MDRD equation compared between diabetics ( $75.44 \pm 30.85$  mL/min/1.73 m<sup>2</sup>) and non-diabetic controls ( $103.52 \pm 24.69$  mL/min/1.73 m<sup>2</sup>) and eGFR by CG compared between diabetics ( $71.34 \pm 32.63$  mL/min) and non-diabetic controls ( $99.44 \pm 25.37$  mL/min) were found significantly decreased in diabetic patients. MTP correlated with eGFR estimated by both the equations ( $r_{\text{MTP-MDRD}} = -0.544$  and  $r_{\text{MTP-CG}} = -0.452$ ) and found to be significant at  $P < 0.01$  and  $< 0.05$ , respectively. It has also been seen that MTP correlation with eGFR (MDRD) is better than MTP correlation with eGFR (CG).

**Conclusion:** There is an additive value of MTP estimation along with eGFR assessment in diagnosing incipient nephropathy and hence, increasing the chances of detecting renal damage at initial stages in Type 2 DM patients.

**Keywords:** Estimated glomerular filtration rate, Incipient nephropathy, Micrototal protein

## INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic diseases in which a person has high blood glucose,

either because the pancreas does not produce enough insulin or because cells do not respond to the insulin that is produced.<sup>1</sup> The global prevalence of diabetes is expected to increase from 4% in 1995 to 5.4% by the year 2025.<sup>2</sup> It is beyond doubt that patients with DM are at an increased risk of developing renal disease, which has significant clinical implications. Several traditional markers (blood pressure, hemoglobin A1c, cholesterol etc.) are at hand to identify those individuals who will develop end stage renal disease (ESRD). The traditional biomarkers have been successfully applied in clinical practice and have proven their clinical usefulness,

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but to diagnose incipient diabetic nephropathy the traditional biomarkers have not come to much avail and thus, new parameters are currently being studied extensively. Renal biomarkers, in particular, micrototal protein estimation in 24 h urine sample and estimated glomerular filtration rate (eGFR), have been recently added in this biomarker list.<sup>3</sup>

The first step in the screening and diagnosis of renal function in Type 2 DM is to measure micro total protein (MTP) in 24 h urine sample. An excretion of more than 150 mg/24 h is considered as abnormal. In subsequent years, the risk for developing overt nephropathy and progressive renal failure is particularly high for those with initial microproteinuria progressing ultimately to overt proteinuria.<sup>4</sup>

In some studies, it has been seen that for patients with Type 2 DM low GFR (<60 mL/min/1.73 m<sup>2</sup>) was present in patients even in the absence of micro- or macro-albuminuria.<sup>5</sup> eGFR can be determined by the recommended equation by the National Kidney Foundation which is the modification of diet in renal disease (MDRD) and the Cockcroft-Gault (CG) equation.<sup>6</sup> Therefore, there exists a dilemma whether GFR be routinely estimated along with urinary protein excretion (UPE) for proper screening of diabetic nephropathy.

## MATERIAL AND METHODS

A total of 30 subjects (of age group 40-60 years) suffering from Type 2 DM were selected from medicine outpatient department and inpatient department of Teerthanker Mahaveer Hospital, Moradabad and 30 age and sex matched normal individuals were selected as controls for the study.

The criteria considered to confirm diagnosis of Type 2 DM was:

- Fasting plasma glucose (FPG) >126 mg/dl on two occasions

The patients of Type 2 DM having any concomitant disease that can alter urinary protein excretion (UPE) such as: Type 1 DM, pregnancy, cardiovascular disease, urinary tract infection, strenuous exercise, inflammation, smoking, and alcoholism were excluded from the study.

Patient history required for the estimation of eGFR i.e., age, sex, ethnic group and weight were recorded. History of DM was confirmed later on by determination of FPG on two occasions.

## Tests Performed

Urinary 24 h MTP concentration was measured by pyrogallol red dye method,<sup>7</sup> plasma glucose (mg/dl) concentration was measured by enzymatic glucose oxidase peroxidase method,<sup>8</sup> serum creatinine (mg/dl) concentration was measured by Modified Jaffe's method,<sup>9</sup> and estimation of eGFR (using MDRD and CG equations).

### MDRD equation:<sup>10</sup>

$$\text{eGFR (mL/min/1.73 m}^2\text{)} = 186 \times (\text{serum creatinine [mg\%]})^{-1.154} \times \text{age (years)}^{-0.203} \times (0.742 \text{ if female}) \times (1.212 \text{ if black})$$

### The CG equation:<sup>11</sup>

$$\text{eGFR (mL/min)} = (140 - \text{age [years]}) \times \text{weight (kg)} / 72 \times \text{S}_{\text{cr}} \text{ (mg\%)} (\times 0.85 \text{ if female})$$

## Statistical Analysis

Mean  $\pm$  standard deviation (SD) were calculated for all the parameters analyzed and were compared by Student's *t*-test using SPSS (Version 16.1). *P* values considered significant were as follows:

- *P* < 0.05\* significant
- *P* < 0.001\*\* highly significant.

Correlation analysis calculating Pearson's correlation coefficient (*r*-value) and determination of the level of significance was also done.

## OBSERVATIONS AND RESULTS

1. False negatives for renal damage with eGFR alone were found to be, *n* = 9 (30%), which were detected by concurrent measurement of MTP in urine
2. With eGFR assessment alone only 66.67% patients were detected to have renal damage (Table 3)
3. With MTP measurement along with eGFR 96.67% patients were detected to have renal damage.

**Table 1: Comparison of different biochemical parameters between controls and Type 2 diabetic patients**

Parameters	Mean $\pm$ SD		<i>P</i> value
	Controls	T2DM patients	
MTP in 24 h urine (mg/24 h)	189.5 $\pm$ 66.72	1913.3 $\pm$ 2084.15	0.000**
eGFR•MDRD (mL/min/1.73 m <sup>2</sup> )	103.52 $\pm$ 24.69	75.44 $\pm$ 30.85	0.05*
eGFR•CG (mL/min)	99.44 $\pm$ 25.37	71.34 $\pm$ 32.63	0.05*

MTP: Micro total protein, eGFR: Estimated glomerular filtration rate, MDRD: Modification of diet in renal disease, CG: Cockcroft-Gault, SD: Standard deviation, DM: Diabetes mellitus



**Table 2: Pearson's correlation coefficient *r* value of various parameters in diabetic patients**

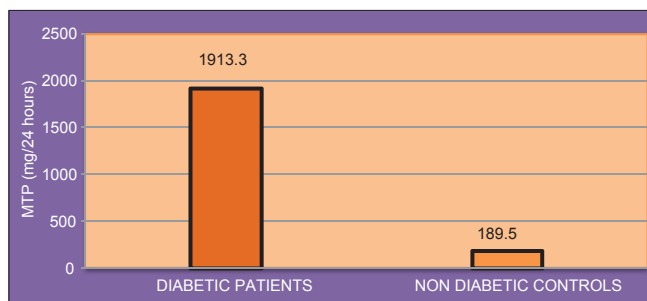
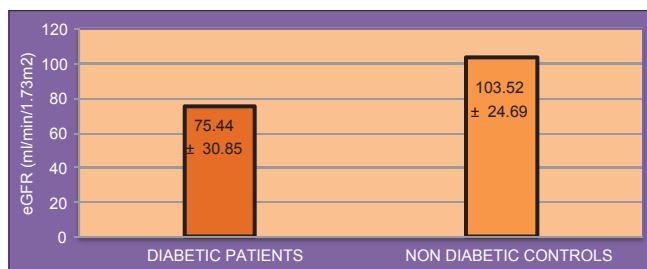
Parameters	<i>r</i> value
eGFR•MDRD-FPG	-0.282
eGFR•CG-FPG	-0.285
MTP-FPG	-0.065
eGFR•MDRD-MTP	-0.544**
eGFR•CG-MTP	-0.452*

$P < 0.01$ \*\* and  $P < 0.05$ \*. MTP: Micro total protein, eGFR: Estimated glomerular filtration rate, MDRD: Modification of diet in renal disease, CG: Cockcroft-Gault, FPG: Fasting plasma glucose

**Table 3: Additive value of MTP and eGFR assessment**

Parameters	Number of Type 2 DM patients (n=30)	% detected with diabetic nephropathy
Decreased eGFR with proteinuria	20	66.67
Normal eGFR with proteinuria	9	30.00

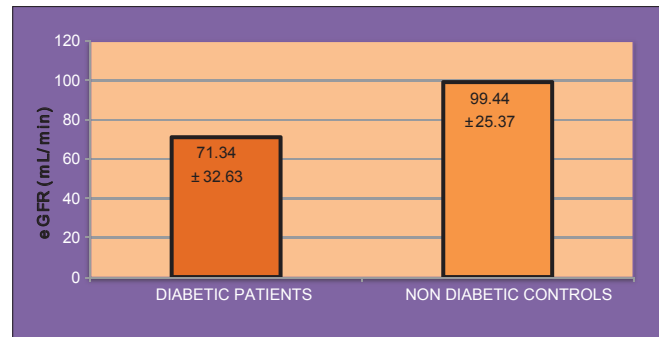
DM: Diabetes mellitus, MTP: Micro total protein, eGFR: Estimated glomerular filtration rate

**Figure 1: Comparison of micro total protein between diabetic patients and non-diabetic controls****Figure 2: Comparison of estimated glomerular filtration rate • modification of diet in renal disease between diabetic patients and non-diabetic controls**

## DISCUSSION

Type 2 DM patients were diagnosed for FPG (mean  $\pm$  SD =  $232.20 \pm 95.30$  mg/dl) on two occasions and compared with FPG (mean  $\pm$  SD =  $90.75 \pm 9.15$  mg/dl) in normal individuals.

Patients who develop diabetic nephropathy usually have no symptoms early on, although the condition puts them at a risk

**Figure 3: Comparison of estimated glomerular filtration rate • Cockcroft-Gault between diabetic patients and non-diabetic controls**

of developing more serious kidney disease. It is important to take steps to protect kidneys before the problem advances.<sup>12</sup> The present study has examined MTP in 24 h urine sample and eGFR for the assessment of early renal damage in Type 2 DM patients and to prevent overt diabetic nephropathy.

MTP in 24 h urine sample and eGFR were examined as independent predictors for renal damage in Type 2 DM patients and their additive values have also been assessed to diagnose incipient diabetic nephropathy. These have been assessed earlier in several other studies also, and have proven their clinical usefulness to a variable extent. In the present study, eGFR has been estimated along with MTP in 24 h urine sample to predict renal damage in Type 2 DM patients. The findings of the present study are as follows:

The quantitative estimation of MTP in 24 h urine sample in Type 2 DM patients ( $1913.3 \pm 2084.15$  mg/24 h), compared with non-diabetic controls ( $189.5 \pm 66.72$  mg/24 h) was determined and found to have highly significant differences at  $P < 0.001$  (Table 1, Figure 1). Thus, it can be inferred that patients had proteinuria related with DM.

Proteinuria, a hallmark of glomerular disease is not only a sign of kidney disease but also results in tubular and interstitial damage and contributes to the progression of chronic renal disease. When too much protein (along with bound materials such as lipids) is filtered, proximal tubule cells endocytose abnormally large amounts. This may have a toxic effect on the cells, and they then express a number of vasoactive and chemotactic factors which lead to ischemia, inflammation, and interstitial fibrosis.<sup>13</sup> Thus, proteinuria and albuminuria are the earliest markers of kidney damage in patients with DM and persistent increases are the most common markers of kidney damage in adults. Proteinuria is reported to be the most important determinant of progression to end stage renal disease (ESRD).<sup>14</sup>

Fabre *et al.* reported a prevalence of 48% with abnormal protein excretion ( $>150$  mg in 24 h) among 510 Type 2

DM patients and 16% had protein excretion in excess of 500 mg in 24 h.<sup>15</sup>

Another study from Rochester, Minnesota in the US, assessed the relationship between proteinuria and ESRD and explains that at the time of diagnosis of diabetes related proteinuria was the strongest risk factor for ESRD. Persistent proteinuria developing after the diagnosis of DM was associated with a cumulative risk for chronic kidney disease (CKD) (10 years later).<sup>16</sup>

Proteinuria is also a potent risk factor for mortality and an early study from the Framingham cohort reported that proteinuria was associated with a substantial increased risk of mortality.<sup>17</sup>

eGFR was done by the two prediction equations MDRD and CG equations. The comparison of eGFR (MDRD) between Type 2 DM patients ( $75.44 \pm 30.85$  mL/min/ $1.73$  m<sup>2</sup>) and non-diabetic controls ( $103.52 \pm 24.69$  mL/min/ $1.73$  m<sup>2</sup>) found to have significant differences at  $P < 0.05$  (Table 1, Figure 2). The eGFR (CG) was compared between diabetic patients ( $71.34 \pm 32.63$  mL/min) and non-diabetic controls ( $99.44 \pm 25.37$  mL/min) was also found to have significant differences at  $P < 0.05$  (Table 1, Figure 3).

The eGFR estimated from both the equations were found to be decreased in DM patients compared to non-diabetic controls, which show that eGFR decrease in diabetic patients more than non-diabetic controls. It has been suggested that using eGFR as a screening tool may also potentially predict and reduce the incidence of CKD, which is associated with increased risk of death.

eGFR estimation from MDRD and CG equations were correlated with MTP in 24 h urine. Pearson correlation ( $r = -0.544$ ) of equation eGFR (MDRD) with MTP in 24 h urine is significant at  $P < 0.01$  and Pearson correlation ( $r = -0.452$ ) of equation eGFR (CG) with MTP is significant at  $P < 0.05$ . There were strong correlations between eGFR (from both MDRD and CG equation) with MTP in 24 h urine sample but the correlation of eGFR (MDRD) with MTP was slightly stronger than correlation of eGFR (CG) with MTP (Table 2).

Hoefield *et al.* showed that cohort based people with DM; effect of time on eGFR shows the prognostic importance of proteinuria upon CKD progression in diabetic CKD. Individuals with DM and macroalbuminuria have more rapid decline in renal function than those without albuminuria. Individuals with microalbuminuria also have an increased rate of decline of eGFR compared with people with normoalbuminuria.<sup>18</sup>

The present study shows a strong correlation of eGFR by both MDRD and CG with MTP in 24 h urine sample to

assess renal damage in Type 2 DM. MTP better correlates with eGFR using MDRD equation than eGFR using CG equation.

Of total 30 patients, 96.7% of the patients had microproteinuria ( $>150$  mg/24 h). Similarly, 66.7% of the patients had decreased eGFR estimated using MDRD ( $<90$  mL/min/ $1.73$  m<sup>2</sup>) and CG ( $<90$  mL/min) equations. Both are the predictors of renal damage in Type 2 DM, as, 66.7% of the diabetic patients had decreased eGFR using both MDRD and CG equations (Table 3). Thus, it can suggest that in order to avoid variations of protein concentration in urine need to assess MTP in 24 h urine sample along with the eGFR by the prediction equations suggested by National Kidney Foundation, which are MDRD and CG equations must be advocated.

Out of 30 diabetic patients, 20 patients (i.e., 66.67%), had microproteinuria along with decreased eGFR. Out of 30 diabetic patients, 09 patients (i.e., 30%) had shown proteinuria in spite of normal eGFR. Thus, 30% of these false negatives for renal damage by assessment of eGFR alone were detected for incipient nephropathy by the concurrent measurement of MTP along with eGFR (MDRD/CG).

## CONCLUSION

MTP in 24 h urine sample along with eGFR was found to minimize the number of false negatives, hence, together serving as better predictors at an early stage of renal damage in Type 2 DM patients. This implies that there is a synergistic role of urinary MTP estimation along with eGFR assessment in diagnosing incipient nephropathy, multiplying the chances manifold in detecting renal damage at initial stages in Type 2 DM patients.

## Limitations

1. Actual measurement of GFR by using radioactive isotopes/inulin needs to be done for exact measurement of GFR
2. CG and MDRD equations have limitations of use in ill and hospitalized patients
3. The measurement of GFR needs to be done to compare actual reliability of estimated GFR by MDRD and CG equations.

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# Isolated Oligohydramnios – Is it an Indication for Induction of Labor?

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## Abstract

**Introduction:** Isolated oligohydramnios (IO) is defined as amniotic fluid index (AFI) below five without maternal or fetal causes. Induction of labor in such cases is done in order to avoid adverse perinatal outcome, mostly end up with in caesarean section. The aim of this study is to evaluate whether induction and cesarean section is really needed in IO.

**Purpose:** To evaluate and analyze the management and outcome between the pregnancies at term with IO and with normal AFI without any other maternal and fetal complications.

**Materials and Methods:** This prospective study was carried out between January 2012 and December 2013 in Vinayaka Mission Medical College, Karaikal, India. 100 IO were compared with 100 cases with normal AFI at term pregnancy.

**Results:** In IO, there is no significant difference in neonatal intensive care unit admissions (12% vs. 7%  $P = 0.33$ ), birth weight <2.5 kg (28% vs. 18%  $P = 0.12$ ), or perinatal mortality but there is increased rate of caesarean section (72% vs. 18%  $P < 0.0001$ ) due to fear of adverse perinatal outcome compared with control group.

**Conclusion:** IO does not adversely affect the perinatal outcome and hence it is not an indication for the induction of labor or elective cesarean section.

**Keywords:** Cesarean section, Isolated oligohydramnios, Perinatal outcome

## INTRODUCTION

Nowadays, indication for induction of labor is increasing. It is done in the majority of the cases to reduce the neonatal morbidity and mortality, mostly in diabetes mellitus, post term pregnancies, intrauterine growth restriction (IUGR), oligohydramnios, twin pregnancy, hypertension and pre-eclampsia. Isolated oligohydramnios (IO) at term is defined as amniotic fluid index (AFI) of <5 cm or maximum vertical pocket <2 cm (Figure 1) without any other maternal or fetal complications.<sup>1</sup> Incidence of IO is 0.5-5% at term.

Theoretically speaking, diminished liquor is a critical one which may cause cord compression and death. However, IO is not an absolute indication to induce labor at once. This may lead to increased maternal risk, iatrogenic prematurity and increase in the cost. Of course, there is no difference in the perinatal outcome.

## MATERIALS AND METHODS

Among 4546 antenatal patients came to our institute, a prospective study done on 200 cases (100 cases of IO with gestational age >37-40 weeks [study group] excluding the other known maternal or fetal causes of oligohydramnios and 100 cases of same gestational age with normal AFI [control group]). The consent from an ethical committee of our college and patient's consent were obtained. The women with previous still birth, IUGR baby, maternal diabetes, pregnancy induced hypertension, IUGR at present pregnancy, premature rupture of membrane

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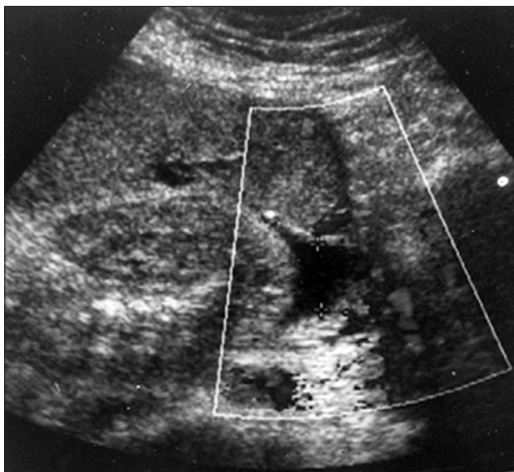
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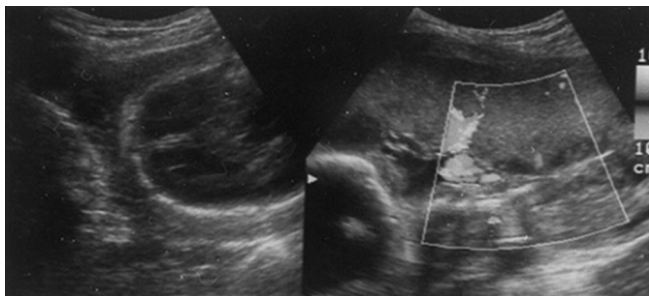


(PROM), structural/chromosomal abnormalities of fetus are excluded, amniotic fluid measurement was estimated according to Phelan *et al.*<sup>1</sup> technique by ultrasound Philips, HD7XE revision 2.0.1 which was equipped with curvilinear transducer AFI <5 without any fetal anomalies or maternal complications is considered as IO (Figure 2).

On admission, non-stress test (NST) was done for all women. If NST was not reassuring, emergency caesarean section was done. If NST was reassuring excluding patient with cephalopelvic disproportion who were not in the labor, induced. When the patient went into active labor, artificial rupture of membranes was done. Partogram was plotted to know the maternal, fetal condition and progress of labor. All cases were monitored by continuous electronic fetal monitoring. If there were late decelerations, persistent bradycardia or persistent tachycardia, the delivery was expedited by operative intervention. All newborns were attended by the pediatrician. The birth weight and Apgar score at 1 min were noted. If the Apgar score was low or the baby had respiratory distress, the baby was admitted to the neonatal intensive care unit (NICU). The outcomes recorded were NST, induced or spontaneous labor, color of liquor, mode of delivery, Apgar score, NICU admission and perinatal mortality.



**Figure 1: 1.8 cm pocket of amniotic fluid indicating oligohydramnios**



**Figure 2: An amniotic fluid index of 4.2 cm, indicating oligohydramnios, absence of amniotic fluid in upper quadrant**

## Statistical Analysis

Baseline characteristics of the two different groups were analyzed by Student's *t*-test. Proportions were compared using the Chi-square test. Fisher's exact tests were used when appropriate. Statistical Package for Social Sciences version 17.0 (SPSS Inc., Chicago, Illinois, USA) was used for statistical analysis. Data are presented as mean  $\pm$  standard deviation.  $P < 0.05$  was considered as statistically different.

## RESULT

Of 4546 patients 200 were studied which were divided into two groups on the basis of the AFI. The 100 comprise of study group (IO) who had AFI <5 and the other 100 were control group with AFI 8-24. There is no demographic difference in age and parity between study and control group as shown in Table 1. There were increased incidence of the induction of labor in study group (82% vs. 20%  $P < 0.0001$ ), non-reassuring fetal heart rate (15% vs. 6%  $P < 0.06$ ), cesarean section for fetal distress (31% vs. 9%  $P < 0.0001$ ), birth weight <2.5 kg (28% vs. 18%  $P = 0.02$ ) Apgar score at 1 min (18% vs. 12%  $P = 0.32$ ), thick meconium stained liquor (16 vs. 03  $P < 0.002$ ), NICU admissions (12% vs. 7%  $P = 0.33$ ) (Table 2). There were increased incidence of cesarean section due to fetal distress (31% vs. 9%  $P < 0.0002$ ) and failed induction (38% vs. 5%  $P < 0.0001$ ) as shown in Table 3.

The data shows increased incidence in thick meconium, non-reassuring fetal heart rate and caesarean delivery in study group compared to control group. No significant difference in baby needing ventilator support and perinatal death in both groups.

## DISCUSSION

The AFI is calculated based on the four quadrant technique. IO is defined as AFI  $\leq 5$  cm without any other known maternal or fetal causes of oligohydramnios.<sup>1</sup>

Oligohydramnios is caused by PROMs, maternal diseases such as chronic hypertension, pregnancy induced hypertension, post term pregnancy, intrauterine infections, IUGR, bacterial vaginosis, other causes of utero placental

**Table 1: Base line data**

Characteristics	Study group (n=100)	Control group (n=100)
Average age	26.8	27.2
Parity		
Primigravidae	48	46
Multigravidae	52	54



insufficiency and fetal causes like malformations, congenital renal abnormalities like aplastic kidney, ureter obstruction, potters syndrome, inborn errors of metabolisms and chromosomal abnormalities. Acute oligohydramnios may occur from ruptured membrane, usually diagnosed by clinical signs as vaginal fluid with altered PH and a ferning pattern.<sup>2</sup> The exact etiology of IO is unknown.

Pregnancies complicated by IO are more prone for induction of labor and end up in preterm deliveries or cesarean delivery. Hence, neonatal morbidity is increased due to preterm and caesarean section. Hence, conservative management is preferable.<sup>3</sup>

In our study, the rate of cesarean is higher due to non-reassuring fetal status and failed induction in oligohydramnios group when compared to control group. There is no difference in perinatal morbidity and mortality between study group and control group. Similar findings have been noted by Manzanares *et al.* showing that increased rate of cesarean delivery for non-reassuring fetal status as well as operative vaginal deliveries increased in isolated hydramnios group, which cause increase in hospital stay and cost. Whereas there is no difference in the perinatal morbidity and mortality in both groups.<sup>4</sup>

**Table 2: Comparison of outcome in study**

Characteristics	Study group (n=100)	Control group (n=100)	P value
Non-reassuring NST	15	6	0.06 (NS)
Induced labor	82	20	0.0001 (S)
Mode of delivery			
Vaginal	28	82	0.0001 (S)
Caesarean	72	18	0.0001 (S)
Color of liquor			
Clear	78	85	0.27 (NS)
Thin meconium	06	12	0.21 (NS)
Thick meconium	16	03	0.002 (S)
Apgar score			
1 min<7	18	12	0.32 (NS)
NICU admission	12	07	0.33 (NS)
Birth weight<2.5 kg	28	18	0.12 (NS)
Babies needing ventilatory support	0	0	
Perinatal death	0	0	

NST: Non stress test, NICU: Neonatal intensive care unit, S: Significant, NS: Non-significant

**Table 3: Indication of cesarean section**

Characteristics	Study group (n=100)	Control group (n=100)	P value
Fetal distress	31	9	0.0002 (S)
Failed induction	38	05	0.0001 (S)
CPD	03	04	1.00 (NS)
Total	72	18	0.0001 (S)

CPD: Cephalopelvic disproportion, S: Significant, NS: Non-significant

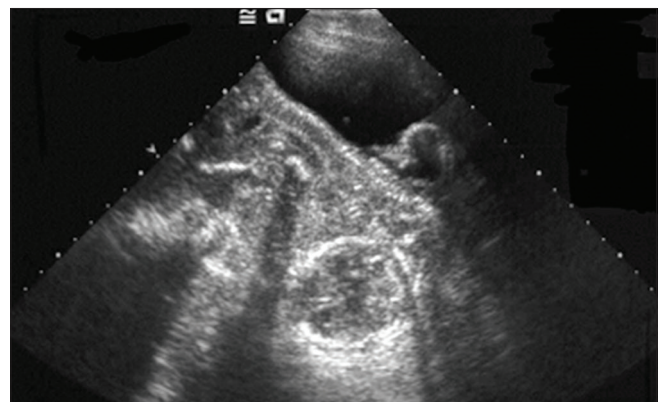
The neonatal outcome studied by the Apgar score at the time of delivery showed no difference between the study group and the control group in our study. Ek *et al.* observed similar neonatal outcome in their study.<sup>5</sup> Similar to our study, a cohort study done in 287 patients of IO and control group comprising 22,280 showed no significant difference in adverse perinatal effect.<sup>6</sup>

In IO in spite of the fact does not affect perinatal outcome still it is nightmare and obstetrician do intervene pregnancy because there is no valuable protocol and enough studies.<sup>7</sup> There are plenty of studies showing no significant difference in perinatal outcome in both group. Of course, the rate of caesarean section in study group however is increased.<sup>8</sup>

In another study, it was RADIUS trial in 15,151 women the incidence has also been noted that IO is not associated with adverse perinatal outcome when compared the same with normal pregnancy without any complications.<sup>9</sup> In some case studies, it was noted that IO does not affect the rate of operative deliveries in spite of the abnormal fetal heart rate tracing.<sup>10</sup>

## CONCLUSION

Oligohydramnios is a condition wherein the AFI <5 cm hence induction of labor is done, so failure to progress results in maternal exhaustion, non-reassuring fetal status and finally cesarean section. Surprisingly the neonatal outcome is good. It is a challenging situation in the field of obstetrics. Here we studied the perinatal outcome in IO. Honestly speaking most of the cases which showed non-reassuring fetal heart status, thick meconium staining, AFI even <3 (Figure 3) where caesarean section was done in the fear of poor perinatal outcome, there is no significant difference in perinatal morbidity and mortality. All of us know that induced labor when compared to spontaneous labor leads to unwanted caesarean section. To conclude IO



**Figure 3: Transabdominal sonogram of an intrauterine pregnancy with marked oligohydramnios**

does not adversely affect the perinatal outcome and hence it is not an indication for the induction of labor or elective caesarean section. Future research and prospective studies are needed for a further conclusion.

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# Prevalence and Etiological Factors Causing Hearing Loss in School Going Children of Vizianagaram District

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## Abstract

**Introduction:** Normal hearing in children provides the primary source for acquisition of speech, language and cognitive skills. Hence, hearing loss in children will cause poor academic and cognitive performance and is a major public health concern in developing countries.

**Aim:** The aim of this study is to know the prevalence and etiological factors causing hearing loss among primary school children in Vizianagaram district.

**Materials and Methods:** In this cross-sectional, observational study 2735 students from 30 schools in Vizianagaram district were screened for hearing loss from April 2014 to September 2014 for a period of 6 months. Primary information was obtained by history, free field conversational voice test, clinical ENT examination, Otoscopy and pure tone audiometry. Statistical analysis was performed using MS excel 2007 and Epi Info software.

**Results:** Of the 2735 children screened 342 school children (12.5%) had hearing loss. Impacted ear cerumen (wax) was the most common cause for hearing loss seen in 184 children (53.8%), followed by Otitis media with effusion in 70 cases (20.46%), chronic suppurative otitis media (CSOM) in 60 cases (17.54%). Among 342 children, 329 (96.19%) showed conductive type of hearing loss. Maximum number, i.e., 151 (44.15%) of children were in the age group of 9-12 years. School children having hearing loss showed bad academic performance than normal hearing children ( $P < 0.001$ ).

**Conclusion:** This study emphasizes the fact that most of the etiological factors in causing hearing loss in school going children are temporary and treatable. Hence, deafness can be prevented to a large extent if remedial measures are taken in time.

**Keywords:** Cerumen, Cross-sectional studies, Hearing loss, Otitis media with effusion

## INTRODUCTION

In the process of global epidemiological transition, the economic burden associated with chronic diseases is on the rise, especially in low- and middle-income countries.<sup>1</sup>

Hearing loss has a significant effect on both individual and society. Hearing impairments in children can create various disabilities in children like speech and language problems, cognitive impairment and poor academic performance.<sup>2,3</sup>

Population-based surveys in 2003 in India using the World Health Organization (WHO) protocol estimated the prevalence of hearing impairment to be 6.3% or approximately 63 million people suffering from significant auditory loss.<sup>4</sup> The estimated prevalence of adult-onset deafness in India was found to be 7.6% and childhood onset deafness to be 2%.

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As per National sample survey office (NSSO) Survey in India, currently there are 291 persons per one lakh population who are suffering from severe to profound hearing loss (NSSO, 2001). Of these, a large percentage is children between the ages of 0-14 years. With such a large number of hearing impaired young Indians, it amounts to a severe loss of productivity, both physical and economic.

It has been noted by WHO that half the causes of deafness are preventable and about 30%, though not preventable, are treatable or can be managed with assistive devices. Thus, about 80% of all deafness can be said to be avoidable.<sup>4</sup>

Since no previous similar studies were conducted in this region, the present study was undertaken to know the prevalence and etiological factors of hearing loss among school going children. By this study we, to some extent can prevent, detect hearing loss and interventions can be made early.

## MATERIALS AND METHODS

For this cross-sectional observational study informed consent from school children and their teachers were taken and also clearance from Ethical Committee.

Screening was done for 2735 school children ranging between 5 and 16 years of age from 30 co-educational urban and semi-urban schools in Vizianagaram district which is in southern part of India from April 2014 to September 2014 for a period of 6 months. Screening was conducted according to the guidelines of National program for prevention and control of Deafness (NPPCD) 12<sup>th</sup> 5-year plan, ministry of health and family welfare, Government of India.

Special attention for clinical examination was given to all students with a history of any ear problem or complaint, found to have impaired hearing in free field conversational voice test and students with poor academic performance. Their academic performance in the prior 1 year was assessed with the help of the marks lists supplied by the school teacher.

Complete medical and personal history was taken including age, socioeconomic status which was graded according to modified Kuppaswamy scale.

All the school children underwent clinical ENT examination, Otoscopy examination and tuning fork tests. Children who showed some abnormality in the audiometric screening were referred to our hospital for complete hearing

assessment, which included pure tone audiometry, speech audiometry and impedance audiometry. Results were analyzed using standard statistical methods MS excel 2007 and Epi Info software. Frequencies, percentages and tests of significance were applied where necessary.

## RESULTS

A total of 2735 school children were examined in the present study 0.342 (12.5%) students were found to have hearing impairment (Table 1). Of the total 342 children who had hearing loss, 101 (29.53%) children were in the age group 5-8 years, 151 children (44.15%) were between 9 and 12 years and 90 (26.31%) children were between 13 and 16 years (Table 1). 139 (40.65%) were male children and 203 (59.35%) were female children with a male to female ratio of 1:1.46 (Table 2).

Among the causes for hearing loss, impacted ear wax was found to be the commonest cause seen in 184 cases (53.8%), followed by secretory otitis media (SOM) or otitis media with effusion in 70 cases (20.46%), chronic supportive otitis media in 60 cases (17.54%), acute suppurative otitis media in 7 (2.04%), otitis externa in 4 (1.17%) and otomycosis in 4 (1.17%). Sensory neural hearing loss was seen in 13 children (3.8%) of which 2 cases are congenital (Table 3).

Conductive type of hearing loss is present in 329 school children (96.19%) and sensory neural hearing loss (SNHL) in 13 children (3.8%) (Table 4). Degree of hearing loss mostly fall in mild degree in 283 cases (82.74%) followed by moderate degree hearing loss in 50 cases (14.62%), severe hearing loss in 7 cases (2.04%) and profound in

**Table 1: Prevalence of hearing loss among school children**

Total number of students	Students with hearing loss	Prevalence
2735	342	12.5%

**Table 2: Socio demographic variables of study subjects with hearing impairment (n=342)**

Variable	Number	%
Age		
5-8 years	101	29.53
9-12 years	151	44.15
13-16 years	90	26.31
Sex		
Male	139	40.65
Female	203	59.35
Area		
Urban	96	28.07
Semi urban	246	71.92



2 cases (Figure 1). Hearing loss was unilateral in 146 cases (42.69%) and bilateral in 196 (57.31%).

Semi-urban school children are affected more (13.87%) than urban schools (9.97%). Children belonging to poor socio-economic statuses were more affected. Of the 13 school children with SNHL 8 school children (61.5%) had bad school performance while in 329 students with CHL only 119 students (36.17%) have bad school performance (Table 5). This difference was found to be statistically significant ( $P < 0.001$ ).

**Table 3: Causes of hearing loss and their prevalence (n=342)**

Cause	Number	Prevalence %
Congenital	02	0.05
SNHL	11	3.21
Impacted wax	184	53.8
Otitis externa	04	1.17
Otomycosis	04	1.17
SOM	70	20.46
CSOM	60	17.54
Acute suppurative otitis media	07	2.04

SOM: Secretary otitis media, CSOM: Chronic suppurative otitis media, SNHL: Sensory neural hearing loss

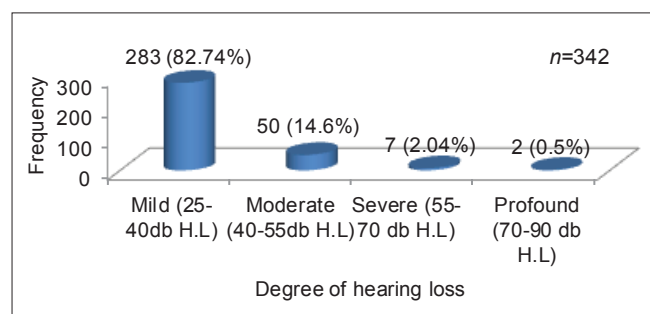
**Table 4: Type of hearing loss and their prevalence**

Type of hearing loss	Total number	Percentage
Conductive	329	96.19
Sensori neural	13	3.80

**Table 5: Hearing loss versus academic performance among school children (n=2735)**

	Good academic performance (%)	Poor academic performance (%)	Total
SNHL	5 (38.5)	8 (61.5)	13
CHL	210 (63.8)	119 (36.2)	329
Normal	2034 (85)	359 (15)	2393
Total			2735

Chi square: 105.71;  $P < 0.001$ , CHL: Conductive hearing loss, SNHL: Sensory neural hearing loss



**Figure 1: Degree of hearing loss in students with impaired hearing (n = 342)**

## DISCUSSION

Ear disease in children is a major public health concern in developing countries. Preventable ear diseases have been found to be important health problems among children.<sup>5</sup> The WHO suggests that, in developing countries, children should be screened at school entry using a simple audiometer and the external ear be inspected for the presence of discharge to study the extent of the problem in the community.<sup>6</sup>

In our study, prevalence rate of hearing loss was found as much as 12.5%. These results were similar to studies conducted by Mishra *et al.*,<sup>7</sup> Pand Tuli *et al.*<sup>8</sup> who found a prevalence rate of 11.7% and 12.5%, respectively. This high prevalence can be attributed to poverty, lack of health awareness and lack of medical facilities. Maximum prevalence of hearing handicap was in the age group 9-12 years as found in our study and also in the study in north India by kalpana *et al.*<sup>9</sup> Female children are more affected than males in our study. Children are belonging to low socio-economic statuses were more affected in our study and also in the study conducted in Nepal by nepali.<sup>10</sup>

In our study, conductive type of hearing loss (CHL) is more common compared to SNHL. The overall prevalence of conductive deafness in the affected children was 93.86% unlike Sukhthankar and Chamyal<sup>11</sup> who in their study of conductive deafness found an overall incidence of 24%. As CHL is correctable by proper management, early detection of this disability can reduce the incidence of this handicap. Mild degree hearing loss is most common in our study and also in the study by Chishty.<sup>12</sup> Impacted wax was the most common etiological factor in our study (53.8%). Similar results were found in the study in northern India conducted by Sharma *et al.*<sup>13</sup>, Chadha<sup>14</sup> and also in the study in Tanzania by Minja<sup>15</sup> who reported wax as the most common cause of hearing impairment, which accounted for 50%, 47.28% and 56.7% of cases respectively. In other studies carried out by Hatcher *et al.*,<sup>16</sup> Mann *et al.*,<sup>17</sup> Elango *et al.*<sup>18</sup> and Jacob *et al.*<sup>19</sup> reported prevalence rates of impacted ear wax ranging only from 8.6% to 29.8%.

SOM which is caused mainly due to combination of infection and eustachian tube dysfunction<sup>20</sup> falls in the second commonest cause for hearing loss in our study and also in other studies by Haddad and Snashall.<sup>21,22</sup> This could be explained by frequent upper respiratory tract infections in children in our region.

CSOM is a major health problem throughout the world in developing countries, including Nepal.<sup>23</sup> About 17.54%



prevalence of this disease in our study was explained by poor hygiene and low socio-economic status. Similar results were obtained in the study conducted by Olatoke in Nigeria.<sup>24</sup> It is the most common cause of persistent mild to moderate hearing impairment in children and young adults in the study by Biswas in Bangladesh.<sup>25</sup>

SNHL is found in 13% of cases. Providing rehabilitation in the form of hearing aids for SNHL children can reduce the handicap. The present study shows that 82.7% (283) of the children with impaired hearing suffer from a mild degree only.

Poor academic performance was observed in children with hearing impaired (significant  $P < 0.001$ ), which causes a significant effect on productivity and put burden in individual, family and society as well.

Awareness of this problem among parents and school teachers is of utmost importance to detect this disability at an early age and hence that we can provide the child the benefit of proper medical attention before the disability reaches serious proportions. Role of Pediatricians is also crucial as most of the children first attend to pediatrician. Conducting regular screening camps in schools as directed by NPPCD that includes free field voice testing and tympanometry for SOM<sup>26</sup> are highly essential. Our study can be improved further by visiting more number of schools, screening more number of children and involving parents as well.

## CONCLUSION

Hearing impairment is a major problem in early life because it affects school performance and normal social communication ability. There was a high prevalence (12.5%) of hearing loss in school children in our study. Children with hearing loss showed bad academic performance in school. Impacted wax was the most common cause of hearing loss in our study. Most of the causes for hearing loss in our study were treatable and reversible. Hence, regular screening programs for detection of hearing loss in school children, effective, and early management of ear diseases can reduce this handicap. Health education, improvement of socioeconomic status and health facilities will be helpful in reducing the prevalence of deafness.

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# A Study of Malignant Ovarian Tumors with Special Emphasis on Malignant Epithelial Tumors

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## Abstract

**Background:** Ovarian carcinoma is the common cancer among women globally as well as in India. Malignant tumor mostly occurs in older ages. Among these tumors, germ cell tumors are most common.

**Purpose:** The purpose of the present study is to highlight the interpretation of histopathological study of malignant ovarian tumors with special emphasis on malignant epithelial tumors.

**Materials and Methods:** The specimens from cystectomy, oophorectomy and hysterectomy with bilateral salpingo-oophorectomy received, were subjected for histopathological examination. Specimen were processed and stained with H & E and special staining.

**Results:** Out of 100 malignant cases, most common incidence was of epithelial tumors 72%, followed by sex cord stromal tumors 15%, metastatic tumors 7%, and germ cell tumors 6%. In malignant epithelial tumors 72 (100%) serous carcinoma is most common 54 (75%), followed by mucinous tumors 13 (18.05%), of epithelial tumors, serous tumors of low malignant potential (LMP) 2 (2.77%) and 3 (4.16%) cases were not otherwise specified. In epithelial carcinomas universal Grade 2 tumors were commonest 64.29%, followed by Grade 1, 31.4% and Grade 3 was least common 1.43%. In sex cord stromal tumors 15% were granulosa cell tumors (GCTs) and 93.33% of these were adult GCTs and only 6.66% were juvenile granulosa cell metastatic tumors constituted 7% of all ovarian tumors out of this Krukenberg tumor and metastatic adenocarcinoma were 42.85% each while metastatic squamous cell carcinoma constituted 14.28% of all metastatic tumors. Bilaterality was seen in 38% of all malignant ovarian tumors out of this primary malignant tumor was maximum in serous carcinoma 31% and metastatic tumors incidence of bilaterally was 85.71%.

**Conclusion:** In conclusion, ovarian tumors are the common neoplasms of the female genital tract. In malignant tumor of ovary majority belonged to surface epithelial group, followed by sex cord stromal tumors, metastatic tumors and germ cell tumors. Thus categorizing and histological grading of them helps us to know about clinical outcome, treatment and prognosis of patient.

**Keywords:** Malignant tumor, Ovary, Sex-cord stromal, Surface epithelial

## INTRODUCTION

Worldwide, ovarian carcinoma is sixth most common cancer in women. In most western countries, ovarian carcinoma is the fifth most common malignancy and ranks fourth in cancer mortality.<sup>1</sup> Life time risk of having ovarian

carcinoma is 1 in 70 women. Age is a common risk factor. Malignant tumors are common in older women between the age of 40 and 65 years.<sup>2</sup> Epithelial tumors are the most common comprising about 58% of all ovarian tumors and 85% of all malignant ovarian neoplasms.<sup>3</sup>

Of all the germ cell tumors, only mature teratoma is benign and most common lesion in this group. All other tumors are malignant and account for <5% of all malignant ovarian tumors. Neoplasms derived from sex-cords or mesenchyme comprises 5-12% of all ovarian neoplasms.<sup>4</sup> Metastatic tumors represent 10% of all ovarian tumours. Gastrointestinal tract, breast and uterine carcinomas frequently metastasize to the ovaries.<sup>3</sup>

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Germ cell tumors are 2<sup>nd</sup> most common and representing 15-20% of all ovarian neoplasms. Ovarian malignancy is a silent killer because the disease is usually not detected until an advanced stage. The best tools currently available for detecting early- state ovarian cancer are transvaginal sonography (TVS) and serum biomarker testing and the most well studied ovarian cancer biomarker is CA-125.<sup>5</sup> Traditional management of advanced ovarian carcinoma is surgical de-bulking, followed by chemotherapy; however there is an increasing tendency for neoadjuvant chemotherapy, followed by surgery.<sup>6</sup> It was found that histological grade and size of the residual tumor after surgery are the most important factors influencing the survival.

In the present study, an attempt has been made to find out various histological types of malignant ovarian tumors and grading the ovarian adenocarcinoma according to universal grading system.

## MATERIALS AND METHODS

This study was hospital based prospective study, which was carried out in the Department of Pathology, Sardar Patel Medical College and Associated Group of Hospitals, Bikaner including all clinically suspected and microscopically verified cases of malignant ovarian tumor.

The material for study will comprise of:

**Biopsy:** From surgical sample includes cystectomy, oophorectomy and hysterectomy with bilateral salpingo-oophorectomy.

**Sample size:**

A sample of 100 cases of ovarian mass was taken for this study.

**Inclusion criteria:**

1. Patients of all ages
2. All new and undiagnosed cases which are malignant in nature on histopathological examination.

**Exclusion criteria:**

1. Patients presenting with benign nature of lesion
2. Inconclusive biopsy material
3. Benign tumor or inflammatory lesion on histopathological examination.

Cases fulfilling the laid down criteria were included in the study. After obtaining informed consent, detailed history was taken. Clinical examination of each case was carried out. Most of the cases had an ultrasonographic (USG)

examination of the ovarian mass and serum CA-125 estimation before advising surgery.

These biopsies will be received in 10% formalin. Gross features of the specimens received will be recorded and representative sections taken and processed. Then staining will be carried out with hematoxylin and eosin (H and E) stain and/or special stain when required.

## RESULTS

Total 100 cases of ovarian malignancy were diagnosed on histopathological study and these were studied in relation to age distribution pattern, histopathological features and classified according to WHO classification.

Age range of malignant ovarian tumor was 4-80 years with mean age of  $46.83 \pm 13.69$ . Peak incidence was seen in 41-60 years with 62 cases in this age group. Epithelial tumors, sex cord tumors, germ cell tumors and metastatic tumors are most frequent between 41 and 60 years with mean age of  $48.29 \pm 11.21$ , 51-70 years of age with mean age of  $52.2 \pm 16.87$ , 11-20 years with mean age of  $20.16 \pm 7.4$ , 31-50 years with mean age of  $43.14 \pm 8.41$  years, respectively.

Of 100 malignant cases, frequency of different malignant ovarian tumors according to WHO classification were most common incidence was of epithelial tumors 72, (72%), and next frequent was sex cord stromal tumors 15, (15%) and then metastatic tumors 7, (7%) and germ cell tumors 6, (6%).

In malignant epithelial tumors 72 (100%) serous carcinoma is most common group constituting 54 (75%), followed by mucinous tumors constitute second most common group forming 13 (18.05%) of epithelial tumors. serous tumors of LMP constitute 2 (2.77%) of all malignant epithelial tumors and 3 (4.16%) cases were not otherwise specified either into serous or mucinous carcinoma.

Incidence of Grade 2 tumors is maximum (64.28%), followed by Grade 1 (31.43%) and Grade 3 (1.43%). Grading of 2.86% tumors was not determined.

Malignant sex cord stromal tumor constitute 15 (15%) of all malignant ovarian tumors. Adult granulosa cell tumors (GCTs) are 14 (93.33%) and Juvenile GCTs were 1 (6.66%) of all GCTs. In our study one case of juvenile GCT was detected in 18 years old girl.

Malignant germ cell tumors in index study constitutes 6, (6%) of all malignant ovarian tumors. Dysgerminoma is the most common malignant germ cell tumor constituting 4 (66.66%) of all malignant germ cell tumors, followed



by yolk sac tumor and immature teratoma constituted 1, (16.66%) each.

In metastatic common tumor was Krukenberg tumors and metastatic adenocarcinoma each form 3, (42.85%) of all metastatic tumor. One case of metastatic squamous cell carcinoma was detected forming 1, (14.28%). In our study 52, (52%) cases were cystic + solid, 30 (30%) were solid and 18 (18%) were cystic.

## DISCUSSION

### Ovarian Cancer

#### Epidemiology

Worldwide ovarian cancer is the sixth most common cancer in women. In the western hemisphere it accounts for 4% of cancer in women and is the most frequent cause of death from gynecologic cancer. Annual incidence rates of ovarian carcinoma range from <5/1,00,000 women in Brazil, Thailand, India to >13/1,00,000 in UK, United States, Germany, Norway, Denmark, Sweden. In general, the disease is more common in industrialized countries.

Epithelial ovarian carcinoma is predominantly a disease of peri-menopausal and postmenopausal women with 80 to 90% of ovarian cancer occurring after the age of 40.<sup>12</sup>

Age is a major risk factor.

In 2009 Wasim *et al.*, studied 110 patient and found mean age of malignancy was  $49.07\% \pm 18.5$  years.<sup>4</sup>

In 2002 Bhurgri *et al.* studied 337 cases of ovarian malignancy and concluded that mean age was 45.7 years. He detected 11% cases of childhood cancer, 13% cases of adolescents, 37.4% cases in reproductive age group and 55.8% cases in 45+ age group and concluded that incidence of malignancy increases with age.<sup>7</sup>

#### Clinical Features

Most women with ovarian cancer report one or more symptoms such as abdominal pain or discomfort, an abdominal mass, bloating, back pain, urinary urgency, constipation, tiredness, and a range of other nonspecific symptoms as well as more specific symptoms such as pelvic pain, abnormal vaginal bleeding or involuntary weight loss.<sup>8</sup>

#### Grading of Epithelial Carcinoma<sup>9</sup>

The histopathologic grade of epithelial ovarian carcinoma generally had been found to be a prognostic factor. The recently developed universal grading system addresses some of these limitations. Although still cumbersome, it is reproducible. It is based upon architectural pattern, nuclear pleomorphism and mitotic figure counts per high-power field.

#### Criteria for grading of ovarian adenocarcinoma according to universal grading system

Score	Architecture	Atypia	MF/10 HPF
1	Glandular	Slight	0-9
2	Papillary	Moderate	10-24
3	Solid	Marked	>25

HPF: High-power field

Grade 1 = 3-5 points

Grade 2 = 6 or 7 points

Grade 3 = 8 or 9 points

In 2006, Surowiak *et al.*, studied 43 cases of malignant epithelial tumors and found 16% cases were Grade 1, Grade 2 and Grade 3 were 42% each.<sup>10</sup>

In 2011 Deniz and Sezen studied 71 serous tumors and found 28 cases as carcinoma. Among these 28 cases highest frequent was Grade 2 tumors (42.85%), next frequent was Grade 1 (32.14%), and Grade 3 was least common (25%).<sup>11</sup>

#### Malignant Sex Cord Stromal tumors

In 2000, Ahmed *et al.* concluded that in sex cord stromal tumors, GCT is the commonest and adult GCTs constitute 87.5% of all GCT and Juvenile GCT, constitute 12.5% of all tumours.<sup>12</sup>

In 2004 Isabell studied ovarian tumors of sex-cord stromal origin and concluded that GCT is the most common tumor. Among juvenile and adult types, adult GCT constitute 95% of tumors and these tumors almost always contain theca component.<sup>13</sup>

#### Germ cell Tumours

In 2000, Breen *et al.* studied ovarian malignancies in children and found that germ cell tumors constitute 70% of all ovarian tumors in children. Among germ cell tumors, dysgerminoma is most common. Average age at the time of detection is 22 years.<sup>7</sup>

In 2001 - Gerardo *et al.* studied 169 women with malignant germ cell tumors and found 70 cases of dysgerminoma, 28 endodermal sinus tumor, 24 mixed tumor and 47 immature teratoma.<sup>14</sup>

In 2009, Basu *et al.* studied 202 patients and found a mean age of the patient with germ cell tumor was  $26.0 \pm 12.9$  years.<sup>15</sup>

#### Metastatic Carcinoma

In 2002, Holtz and Wheelock studied 27 cases of Krukenberg tumors. All cases were characterized by presence of mucinous signet ring cells in cellular non-neoplastic ovarian stroma. The patient mean age was 20-70 years, half

**Table 1: Grading of malignant epithelial tumours according to universal grading system**

Grade	Malignant epithelial tumours (%)
Grade 1	22 (31.43)
Grade 2	45 (64.28)
Grade 3	1 (1.43)
Not determined	2 (2.86)
Total	70 (100)

**Table 2a: Grading of serous carcinoma (n=54))**

Grade	Serous carcinoma (%)
Grade 1	13 (20.07)
Grade 2	40 (74.07)
Grade 3	1 (1.85)

**Table 2b: Grading of mucinous carcinoma (n=13)**

Grade	Mucinous carcinoma (%)
Grade 1	8 (61.54)
Grade 2	5 (38.46)
Grade 3	0

**Table 3: Distribution of bilaterally in various malignant ovarian tumours**

	Bilateral (%)	Unilateral (%)	Total (%)
Malignant epithelial tumours			
Serous tumour of LMP	-	2	2
Serous carcinoma	30 (50.55)	24 (44.44)	54 (100)
Mucinous carcinoma	1 (7.69)	12 (92.30)	13 (100)
Adeno carcinoma (NOS)	-	3	3
Total	31 (43)	41 (56.94)	72 (100)
Malignant sex cord tumor			
Granulosa cell tumor	1 (6.66)	14 (93.55)	15 (100)
Total	1	14	15
Germ cell tumor	-	6	6
Metastatic tumors			
Krukenberg	3	-	3
Metastatic SCC	1	-	1
Metastatic adeno carcinoma	2	1	3
Total	6 (85.71)	1 (14.28)	7 (100)
Grand total	38 (38)	62 (62)	100

LMP: Low malignant potential, SCC: Squamous cell carcinoma

were 40 years or younger. A primary carcinoma of stomach (16 cases) and colon (4 cases) were found.<sup>16</sup>

### Prognostic Factors

For survival prognostic factors are age, stage, histology, grade, volume of ascites, performance status, molecular markers, CA-125, postoperative tumor mass, lymph node status and newer molecular biological factors as Her-2 status, plasminogen activator inhibitor-1, matrix metalloproteinases, vascular endothelial growth factor and CD24.

**Table 4: Distribution according to calcification/psamomma bodies in malignant ovarian tumors**

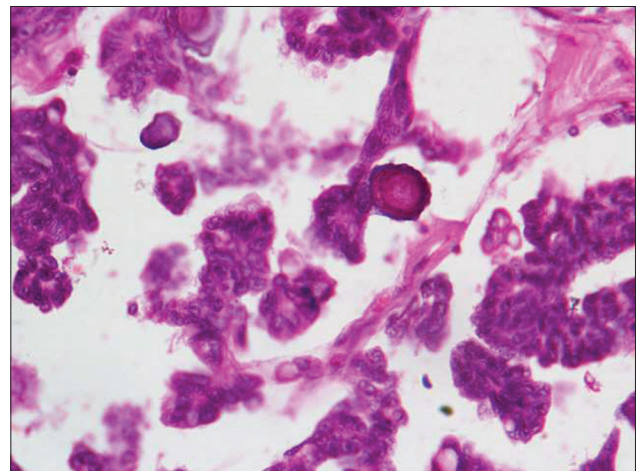
	Number of cases with calcification (%)	Total (%)
Malignant epithelial tumor		
Serous tumors of LMP	1	2
Serous carcinoma	20 (37.03)	54 (100)
Mucinous carcinoma	-	13
Adeno carcinoma (NOS)	-	3
Total	21 (29.16)	72 (100)
Sex cord tumor	1	15
Germ cell tumor	-	6
Metastatic tumour	-	7
Grand total	22	100

LMP: Low malignant potential

**Table 5: Incidence of metastasis in various malignant ovarian tumors**

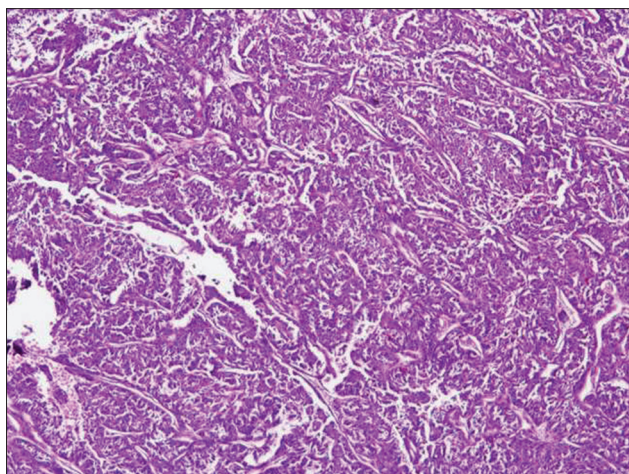
	Number of cases with metastasis (%)	Total (%)
Malignant epithelial tumor		
Serous tumor of LMP	-	2
Serous carcinoma	22	54
Mucinous carcinoma	1	13
Adenoma carcinoma (NOS)	-	3
Total	23 (31.94)	72 (100)
Germ cell tumor		
Dysgerminoma	-	4
Yolk sac tumor	1	1
Immature teratoma	-	1
Total	1 (16.66)	6 (100)
Sex cord stromal tumor	-	15
Metastatic tumor	-	7
Grand total	24 (24)	100 (100)

LMP: Low malignant potential

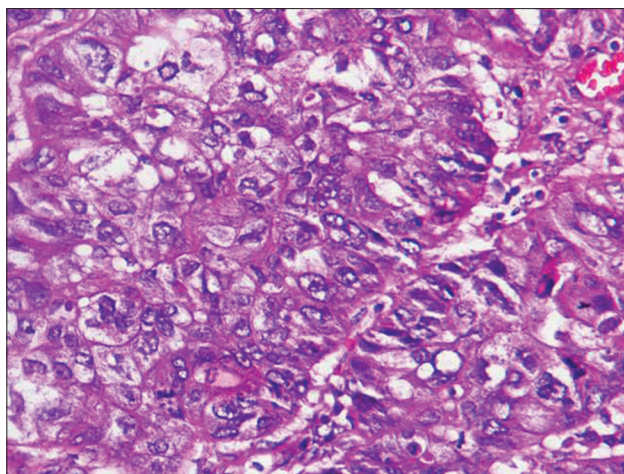
**Figure 1: Serous tumor of low malignant potential shows presence of psamomma bodies in cyst wall (H and E, 40x)**

The tumor marker CA-125 one of the most extensively studied and useful molecular marker. At an upper limit normal cut-off of 35 U/ml, CA-125 achieves a sensitivity of 78.3% and a specificity of 82%. However, the drawback

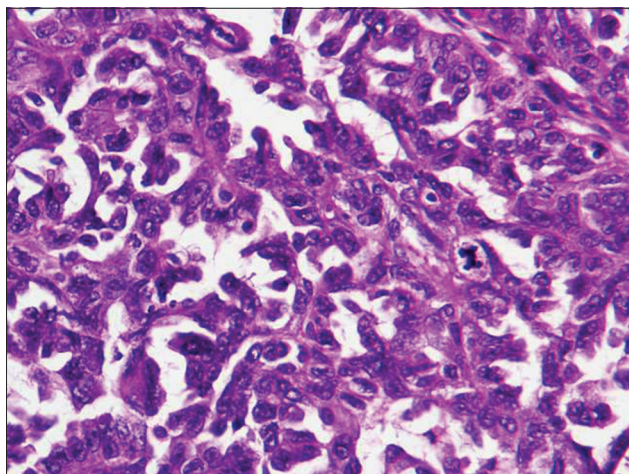




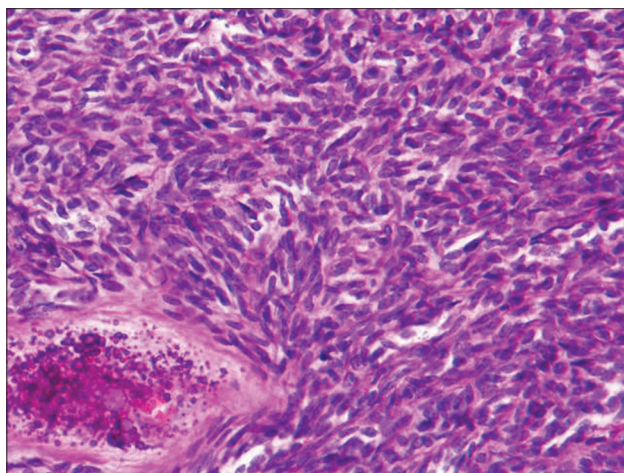
**Figure 2: Serous CA (Grade 2) with papillary pattern (H and E, 4x)**



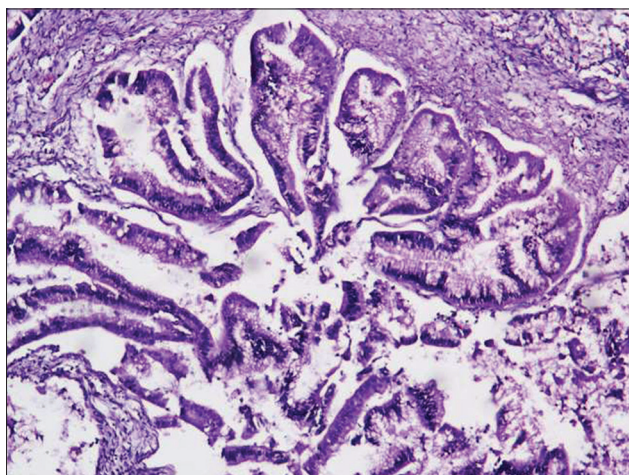
**Figure 5: Serous carcinoma showing marked pleomorphism in nuclei (40x)**



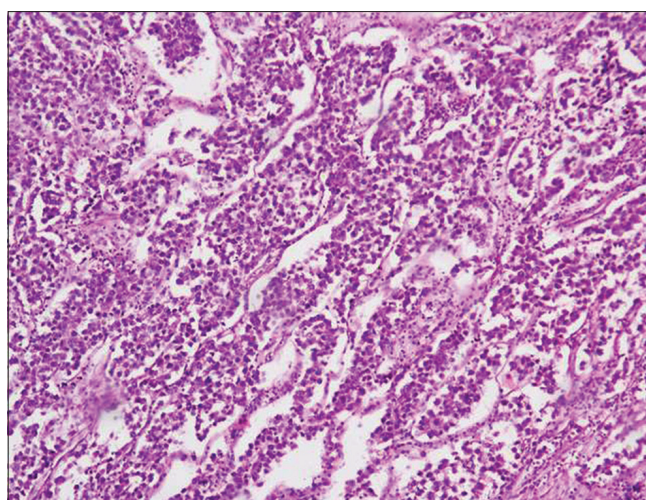
**Figure 3: Section shows moderate pleomorphism in nuclei and presence of mitotic figure (H and E, 40x)**



**Figure 6: Granulosa theca cell tumor with calcification (40x)**

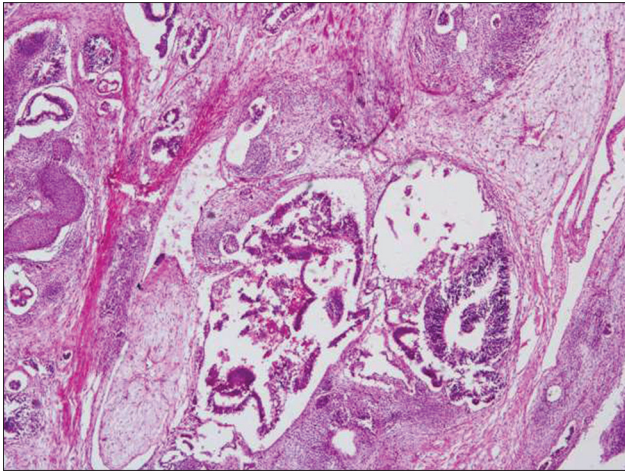


**Figure 4: section shows mucinous carcinoma with glandular pattern and presence of intestine type lining in gland (H and E, 10x)**

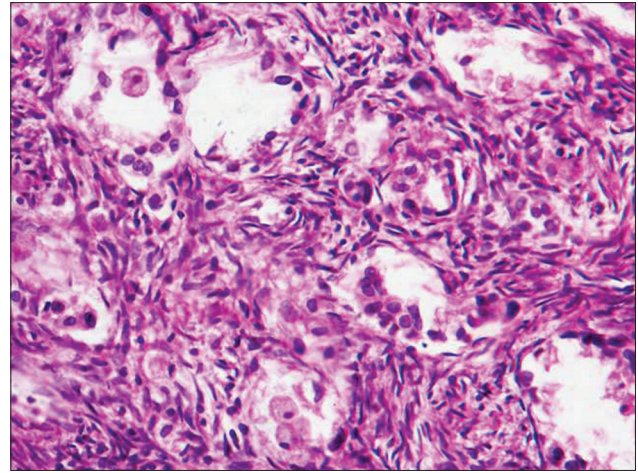


**Figure 7: Dysgerminoma tumor cells and lymphocytes (H and E, 10x)**

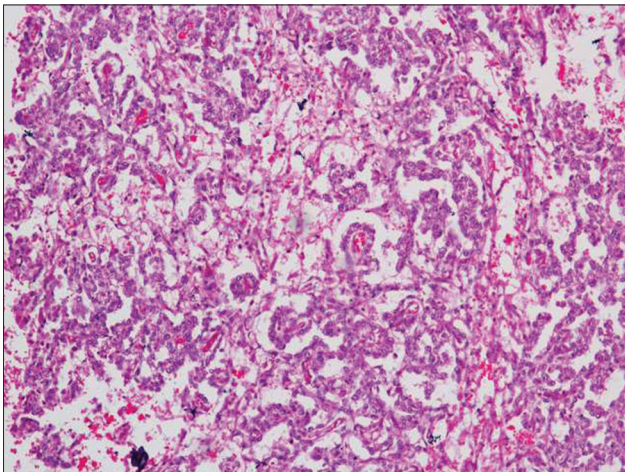




**Figure 8: immature teratoma showing neuroepithelium (H and E, 10x)**



**Figure 10: Signet ring cell in stroma of Kurkenberg tumor (H and E, 40x)**



**Figure 9: Yolk sac tumor showing presence of schiller duval body and hyaline globules (H and E, 10x)**

is that it is not absolutely specific. TVS provide higher resolving power for ovarian abnormalities than trans-abdominal USG.

## CONCLUSION

In conclusion ovarian tumors are the common neoplasms of the female genital tract. In malignant tumor of ovary majority belonged to surface epithelial group followed by sex cord stromal tumors and then metastatic tumors and germ cell tumors. Thus, categorizing and histological grading of them helps us to know about clinical outcome, treatment and prognosis of patient.

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# Computed Tomography Evaluation of Intracranial Space Occupying Lesions in Adults

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## Abstract

**Introduction:** Neoplasms of the brain present a remarkably diverse spectrum of growths. Computed tomography (CT) has now become the primary imaging modality for intracranial space occupying lesions (SOL) with efficacy of 90-98%.

**Aim:** The aims and objectives of this study are to know the frequency of occurrence of various intracranial SOL in adults and to analyze the CT brain scan data to determine the diagnostic sensitivity and specificity of CT.

**Materials and Methods:** A total of 100 cases of intracranial SOL were studied in patients above the age group of 18 years. Patients were followed up over a period of 2 years for histological co-relation. Data collected was analyzed with review of the literature.

**Results:** This review has indicated that intracranial SOL often show characteristic features on CT that help in making a confident diagnosis. It is possible to attempt grading of the tumor with a fair degree of reliability.

**Conclusion:** CT assessment supported by a sound understanding of clinical etiology and neuropathology helps to differentiate between those non-neoplastic SOL which may mimic a brain tumor. It provides an easy and effective mode for close monitoring of response to antibiotic and anti-tuberculous therapy resulting in significantly improved clinical results. Accurate determination and precise localization allow confident timing and choice of surgical approach in patients of intracranial SOL.

**Keywords:** Adults, Computed tomography, Intracranial space occupying lesions

## INTRODUCTION

The neoplastic disease of brain present a remarkably diverse spectrum of growths arising from brain tissues, it's coverings, cranial nerves, intracranial embryonic remnants, vascular elements, the pituitary gland and metastases from tumors at other sites. Neoplasms of brain are challenging areas for diagnosticians for a number of reasons. First, a large number of patients have already a large growth by the time they present. This is so because the patient generally has a long history of

relatively trivial and nonspecific complaints. Moreover certain areas of the brain are clinically silent and permit growth of tumor to a large size before any signs manifest. Second, they rarely metastasize to peripheral locations outside intracranial cavity. And thirdly many of the essentially benign lesions behave as malignant, by virtue of their strategically inaccessible locations. The advent of computed tomography (CT) revolutionized the neuroradiological practice. Since it's early development CT has undergone rapid evolution, in the form of technical finesse, and has now become the primary imaging modality for intracranial space occupying lesions (SOL) with efficacy of 90-98%.<sup>1</sup> Despite increasing the health care expenditures, CT has proven to be cost effective.<sup>1</sup> In those centers where magnetic resonance imaging is available, it may be preferred to CT because it involves no ionizing radiation and because it has distinct advantages over CT in certain areas. However, it's used is still limited by cost and availability.

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## Aim

The study was carried out to evaluate patients clinically suspected of having an intracranial SOL, on the basis of data from the history and neurological examination, by CT as a baseline investigation. The aims and objectives of the study are to know the frequency of occurrence of various intracranial SOL in adults and to analyze the CT brain scan data in intracranial SOL in reference to attenuation, enhancement, calcification and locations etc. and hence to determine the diagnostic sensitivity and specificity of CT when a tumor is suspected.

## MATERIALS AND METHODS

The present study was conducted in the Department of Radiology, CT scan section, of Government Medical College, Nagpur over a period of 2 years. A total of 100 cases of intracranial SOL were studied in patients above the age group of 18 years. All those patients suspected of having an intracranial SOL on the basis of clinical details were subjected to CT scan of the head as the first line of investigation. CT criteria for all the patients were kept the same. A third-generation scanner Shimadzu XCT 3000 was used. Standard CT head parameters were employed. The data were augmented using coronal sections and sagittal and oblique reconstructions. Both plain and post-contrast evaluation was done. Low iodinated contrast agent was used in the dose of 40-50 cc as a rapid bolus injection. The clinic- radiological findings were recorded as follows:

Mass: Size, site, density (hyperdense, hypodense, isodense, mixed), necrosis, cystic changes, calcification, hemorrhage.

Mass effect: Perifocal edema, ventricle compression/distortion, herniations (subfalcine, ascending/descending tentorial, tonsillar)

Contrast enhancement: Density, pattern (homogenous, heterogeneous, ring/whorl, nodular)

Bony changes: Erosion, hyperostosis

Finally, these patients were followed up over a period of 2 years for histological co- relation. Data thus generated was compared with a review of the literature.

## RESULTS

Histopathological co-relation was obtained in 72% of cases. Remaining 28% of cases included those patients with a centrally located deep-seated mass, in whom surgical intervention was not possible, and those patients with

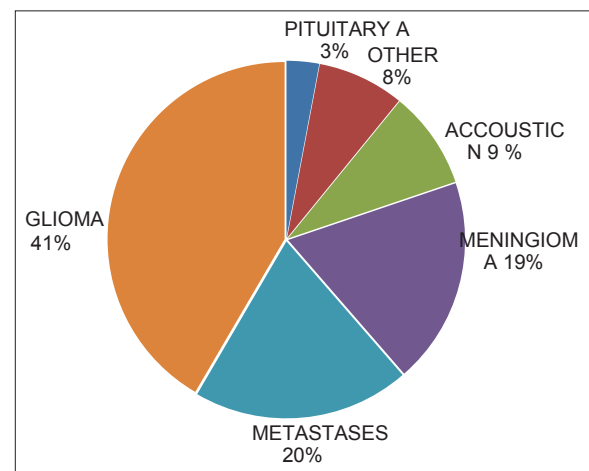
tuberculomas in whom the diagnosis was confirmed on the basis of response to anti-tuberculosis therapy (Table 1).

Thus, gliomas formed the maximum number of cases recording a percentage of 41%, followed by metastases 20% and meningiomas 18% (Figure 1). A slight overall male preponderance of 1.6 over females was noted. Majority of brain tumors occurred in second and fourth decades, (26% and 23 % respectively). The youngest patient in this series was 18 years old while the oldest was 79 years old. Maximum number of SOL (68%) were located in the supratentorial compartment. The most common infratentorial tumor seen besides glioma was acoustic neuroma (Table 2).

Astrocytomas formed the major group of gliomas constituting 66.6% cases (Table 3). On precontrast CT most of the Grade I astrocytomas (85%) were hypodense, whereas most of the Grade III astrocytomas showed mixed density pattern (Figure 2). Following contrast injection

**Table 1: The analysis of 100 cases in the present study showed following results**

Diagnosis	No. (%)
Neoplastic	79 (79)
Gliomas	33 (41)
Metastases	16 (20)
Meningioma	15 (18)
Acoustic neuroma	7 (8)
Pituitary adenoma	2 (2.5)
Craniopharyngioma	3 (3)
Others	
Pineal tumor	1 (1)
Epidermoid	1 (1)
Chordoma	1 (1)
Non-neoplastic	21 (21)
Granuloma	16 (16)
Abscess	5 (5)
Total	100



**Figure 1: Incidence of brain tumors in adults**

94% of gliomas showed enhancement. Several patterns of enhancement were seen, most common being whorl enhancement seen in 38.7% of cases most of which belonged to Grade III astrocytoma (Figure 3).

About 81.8% of gliomas showed mass effect, while the remaining did not, which were mostly low Grade (i.e., I and II) astrocytomas while one was Grade III astrocytoma. All the cases of ependymoma (Figure 4) and glioblastoma multiforme (Figure 5) showed varying degrees of ventricular distortion and hydrocephalus. Most of the Grade III astrocytomas showed mass effect in the form of internal herniations. The lone case of oligodendroglioma caused displacement of ipsilateral ventricle and dilatation of contralateral.

In this study, 62.5% of the metastases were multiple while the remaining were solitary. Most of them were hypodense on plain scans. All the metastatic tumors enhanced intensely following contrast administration. Ring enhancement pattern was dominant and was seen in 56% of cases. Cerebral edema of mostly moderate to extensive severity was seen in all (100%) of the cases.

Most of the tuberculomas found in the study were supratentorial (75%), solitary (56%) and hyperdense (62.5%) on pre-contrast scans. Ring enhancement was seen in 87.5% of cases. 5 cases of cerebral abscesses were included in the series as they caused perifocal edema, ventricular distortion and enlargement.

**Table 2: Location of various tumor types**

SOL	Location		
	Central	Supratentorial	Infratentorial
<b>A. Neoplastic</b>			
Glioma	-	25	08
Meningioma	-	12	03
Metastases	-	12	04
Acoustic neuroma	-	-	07
Craniopharyngiomas	03	-	-
Miscellaneous	04	01	-
<b>B. Non-neoplastic</b>			
Granuloma	-	14	01
Abscess	-	04	01
Total	07	68	25

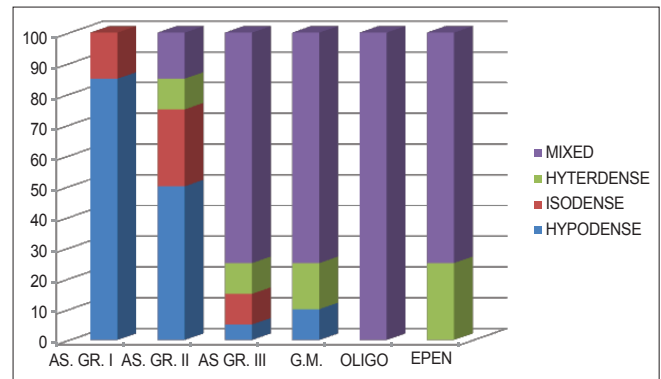
SOL: Space occupying lesions

**Table 3: Frequency of various tumor types in gliomas**

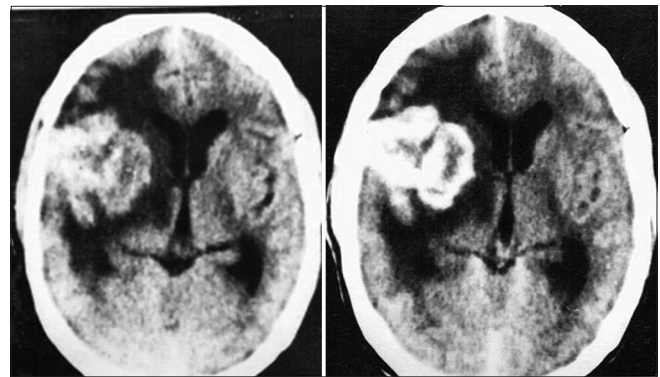
Tumor type	No. of cases	Percentage
Astrocytoma-Grade I	04	12
Astrocytoma-Grade II	08	12.5
Astrocytoma-Grade III	10	30.3
Glioblastoma multiforme	05	15
Oligodendroglioma	01	03
Ependymos	05	15

## DISCUSSION

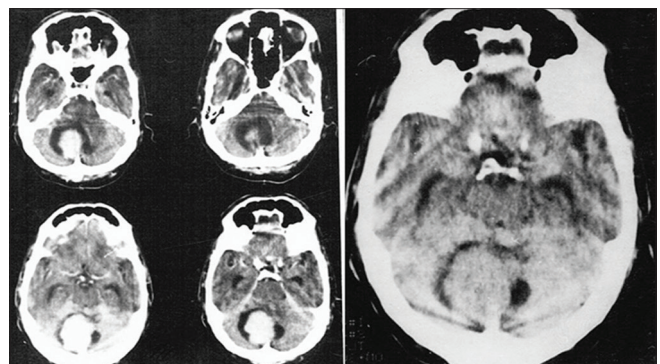
An incidence of 79% neoplastic and 21% non-neoplastic SOL was noted in this series. Thus a slightly higher incidence of infective non-neoplastic SOL was noted in the present series as compared to earlier studies of Davis *et al.*<sup>2</sup> Of the neoplastic SOL, gliomas formed the largest group and were seen in 41% of cases in our study, which is slightly higher than the 31% incidence found by Zimmerman *et al.*<sup>3</sup> Sex distribution in 100 patients studied showed a slight (62%) male preponderance over females (38%). Although an overall male preponderance



**Figure 2: Density patterns in gliomas**



**Figure 3: Glioma showing whorl enhancement and perifocal edema**



**Figure 4: 4<sup>th</sup> ventricle ependymoma**

in the study was seen, however a female preponderance was seen in cases of pituitary adenomas. Both the cases of pituitary adenomas in this series were female. Naidich *et al.*<sup>4</sup> in their study of sellar and parasellar regions also found similar results. Maximum number of cases in our study were found in the 2nd and the 4th decade. New *et al.*<sup>5</sup> found the peak incidence at a slightly latter age group of 5<sup>th</sup> and 7<sup>th</sup> decades. The relatively lower age incidence found in India could be related to younger mean age of the population of India.<sup>6</sup> Maximum number (66.6%) of gliomas found were of Grade III astrocytoma (Kernohan's classification). In Thompson's<sup>7</sup> series of 100 histologically proven gliomas also higher grade gliomas predominated (65%). On precontrast scans a mixed density pattern of high and low attenuation was seen in 89% of the cases, of which 67% were astrocytoma Grade II and III, 15% glioblastoma multiforme and 15% astrocytoma Grade I. However Ethier *et al.*<sup>8</sup> found that majority of Gliomas presented as low density lesions. Calcification was seen in predominantly low grade gliomas, the incidence was comparable to that reported in literature (Table 4).<sup>7,9</sup> Following contrast administration 94% of the Gliomas showed enhancement. The 6% cases which did not enhance were Grade I and Grade II astrocytomas. Enhancement patterns are reported as quite variable in the literature, with nearly equal numbers of authors reporting the lesions as homogenous, inhomogenous or

ring enhancing.<sup>7</sup> 60% of the ependymomas in the present series were hyperdense while 40% exhibited mixed density. Irregularly speckly calcification was seen in 25% and dense homogenous enhancement was seen in all those which were hyperdense on pre-contrast scans, while the remaining exhibited mixed patchy enhancement. At great variance are the findings of Armington *et al.*<sup>10</sup> Cerebral metastases formed 20% of the neoplastic SOL in this study. 37% of the secondaries were single while 62.5% were multiple. Bilaniuk *et al.*<sup>11</sup> reported 14-35% of secondaries as solitary, moreover they also claimed that secondaries from renal cell carcinoma and carcinoma breast were more after solitary. However both the cases of secondaries from carcinoma breast in this study were multiple. 80% of the metastases were hypodense on pre-contrast scans and 20% were hyperdense (Table 5 and Figure 6). Of the hyperdense variety one was from chronic carcinoma while two were from unknown primary. Ring enhancement was seen in 56.4% cases in our study while the rest showed diffuse homogenous enhancement. Chang *et al.*<sup>12</sup> have found a co-relation between the initial unenhanced density of metastases and their enhancement following contrast administration. According to them higher the initial density, lesser is the enhancement, more hypodense a lesion more florid is its enhancement. However this was not noted in our study, as the single case of secondary from chorionic carcinoma in this series which was hyperdense on plain scan, also enhanced greatly following contrast administration. All the above studies have reported extensive perifocal cerebral edema and associated mass effect with secondaries, and it was seen

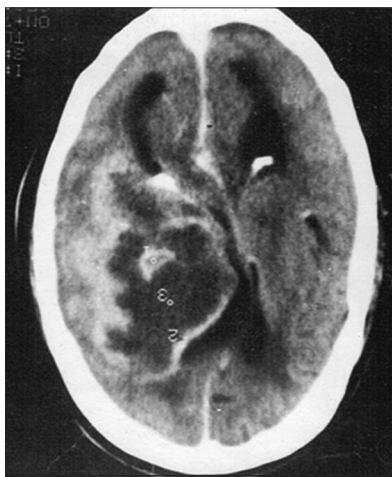


Figure 5: Glioblastoma multiforme causing mass effect

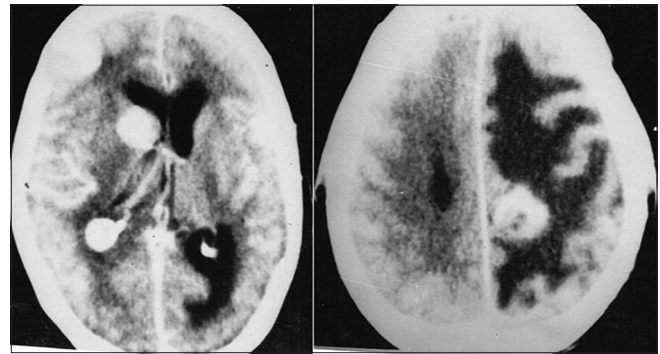


Figure 6: Metastases

Table 4: Presence of calcification in gliomas

Tumor type	No. of cases	Percentage
Astrocytoma-Grade I	04	12
Astrocytoma-Grade II	08	24.5
Astrocytoma-Grade III	10	30.3
Glioblastoma multiforme	05	15
Oligodendroglioma	01	03
Ependymoma	05	15

Table 5: Density patterns of various secondaries on precontrast CT

Metastases	Hyperdense	Hypodense
Carcinoma bronchus	-	4
Carcinoma breast	-	2
Choriocarcinoma	1	-
Squamous cell carcinoma	-	1
Unknown primary	2	6

CT: Computed tomography



in 100% of cases in our study. Meningiomas formed 18% of the cases in this study and were scattered evenly between 3<sup>rd</sup> and 6<sup>th</sup> decade (Table 6). In the present series, most of the cases (93%) were hyperdense on initial plain scans (Figure 7). One case exhibited a central hypodensity. Dense enhancement was shown by all, which was homogenous in all but one case, where the central hypodensity failed to opacify. Mild to moderate perifocal edema was exhibited by 60% of the cases. Similar findings were reported by Budzilovich *et al.*<sup>13</sup> Hyperostosis was seen in 20% of convexity meningiomas. No literature regarding the exact incidence of hyperostosis among meningiomas could be elicited. Eight cerebellopontine (CP) angle tumors (11%) were seen of which seven cases (87.5%) were acoustic neuromas (Figure 8) and one 12.5% epidermoid (Table 7). Majority of cases (85%) were hypodense on initial scans and showed homogenous enhancement following contrast administration. Naidich *et al.*<sup>14</sup> review of posterior fossa extra-axial masses revealed widening of IAM in 65 of the cases in our study it was seen in 57% of the cases (Figure 9). The single case of epidermoid seen in the present series was found in CP angle, in second decade and was hypodense on plain scan with attenuation of 15 HU. It showed small nodule of calcification around the rim and did not enhance on post contrast CT. Findings of pituitary adenomas and craniopharyngiomas in this series were found to be not

unlike those of Naidich *et al.*<sup>14</sup> series of 84 sellar and parasellar masses. No evidence of sellar hyperostosis reported by them in cases of pituitary adenoma was seen in the present series. A single case of pineal germinoma found in this series could not be diagnosed on CT. On CT a diagnosis of craniopharyngioma was kept with the findings of mixed attenuation suprasellar mass, showing heterogeneous calcification and patchy enhancement. Of the 21% non-neoplastic SOL, tuberculomas were seen in 76% of cases while abscesses accounted for 24% of cases. The overall incidence of tuberculomas among 100 intracranial SOL studied was 20%, however in a study conducted in Britain they were found in 0.15%.<sup>15</sup> Thus, the

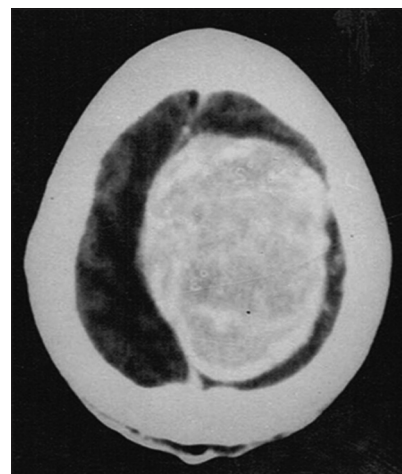


Figure 7: Meningioma: Hyperdense on plain scan

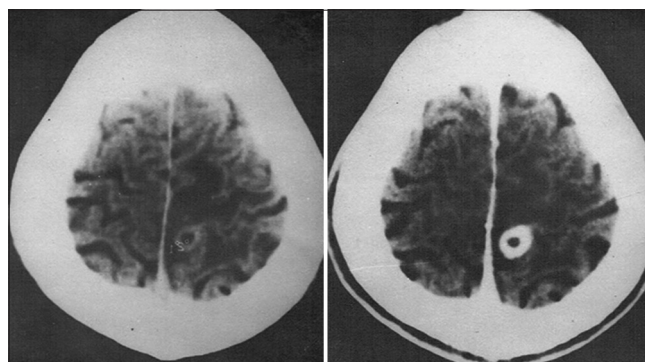


Figure 8: Tuberculoma

**Table 6: Various CT features of 15 cases of meningiomas**

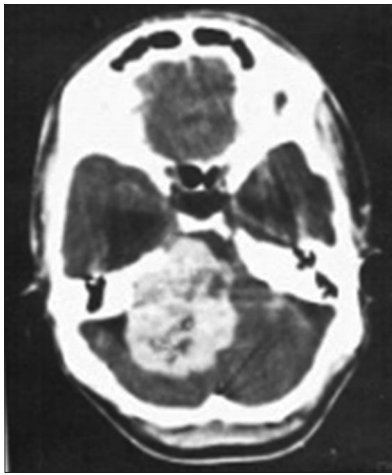
	CT features	No. of cases	Percentage
I	Density		
	Hyperdense	14	93
	Central hypodensity	1	7
II	Enhancement		
	Homogenous	13	87
	Mixed	2	13
III	Perifocal edema		
	Present	9	60
	Absent	6	40
IV	Mass effect	13	80
V	Bony changes		
	Hyperostosis	3	20

CT: Computed tomography

**Table 7: CT features of miscellaneous tumors**

Tumors	No.	Density				Calcification	Mass effect	Enhancement				Site	Bone changes
		Hypo	Iso	Hyper	Mixed			Homo	Patchy	Ring	None		
Acoustic neuroma	7	6	-	-	1	-	5	5	1	1	-	CP angle	*
Craniopharyngioma	3	-	-	-	3	3	3	-	3	-	-	Central	**
Pituitary adenoma	2	-	1	1	1	-	1	2	-	-	-	Sellar	***
Pineal (germinoma)	1	-	-	1	-	+	+	-	+	-	-	Suprasellar	-
Epidermoid	1	+	-	-	-	+	-	-	-	-	+	CP angle	****
Chordoma	1	-	-	-	-	+	+	-	+	-	-	Supra sellar	**

\*Widening of IAM, \*\*Erosion of post clinoids, \*\*\*Widening and erosion of sella, \*\*\*\*Erosion of petrous apex, CT: Computed tomography



**Figure 9: Acoustic neuroma causing widening of internal auditory canal**

incidence of tuberculomas in India is still fairly high when compared to other countries. Patterns of enhancement of tuberculosis as described by Whelan *et al.*<sup>16</sup> were seen to occur in this series also with predominantly ring enhancement seen in 87% of cases.

## CONCLUSIONS

This review has indicated that intracranial SOL often show characteristic features on pre-contrast CT and a range of patterns on post-contrast study that help in making a confident diagnosis. CT scan provides improved visualization and allows an assessment of the grading of tumor with a fair degree of reliability. CT assessment supported by a sound understanding of clinical etiology and neuropathology helps to differentiate between those non neoplastic SOL, which may mimic a brain tumor. It provides an easy and effective mode for close monitoring of response to antibiotic and anti-tuberculous therapy resulting in significantly improved clinical results. Accurate determination and precise localization allows confident

timing and choice of surgical approach in patients of intracranial SOL.

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# Hepatic Biochemical Parameters Changes in *Plasmodium falciparum* malaria

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## Abstract

**Introduction:** Malaria is one of the most common parasitic diseases in the tropical countries. On an average 30-35% cases of malaria are due to *Plasmodium falciparum* and hepatic involvement is quite common, but information in urban Bangalore is very limited, hence this study was carried out. The objective of this study was to see the changes in hepatic biochemical parameters and to understand the pathogenesis in *P. falciparum*.

**Materials and Methodology:** Serum aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase activities, bilirubin (total and direct) i.e., total bilirubin and direct bilirubin, total protein (TP) and albumin (ALB) levels were assayed in 50 patients presenting with *P. falciparum* malaria infection and 50 subjects without malaria infection were measured using auto analyzer Beckman Coulter Synchron DxC by using Beckman Coulter Kits (USA). Patient selection was done by simple random sampling from those presenting at Vydehi Institute of Medical Sciences and Research Centre, Bangalore, with a history of fever, chills and malaise and who were subsequently confirmed to be malaria positive by Giemsa stained peripheral blood film.

**Results:** The study shows, increase in the values (except ALB and TP) for *P. falciparum* infected patients were significant ( $P < 0.001$ ) when compared with the values for the non-infected subjects.

**Conclusion:** Evidence from this data indicates a measure of liver dysfunction and a higher incidence of jaundice and predominantly of conjugated hyper-bilirubinemia.

**Keywords:** Bilirubin, Liver, Malaria, *Plasmodium falciparum*, Transaminases

## INTRODUCTION

Malaria continues to pose a major public health threat in India, particularly due to *Plasmodium falciparum* that is prone to complications. In India about 27 percent population lives in malaria high transmission (>1 case/1000 population) areas and about 58% in low transmission (0-1 case/1000 population) areas.<sup>1</sup> The most affected states are North-eastern states, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa, Andhra Pradesh, Maharashtra, Gujarat, Rajasthan, West Bengal and Karnataka. However, the other states are also vulnerable with local and focal outbreaks of malaria. Much of these areas are remote and inaccessible, forest or

forest-fringed with operation difficulties and predominantly inhabited by tribal population.<sup>2</sup>

Karnataka is one among the most affected states, and Bangalore is one of the 15 major cities including four metropolitan cities that account for nearly 80% of malaria cases covered under urban malaria control schemes. Malaria is one of the most common parasitic diseases in tropical countries characterized by febrile paroxysm occur with definite intermittent periodicity repeating every 3<sup>rd</sup> or 4<sup>th</sup> day depending upon the species of the parasite involved.<sup>3</sup> Malaria is a disease transmitted by the female Anopheles mosquito. The disease is caused by protozoan parasites of the genus Plasmodium. Four species of the Plasmodium parasite can infect humans.<sup>4</sup> In India, 60-65% cases of malaria are due to *Plasmodium vivax* and 30-35% cases are due to *Plasmodium falciparum*.<sup>5</sup> Although *P. vivax* infections are more common, worldwide, *P. falciparum* malaria represents the most serious public health problem due to its tendency toward severe or fatal infections.<sup>6</sup> Malarial transmission to the human host is established by sporozoites infection to

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the liver. The malarial sporozoites once injected in the blood by the bite of female *Anopheles* mosquitoes are attached to hepatocytes through receptor for thrombospondin and properdin.<sup>7</sup> Liver dysfunction has been recognized in malaria infection.<sup>8</sup> However, the information about geographical variation in urban Bangalore is scarce. This research attempts to report the changes in liver function biomarkers in *P. falciparum* malaria-infected patients in urban Bangalore in comparison with normal.

## MATERIALS AND METHODS

### Study Center and Period

This duration based study was carried out from January 2012 to December 2013 in Department of Biochemistry, Vydehi Institute of Medical Sciences and Research Centre (VIMS and RC), Bangalore.

### Subject Selection

Patient's selection was done by simple random sampling from those presenting at VIMS & RC, Bangalore, with a history of fever, chills and malaise and who were subsequently confirmed to be *P. falciparum* malaria positive by Giemsa stained peripheral blood film. Based on the following selection criteria 50 *P. falciparum* patients were selected. Totally 50 subjects in apparent good health and malaria parasite negative were included as control individuals. Consent was sought and obtained from both cases and controls.

### Exclusion Criteria

Patients on self-medication with any anti-malarial drugs prior to presentation and patients with any type of liver disease and pregnant women were excluded from the study.

### Specimen Collection and Assay

A volume of 5 ml of venous blood sample was taken by aseptic precautions. Samples were centrifuged and serum aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), total protein (TP), albumin (ALB), total bilirubin (TB) and direct bilirubin (DB) were measured by using auto analyzer Beckman Coulter Synchron DxC using Beckman Coulter Kits (USA).

### Statistical Analysis

The data obtained were analyzed using the Student's *t*-test and level of significance was set at  $P < 0.001$  and were expressed as mean  $\pm$  standard deviation.

## RESULTS

Fifty confirmed cases of *P. falciparum* malaria and 50 without malaria infection (control)

Table 1 shows the changes in hepatic function biomarkers of the 50 *P. falciparum* (case) and 50 control subjects. When the *P. falciparum* positive (test) patients were compared with the non-infected subjects, there was an increase in the mean activity values of the AST, ALT, ALP, serum TB and DB. However, serum TP and ALB levels were reduced among the *P. falciparum* infected patients.

Changes in transaminases and bilirubin values for the *P. falciparum* malaria patients were significantly ( $P < 0.001$ ) higher than those for the non-malaria subjects.

## DISCUSSION

Malaria is endemic in India with an estimated 70-100 million cases each year. Of these 45-50% are *P. falciparum*.<sup>10</sup>

Malaria is a mosquito-borne tropical disease caused by the *Plasmodium* species of protozoa. It affects mainly the hepatocytes and red blood cells (RBCs) and manifests clinically as fever and splenomegaly.<sup>11</sup>

### Liver Dysfunction

Mild hemolytic jaundice is common in malaria, severe jaundice is associated with *P. falciparum* infections, is more common among adults than among children and results from hemolysis, hepatocytic injury and cholestasis. When accompanied by other vital organ dysfunction (often renal impairment) liver dysfunction carries a poor prognosis. Hepatic dysfunction contributes to hypoglycemia, lactic acidosis and impaired drug metabolism. The hemolysis results from the invasion of the erythrocytes by malarial parasites. *Plasmodium malariae* is known to invade mature RBCs, whereas *P. vivax* and *Plasmodium ovale* are known to invade young RBCs. *P. falciparum* parasites are capable of invading RBCs of any age and hence can lead to very high levels of parasitemia; while parasitemia is limited in all other types of *Plasmodium* infections.<sup>12</sup>

In this study, it was observed that the values for hepatic function profiles among *P. falciparum* patients were elevated when compared with those without infection. The

**Table 1: *P. falciparum* malaria with controls**

Parameters	<i>P. falciparum</i>	Controls	t-test value	df	P value
TBIL	6.41 $\pm$ 2.68	0.58 $\pm$ 0.20	10.854	48	<0.001
DBIL	4.29 $\pm$ 1.85	0.09 $\pm$ 0.06	11.366	48	<0.001
TP	5.24 $\pm$ 0.97	7.10 $\pm$ 1.46	-5.316	48	<0.001
ALB	2.68 $\pm$ 0.43	4.26 $\pm$ 0.42	-13.165	48	<0.001
AST	176.88 $\pm$ 59.81	24.48 $\pm$ 5.55	12.686	48	<0.001
ALT	172.96 $\pm$ 79.31	20.80 $\pm$ 7.07	9.554	48	<0.001
ALP	171.40 $\pm$ 23.47	86.04 $\pm$ 20.94	13.567	48	<0.001

df: Degree of freedom, AST: Aspartate aminotransferase, ALT: Alanine aminotransferase, ALP: Alkaline phosphatase, TP: Total protein, ALB: Albumin, TBIL: Total bilirubin, DBIL: direct bilirubin, *P. falciparum*: *Plasmodium falciparum*



observed increase ( $P < 0.001$ ) in serum liver enzymes (AST, ALT and ALP) could be due to leakage from hepatic cells that were killed or injured by the auto-immune progress and/or by abnormal cell activation induced by the parasites. This finding supports previous reports.<sup>4</sup>

TP and ALB levels were reduced in malaria patients, may be because liver, which is the primary organ for protein synthesis, is the site for parasite multiplication in the case of *P. falciparum*. It can also be a part of the acute phase response. The reduced TP and ALB finding supports previous reports.<sup>7</sup>

According to WHO, jaundice is one of the important manifestations of severe malaria. There is evidence of focal hepatocyte necrosis, cholestasis, bile stasis, granulomatous lesion or malarial nodules.<sup>8</sup> Anand *et al.* conducted a study on 39 patients with *P. falciparum* malaria and jaundice, out of whom 13 had serum bilirubin around the mean value of 16.3%, and most had predominantly conjugated hyperbilirubinaemia.<sup>9</sup> Especially noted is the elevation of alanine transaminase to more than three times the upper limit of normal value.<sup>13</sup> The elevation of serum transaminases in *P. falciparum* malaria patients is more than 5 times the upper limit of the reference range.<sup>14</sup>

## CONCLUSION

Incidence of jaundice was found to be higher in *P. falciparum* malaria. Predominantly conjugated hyperbilirubinemia with a moderate to severe increase in liver enzymes. From this, it is possible to conclude that hepatic parenchymal involvement by the parasite is the main cause of jaundice

in *P. falciparum* and hence hepatic biochemical parameters should be investigated as soon as *P. falciparum* is positive and should be treated appropriately to prevent the complications.

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# Safety and Efficacy of Low Dose Continuous Graded Epidural Anesthesia in Patients with Left Ventricle Dysfunction, Scheduled for Elective Below Umbilical Surgeries: Clinical Study

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## Abstract

**Introduction:** In patients with left ventricular dysfunction and 2-D echocardiography finding of regional wall motion abnormality, anesthesia carries high risk for surgery. Ejection fraction is the most commonly used estimate of left ventricular systolic function. Ejection fraction below 50 usually carries high anesthetic mortality and morbidity.

**Objectives:** The aim of this study was to evaluate the safety and efficacy of low-dose continuous graded epidural in patients with left ventricular dysfunction with ejection fraction below 50, scheduled for below umbilical elective surgeries.

**Materials and Methods:** In the present study, 30 patients who are scheduled for elective below umbilical surgeries with left ventricle dysfunction with ejection fraction of 50 and below are enrolled in this study. Lorazepam 2 mg orally given in the night before surgery, and midazolam 1 mg administered as pre-medicant 1 h before surgery. In sitting position, under the aseptic precaution L3- L4 epidural space is identified and 4 ml of 2% lidocaine given in the epidural space. Epidural catheter passed and secured and patient kept in lying posture. With a gap of 4 min 4 ml of 2% lidocaine given 2 times. After 45 min of the first dose of lidocaine 6 ml of 0.25 % ropivacaine administered and continued at rate of 6 ml/h for 48 h. Butorphanol 1 mg given intravenously as an intraoperative analgesic. Buprenorphine administered 60 µg epidural every 12 h for 2 days.

**Results:** Male female ratio is 18:12 and means age of the patients is 66.72±9.52, mean ejection fraction is 42.66±6.70. Mean duration of onset of epidural is 9.51±1.21, mean duration of surgery is 50.26±14.57. Buprenorphine 240 µg administered epidural in the post-operative period for 48 h. Stay of the patient in I.C.U. is 48 h.

**Conclusion:** Low-dose continuous graded epidural anesthesia is safer and ideal anesthesia technique in patients with left ventricle dysfunction scheduled for below umbilical surgeries.

**Keywords:** Coronary disease, Epidural, Stroke volume, Ventricular dysfunction

## INTRODUCTION

In patients with left ventricle dysfunction and regional wall motion abnormality hemodynamic management is tailored

to avoid factors known to increase myocardial oxygen demand. The principal determinants of myocardial oxygen demand are wall tension and contractility. Laplace law states that wall tension is directly proportional to intra-cavitary pressure and ventricular radius, and inversely proportional to wall thickness. Therefore, myocardial oxygen demand can be reduced by interventions that prevent or promptly treat ventricular distention and decrease the intra-ventricular pressure.<sup>1</sup>

One of the primary goals of successful anesthetic management is prevention of myocardial ischemia. Failing

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that, prompt identification and treatment of new ischemic episodes is essential. The anesthetic management is directed to reduce and controlled those factors that increase myocardial oxygen demand (heart rate, contractivity and wall tension) at the same time every attempt is made to optimize coronary blood flow, notably, maintaining coronary perfusion pressure and decreasing diastolic time. The goals for patients with coronary heart disease are slow, small and well perfused.<sup>2</sup>

Ideal monitoring technique is not available. Analysis of the ST segment in multiple leads (most common leads II and V<sup>4</sup> or V<sup>5</sup>) is currently the standard.

Favorable conditions for oxygen balance of are more likely those of lower heart rate and higher blood pressure than tachycardia and hypotension that is achieved by graded epidural anesthesia.<sup>3</sup>

Lidocaine is selected as local anesthetic for graded epidural for its lower cardiotoxicity than bupivacaine, levobupivacaine and ropivacaine, although all local anesthetics block the cardiac conduction system via a dose-dependent block of sodium channels, two features of bupivacaine sodium channel blocking abilities may enhance its cardiotoxicity, first bupivacaine exhibits a much stronger binding affinity to resting and inactivated sodium channels than lidocaine, second local anesthetics bind to sodium channels during systole and dissociate during diastole. Bupivacaine dissociates from sodium channels during cardiac diastole much more slowly than lidocaine. Indeed, bupivacaine dissociates so slowly that the duration of diastole at physiological heart rates does not allow enough time for complete recovery of sodium channels and Bupivacaine conduction block accumulates. In contrast, lidocaine fully dissociates from sodium channels during diastole and little accumulation of conduction occurs. Thus enhanced electrophysiological effects of bupivacaine, ropivacaine on the cardiac conduction system may explain their increased potential to produce sudden cardiovascular collapse via cardiac dysrhythmias. Increased potency for direct myocardial depression from bupivacaine, ropivacaine is another contributing factor to increased cardiotoxicity

## MATERIALS AND METHODS

After obtaining intuitional ethics committee approval, the study was conducted in the Department of Anesthesiology Government Medical College Anantapuramu. Informed high risk consent was obtained from all the patients. The study was conducted over a period of 1 year 6 months.

### Inclusion Criteria

Patients with 2-D echocardiography finding of regional wall motion abnormality with ejection fraction below 50.<sup>4</sup>

### Exclusion Criteria

Patients with 2-D echocardiography finding of regional wall motion abnormality with ejection fraction above 50, patients with 2-D echocardiography finding of no regional wall motion abnormality, unwilling patients.

Patient attendees' were explained about the risk of recurrence of ischemic attacks in the Intra-operative and post-operative period and possibility of high mortality rates.<sup>5</sup> Patients who were on long-term oral anticoagulant therapy were advised to stop them, and kept on low molecular weight heparin enoxaparin and patients are posted for surgery after achieving prothrombin time of less than 15 s and international normalized ratio below 1.5.<sup>6</sup> Low molecular weight heparin enoxaparin 40 mg administered BD until 48 h after surgery and thereafter kept on oral anticoagulant therapy.<sup>4</sup> Patients were administered lorazepam 2 mg orally night before surgery.

Patients are advised to remain in the fasting state from 9 pm, night before surgery. After taking high risk consent patients are taken into operation theatre, multichannel monitor is connected with 6 lead electrocardiography (ECG) and patient monitored for Spo<sub>2</sub>, noninvasive blood pressure (NIBP) pulse rate, ECG change and temperature and central vein cannulation done.<sup>7</sup> Injection midazolam 1 mg intra-venously administered to allay the anxiety.

Patient kept in sitting posture and under strict precautions L3-L4 epidural space is identified by loss of air resistance technique and hanging drop test by using 18G epidural needle. 4 ml of 2% lidocaine administered epidural, epidural catheter threaded into epidural space up to 2 dot mark i.e., 10 cm and firmly secured. Patient kept in lying posture and after gap of 4 min 4 ml of 2% lidocaine given epidural again after a gap of 4 min 4 ml of 2% lidocaine given epidural. Onset time of block (time for surgical anesthesia) was defined as the time gap between the completion of epidural 2% lidocaine injection to pinprick discrimination. 100% oxygen inhalation by face mask given. Patient monitored continuously for evidence of recurrent ischemic attacks.<sup>8</sup> After onset of epidural injection butorphanol tartrate 1 mg administered as intra-operative analgesic.

Patients were continuously monitored for Spo<sub>2</sub>, pulse rate, NIBP, ECG, central venous pressure, temperature throughout the intra-operative period and in the post-operative intensive care unit for 48 h.<sup>9</sup>

After 50 min of epidural administration of the first dose of 2% lidocaine, 0.25% ropivacaine administered epidural at the rate of 6 ml/h continuously for 48 h. Buprenorphine administered epidural at the dosage of 60 µg twice a day for 48 h as a post-operative analgesic.<sup>10</sup> Assessment of blood loss was done and fluid was administered as per the loss. Duration of surgery was noted. After 48 h epidural Catheter removed and patients shifted to post-operative ward.

## RESULTS

The study conducted over a period of 1 year and 6 months in the department of anesthesia Government general hospital Anantapuramu. Male:female ratio is 18:12 in the study and the mean age of the patients are 66.72 with standard deviation of  $\pm 9.52$  (Table 1).

The mean onset time of graded epidural anesthesia is 9.51 with standard deviation of  $\pm 1.21$  and the mean duration of surgery is 50.26 with standard deviation of  $\pm 14.57$  (Table 2).

Patients underwent different types of surgery and the following are the distribution of surgeries (Table 3).

Vital parameters like Spo2, pulse rate, systolic blood pressure and diastolic blood pressure were recorded pre-operatively and at the intervals of 3 min, 5 min, 10 min, 15 min, 20 min, 25 min, 30 min, 35 min, 40 min, 45 min, 50 min, 55 min, 60 min, 65 min, 70 min, 75 min, 80 min, 85 min and 90 min intervals (Tables 4-7).

Hemodynamics were maintained very well during the intra-operative and in post-operative period (Figure 1-4). The average stay of the patient in the post-operative intensive care unit is

2 days and recurrence of ischemic attacks in the post-operative intensive care unit is 0%.<sup>11</sup> The average epidural administration of buprenorphine is 240 µg. The average hospital stay of the patient is 10 days with 100% hospital discharge rate.

## DISCUSSION

Regional anesthesia by using graded epidural anesthesia has been used as an ideal alternative to general anesthesia and spinal anesthesia in patients with echocardiography finding of regional wall motion abnormality i.e. with left ventricular dysfunction who carries high mortality and morbidity under

**Table 4: Mean Spo2 with SD**

Time of event	Mean with SD
Pre-operative	97.5 $\pm$ 2.08
3 min after epidural	97.5 $\pm$ 2.08
5 min after epidural	97 $\pm$ 3.53
10 min after epidural	95 $\pm$ 5.0
15 min after epidural	94.6 $\pm$ 5.03
20 min after epidural	96.0 $\pm$ 3.60
25 min after epidural	95.66 $\pm$ 4.04
30 min after epidural	96.66 $\pm$ 3.05
35 min after epidural	96.66 $\pm$ 2.88
40 min after epidural	96.33 $\pm$ 3.51
45 min after epidural	95.66 $\pm$ 4.50
50 min after epidural	96.66 $\pm$ 3.05
55 min after epidural	95.66 $\pm$ 4.50
60 min after epidural	95.33 $\pm$ 4.50
65 min after epidural	96.33 $\pm$ 4.04
70 min after epidural	95.66 $\pm$ 4.04
75 min after epidural	97.33 $\pm$ 2.51
80 min after epidural	97.66 $\pm$ 2.08
85 min after epidural	98.33 $\pm$ 1.52
90 min after epidural	98.66 $\pm$ 1.52

SD: Standard deviation

**Table 5: Mean pulse rate with SD**

Time of event	Mean pulse rate with SD
Pre-operative	82.4 $\pm$ 6.22
3 min after epidural	87.2 $\pm$ 7.29
5 min after epidural	84.5 $\pm$ 8.22
10 min after epidural	84.6 $\pm$ 8.32
15 min after epidural	73.6 $\pm$ 9.07
20 min after epidural	73.0 $\pm$ 10.14
25 min after epidural	78.33 $\pm$ 15.82
30 min after epidural	78.0 $\pm$ 19.07
35 min after epidural	80.0 $\pm$ 17.08
40 min after epidural	72.0 $\pm$ 9.16
45 min after epidural	73.0 $\pm$ 25.51
50 min after epidural	79.33 $\pm$ 9.45
55 min after epidural	79.0 $\pm$ 7.54
60 min after epidural	80.33 $\pm$ 3.51
65 min after epidural	82.0 $\pm$ 8.0
70 min after epidural	79.33 $\pm$ 9.45
75 min after epidural	81.33 $\pm$ 10.26
80 min after epidural	93.33 $\pm$ 2.30
85 min after epidural	83.33 $\pm$ 8.08
90 min after epidural	85.33 $\pm$ 8.33

SD: Standard deviation

**Table 1: Demographic profile**

Parameter	Age (mean $\pm$ SD)	Gender (M: F)
	66.72 $\pm$ 9.52	18:12

SD: Standard deviation

**Table 2: Onset time of graded epidural and duration of surgery**

Parameter	Onset time of graded epidural	Duration of surgery
	9.51 $\pm$ 1.21	50.26 $\pm$ 14.57

**Table 3: Type of surgeries done**

Type of surgery	Number of surgeries
Lower limb orthopedic surgery	16
Inguinal hernia surgery	5
Caesarian section	7
Vaginal hysterectomy	2



**Table 6: Mean systolic blood pressure with SD**

Time of event	SD
Pre-operative	143.2±17.8
3 min after epidural	143.4±20.34
5 min after epidural	133.33±11.06
10 min after epidural	117.0±8.54
15 min after epidural	111.0±8.88
20 min after epidural	107.6±11.59
25 min after epidural	108.0±10.44
30 min after epidural	108.0±5.29
35 min after epidural	115.66±17.95
40 min after epidural	111.66±43.48
45 min after epidural	107.07±25.51
50 min after epidural	116±38
55 min after epidural	116.33±38
60 min after epidural	118.66±36.01
65 min after epidural	121.33±27.15
70 min after epidural	124.33±25.02
75 min after epidural	135.66±13.07
80 min after epidural	129.33±18.61
85 min after epidural	136.33±11.15
90 min after epidural	131.33±4.16

SD: Standard deviation

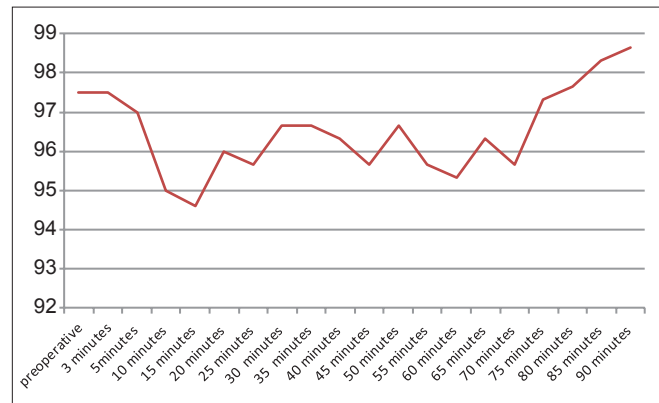
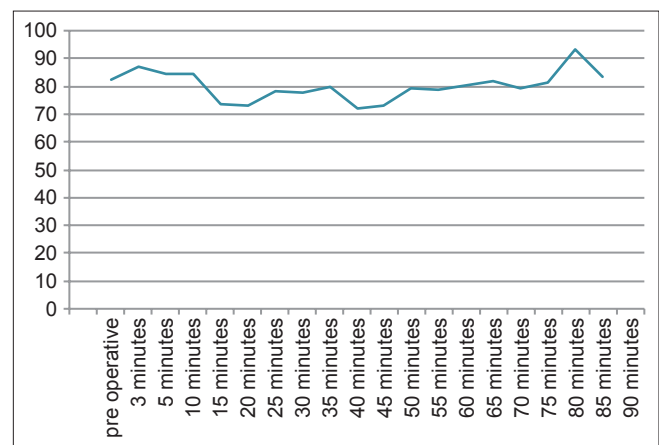
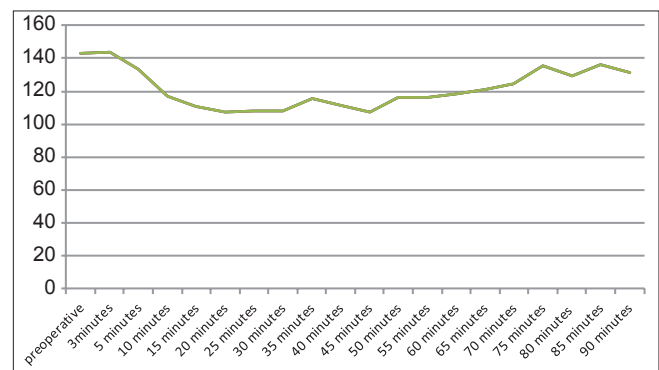
**Table 7: Mean diastolic blood pressure with SD**

Time of event	Mean diastolic pressure with SD
Pre-operative	88.33±9.24
3 min after epidural	84.6±12.8
5 min after epidural	77.33±6.05
10 min after epidural	66.6±6.42
15 min after epidural	65.3±3.78
20 min after epidural	62.66±4.93
25 min after epidural	62.66±6.65
30 min after epidural	64.33±8.21
35 min after epidural	72.08±19.28
40 min after epidural	63.06±10.44
45 min after epidural	67.33±23.80
50 min after epidural	70±26.48
55 min after epidural	69.33±21.19
60 min after epidural	77.01±13.52
65 min after epidural	74.0±19.92
70 min after epidural	74.66±19.39
75 min after epidural	81.33±16.05
80 min after epidural	78.5±13.47
85 min after epidural	85.66±8.12
90 min after epidural	80±4.16

SD: Standard deviation

general anesthesia and spinal anesthesia. Low dose continuous graded epidural provided excellent post-operative analgesia for 48 h, which prevented the incidence of recurrent ischemic attacks and early mobility of the patients.<sup>12</sup>

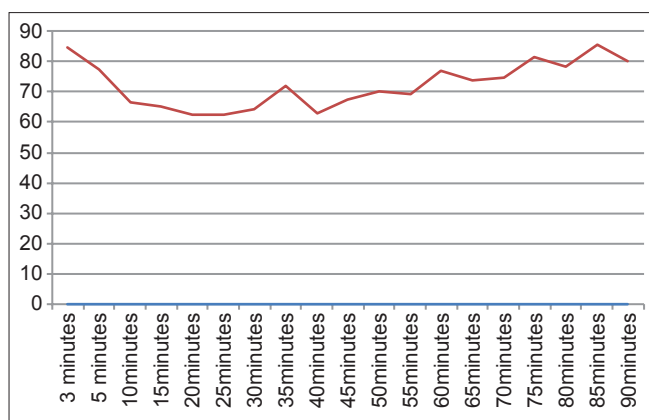
In the present study different surgeries were performed, majority being lower limb orthopedic surgeries and the rest are for inguinal hernia, vaginal hysterectomy and caesarian section. All the patients tolerated surgeries very well with 0% mortality.<sup>13</sup> Lidocaine is preferred as a local anesthetic for its cardiac stability and Bupivacaine is excluded as a local anesthetic for its cardio toxicity. To conclude in view of

**Figure 1: Mean SpO2****Figure 2: Mean pulse rate****Figure 3: Mean systolic pressure**

good intra-operative hemodynamic stability, excellent post-operative analgesia, reduced incidence of recurrent ischemic attacks low dose continuous graded epidural anesthesia an ideal choice for patients with left ventricular dysfunction scheduled for elective below umbilical surgeries.<sup>14</sup>

## CONCLUSION

Low dose continuous graded epidural anesthesia is ideal anesthetic of choice in patients with left ventricular



**Figure 4: Mean diastolic pressure**

dysfunction scheduled for below umbilical surgeries. Excellent intra-operative and post-operative hemodynamic stability is an added advantage. Good post-operative pain management by continuous epidural reduces the recurrent ischemic attacks.

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# Evaluation of Dry Powder Inhaler-Emitted Aerosol of Budesonide and Formoterol demonstrated by Andersen Cascade Impactor Using Respirable Fraction: An *In-Vitro* Study

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## Abstract

**Background:** Success of Inhalational therapy using dry powder inhaler (DPI) device depends on several factors including flow kinetics with consequent drug dose delivered to lower respiratory tract. The Fine particle fraction (FPF), mass median aerodynamic diameter (MMAD) and respirable fraction (RF) of the pharmaceutical aerosols play a key role in governing the drug deposition in lower respiratory tract.

**Aim:** This *In vitro* study was conducted to validate the aerodynamic effect of test formulation (fixed dose combination of budesonide (BUD) and formoterol in a single capsule dispensed in Airtec FB\* inhaler) aerosol that uses a novel patented platform technology for improved lung deposition rates.

**Materials and Methods:** A *In-vitro* lung deposition study was conducted using drug samples of formoterol fumarate and BUD using Andersen Cascade Impactor at Bombay College of Pharmacy, Kalina Mumbai.

**Results:** The results demonstrated better aerodynamic particle size properties for Airtec FB® formulation ingredients when loaded with Instahaler-P Device. The MMAD was 2.4 µm with FPF of 57.2% and 55.4% for formoterol or BUD respectively. Similarly the RF (<4.7 µm) was 40.6% and 40% for formoterol or BUD respectively.

**Conclusion:** The results showed better aerodynamic particle size kinetics or RF for Airtec FB® Instacaps when loaded on to DPI device instahaler-P while demonstrating the pharmaceutical equivalency to target-delivered dose shown by other marketed inhaler capsule formulations in India

**Keywords:** Andersen cascade impactor, Formoterol budesonide, Dry powder inhaler, Respirable fraction

## INTRODUCTION

Inhalational therapy is the preferred method for drug administration for the treatment of obstructive respiratory diseases including bronchial asthma or chronic obstructive pulmonary disease.<sup>1-4</sup>

For a therapeutic action, the inhaler is required to contain the proposed drug, in the amount specified for each dose, and producing appropriately sized particles that will reach the lower airways. Aerodynamic size diameter is usually the most important particle related factor, affecting aerosol deposition, which is determined by impaction, sedimentation, and diffusion depending on the inhalation flow rate and aerodynamic size. Particles more than 5 µm in the diameter deposit by impaction onto the oropharynx and are swallowed. The percentage of particles <5 µm in diameter in an aerosol is designated the fine particle fraction deposit primarily in the bronchi and large airways. In terminal bronchioles and alveolar region where air velocity is negligible, deposition of small particles (<2 µm) is mainly by diffusion.<sup>5</sup>

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Dry powder inhalers (DPIs) therefore encompass formulations that involve micronized drug blended with inert carrier vehicles for therapeutic delivery to the intended site of action. The DPI formulation aims to achieve adequate lung deposition of drug through uniform drug distribution even in the small doses with good pharmacokinetic release kinetics despite absence of propellant. However, the success with this therapy is often hampered by patient and formulation dependent factors including drug dose stability or Aerosol kinetics for optimum deposition in the lower respiratory tract.<sup>6</sup>

Successive refinements in the manufacturing technique for these DPI inhaler capsules have strived to offer better lung deposition rates by offering

- High fine particle fraction (20-40%) and respirable fraction (RF)
- High deposition of emitted dose (20-40%),
- Mean mass aerodynamic diameter (between 1 and 5 microns).

The objective of the current study was to evaluate and validate the *in vitro* aerodynamic effect of a test formulation (fixed dose combination of budesonide (BUD) and formoterol (FF) in a single capsule dispensed in Airtec FB® inhaler) aerosol involving novel patented platform technology in relation to reference formulation currently marketed in India

## MATERIALS AND METHODS

This *in vitro* study was conducted at Bombay College of Pharmacy, Kalina Mumbai using Andersen Cascade Impactor. Andersen Cascade Impactor (Copley Scientific, UK) was assembled with glass fiber filter paper in place on filter stage. The Capsule was placed in DPI device and opened as per instruction. Device was placed in adaptor and vacuum pump was switched on to the apparatus for 4 s set at  $60 \pm 5$  L/min (Figure 1). The DPI device was removed, and discharge sequence was repeated. A total 10 discharge was given to the impinger. The filter was removed carefully, and active substance was extracted using a suitable solvent.

The procedure was completed as per the Indian pharmacopoeia 2007 guidance. The characteristics of the aerosol were determined and assessed using several parameters including capsule retention (CR), fine particle fraction (FPF), mass median aerodynamic diameter (MMAD) and RF. The definitions included, CR: Drug dosage retained in the capsule; FPF: Refers to the fraction of the aerosol that is in a size range with the potential to penetrate and deposit in the airways and represents

the fine particle dose divided by the total delivered dose; MMAD: Defined as diameter of drug particles at which 50% of particles by mass are larger and 50% are smaller; RF: Fraction of emitted dose that deposits in lung alveoli with drug particle size of  $<4.7 \mu\text{m}$ .<sup>7,8</sup> Mean recovery of FF and BUD from the two formulations DPI Capsule I (Airtec FB® 200 Instacaps) and DPI Capsule II (Foracort® 200 rotacaps) was evaluated while using a multitude of Inhaler DPI devices *viz.* Device-I (Instahaler-P), Device-II (Rotahaler), Device-III (Revolizer).

## RESULTS

The study was completed using Andersen Cascade Impactor at 60 L flow rate. The recovered active substance from each stage of the Cascade Impactor was processed in the CITDAS software provided by Copley Scientific Ltd. UK.<sup>9</sup> The consolidated results showing comparatively superior FPF of formoterol and BUD delivery from instahaler-P DPI device using DPI Capsule-I.

Similarly the consolidated results for FPF, RF with formoterol and BUD from Reference formulation (fixed dose combination of BUD and FF dispensed in a single



Figure 1: Andersen Cascade Impactor with simulated aerodynamic particle size distribution in humans.

Table 1: Comparison of CR, FPF, RF in several DPI devices using DPI capsule-I

	Device-I	Device-II	Device-III
CR*			
Formoterol	1.56 $\mu\text{g}$	0.62 $\mu\text{g}$	3.41 $\mu\text{g}$
BUD	95.25 $\mu\text{g}$	31.4 $\mu\text{g}$	197.4 $\mu\text{g}$
MMAD			
Formoterol	2.40 $\mu\text{m}$	2.63 $\mu\text{m}$	3.07 $\mu\text{m}$
BUD	2.40 $\mu\text{m}$	2.63 $\mu\text{m}$	3.45 $\mu\text{m}$
FPF* (%)			
Formoterol	57.2	22.3	16.54
BUD	55.39	21.15	15.64
RF* (%)			
Formoterol	40.59	18.25	11.25
BUD	40.01	16.86	9.52

\*Mean of 10 capsules, CR: Capsule retention, FPF: Fractional particle fraction, MMAD: Mass median aerodynamic diameter, RF: Respirable fraction, BUD: Budesonide, DPI: Dry powder inhaler



capsule of Foracort® 200) while using Device-II or Device-III are highlighted below (Table 2)

## DISCUSSION

One of the key elements in Asthma management remains regular use of inhaled maintenance medications including ICS and LABA combination of Formoterol and BUD. The therapeutic effect of this inhalational product is highly dependent on the drug's deposition profile within the lung while taking into consideration the pharmacological properties of the drug.

Aerosols with a MMAD (the diameter that divides the power spectral density in half as a function of mass) of 1-5 µm are considered to be respirable by humans. At the same time, the FPF is representative for those particles that have a high probability of penetrating into the deep lung with maximum deposition in the alveolar region occurring for particles of approximately 2 µm aerodynamic diameter.

The current study was conducted to validate the *in-vitro* aerodynamic effect of DPI capsule using novel patented platform technology using Airtec FB® instacap with various marketed DPI devices. The results indicated FPF for Device-I using DPI capsule-I for formoterol and BUD was 57.2% and 55.39% respectively. The results were comparable to the recent study conducted by Sanduzzi et al with DPIs. The observed FPF for Turbuhaler® Formoterol/BUD was 44-46%.<sup>10</sup> In other similar studies, the FPF ranged from 18% to 42% (Naikwade 2009).<sup>11</sup> However at the stated flow rates of 60 L/min, Tarsin reported FPF of 28.6% with the turbuhaler multi-dose device.<sup>12</sup>

The results of this *in vitro* study performed with application centric infrastructure demonstrate that the FPF was

similar in the test and reference formulations and can be considered as pharmaceutically equivalent. The FPF values for the reference formulation i.e. Foracort® capsule loaded on Device II or III showed values that were within the range of 75-125% of the specified target delivered dose in accordance with the US pharmacopeial convention recommendations.<sup>8</sup>

The study also for the first time documents the RF for the reference and test formulations with the same defined as fraction of the emitted dose that is more like to deposit in lung alveoli with drug particle size of <4.7 µm

Although the aerodynamic particle size distribution is known to impact lung deposition, its relationship with regional lung deposition and clinical efficacy are not fully understood. Two pharmaceutical aerosols, which have the same FPF may differ in particle size distribution that may have to be further explored with pharmacodynamics systemic exposure or clinical endpoint studies

## CONCLUSION

The results showed better Aerodynamic particle size kinetics for Airtec FB Instacaps when loaded on to DPI device instahaler-P while demonstrating the pharmaceutical equivalency to target-delivered dose shown by other marketed inhaler capsule formulations in India

The RF representing fraction of the emitted dose with drug particle size of <4.7 µm that is more likely to deposit in lower airways of respiratory tract was again documented to be well within the recommendations of the US pharmacopeial convention.

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**Table 2: Comparison of CR, FPF, and RF in several DPI devices using DPI capsule-II**

	Device-I	Device-II	Device-III
CR*			
Formoterol	1.06 µg	2.98 µg	2.49 µg
BUD	131.57 µg	191.54 µg	171.55 µg
MMAD			
Formoterol	2.6 µm	2.6 µm	2.6 µm
BUD	2.8 µm	2.9 µm	2.9 µm
FPF* (%)			
Formoterol	53.68	45.41	45.41
BUD	57.04	52.10	47.47
RF*			
Formoterol	34.35	18.48	16.71
BUD	32.28	16.09	13.31

\*Mean of 10 capsules, CR: Capsule retention, FPF: Fractional particle fraction, MMAD: Mass median aerodynamic diameter, RF: Respirable fraction, DPI: Dry powder inhaler, BUD: Budesonide

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# Prospective Evaluation of Outcome of Pregnancy of Unknown Location

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## Abstract

**Introduction:** Pregnancy of unknown location is used whenever there is no sign of either intra- or extra-uterine pregnancy or retained products of conception on transvaginal ultrasound (TVS), despite a positive pregnancy test. Still, there is no consensus for the diagnostic evaluation and management of women with pregnancy of unknown location. This study is done to evaluate the optimal strategy to predict the outcome of pregnancy in women with pregnancies of unknown location.

**Purpose:** The aim was to find the fate of pregnancy of unknown location in early pregnancy and to evaluate the management of the same in different models.

**Materials and Methods:** The prospective study carried out in our institute for a period from January 2013 to October 2014 involving 57 patients diagnosed of pregnancy of unknown location. This study evaluated by taking serum progesterone on day 1, serum human chorionic gonadotropin and TVS on day 1 and repeated every 48 h until the final pregnancy outcome is known.

**Results:** In our study, 57 patients had pregnancy of unknown location of them 20 patients (35%) had intrauterine pregnancy, 7 patients (12.2%) had ectopic pregnancy, 29 (50.8%) had spontaneous resolution of pregnancy of unknown location and 1 patient (1.7%) had persistent pregnancy of unknown location.

**Conclusion:** Pregnancy of unknown location always is a dilemma, and patient needs repeated blood test and TVS. Management may be conservative/medical or surgical according to the final outcome of pregnancy.

**Keywords:** Pregnancy of unknown location, Serum  $\beta$  human chorionic gonadotropin, Ultrasonography

## INTRODUCTION

The commonly used early diagnostic tool of pregnancy is urine pregnancy test (UPT). At the first visit it may not be possible to confirm if a pregnancy as intrauterine or extra-uterine in 8-31% cases even with expert use of transvaginal ultrasound (TVS) using agreed criteria.<sup>1</sup> In some cases even when the UPT is positive, there is no gestational sac visualized on TVS either in intrauterine or in extra uterine location, they are referred as

pregnancies of unknown location (PUL).<sup>2</sup> Such women need long-term follow-up, frequent hospital visits, lab test, repeat TVS to confirm the viability and location of pregnancy.<sup>3</sup>

## Aim

An attempt to make a protocol for the management of PUL in order to make it convenient for the patient and the obstetrician in the follow-up of PUL.

## MATERIALS AND METHODS

All women who attended our out-patient department of Vinayaka Mission's Medical College, Karaikal from January 2013 to October 2014. A total number of 4746 patients with a history of amenorrhea of  $50 \pm 10$  days with lower abdominal pain and bleeding per vaginum were taken in our

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study. The consent from ethical committee of our college and patient's consent were obtained.

#### Inclusion Criteria

- Spontaneous conception
- No intra uterine pregnancy (IUP)/extra uterine pregnancy visualized on TVS
- Hemodynamically stable patient
- No hemoperitoneum.

#### Exclusion Criteria

- Confirmed IUP/extra uterine pregnancy on ultrasound
- Previous history of ectopic pregnancy
- Previous history of salpingitis
- Conceived with assisted reproductive technology

Total number of 4746 patients attended OPD from January 2013 to October 2014 with history of amenorrhea  $50 \pm 10$  days had undergone UPT (card test-CIPLA INDIA) which is done using monoclonal antibodies (sensitivity  $>25$  mIU/ml). Among them, 663 showed pregnancy test positive with history of vaginal bleeding and lower abdominal pain were included in our study. We have taken complete history and examination. All of them had undergone ultrasound (PHILIPS. HD7XE revision 2.0.1 which was equipped with trans vaginal probe of frequency 7 MHz) and serum progesterone. Follow-up of patients done by clinical assessment and serial measurements of serum  $\beta$  human chorionic gonadotropin (hCG) ( $>25$  mIU/ml-positive pregnancy) and TVS done on day 1 and repeated every 48 h until the final pregnancy outcome.

IUP is defined, when  $\beta$ hCG titers doubled after 48 h or TVS suggestive of intrauterine gestational sac with fetal cardiac activity.

Extra-uterine pregnancy is defined, when a heterogeneous mass/a mass with a hyper echogenic ring around the gestational sac in the adnexal region, or the presence of an embryo with or without a heart-beat in the adnexal region accompanied by slow raising or plateau of serum levels of  $\beta$ hCG.

Miscarriage was diagnosed when TVS showed intrauterine gestational sac, but repeated ultrasound showed no cardiac activity and associated with falling levels of serum  $\beta$ hCG.

In a woman with a positive UPT, if the endometrial cavity was empty with no evidence of an intrauterine gestational sac or of any retained products of conception and in the absence of visualized extra-uterine pregnancy on TVS as labelled as PUL.

Spontaneous resolution of PUL is defined, when  $\beta$ hCG is negative ( $<5$  mIU/ml) and no IUP/extra-uterine pregnancy on TVS without any active management.

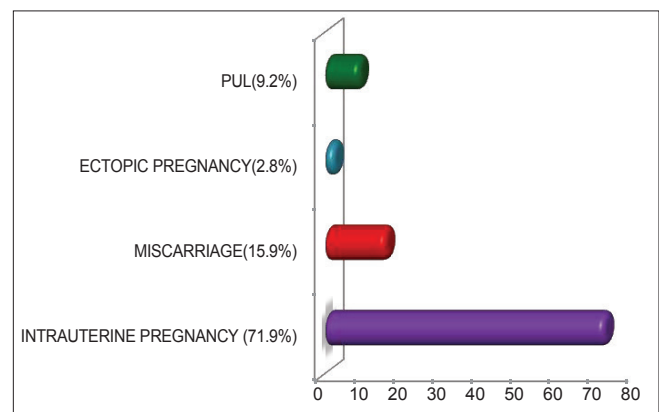
Persistent PUL is defined as, when  $\beta$ hCG is  $>25$  mIU/ml and no intra/extra-uterine pregnancy on TVS even after regular follow-up.

## RESULTS

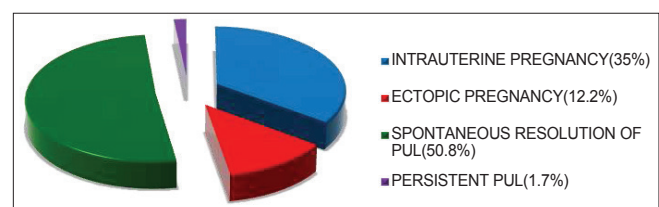
In our study, among 663 patient with early pregnancy complication, IUP was found in 477 patients (71.9%), miscarriage in 106 patients (15.9%), ectopic in 19 patients (2.8%) and pregnancy of unknown location (PUL) in 61 patients (9.2%) (Graph 1). About 38 patients (68%) of PUL had lower abdominal pain, 35 patients (62%) has vaginal bleeding with or without abdominal pain and 50 patients (88%) with a history of amenorrhea. Out of the 61 patients of PUL, 4 patients lost to follow-up. Among the 57 patients of PUL, 20 patients (35%) had IUP (Figure 1), 7 patients (12.2%) had ectopic, 5 had underwent laparoscopic salpingostomy and the remaining 2 was treated with methotrexate and 30 patients (53%) had failed PUL (Figure 2). 29 patient of PUL (50.8%) had spontaneous resolution and one patient (1.2%) had persistent PUL, which was treated with methotrexate (Graph 2).

## DISCUSSION

Pregnancy of unknown location includes a positive pregnancy test, with no pregnancy, visualized on scan and or not interchangeable with ectopic pregnancy.

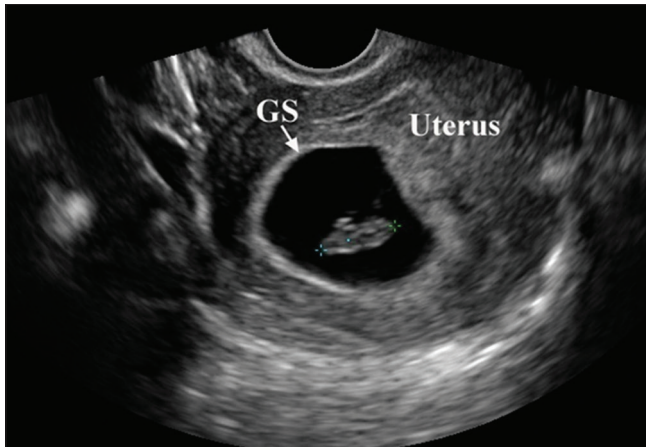


Graph 1: Fate of early pregnancy



Graph 2: Fate of early pregnancy





**Figure 1: Intrauterine pregnancy with 50 days of amenorrhea**



**Figure 2: Pregnancies of unknown location with 50 days of amenorrhea**

A TVS done following a positive pregnancy test shows the presence of an IUP or ectopic pregnancy in 90% of cases, whereas the rest 10% could be pregnancy of unknown location.

In our study, the incidence of PUL was 9.2% who came with early pregnancy complication. PUL can occur in 7-30% of women who present with complaints in early pregnancy, e.g. abdominal discomfort and/or vaginal bleeding according to the study of Kirk *et al.*<sup>4</sup>

We have done  $\beta$ hCG and TVS on day 1 and repeated every 48 h until the final pregnancy outcome is known in patient with PUL. As, two values of  $\beta$ hCG day 1 and repeated after 48 h may not sufficient to predict ectopic pregnancy. Hence in patient with PUL,  $\beta$ hCG repeated every 48 h to improve the prediction as shown in a study done by Zee *et al.*<sup>5</sup>

The serum  $\beta$ hCG and plasma progesterone, followed up by TVS can always find out the final outcome of PUL whether it is a viable IUP or an ectopic or a persisting

PUL. According to the Association of early pregnancy units guidelines.<sup>6</sup> It is advisable to follow-up with  $\beta$ hCG and TVS assessments in PUL patients until the pregnancy is located accurately, or intervention becomes necessary.<sup>7</sup> Hence, repeat serum progesterone estimation was not done in our study.

Among 57 patients of PUL, none of them underwent uterine curettage, as it does not play a role in the classification of PULs or not much accurately differentiate between IUPs and extra-uterine pregnancies and may lead to inadvertent termination of a viable pregnancy.<sup>8</sup>

In our study active intervention was done for 7 ectopic pregnancy, diagnosed by serum  $\beta$ hCG and TVS out of 57 PUL patient.<sup>9</sup> Patient with <3.5 cm adnexal mass/ no cardiac activity not hypersensitive to methotrexate and hemodynamically stable were treated with 50 mg/m<sup>2</sup> methotrexate intramuscularly. Other patients not fitting this criterion were treated with laparoscopic salpingostomy and specimen sent for histopathological confirmation.

The medical management was done in one patient with persistent PUL with intramuscular methotrexate of 50 mg/m<sup>2</sup>. This patients were followed up with  $\beta$ hCG every 48 h till the level declines to <5 mIU/ml.

Spontaneous resolution was observed in 29 patient (50.8%) and 20 patient had IUP (35%). The reduction in the number of interventions in our study was accomplished by keeping regular follow-up of the patient and may be due to increased experience in managing these cases. Hence, we confirm that women with PUL, who are clinically stable, could be safely managed expectantly with the majority of pregnancies resolving spontaneously as previously reported.<sup>10,11</sup>

## CONCLUSION

The frequency of PUL incidents has increased with as women are presenting at earlier gestations and are having earlier scans. The repeated serum hCG and TVS assessment seems to be good diagnostic tool to predict the outcome of PUL. Although the vast majority will be failing PUL or IUPs, a small proportion will be ectopic pregnancies. Expectant management is safe in most of the patients with PUL although, importance of cautious monitoring and timely intervention is needed.

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# Magnitude and Risk Factors for Physical Domestic Violence during Pregnancy

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## Abstract

**Introduction:** Domestic violence or intimate partner violence (IPV) against women is a major public health and human rights concern. It is amongst the most pervasive forms of violence against women.

**Aims and Objectives:** (1) To study the magnitude physical domestic violence during pregnancy among women delivering at a government run tertiary hospital of an urban area in India. (2) To study risk factors for physical domestic violence of the studied population.

**Materials and Methods:** An institution based cross-sectional study was conducted amongst women delivering at Sassoon General Hospitals, Pune. Patients were included by simple random sampling. A structured interview schedule was used to collect the data. The dependent variable was physical domestic violence. The independent variables were wife's age, education, occupation, husband's age, education, residence, parity, duration of marriage and substance abuse in the husband. Quantitative data were analyzed by Fishers Exact test and calculation of odds ratio with 95% confidence interval (CI). For qualitative data, content analysis was done in which key themes were identified.

**Results:** A total of 404 women was included in the sample. The prevalence of physical domestic violence was 9.15% (95% CI of 6.28% to 12.02%). In 35 (95%) cases, husband was the perpetrator. Urban residents were at 4.2 times, and poverty was having 3 times more risk of physical violence during pregnancy. Women with married life of less than 1 year were 6.9 times while women with alcoholic husbands were 4.56 times more likely to experience physical violence. Tobacco-chewing, gutkha and smoking were not associated with physical domestic violence.

**Conclusion:** Well-designed protocols and referrals systems along with legal and counseling options should be put in place so that women get timely, appropriate care; follow-up and support services. Women should be able to disclose their experiences in a secure environment.

**Keywords:** Domestic violence, Pregnancy, Risk Factors

## INTRODUCTION

Violence against women is a major public health and human rights concern. Domestic violence or intimate partner violence (IPV) and sexual violence are amongst the

most pervasive forms of violence against women. IPV is a worldwide problem.

Violence to women in urban slums of Pune was reported to be as high as 62%.<sup>1</sup>

Pregnancy does not protect women from IPV. A number of studies conducted in India have reported physical abuse in pregnancy.<sup>2-4</sup> A global systematic review described a prevalence of 1% to 20% for domestic violence during pregnancy.<sup>5</sup> The prevalence rate of domestic violence was reported to range from 4% to 48%, and a review of Indian studies reported a prevalence of 21-28%.<sup>6,7</sup>

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The prevalence of violence among pregnant women in developing countries ranges from 4% to 29%.<sup>8</sup> A review of the prevalence of violence against pregnant women in developed countries has shown a range of 1-20%.<sup>5</sup> Physical domestic violence during pregnancy can result in miscarriage, premature labor, low birth weight as well as depression and mental ill health for the mother.

With this background this study was undertaken with the aim of answering two research questions viz. (a) What is the magnitude physical domestic violence during pregnancy among women delivering at a government run tertiary hospital of an urban area in India? (b) What are the risk factors for physical domestic violence during pregnancy of the studied population?

## MATERIALS AND METHODS

An institution based cross-sectional study was conducted amongst women delivering at Sassoon General Hospitals (SGH) during the period October 1, 2013 to December 31, 2013. Ethical clearance was taken from the Institutional Ethics Committee.

A total of 404 women who delivered at SGH during the study period was included in the sample. Every day a list of women who had delivered the previous day was obtained, and three women were randomly selected by simple random sampling to be included in the sample. A structured interview schedule was used to collect the data.

The women were asked whether they have ever been hit, slapped, kicked or physically hurt by anyone during the current pregnancy.

Cases were defined as women reporting physical domestic violence during the current pregnancy. Controls were defined as women not reporting any physical domestic violence during the current pregnancy. The dependent variable was physical domestic violence. The independent variables were wife's age, education, occupation, husband's age, education, residence, parity, duration of marriage and substance abuse in the husband. The interview schedule included a few open-ended questions regarding the type of abuse, circumstances under which abuse took place and the respondent's reaction to the abuse.

The study was approved by the institutional ethics committee. Written informed consent was taken from each participant. Quantitative data were analyzed by Fishers Exact test and calculation of odds ratio (OR) with 95% confidence interval (CI). For qualitative data, content analysis was done in which key themes were identified.

## RESULTS

The prevalence of physical domestic violence was 9.15% (95% CI of 6.28% to 12.02%).

Table 1 describes the association of age and education of the couple with the physical domestic violence. The wife's age and education were significantly associated with physical violence. Husband's education was significantly associated with physical violence.

Table 2 describes the relation between other socio-demographic characteristics and physical domestic violence. Women from urban areas were 4.2 times more at risk of physical violence during pregnancy. Women from Below Poverty Line (BPL) families were 3 times more at risk of physical violence. When the duration of marriage was less than 1 year, the wife was 6.9 times more likely to experience physical violence.

Table 3 describes the association of substance abuse amongst husband and physical domestic violence. Women whose husbands were alcoholics were 4.56 times more likely to experience physical violence. Consumption of tobacco, gutkha and smoking were not associated with physical domestic violence.

A significantly more proportion of women with preterm deliveries reported physical domestic violence during pregnancy (9 [24.32%] vs. 40 [10.89];  $P = 0.029$ ; OR = 2.66 [1.07-6.47]).

The majority of the women said that they were slapped or beaten on the head or back. A few said they were punched in the back while one said her hair was pulled, and another mentioned that she was kicked in the back.

In 35 (95%) cases, husband was the perpetrator, in one case in-laws and in another case neighbors were reported to be the perpetrators.

A total of 21 respondents reported that they had experienced physical violence once, 10 reported it for a few instances while 6 said they had experienced physical violence many times during the current pregnancy.

Quarrel with the husband led to the physical violence. The couple quarreled for a variety of reasons.

Table 4 describes the reasons that led to physical domestic violence by the husband.

A woman said "My mother in law and sister in law wanted me to undergo an abortion so that my husband could get another



**Table 1: Association of age, education with physical domestic violence**

	Cases (%) (N=37)	Controls (%) (N=367)	P value	OR (95% CI)
Wife's education				
Less than secondary school	23 (62.16)	114 (31.06)	0.0004	3.64 (1.72-7.78)
Secondary school and above	14 (37.83)	253 (68.93)		
Wife's age				
<25 years	32 (86.48)	227 (61.85)	0.0021	3.95 (1.42-1.83)
25 years and above	5 (13.51)	140 (38.14)		
Husband's education				
Less than secondary school	18 (48.64)	95 (25.88)	0.0062	2.71 (1.29-5.67)
Secondary school and above	19 (51.35)	272 (74.11)		
Husband's age				
<30 years	27 (72.97)	223 (60.76)	0.16	1.74 (0.78-3.98)

CI: Confidence interval, OR: Odds ratio

**Table 2: Socio-demographic characteristics and physical domestic violence**

Variable	Group	Cases (%) (N=37)	Controls (%) (N=367)	P value	OR (95% CI)
Residence	Urban	29 (78.37)	169 (46.04)	0.0002	4.25 (1.79-10.38)
	Rural	8 (21.62)	198 (53.95)		
BPL household	Yes	19 (51.35)	95 (25.88)	0.0019	3.02 (1.45-6.33)
	No	18 (48.64)	272 (74.11)		
Type of family	Nuclear family	14 (37.83)	114 (31.06)	0.46	1.35 (0.63-2.86)
	Others	23 (62.16)	253 (68.93)		
Parity	One	17 (45.94)	139 (37.87)	0.377	1.39 (0.67-2.89)
	More than one	20 (54.05)	228 (62.12)		
Duration of marriage	Up to 1 year	18 (48.64)	44 (11.98)	0.0001	6.95 (3.2-15.13)
	More than 1 year	19 (51.35)	323 (88.01)		
Wife's working status	Working	2 (5.40)	36 (9.80)	0.56	0.53 (0.084-2.36)
	Housewife	35 (94.59)	331 (90.19)		

CI: Confidence interval, OR: Odds ratio

**Table 3: Substance abuse in husband and physical domestic violence**

Use	Cases (%) (N=37)	Controls (%) (N=367)	P value	OR (95% CI)
Alcohol				
Yes	21 (56.75)	82 (22.34)	0.0001	4.56 (2.16-9.68)
No	16 (43.24)	285 (77.65)		
Tobacco				
Yes	18 (48.64)	141 (38.41)	0.29	1.52 (0.73-3.15)
No	19 (51.35)	226 (61.58)		
Ghutki				
Yes	6 (16.21)	39 (10.62)	0.28	1.63 (0.57-4.24)
No	31 (83.78)	328 (89.37)		
Smoking				
Yes	4 (10.81)	16 (4.35)	0.099	2.66 (0.71-9.17)
No	33 (89.18)	351 (95.64)		

CI: Confidence interval, OR: Odds ratio

wife. When my husband came to know of this, he hit his mother and sister. I went away and stayed with my aunt till the 7<sup>th</sup> month after which I went to my mother's home for delivery."

In the majority of cases, a woman cried after the episode of the violence and after a few hours everything was normal

routine. In two cases, the respondent said she went to her mother's place after the incidence. In three cases, the respondent said she told her mother about the incident.

Only two women had tried to report the incidence of physical domestic violence; one to a local leader/women's group and another to the police.

In another case a woman said that "My husband used to snatch my hair and slap me till the 7<sup>th</sup> month of pregnancy when I went to my mother's place for delivery. When my husband came to visit me, he hit my mother too. I had gone to the police station to lodge a complaint but decided to carry on with the legal action after delivery."

## DISCUSSION

The prevalence of physical intimate IPV was estimated to be 9.15% in this study. A population-based cross-sectional sample survey covering married women in Orissa, West Bengal, and Jharkhand states the prevalence of physical

**Table 4: Reasons which led to physical domestic violence by the husband**

Dimension	Reasons	Quotes
Not performing the role expected from a wife	Refusal to give food/water Not getting up early	"My husband was angry because I did not give him food on time" "I did not get up early in the morning and was sleeping when my husband got angry and hit me"
	Refusal to have intercourse	"My husband hit me because I refused intercourse. This happened thrice; in the 2 <sup>nd</sup> , 4 <sup>th</sup> and 5 <sup>th</sup> month of pregnancy. When I refused to have intercourse because of pregnancy, he gave me bad words and slapped me"
Did things not expected from her	Quarrel with in laws	"My husband was angry with me because I had quarreled with my in-laws"
	Did things without permission	"My husband was angry with me because I had gone out without his permission"
	Beating children	"I was angry with my children as they were not listening to me and began beating them. When my husband saw this, he was angry and started beating me"
	Alcohol	"My husband drank alcohol and came home late; I was arguing with him that he should not drink alcohol and told him she won't take him into the house or would go to her mother's place when he slapped me on my face"
Suspicion	Back answered	"I had missed my medication and when my husband questioned me about it, I back-answered. He was angry and hit me"
	Infidelity	"We fought as he suspected I had an extra marital affair"

domestic violence during recent pregnancy was 7.1% while the lifetime prevalence during all pregnancies was 8.3%.<sup>9</sup> In a study amongst women attending antenatal clinics in Delhi 26.9% of the women reported experience of physical abuse.<sup>10</sup> In a study conducted in Mumbai slums 12% women reported physical IPV during and after pregnancy.<sup>11</sup>

This study brings out the fact that young women in BPL households from urban slums are a marginalized group with higher risk of physical domestic violence. A number of socio-demographic factors were identified as risk factors for physical domestic violence during pregnancy. These included urban residence, belonging to BPL families, woman's age and education, husband's education and duration of marriage less than 1 year. Similar risk factors have been reported to be significantly associated with domestic violence in other studies too.<sup>12,13</sup> This should help us identify high-risk setups and individuals where health-care professionals should be alert to the symptoms and signs of domestic violence. Health care professional and paraprofessionals working in health care setups which provide services to this group of the community should be sensitized and trained to recognize and respond to violence during pregnancy.

Alcoholism in husband was identified to be an important risk factor for physical domestic violence in this study. It has been reported that alcohol use increases the occurrence and severity of domestic violence.<sup>14</sup> Alcohol use directly affects cognitive and physical functions, reduced self-control leaving individuals less capable of negotiating a non-violent resolution to conflicts within relationships.<sup>15</sup> Excessive drinking by one of the partners can exacerbate financial problems, childcare problems and other family stressors leading to an unhappy, stressful partnership that increases the risk of conflict and violence.<sup>16</sup>

Very few women who experienced physical violence during pregnancy reported it to another family member or to the grievance redressal agency. It has been noted that most of the women who report IPV are likely to think it is justifiable with many accepting it.<sup>13</sup> Though the physical domestic violence to the pregnant women was not acceptable to the women (cases) in our study, except for a few women none of them were having any complaints against the husband and were in a mentality to forget and forgive.

Preterm delivery was more common amongst women who reported physical domestic violence. Untoward outcomes of pregnancy were not significantly associated with physical violence as majority of the episodes of violence were of moderate nature.

The reasons for violence and circumstances of violence are similar to those reported in other studies.<sup>13</sup>

Considering these factors the male partner should be encouraged to accompany the woman during antenatal visits so that he can be involved in the process of providing care to the pregnant woman. This can also arise a sense of responsibility, importance, worth, positive attitude, hope, and a paternal instinct.

## CONCLUSION

Well-designed protocols and referrals systems along with legal and counseling options should be put in place so that women get timely appropriate care, follow-up and support services. Women should be able to disclose their experiences in a secure environment. This would further help in women safety and security in pregnancy and childbirth.

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# Prevalence and Characteristics of Molar Incisor Hypomineralization in Children Residing in South Bangalore, India

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## Abstract

**Introduction:** The term molar incisor hypomineralization (MIH) was introduced in 2001 to describe the clinical appearance of enamel hypomineralization of systemic origin affecting one or more first permanent molars that are frequently associated with affected incisors. Most prevalence studies on MIH have been carried out in European countries, and data from Asia are lacking.

**Aim:** To investigate the prevalence and characteristics of MIH in children residing in south Bangalore region of India.

**Materials and Methods:** A cross-sectional survey including 1000 children in age group of 8-12 years studying in primary schools of south Bangalore and attending the Outpatient Department of VS Dental College and Hospital was carried out. The dental examination was carried out by a single examiner in daylight conditions. Full mouth inspection of the wet teeth was conducted using European Academy of Pediatric Dentistry 2003 criteria for diagnosis of MIH. Prevalence and characteristics of MIH was recorded and statistically analyzed using the Chi-square test.

**Results:** Totally, 29 children were diagnosed with MIH, revealing a prevalence of 2.9% in south Bangalore. Almost 19 (65.5%) of the children affected with MIH were males, and 10 (34.5%) were females. Maxillary teeth (53.5%) in total were affected more when compared to the mandibular. However, when molars were evaluated, mandibular teeth (55.2%) were more affected than maxillary teeth. Majority of incisors showed mild defects while molars showed mild as well as severe defects.

**Conclusion:** Prevalence of MIH using EAPD 2003 criteria was found to be lower to other studies conducted in India. More studies have to be conducted in other Indian regions, to evaluate the prevalence, characteristics and treatment needs for this clinically demanding condition.

**Keywords:** Clinical characteristics, Molar incisor hypomineralization prevalence, Molar incisor hypomineralization severity

## INTRODUCTION

Dental enamel is a unique, highly mineralized tissue of ectodermal origin. It is characterized by a lack of metabolic activity once formed which means disturbances during development can manifest as permanent defects in the erupted tooth. Disturbances in the initial matrix secretion phase of amelogenesis will likely present as quantitative

or morphologic defects (hypoplasia). Disruptions in the calcification or maturation processes may produce morphologically normal but structurally or qualitatively defective enamel (hypo mineralization/hypo maturation).

In last few decades, various patterns of enamel defects have been defined in the literature. Molar incisor hypomineralization (MIH) is one of them. Many studies have described this condition.<sup>1-3</sup>

The term MIH was introduced in 2001 following a meeting of the European Academy of Pediatric Dentistry (EAPD).<sup>4</sup> According to these authors, the definition of MIH would be hypo mineralization of systemic origin that affects one to four FPMs that can be associated with affected permanent incisors. The subsequent meeting of

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EAPD 2003 established the judgment criteria for MIH in epidemiological studies.<sup>5</sup> Since then, many prevalence studies have been conducted using the EAPD criteria with a reported prevalence of 2.4-40.2%.<sup>6</sup>

Prevalence studies on MIH have mostly been carried out in European countries<sup>7,8</sup> and data from Asia are lacking. In India, only a few studies in northern and western states have been reported.<sup>9,10</sup> As per the available literature there are no studies regarding the prevalence of MIH in southern states of India.

Therefore, the purpose of this study is to investigate the prevalence and clinical characteristics of MIH in children residing in south Bangalore region of India.

## MATERIALS AND METHODS

The study was a cross-sectional survey. It included 1000 children in age group of 8-12 years. The study was carried out in four primary schools in a rural area of south Bangalore and Department of Pediatric and Preventive Dentistry of our college. Institutional ethical clearance was obtained for the study. Signed written informed consent was obtained from the parents or caregivers of all the children.

Children having fully erupted permanent first molars, and incisors were included in the study. Children with any other defects of enamel such as amelogenesis imperfecta, enamel hypoplasia, white spot lesions, tetracycline staining, erosion and fluorosis were excluded.

A single examiner conducted the dental examination in daylight conditions. Full mouth inspection of the wet teeth was conducted using EAPD 2003 criteria for diagnosis of MIH (Table 1). The severity of MIH was assessed by the criteria given by Jasulaityte *et al.*<sup>11</sup> and recently included in the EAPD recommendations.<sup>12</sup> According to these criteria, demarcated enamel opacities without enamel breakdown, occasional sensitivity to external stimuli e.g. air/water and mild esthetic concerns of discoloration of the incisors are included in a mild category. In severe cases, there are demarcated enamel opacities with breakdown, caries, persistent hypersensitivity affecting function e.g. while brushing and high esthetic concerns that may have socio-psychological impact. Prevalence and characteristics of MIH was recorded. The statistical analysis was done using SPSS software version 17. A descriptive analysis of the prevalence and clinical characteristics was performed. Inter group comparison was done using the Chi-square test. P value of 0.05 or less was considered to be of statistical significant for all the tests.

## RESULTS

In a total of 1000 children of age group 8-12 years, 838 were examined in the schools and 162 in our department. Of the study sample, 534 (53.4%) were males, and 466 (46.6%) were females. 29 children were diagnosed with MIH, revealing a prevalence of 2.9% in south Bangalore.

With respect to the age distribution, 10-year-old children had a statistically significantly ( $P = 0.044$ ) higher MIH prevalence (31%), as compared with the rest of the age groups (Table 2, Graph 1)

19 (65.5%) of the children affected with MIH were male, and 10 (34.5%) were females. This difference was found to be statistically significant ( $P < 0.05$ ).

In a total of 29 children, 125 teeth were affected (85 first permanent molars [FPMs] and 40 permanent incisors) with an average of 4.31 teeth per individual. In the molar group, 42 were mildly affected, and 43 were moderate-severely

**Table 1: Diagnostic criteria for MIH (Weerheijm 2003)**

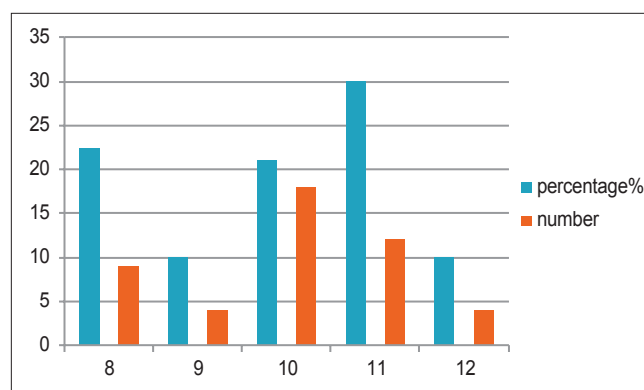
Absence or presence of demarcated opacities (defect altering the translucency of the enamel)
Posteruptive enamel breakdown (loss of surface enamel after tooth eruption, usually associated with a pre-existing opacity)
Atypical restorations (frequently extended to the buccal or palatal smooth surfaces reflecting the distribution of hypoplastic enamel)
Extracted molars due to MIH
Failure of eruption of a molar or incisor

MIH: Molar incisor hypomineralization

**Table 2: Age wise distribution of MIH**

Age	Number	Percentage
8	4	13.7
9	7	24.1
10	9	31
11	5	17.2
12	4	13.7

MIH: Molar incisor hypomineralization



**Graph 1: Distribution of molar incisor hypomineralization according to age**

affected. Most commonly affected teeth were left mandibular first molars (25) followed by mandibular right (22), maxillary left (20) and maxillary right molars (18) (Table 3, Graph 2).

Of the incisors, maxillary left central incisors ( $n = 12$ ) were most commonly affected followed by maxillary right central incisors ( $n = 9$ ) (Table 3, Graph 2). Severe MIH was found only in two incisors, and both were maxillary central incisors (Figure 1).

Overall ( $P = 0.007$ ) maxillary teeth (53.6%) were affected more than mandibular teeth (46.4%). However, when molars were considered mandibular molars (55.3%) were affected more than maxillary molars (44.7%). Left side revealed more affected teeth than the right ( $P = 0.033$ ).

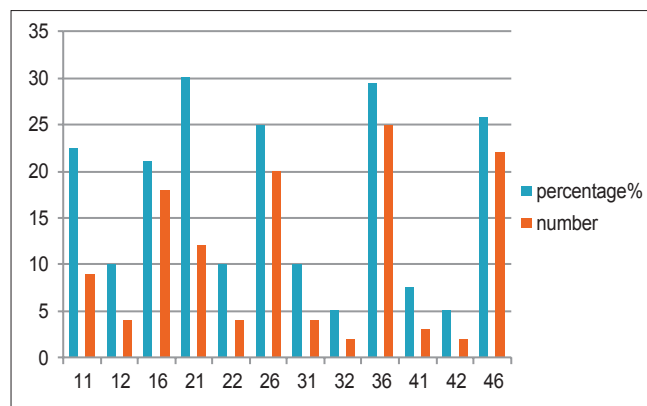
### Severity Levels of Affected Teeth

Totally, 38 out of 40 (95%) incisors revealed mild defects, while 42 out of 85 (49.5%) molars were mildly affected. Almost 43 out of 85 (50.5%) molars were severely affected (Figure 2). Overall, mild abnormalities were found in 80 out of 125 teeth (64%) of affected teeth and severe defects in 45 out of 80 affected teeth (36%) (Figures 3 and 4).

**Table 3: Distribution of MIH in various index teeth**

Tooth number	Number	Percentage
11	9	22.5
12	4	10
16	18	21.1
21	12	30
22	4	10
26	20	25
31	4	10
32	2	5
36	25	29.4
41	3	7.5
42	2	5
46	22	25.8

MIH: Molar incisor hypomineralization



**Graph 2: Distribution of molar incisor hypomineralization according to the teeth affected**

## DISCUSSION

The aim of the present study was to determine the prevalence and clinical characteristics of MIH in an Indian child population residing in south Bangalore, India. The findings of this study indicate that MIH is less prevalent in this area with only 3 out of 100 children being affected by it.

Most prevalence studies on MIH have been carried out in European countries, and data from Asia are less. In India,



**Figure 1: Severe molar incisor hypomineralization affecting maxillary incisors**



**Figure 2: Molar incisor hypomineralization affecting all the molars in an 11-year-old boy**



**Figure 3: Mild hypomineralization seen in incisors**



**Figure 4: Typical “cheese molars” appearance of mandibular molars**

only a few studies in northern and western states have been reported. As per the available literature there are no studies regarding the prevalence of MIH in southern states of India.

EAPD, in their 6<sup>th</sup> Interim workshop on MIH<sup>6,12</sup> had suggested that the variation in data regarding the prevalence and severity appearing in various studies worldwide was due to different criteria used for diagnosis of MIH. In the present study criteria used for the diagnosis of MIH was that given by EAPD in 2003. The same criteria have been employed in most of the published studies since 2003. Finally, a single investigator was involved in the current study in order to have the best possible consistency and reproducibility for the dental examinations.

The results revealed prevalence of MIH to be 2.9% in South Bangalore. This was significantly less when compared to the prevalence reported in other regions of India (9.2% in Gandhinagar,<sup>10</sup> 9.4% in Udaipur<sup>9</sup> and 6.3% in Chandigarh<sup>13</sup>). In addition, three more studies in other Asian regions revealed prevalence rates of 2.8% in Hong-Kong,<sup>14</sup> 17.6% in Jordan<sup>15</sup> and 18.6% in Iraq.<sup>16</sup>

Many previous studies had excluded carious or restored teeth from their assessment. Also, post-eruption enamel breakdown was incorrectly classified as hypoplasia. In addition, severely affected molars that required extensive restorations or extraction superimposed the developmental defects. This was particularly seen in studies including children over 10 years of age. All these problems may have led to an underestimation of MIH. In our study, we included children from 8 to 12 years to rule out the above-mentioned problems. Also, the number of children examined in the present study was high (1000). This made sure that a “true” reflection of the prevalence of MIH in our area was obtained.

Prevalence of MIH was found to be slightly higher in boys (65.5%). These findings were similar to other studies of MIH conducted in Germany,<sup>17</sup> Spain,<sup>18</sup> Iraq,<sup>16</sup> and Gujrat (India).<sup>10</sup> Studies on Australian<sup>19</sup> and Jordanian<sup>15</sup> children, however, have reported a higher prevalence in girls.

The average age of children affected with MIH in the present study was 10.2 years. Older children showed more prevalence of MIH. This might have been due to easier recognition and diagnosis once post-eruptive discoloration and breakdown in these children had occurred. In younger children, mild defects often go unnoticed.

In the present study, more maxillary teeth (53.5%) in total were affected compared to the mandibular. However, when molars were evaluated, mandibular teeth (55.2%) were more affected than maxillary teeth. Similar findings were reported in previous studies<sup>6,10,11</sup> but this was contrary to studies indicating negligible differences between the maxillary and mandibular teeth.<sup>4,19</sup>

When anterior teeth were considered, maxillary incisors in total were much more frequently affected than mandibular, which was in agreement with all previous reports. Similar findings were reported in most of the previous studies<sup>12,17</sup> but contradicted others.<sup>11,15</sup>

The vast majority (64%) of the affected teeth in the present study revealed mild defects. This finding is also in accordance with previous studies.<sup>8,10,12</sup>

## CONCLUSION

Research has shown that MIH is a widespread problem all over the world. In India, a few studies have been reported on the prevalence of MIH. Although this study showed the prevalence of MIH to be significantly low when compared to previous studies in India, this does not rule out the fact that MIH threatens to become a concerning developmental enamel defect. Therefore, more prevalence studies on larger scales have to be conducted.

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# Computer Aided Photogrammetric Analysis of the Dental and Facial Midline Relationship: A Clinical Study

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## Abstract

**Introduction:** Facial symmetry is one of the factors that contribute to facial esthetics and harmony. In a symmetric face, teeth midline and midline of the face should coincide, but it is not usually found. Perfectly bilateral face and body symmetry is largely a theoretical concept that seldom exists in living organisms.

**Aims and Objective:** This study was conducted to analyze the axial symmetry between the bipupillar midline and maxillary central incisors midline in the target population.

**Materials and Methods:** A sample of 100 subjects with no teeth missing and who had never been subjected to any dental treatment were selected. A digital camera (Nikon Coolpix 1820) was used to capture images. The images then were transferred to the laptop using adequate software tools (Corel-draw Graphic Suite 12). Then, center of each pupil of each subject was found out, and the line was drawn from the center of one pupil to the center of other pupil. A straight line was traced perpendicular and median to this line that was taken as facial midline. Another line was drawn from the center of the central incisors which was taken as dental midline. The difference between these lines was observed, in order to observe whether there was coincidence or deviation of the facial midline with the dental midline. The data so collected were subjected to statistical analysis.

**Results:** There was no significant correlation between bipupillar midline and the maxillary dental midline, irrespective of gender.

**Conclusion:** Lack of exact coincidence between the location and direction of the two midlines is common and therefore the exact coincidence of facial and dental midline is not necessarily an esthetic liability when planning restorative treatment.

**Keywords:** Dental midline, Esthetics, Facial midline, Gingival margins, Prosthodontics, Smile

## INTRODUCTION

Face, the most expressive part of the human body, determines an individual's social acceptance.<sup>1</sup> Loss of teeth affects not only facial appearance but also creates

psychological trauma to a person. Hence it is essential that an esthetically pleasing and functionally comfortable replacement of the missing teeth should be provided.<sup>2</sup>

The arrangement of maxillary anterior teeth plays an important role in facial esthetics. If they are in harmony with the other oro-facial components they significantly contribute to the aesthetics of the face.

Complete dentures must be pleasing and natural in appearance. An important consideration in the arrangement of the anterior teeth is symmetry, a key factor being the establishment of dental midline. This is an imaginary

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line that separates the two maxillary central incisors. The midpoint of the interpupillary line or a line from the center of the brows generally is used to locate the facial midline.

The first step in the arrangement or fabrication of anterior prostheses, whether fixed or removable, is to establish the dental midline because the dental components should give a general feeling of symmetry and balance in order to have an acceptable appearance.<sup>3</sup>

The major question is, where should the dental midline be placed?

The answer is obtained from the dental literature with two different recommendations:

- One is to establish the dental midline coinciding with the facial midline.
- The other is, never establish the dental midline coinciding with the midline of the face since it may contribute to an artificial appearance.<sup>4</sup>

The purpose of this study therefore, was to investigate the coincidence of the maxillary dental midline with the facial midline and hence that this relationship can be used to achieve natural and pleasant replacement of teeth in fixed prosthesis and in complete denture patients.

### Aim

To analyze the coincidence between the facial midline and maxillary central incisors midline (dental midline) in the subjects selected.

### Objectives

1. To evaluate the amount of deviation between facial midline and maxillary central incisor midline if at all it exists in the subjects selected
2. To compare midline deviation between men and women in the subjects selected.

## MATERIALS AND METHODS

The study was carried out on the students of Rama Dental College-Hospital and Research Centre, Kanpur from May 2014 to August 2014. Ethical clearance was obtained from Ethical Committee of the institute, and informed consent from patients was taken.

### Armamentarium

1. Mouth mirror
2. Straight probe
3. Tweezer
4. Kidney tray
5. Gloves, masks and head caps
6. Digital camera (Nikon Coolpix l820)

7. Personal computer (Compaq Presario CQ61)
8. Specialized computer software (Corel-draw software)
9. Tripod (Simplex 333).

### Source of Data

A total of 100 students with the age range of 18-27 years were selected randomly. The students having prosthetic maxillary and mandibular anterior teeth, any history of facial or dental trauma, midline diastema or any craniofacial anomaly were excluded. The patients were observed to check if the maxillary dental midline coincides with the facial midline. The observable deviation of these midlines was determined from photographs in the present study.

### Collection of the Photographic Data

A digital camera (Nikon Coolpix l820) was used to capture images. The camera was mounted on a tripod, with a standardized focus and at a standardized distance of 5 feet (1.5 m) from the subject. The subjects were made to sit upright and the head of the subjects were positioned in such a way that Frankfort Horizontal Plane remained parallel with the surface of the floor, and subjects were asked to direct their sight in the distance. Digital frontal photos of the face with the posed smile of all subjects were made. Photos covered the chin area to the top of the forehead, but lenses were centered between eyes. In that way the possibility of distortion was reduced, and photos were standardized.

### Image Analyses

The images were transferred to a computer and by using adequate software tools (Corel-draw Graphic Suite 12), the center of each pupil was found out, and then a line was drawn from the center of one pupil to the center of other pupil. A straight line was traced perpendicular and median to this line that was taken as facial midline. Another line was drawn from the center of the central incisors which was taken as dental midline. The difference between these lines was observed, in order to observe whether there was coincidence or deviation of the facial midline with the dental midline (Figures 1 and 2).

### Statistical Analysis

The data so collected were subjected to statistical analysis. Analysis of the axial symmetry related to the bipupillar perpendicular midline bisector was performed, classifying the cases of coincidence as Yes (Group Y) and the others as No (Group N). Group N were submitted to secondary analysis in which the amount of displacement of the median line were assessed. The value so obtained was compared between men and women using Chi-square test and Mann-Whitney U-test in order to find out whether the difference obtained was statistically significant at  $P < 0.05$ .

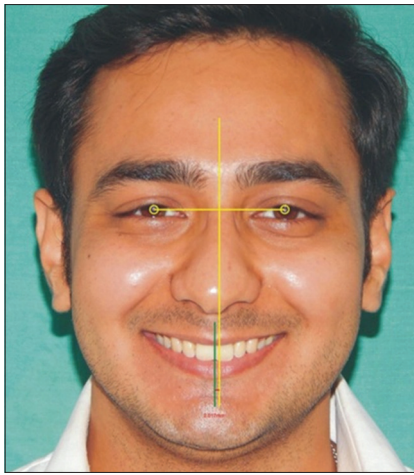


Figure 1: Male subject with midline deviation of 2.017 mm

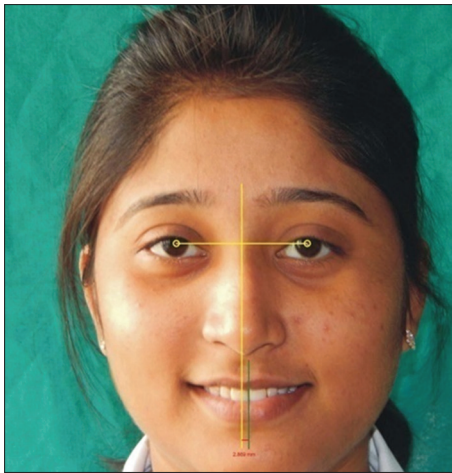


Figure 2: Female subject with midline deviation of 2.8 mm

## RESULTS

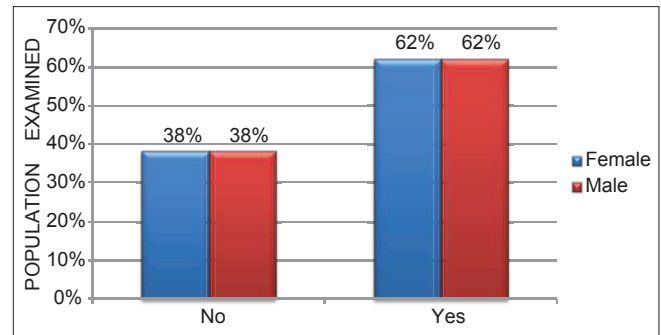
In this study, it was observed that in males no midline deviation was seen in 38% of the population, and 62% of the population shows midline deviation. Similar results were found among female subjects, i.e., no midline deviation was seen in 38% of the population, and 62% of the population shows midline deviation. Population showed deviation ranging from 0.00 to 3.296 mm. No difference was found between males and females with respect to midline deviation, which stated that no gender difference was found in the midline deviation.

### Chi-square Test (Table 1, Graph 1)

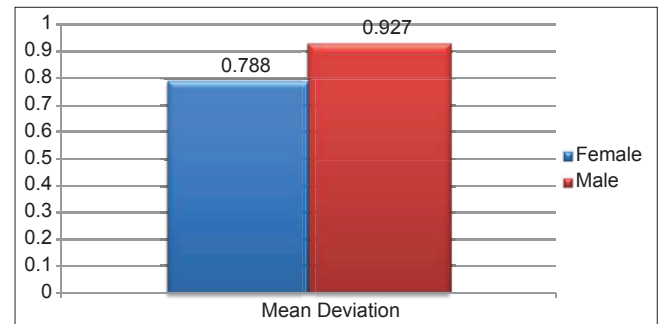
There was no difference in the distribution of the deviation between males and females ( $P > 0.99$ ).

### Mann-Whitney U-test (Table 2, Graph 2)

No significant difference in the mean deviation between males and females ( $P = 0.498$ ).



Graph 1: Percentage of midline coincidence and midline deviation in males and females



Graph 2: Mean deviation of midline deviation in males and females

Table 1: Comparison of midline deviation between male and female subjects

	Number of subjects (%)		P value
	Female	Male	
Deviation			
No	19 (38.0)	19 (38.0)	>0.99; NS
Yes	31 (62.0)	31 (62.0)	

NS: Not significant

Table 2: Comparison of mean deviation of midline deviation between male and female subjects

	Sex				P value
	Female		Male		
	Mean	SD	Mean	SD	
Deviation	0.788	0.796	0.927	0.911	0.498; NS

NS: Not significant

## DISCUSSION

The goal for esthetic treatment should be an enhanced, but natural appearance that imparts a vibrant and believable appearance to the patient. The goal of esthetic dentistry should be “bright, beautiful, but believable.”<sup>5</sup> As esthetic demands in smile design continually rise, critical factors such as; dental midline, smile line, incisal embrasures,

tooth position, width to length crown ratio, symmetry of contra-lateral gingival margins, and gingival display, need to be taken into consideration.<sup>6</sup>

During this study, the midpoint of interpupillary line was used to determine the facial midline. The results of this study are in agreement with the results obtained in the study conducted by Eskelsen *et al.* They examined 102 dental students (both genders) distributed across five Brazilian dental schools. Analysis of the axial symmetry related to the bipupillar perpendicular midline bisector was performed, there was not much coincidences between the maxillary midline and the perpendicular bisector of the interpupillar distance.<sup>7</sup> Approximately similar results were obtained in another study looking at dental students done by Soares *et al.* He found that the coincidence of facial midline with the arch midline occurred in only one half of the students.<sup>8</sup>

## CONCLUSION

As a result of the methodology applied and the results obtained in this study, it could be concluded that lack of exact coincidence between the location and direction

of the two midlines is common and therefore the exact coincidence of facial and dental midline is not necessarily an esthetic liability when planning restorative treatment. However, the basic principles of esthetics should not be ignored as in some individuals it is of paramount importance.

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# Clinical, Radiographic and Histopathologic Features of Ameloblastoma: A Retrospective Analysis of 21 Cases

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## Abstract

**Background:** Ameloblastoma is the second most common tumor of the oral cavity. A small number of studies have been reported among Asians, especially about the frequency and characteristics of this tumor.

**Aims and Objectives:** The aim was to analyze and correlate the clinical, radiographic and histopathologic features of ameloblastoma.

**Materials and Methods:** Demographic data, clinical and radiographic findings were collected from hospital records of the patients. Histopathologic slides for each case were reviewed and classified according to histologic patterns. The outcome of the condition and recurrence rate was determined based on the follow-up records. Data was entered accordingly in tabulated form. MS excel was used for statistical analysis.

**Results:** A total of 21 cases of ameloblastoma were diagnosed and treated for ameloblastoma over a period of 8 years. Male to female ratio was 1.3:1 with mean age of occurrence 37.57 years. Radiographically, 61.90% had unilocular radiolucency and 38.09% had a multilocular radiolucency. The most common histologic type was plexiform and mural unicystic ameloblastoma and mural unicysticameloblastoma (UA). Of the 21 patients, 4 patients experienced recurrence of which two cases were unilocular and 2 were multilocular, but period of recurrence was different in all 4 patients. No recurrence was seen in patients with UA. The average age of recurrence was 38.5 years.

**Conclusion:** Data related to gender, location, radiographic appearance, size, symptoms, clinicopathologic subtypes and recurrence were similar to previous studies conducted in various parts of the world. In contrast to other reports, we observed that ameloblastoma can occur in young patients with predominant unilocular radiographic pattern and hence a biopsy should be mandatory in case of suspicion. Recurrence was more common in solid ameloblastoma as compared to unicystic ameloblastoma.

**Keywords:** Ameloblastoma, Recurrence, Odontogenic tumors, Tumor, Unicystic ameloblastoma

## INTRODUCTION

Odontogenic tumors (OTs) derived from tooth forming apparatus or its remnants constitute a wide range and

diverse kind of lesions. OTs originate from epithelium or ectomesenchyme or from both, showing varying degrees of inductive interaction between embryonic components of the developing tooth germ. Ameloblastoma is a true neoplasm of odontogenic epithelium and is the second most common tumor of the oral cavity.<sup>[1]</sup> It represents about 1% of all oral ectodermal tumors and 9% of odontogenic tumors.<sup>[2]</sup> It is usually first recognized between third and fifth decades of life. 70% of the ameloblastomas develop in the molar region and typically have a multilocular appearance on radiographs. Most ameloblastomas contain microcysts but the unicystic variant has a lining of flattened

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tumor cells which resemble those of non-neoplastic cysts with nodular proliferation into the lumen without infiltration of tumor cells into the connective tissue wall. Over 80% of these cystic tumors enclose the crown of a tooth and mimic dentigerous cysts radiographically. Ameloblastoma is often aggressive and destructive with the capacity to attain great size, erode bone and invade adjacent structures.<sup>[3,4]</sup>

The term “ameloblastoma” was coined by Churchill in 1933 but the first detailed description was given by Falkson in 1879.<sup>[5]</sup> It is an neoplasm that arises from remnants of the dental lamina and dental organ (odontogenic epithelium).<sup>[5]</sup> Its histological appearance is similar to that of the early cap-stage ameloblastic elements of developing tooth without complete differentiation to stage of enamel formation.<sup>[1]</sup> Diverse histological patterns have been described in the literature, including those with follicular, plexiform, acanthomatous, papilliferous, keratotic, desmoplastic, granular cells, vascular and with dentinoid induction.<sup>[5]</sup>

In general, odontogenic tumors have been reported to be rare and that it takes considerable time for any centre to collect representative cases in sufficient numbers. Several studies on ameloblastoma have been published from many parts of the world with different prevalence. A small number of studies have been reported among Asians, especially about the frequency and characteristics of this tumor.<sup>[6]</sup> None of them have attempted to correlate the clinical, radiologic and histopathologic features of ameloblastoma. So this study sought to correlate the clinical, radiologic and histopathologic features of cases already diagnosed with intraosseous ameloblastoma.

## MATERIALS AND METHODS

This study was conducted in the Department of Oral Medicine and Radiology, MCODES, Manipal. All the patients diagnosed and treated for ameloblastoma from 2005 to 2013 were included in the study. Ethical committee clearance was taken to assess the data from previous hospital records. The demographic data, clinical and radiographic findings were collected from hospital records of the patients. Incomplete clinical, radiographic, histopathologic or treatment data was not considered for study. Histopathologic slides for each case were reviewed and classified according to histologic patterns. The patients either treated conservatively (i.e., with enucleation and curettage, or both) or radically (i.e., with partial or complete jaw resection) were included in the study. The outcome of the condition and recurrence rate was determined based on the follow up records. Data was entered accordingly in

a tabulated form. The percentage of the patients affected in different groups was calculated and MS excel was used for statistical analysis.

## RESULTS AND OBSERVATIONS

Totally 21 cases of ameloblastoma diagnosed and treated for ameloblastoma from 2005 to 2013 were selected. The study consisted of 12 males (57.14%) and 9 female patients (42.85%) (Table 1) with a mean age of 37.57 years (Table 2), followed-up for a mean period of 60 months.

In 8 patients (38.09%) the tumors were located in body and ramus region of mandible (Figures 1 and 2), in 7 patients (33.33%) tumors were in region of mandibular body only, in 2 patients (9.52%) tumors were involving angle and body of mandible, in 3 patients tumors were crossing the midline of mandible, but involving only anterior region in one patient (Figure 3), in another 2 patients it was crossing midline and approaching till the ramus region on other side. In one patient, tumor was present in anterior region of mandible on one side (Table 3).

Swelling was the most common symptom experienced by 17 out of 21 patients (Figures 1 and 2). In 8 patients (38.09%), only complaint was swelling. Swelling and pain were present in 3 patients (14.28%) and in 3 patients (14.28%) there was history of delayed healing of extraction socket with

**Table 1: Sex distribution of ameloblastoma**

Sex	No. of patients	Percentage
Male	12	57.14
Female	9	42.85

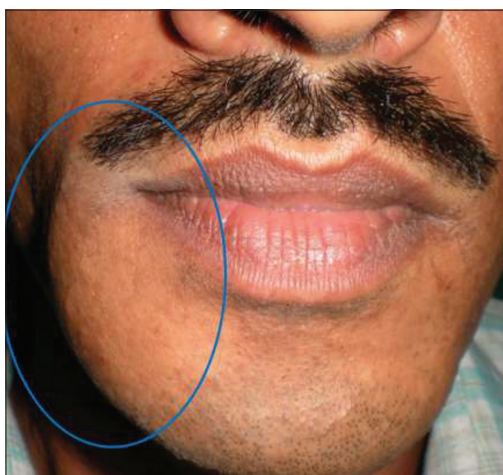
**Table 2: Age distribution of ameloblastoma**

Age	No. of patients	Percentage
0-19	3	14.28
20-39	9	42.86
40-59	8	38.09
Above 60	1	4.76

**Table 3: Site distribution of ameloblastoma**

Site	No. of patients	Percentage
Mandible body	7	33.33
Angle of mandible	0	0
Crossing midline (Ant.)	1	4.76
Angle and body	2	9.52
Angle and ramus	0	0
Body and ramus	8	38.09
Maxilla	0	0
Crossing midline (ant to ramus)	2	9.52
Mandibular anterior region	1	4.76

associated swelling. In 2 patients (9.52%), swelling and pain with purulent discharge were reported. Swelling and pain with paraesthesia were reported in 1 patient (4.76%). Only pain as the symptom was reported in 3 patients (14.28%).



**Figure 1: Ameloblastoma affecting body of mandible region**



**Figure 2: Ameloblastoma affecting ramus of mandible region**



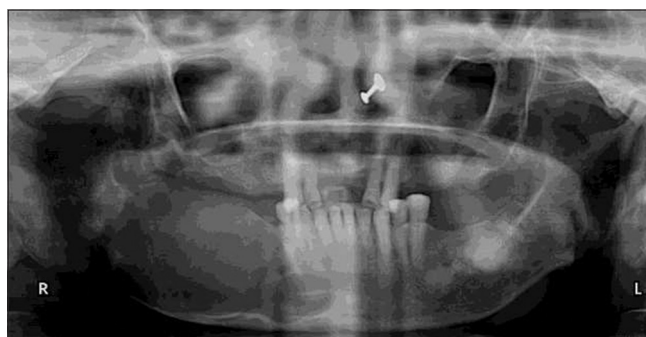
**Figure 3: Ameloblastoma crossing midline**

In 1 patient, there were no symptoms and ameloblastoma was an incidental finding in radiograph (Table 4).

Radiographically, 13 patients (61.90%) had unilocular radiolucency (Figures 4 and 5) and 8 patients (38.09%) had a multilocular radiolucency (Figure 6).

Based on histologic criteria, six patients (28.57%) had plexiform unicystic ameloblastoma, six had mural unicystic ameloblastoma (Figure 7), three had luminal unicystic ameloblastoma (Figure 8), two had follicular ameloblastoma, two had acanthomatous and one each had desmoplastic and cystic variety.

The relationship between histologic and radiographic findings was evaluated in our study. Out of 6 patients



**Figure: 4 Unilocular Ameloblastoma involving right body and ramus of mandible**



**Figure 5: Unilocular Ameloblastoma involving right body of mandible**



**Figure 6: Multilocular appearance of ameloblastoma in anterior mandibular region**



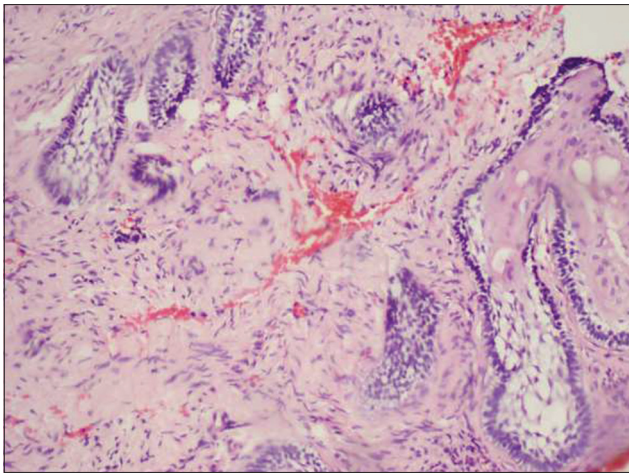


Figure 7: Mural variant of ameloblastoma (10x)

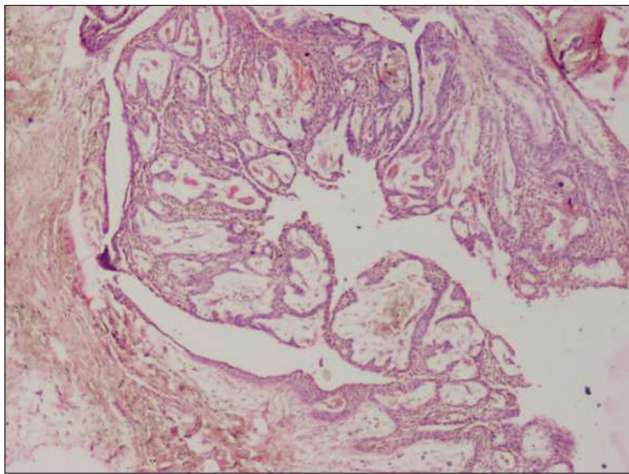


Figure 8: Luminal variant of ameloblastoma (4x)

**Table 4: Symptoms reported by patients**

Symptom	No. of patients	Percentage
Only swelling	8	38.09
Only pain	3	14.28
Pain+swelling	3	14.28
Swelling+non healing of extraction socket	3	14.28
Pain+paraesthesia	1	4.76
Pain+swelling+pus discharge	2	9.52
No symptoms	1	4.76

with plexiform UA, 4 were unilocular and 2 multilocular. All 3 cases of luminal UA were unilocular. 50% cases with mural UA were unilocular and 50% were multilocular in appearance. All cases of follicular ameloblastoma, desmoplastic ameloblastoma and cystic ameloblastoma were unilocular. One case with acanthomatous was unilocular and other one was multilocular.

Of the 21 patients, 4 patients experienced a recurrence (Table 8), two cases were unilocular and 2 were multilocular

**Table 5: Age wise distribution of ameloblastoma according to radiographic appearance**

Age	Unilocular (n=13)	Multilocular (n=8)
0-19	3	3
20-39	5	5
40-59	4	0
Above 60	1	0

**Table 6: Distribution of ameloblastoma according to histologic pattern**

Type of ameloblastoma	Number	Percentage
Plexiform unicystic ameloblastoma	6	28.57
Mural unicystic ameloblastoma	6	28.57
Luminal unicystic ameloblastoma	3	14.28
Follicular ameloblastoma	2	9.52
Acanthomatous ameloblastoma	2	9.52
Desmoplastic ameloblastoma	1	4.76
Cystic variety ameloblastoma	1	4.76

**Table 7: Relationship between radiographic and histologic findings**

Histologic type	Unilocular	Multilocular	Total
Plexiform UA	4	2	6
Luminal UA	3	-	3
Mural UA	3	3	6
Follicular	2	-	2
Cystic	1	-	1
Acanthomatous	1	1	2
Desmoplastic	1	-	1

UA: Unicystic Ameloblastoma

**Table 8: Period of recurrence**

Follow-up	No. of patients	No. of patients
1-<2	5	1
2-<3	2	1
3-<4	5	0
4-<5	3	1
5-<10	6	1
Total	21	4

(Table 9), period of recurrence was varied in all 4 patients (Table 8), no recurrence was seen in patients with unicystic ameloblastoma. 2 cases of follicular variant, 1 case of acanthomatous and 1 case of desmoplastic showed recurrence (Table 10).

## DISCUSSION

Male to female ratio of 1.3:1 is observed in our study, which is in agreement with a study by Waldron and El-Mofty, in which they reported that in 116 tumors, the male-to-female ratio was 1.2:1.<sup>[7]</sup> Most studies have reported



**Table 9: Outcome after conservative therapy for ameloblastoma according to radiographic type**

Result of therapy			
Radiographic type	No. of patients	Tumor free	Recurrence
Unilocular	14	12	2
Multilocular	7	5	2
Total	21	17	4

**Table 10: Outcome after conservative therapy for ameloblastoma according to histologic type**

Result of therapy			
Histologic type	No. of cases	Tumor free	Recurrence
Plexiform UA	6	6	0
Luminal UA	3	3	0
Mural	6	6	0
Follicular	2	0	2
Cystic	1	1	0
Acanthomatous	2	1	1
Desmoplastic	1	0	1
Total	21	17	4

UA: Unicystic Ameloblastoma

an equal gender distribution of ameloblastomas, but a male preponderance was reported in Nigerian, Egyptian, Chinese and Indian population. Our study showed that ameloblastoma has a marked predilection for the mandible as none of the cases were reported in the maxilla. Regarding the anatomic site of occurrence, ameloblastoma has a high predilection for the mandible, whereas the incidence of maxillary lesions is less considerably among published studies. Mean age of occurrence in our study was 37.57 years. Reichart *et al.* (1995) conducted a meta-analysis in which 3677 ameloblastoma cases were found with a mean occurrence age of 36 years. In their study, ameloblastoma was frequently seen in men (53%) and the mandible was affected in 84.3% of the cases.<sup>[8]</sup> Most common tumor site in our study was the body, angle and ramus region of mandible. Ladeinde *et al.* observed that the most common site of occurrence for ameloblastoma is the posterior region of mandible (premolar-molar region).<sup>[9]</sup> In 3 patients, tumors were crossing the midline of mandible with involvement of anterior region in one patient and approaching till the ramus region in 2 patients. All the cases crossing midline were diagnosed as unicystic ameloblastoma. Few cases have been reported in literature in which unicystic ameloblastoma was crossing the midline structures of mandible.<sup>[10]</sup> Regarding the anatomic site of occurrence, ameloblastoma has a high predilection for the mandible, while the incidence of maxillary lesions is less considerably among published studies.<sup>[10-18]</sup>

Swelling was the most common symptom in our study with associated symptoms like pain, paraesthesia, purulent

discharge, delayed extraction socket and was similar to the observation made by Kim *et al.*<sup>[11]</sup> Few patients presented with only slow growing swelling, similar observation is reported in literature.<sup>[11,19,20]</sup>

Radiographically, 13 patients (61.90%) had unilocular radiolucency and 8 patients (38.09%) had a multilocular radiolucency. These findings were similar to study by Kim *et al.* in, which they observed 59.2% (42 of the 71 tumors) were unilocular with a well-demarcated border.<sup>[11]</sup> Of the remaining 29 cases, 14 were multilocular, 2 were of soap-bubble shape and 13 were unknown in appearance. In another study by Montes *et al.*, similar findings with predominantly unilocular lesions were observed.<sup>[12]</sup>

The most common histologic type was plexiform unicystic ameloblastoma and mural UA in our study. The results were contrary to a study by Adebisi *et al.* in which follicular ameloblastoma was the most common form.<sup>[13]</sup>

The relationship between histologic and radiographic findings was evaluated. Out of 6 patients with plexiform UA, 4 were unilocular and 2 multilocular. All the 3 cases of luminal UA were unilocular. 50% cases with mural UA were unilocular and 50% were multilocular in appearance. All cases of follicular ameloblastoma, desmoplastic ameloblastoma and cystic ameloblastoma were unilocular. One case with acanthomatous was unilocular and other one was multilocular. Kim *et al.* reported 15 cases, each of the plexiform and follicular tumors which manifested with unilocular radiographic findings.<sup>[11]</sup> Most of the unilocular tumors were diagnosed with unicystic ameloblastoma. However, in our study, the radiographic appearance was not indicating to the histological type of ameloblastoma.

Of the 21 patients, 4 patients experienced recurrence, 2 were unilocular and 2 were multilocular, but the period of recurrence was different in all 4 patients. No recurrence was seen in patients with unicystic ameloblastoma. Two cases of follicular variant and one case each of acanthomatous and desmoplastic variety showed recurrence. Our results demonstrate that the cases of solid ameloblastoma were more recurrent as compared to the UA cases. These figures are in accordance with the previous studies by Reichart and Ledesma-Montes *et al.*<sup>[8,12]</sup>

The average age of recurrence was 38.5 years in our study. Olaitan *et al.* studied 26 cases of recurrent ameloblastoma of the jaws within a 15-year period. The highest incidence was found in the third decade of life.<sup>[14]</sup> Over 80% of the recurrences presented within 5 years of primary surgery, emphasizing the need for adequate and intensive follow-up during this critical period.

Post-operative follow-up is important in the management of ameloblastoma because more than 50% of all recurrences occur within 5 years of surgery as suggested in our study. Kim *et al.* observed similar results in their study.<sup>[11]</sup> In an study, Antonoglou et al made strong clinical recommendations that resection may be preferable in both unicystic and solid or multicystic ameloblastomas.<sup>[15]</sup>

## CONCLUSION

The present study aimed to analyze and correlate the clinical, radiographic and histopathologic features of ameloblastoma. Data related to gender, location, radiographic appearance, size, symptoms, clinicopathologic subtypes and recurrence were similar to previous studies conducted in various parts of the world. In contrast to other reports, we found that ameloblastoma occurred in younger patients and unilocular radiographic pattern was predominantly seen in such cases, and hence biopsy should be mandatory in case of suspicion. Our results demonstrate that the solid ameloblastoma cases are more recurrent when compared with the UA cases. The average age of patients experiencing recurrence was also younger (mean age 38.5 years). Long-term follow-up at regular intervals after surgery is also recommended.

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# Closure versus Non-closure of Peritoneum in Cesarean Section and Evaluation of Post-operative Pain: A Hospital Based Study

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## Abstract

**Background:** Cesarean section (CS) is the most commonly done surgical procedure globally. Suturing the peritoneal layers at CS may or may not confer needful benefits, hence there is a need to evaluate whether this step should be carried on or omitted.

**Objective:** The objective of this study is to evaluate the effects of leaving the peritoneum open at lower segment CS (LSCS) measured by post-operative pain.

**Material and Methods:** The study was done in the Department of Obstetrics and Gynaecology, Punjab Institute Of Medical Sciences, Garha Road, Jalandhar. A total of 100 cases who underwent LSCS were randomly assigned equally to either closure of both, visceral and parietal peritoneum or no peritoneum closure. Duration of operation, pain scores, analgesic requirements, alteration of hemoglobin levels and febrile morbidity were assessed accordingly.

**Results:** The principal outcome measure was the post-operative pain assessed by visual analog scale. Other outcomes were usage of analgesics, post-operative complications, bowel function, and hospital stays. Pain scores, analgesic requirements those were assessed at 24 h and operation duration was significantly lower in non-closure group as compared to closure group. No significant difference was seen in the incidence of post-operative complications, e.g. febrile conditions and change in hemoglobin levels.

**Conclusion:** Non-closure of both visceral and the parietal peritoneum when performing a CS produces significant reduction of pain, fewer analgesic requirements and a shorter operation duration without increasing the febrile morbidity and changes in haemoglobin levels as compared to the standard methods.

**Keywords:** Analgesics, Cesarean section, Pain, Visual analog scale

## INTRODUCTION

Globally cesarean section (CS) is considered as one of the most frequently performed surgical procedure in about 5% to over 20% of all deliveries.<sup>[1]</sup> Most common surgical complications those occur in CS are fever, post-operative pain, wound infection and then in normal vaginal delivery.

These all conditions affect the postnatal care of newly born infants. Since many years suturing of peritoneal layers in CSs has been practices, but in many randomized clinical trials conducted, this stage has been omitted since it reduces morbidity rate.

Various reasons are noted for closure of the peritoneum that includes restoring the anatomy and approximating tissues, minimizing infection by re-establishing an anatomical barrier, reducing hemorrhage, decreasing wound dehiscence and minimizing adhesions. Some reasons those cited for non-closure of the peritoneum includes reduction of operative duration, shortening of hospitalization admission, earlier return of bowel function, use of less analgesic, reduction of urinary bladder adhesion

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following next CS, and immediate post-operative recovery. It also reduces the number of stitches that is the preferred option.<sup>[2-5]</sup>

Post-operative pain can lead to unpleasant physiologic responses including retention of secretions in the respiratory system, ileus, increased post-operative stay in hospital, increased usage of analgesics and ultimately delayed breast feeding. Decrease in post-operative pain improves mother's comfort and also the outcome of the newborn infant.

Several studies have evaluated the effects of leaving the peritoneum open and compared it with closing after CS. Some studies have also reported lower incidence of post-operative febrile morbidity, earlier return of bowel function and shorter stay in hospital following non-closure of the peritoneum compared to closure technique.<sup>[3-5]</sup> Some other studies have shown no significant difference in relation to wound infection, post-operative febrile morbidity and stay in hospital.<sup>[4,6-8]</sup>

### Objective

Present study was conducted with the objective to know about the outcomes of closure versus non-closure of the visceral and parietal peritoneum following CS, and to compare post-operative morbidity of the same.

## MATERIALS AND METHODS

The present randomized clinical trial was conducted in the Department of Obstetrics and Gynecology, Punjab Institute of Medical sciences, Garha Road in year 2013 to compare the effects of post-operative morbidity following CS with closure versus non-closure of both the visceral and parietal peritoneum. Ethical clearance was obtained from Institutional Ethical Board and Informed consent was obtained from patients. The sample of one hundred females undergoing elective and emergency CS were selected randomly to receive either closure or non-closure procedure of peritoneum.

### Exclusion Criteria

Patients those fitting to below mentioned criteria were excluded:

1. Previous CS and/or abdominal surgery
2. Having lifestyle diseases like hypertension, diabetes mellitus
3. Premature rupture of membrane and preoperative bleeding.

Patients were given spinal anesthesia and were operated by the same surgeon. Transverse incision was given in all

cases. All the females underwent lower segment CS through a pfannenstiell incision. Uterus was closed with continuous sutures with number-1 vicryl thread.

In the control group, the layers of peritoneum were sutured with continuous 1-0 chromic catgut and rectus sheath was closed with a continuous number-1 vicryl.

The skin was approximated and brought closer with continuous sub-cuticular number 1-0 vicryl thread. The other group of subjects underwent a similar procedure of CS but without reapproximation of visceral and parietal peritoneum layers.

Pre-operatively, ceftriaxone 1 g injection of single dose was given by intravenous (I/V) route in elective cases. In the emergency group, I/V injection ceftriaxone 1 g I/V twice a day, injection of metronidazole 400 mg was given 8 h and gentamycin 80 mg injection was given at interval of 12 h on the first 2 days of surgery and oral antibiotics were given for the next 3 days.

After the operation, all patients were kept and were observed in same post-operative ward. Resident doctors and nursing staff were unaware of the study procedure and made all post-operative assessment and management.

Due to the absence of any complications, patients were discharged on 7<sup>th</sup> day of post-operative day. The outcome measures those were noted were total operating time, pain post-operative, duration of ileus, febrile morbidity, time of ambulation, endometritis, wound infection, cystitis and length of the hospital stay.

Analgesic injection diclofenac sodium 75 mg intramuscularly were given 8<sup>th</sup> h, in the first 24 h of surgery and then as needed. Analgesics were changed over to oral on the first post-operative day.

Use of parenteral analgesia after interval of 24 h of surgery was considered as additional dose of analgesia and then it was recorded. Visual analog scale was used to assess post-operative pain. The ratings were (no pain=0, the worst pain ever=10) at 24 h after surgery and daily till the patient gets discharged.

Females were asked to indicate the average intensity of pain they had experienced during the period of last 24 h. Oral alimentation was reintroduced once bowel sounds were returned. Febrile morbidity was defined as the temperature more than 38°C on two occasions at least 12 h apart, excluding the first post-operative day.

In case of uterine tenderness endometritis was diagnosed and was found that there were vaginal discharge and fever.



Cystitis was diagnosed by having positive urine culture growth or more than 1,00,000 colonies/ml of a single species of bacteria. Wound infection was diagnosed when there was serous or purulent discharge from the skin incision with erythema and induration, with or without fever. Significance of difference, if any, in the observations made of variables studied in control/subject groups, in numbers or averages.

Chi-square ( $\chi^2$ ) or Student's *t*-test, as applicable value  $<0.05$  was considered significant were used for statistical analysis and comparison.

## RESULTS

Totally, 100 females those undergone elective and emergency CS under spinal anesthesia were randomly allocated in two groups equally as closure and non-closure.

Table 1 shows no significant differences were noted between the studies groups with respect to age, parity, gestational age and reasons for CS.

Table 2 shows operative time was significantly shorter (6.89 min) in the non-closure group as compared with the closure groups. Febrile condition was recorded as 10% in the experimental group and 14% in the control group. This difference was not significant. One patient in the closure group developed cystitis and one patient in the non-closure group was diagnosed with mastitis that responded to antibiotics. There were two cases of wound infection in either of the two groups of the study. None of the patients needed a return to the operating theater for any further surgery. Patients in the experimental group demonstrated lower pain scores ( $P = 0.0003$ ) and used significantly fewer analgesics when compared with the control groups (Table 2).

## DISCUSSION

The current study showed that the non-closure of the peritoneum was closely associated with short duration of surgery, significantly lower pain scores and less analgesic use compared to traditional practice (closure of the peritoneum). Bamigboye *et al.* in 2005 revealed a reduction in operative time (7.33 min) in women who had both peritoneal surfaces unsutured in comparison with sutured peritoneum by analyzing a total of six studies with 947 participants.<sup>[1]</sup> In addition to the cited study, a series of other studies also supported our findings of the reduction in operative time.

It was observed that there was a significant difference between two groups regarding pain scores and analgesic use in our study. Lower pain scores were observed in women in non-closure group and those received fewer analgesics.

**Table 1: Clinical characteristics of the patients undergoing cesarean delivery by either closure or non-closure technique**

Clinical characteristics	No. (%) (n=50)		df	Chi-square	P value
	Closure	Non-closure			
Age, mean $\pm$ SD					
Maternal age, year	24.5 $\pm$ 5.9	25.2 $\pm$ 5.3			0.92
Gestational age, week	37.6 $\pm$ 4.4	38.3 $\pm$ 5.2			0.46
Parity, no. (%)					
Primigravida	41 (82)	38 (76)	1	0.542	0.46
Multipara	9 (18)	12 (24)			
Main indication of cesarean delivery, no. (%)					
Fetal cause	12 (24)	19 (38)	2	2.981	0.225
Maternal-fetal cause	21 (42)	14 (28)			
Maternal cause	17 (34)	17 (24)			

SD: Standard deviation

**Table 2: Outcomes of cesarean delivery using either closure or non-closure technique**

Factors	No. (%) (n=50)		df	Chi-square	P value
	Closure	Non-closure			
Operative time, min					
<30	11 (22)	14 (28)	2	7.948	0.018
30-40	21 (42)	30 (60)			
>40	18 (36)	6 (12)			
Pain score					
Mild	5 (10)	5 (10)	2	11.136	0.003
Moderate	26 (52)	40 (80)			
Severe	19 (38)	5 (10)			
Analgesic requirement					
No need	27 (54)	40 (80)	2	7.894	0.019
Injection diclofenac	19 (38)	9 (18)			
Injection tramadol	4 (8)	1 (2)			

Pain score: mild<30, moderate=31-70, severe>70

In control group, injection diclofenac was used 3 times and injection tramadol 2.5 times more as compared to the experimental group.

Rafique *et al.*<sup>[9]</sup> in a randomized controlled study of 100 women and Nagle *et al.*<sup>[5]</sup> in 1996 in a randomized trial of 549 women reported less post-operative analgesia when the peritoneum was not sutured at CS. In the former study, pain was the primary outcome measure and investigators found no overall difference in pain scores between the two groups, although there was a trend of lower pain scores in non-closure group. In the latter study, analgesic use only was measured, and authors found lower narcotic use in non-closure group. Both studies supported our findings.

In our study, there was no significant difference between the two groups regarding post-operative febrile morbidity, wound infection, and endometritis. Despite the lower incidence rate of fever and urinary infection in non-closure group in

Nagele's study<sup>[5]</sup> several studies did not show any significant difference regarding wound infection, endometritis, and fever between the closure and non-closure groups<sup>[1,6-8,10]</sup> which also supports our findings. In the present study, difference between pre- and post-operative hemoglobin level in both groups was not significant. Because of short duration of the study, long-term complications like adhesions were not considered and were outside of the scope of this study. A long-term evaluation of morbidity regarding adhesions is necessary to investigate the long-term complications of this approach. In conclusion, our study has confirmed that non-closure of both visceral and parietal peritoneum is associated with shorter operation duration, less pain, less demand for analgesia and is perhaps a preferred way to manage the CS patients because of these benefits.

## CONCLUSION

Non-closure of both visceral and the parietal peritoneum layers when performing a CS produces a significant reduction in pain, use of fewer analgesic and a short operation duration without increasing the febrile morbidity and changes in hemoglobin levels as compared to the standard methods.

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# Evaluation of Patient Satisfaction in Two Different Skin Closure Techniques: Subcuticular Sutures versus Staples: A Hospital Based Study

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## Abstract

**Background:** Caesarean section (CS) is a common operation with no agreed standard on operative techniques and materials to use. After CS skin layer is repaired by stitching subcuticular layer immediately with an interrupted stitch or skin staples.

**Objective:** The objective of the study is to establish the best method of wound closure after CS that would bring patient satisfaction that which includes factors like cosmesis and pain.

**Materials and Methodology:** A sample of 100 patients was randomly selected and divided into two groups. In one group subcuticular sutures and in other group staples were used. Follow-up was done after 6 weeks to evaluate primary outcome like patient satisfaction that includes wound cosmesis and pain and also to know secondary outcome as wound complications.

**Results:** In women undergoing abdominal operations there was no difference as regards the patient satisfaction in both the groups, subcuticular sutures  $n = 51$  versus staples  $n=49$  ( $P = 0.76$ ). It was observed that there is no statistically significant difference in the methods of wound closure as regards the patient satisfaction and the appearance of the scar.

**Conclusion:** There is no conclusive evidence about how the skin should be closed after caesarean section. The question remains still unanswered that which is the best closure technique and material and the outcomes associated. The appearance scar and its strength following caesarean section is important to women and hence the choice of technique and materials should be made by women in consultation with their surgeon.

**Keywords:** Caesarean section, Staples, Subcuticular

## INTRODUCTION

Every year millions of women's undergo gynecological surgery and after surgery they acquire an abdominal scar. Now-a-days women are much more esthetic oriented and place more importance on the appearance of the scar in addition with other symptoms like pain, tenderness and itching.

Aesthetically poor scar appears to be ugly and causes a negative impact on the quality of life causing distress, loss of self-esteem and displeasure.<sup>[1,2]</sup> The outcome of the surgical skin closure depends on and by the location of the surgical site, indication for the procedure and the associated intra-operative or post-operative complications. General medical condition of the patient has also considerable importance. The surgeon, however, can choose the technique of closure and the suture material.<sup>[3]</sup> The technique of closure should be selected in such a way that it should be simple, easy, quick and cost effective, keeping in mind about wound appearance and patient satisfaction. The technique should be selected on evidence and experience of the surgeon. Use of any technique should be able to restore physical integrity and function of the tissue. Along with these factors selection of suture

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material is also very important which will ensure optimal wound healing.<sup>[4-6]</sup>

### Absorbable Sutures

Absorbable sutures are defined as those sutures that lose their maximum tensile strength in 60 days. These sutures are digested by body enzymes.

For examples: Plain, chromic, fast absorbing catgut, polyglycolic acid, polyglactin 910 (vicryl).

### Staples

Staples (clips) are made up of high-quality stainless steel material. They are available in regular and wide sizes. The staples are disposable and applied by stapler.

Most widely used staples are 4-6 mm wide and 3.5-4 mm high.

Wide staples used for thicker skin are 6.5-7.5 mm wide and 4-5 mm high. Staples are less reactive than other traditional suturing materials.<sup>[7]</sup>

## OBJECTIVE

The objective of this study was to determine the patient satisfaction comparing two techniques of skin closure in gynecological surgical procedures by subcutaneous closure verses closure by staples.

## MATERIALS AND METHODS

Randomly selected samples of 100 women were selected to receive either of one: surgical staples or subcuticular sutures. The study was conducted in Department of Obstetrics and Gynecology in Punjab Institute of Medical sciences, Jalandhar in 2012. Ethical clearance was obtained from Institutional Ethical Board and Informed consent was obtained from patients. Patients between the age group of 18-48 years of age were selected those who were undergoing operation for obstetric or gynecologic procedures. Emergency or elective both procedures were included in the study. Women having body mass index (BMI) of more than 40, those who drink alcohol or drug abuse, those who refuse to come back for follow-up and those having diabetes were excluded from study post-operative wound complications.

The surgeon recorded the time taken for wound closure, and only pfannenstiell incisions were included. Subcutaneous fat of only more than 2 cm thick was closed in a separate layer. Continuous subcuticular closure was done using polyglactin (vicryl) suture (No.1-0). The suture was placed in a running fashion subcutically.

From 1-2 mm of wound edge, needle was placed in the dermis 1-2 mm. The needle was not passed through the skin surface. Utmost care was taken to avoid tension of the wounds. In similar manner, staples were used for the other method.

For their application, an assistant averted the skin edges, and the stapler was placed firmly on the skin surface perpendicular to the wound. It was pressed firmly avoiding indenting of the skin. The center mark on the stapler was aligned with the center of the wound margin. The stapler was squeezed, plunging the staple into the skin to form an incomplete rectangle. The depth of the penetration depends on the pressure exerted on the stapler against the skin. To disengage the staple, the handle was released. If the stapler did not automatically release the staple, then the stapler was pulled back. The staples were placed about 1 cm apart. Staples were removed on day 7 post-operatively. The incision was measured at the end of the procedure. Dressings were identical in both groups. Patients were reviewed 6 weeks after the operation.

The wound was evaluated for discharge, any redness and separation of the wound edges. Patients were also asked about pain and cosmesis which was assessed on the scale of 1 to 5. A simple pain scale was used. Where 1 means no pain, 2 means mild pain, 3 means moderate pain, 4 means severe pain and 5 means very severe pain.

Similarly patient satisfaction regarding cosmesis was assessed on a scale of 1-5 where 1 corresponds to extremely satisfied, 2 corresponds to satisfactory, 3 corresponds to neutral, 4 corresponds to not satisfied and 5 corresponds to extremely not satisfied.

## RESULTS

A total of one hundred women was randomized. Only those patients who met the criteria were included in the study. These women were enrolled into the two intervention groups ( $n=49$ ) for the subcutaneous group compared to the staple ( $n=51$ ). Eighty-nine patients completed the study. Eleven were lost to follow-up. Five were lost from the subcuticular groups and six from the staple group.

### Patients Characteristics

These women in the trial groups had similar baseline and demographic details (Table 1). The patients were between 18 and 42 years of age. The median age was of 30 years.

There were only 18 patients who had gynecological surgery as compared to 82 obstetrics patients. Therefore, it was not advisable to do a comparison between the two groups. There was no difference as regards the length of



the incision of the patients randomized to the two methods of wound closure (Table 2).

### Outcome: Patient Satisfaction

Our study demonstrates no statistically significant difference regarding the group ( $P = 0.76$ ). There was no statistically significant difference in the two groups as regarding wound cosmesis. As regards the pain described by the patients there was no statistically significant difference between the two groups ( $P = 0.80$ ). An analysis of covariance was conducted to determine if BMI had any effect on possible differences in patient satisfaction between the groups, but no significant difference was found ( $P = 0.81$ ). Similar to BMI analysis of covariance also indicated that age did not affect the patient satisfaction results ( $P = 0.91$ ). Mean time of closure was 3.5 min for the subcuticular group as compared to the 1.02 min for the staple group. This study demonstrates that staples can be applied at a much faster rate than the subcuticular stitches ( $P < 0.01$ ). Summarizing this study suggest that the two methods of wound closure subcuticular suture versus staple have similar outcomes as regards the patient satisfaction for both the wound cosmesis and pain.

## DISCUSSION

Considering the number of women who undergo operations for gynecological and obstetrical indications around the world each year, the issue of the appropriate method of wound closure is still poorly studied.

The result of this study shows there was no clinically and statistically difference in the two methods of wound closure with regards to patient satisfaction. Patient satisfaction includes both the aesthetic effect of the scar and the degree of pain.

Frishman *et al.*<sup>[8]</sup> in 1997 conducted a study on 50 patients randomized 25 patients in each group (staples vs.

subcuticular sutures) to assess the pain and cosmesis at discharge and 6 weeks post-operatively. He found that there was less post-operative pain if wound was closed by subcuticular sutures when compared to staples ( $P = 0.01$ ) at the time of discharge and at the post-operative visit ( $P = 0.002$ ). Also, incisions closed with subcuticular suture were found to be more cosmetically appealing to both patients ( $P = 0.04$ ) and their surgeon ( $P = 0.01$ ) at the post-operative visit. According to this study less time was required for the approximation of the incision by staples than by subcuticular sutures ( $47 \pm 4$  s vs.  $605 \pm 33$  s).

In a similar study, wound cosmesis was better in the subcuticular suture group than the staple group. The study was done on a small number of patients ( $n = 50$ ), and no comment on blinding was made. They also found that patients had significantly more pain in the staple group. In a study done by Basha *et al.*<sup>[9]</sup> in 2003 reported that patients were less satisfied with staples because of wound complications and their squealers. Wound complications were four fold more in the staple group when compared to the subcuticular group. But when they controlled for the wound complications they found no difference in the patient satisfaction in both the groups i.e. staple versus subcuticular group. One of the important and essential aspects of the patient satisfaction is assessment of pain. Simple factors like overwork and social stresses can make a considerable difference. Also, the magnitude, cause and management of pain are important. It is evident from all the studies reviewed that staples are quick to apply. From the surgeon's point of view it is a quick, easy and safe method as it also decreases the risk of ne the risk of needle stick injuries. From the management point of view, it decreases theatre time and perhaps also the cost of the procedure. But we must keep in mind that the staples are far more expensive, and availability is also an issue. Moreover, the best time to remove the staples is at day 7-10 days.

**Table 1: Patient characteristics**

	Subcuticular sutures	Staples	P value
Number (n)	49	51	
Maternal age (mean)	28	31	0.91
Gynecology (n)	11	06	
Obstetrics (n)	36	47	0.75

**Table 2: Indication of correlation between patient and blind observer scores**

Patient satisfaction variable	Spearman	Spearman P value
Color redness	-0.43	<0.01
Separation of skin edges	-0.28	<0.01
Scars	-0.51	<0.01

In the trial done by Antonella Cromi *et al.*<sup>[10]</sup> in 2003 conducted a study on 180 women undergoing caesarean section were randomized to either subcuticular suture or staple group. Their conclusion was that stapled wounds and those closed with subcuticular sutures result in equivalent cosmetic appearance. They evaluated the patients at 2 months and at 6 months post-operative. A recent study done by Basha *et al.* 435 patients were randomized to evaluate the rate of wound complications using the two different methods of wound closure staples ( $n = 197$ ) versus subcuticular ( $n = 219$ ). The study concluded that staples were associated with a four-fold increased risk of wound separation (odds ratio 4.66; 95% confidence interval [2.07-10.52],  $P < 0.001$ ).

According to the available literature, the inflammatory process continues beyond the 7 days. This is very important point to note as the skin seems intact within days after the injury, but the tissues underneath are still vulnerable to damage and may not be strong enough to withstand daily tensile force the relationship between different closure techniques and wound infection and cosmesis was found not to be clear.

In addition, there was 5-fold decrease in patient satisfaction. In her study, the staples were removed on the third or fourth post-operative day in contrast to all the other studies where staples were removed on the seventh post-operative day. It is possible that the staples were removed too early. Disadvantages included the need for a second operator to avert and re-approximate skin edges during staple placement, a greater risk of crosshatch marking, and less precise wound approximation in the staple group. The cost of surgical staples is usually more than that of suture material. Also, there is a need for patient follow up for removal of staples. Clay *et al.* in their meta-analysis of trials comparing staples and subcuticular sutures found that wound separation and wound.

## CONCLUSION

There is no conclusive evidence about how the skin should be closed after caesarean section. The question remains still unanswered that which is the best closure technique and material and the outcomes associated. The appearance

scar and its strength following caesarean section are important to women and hence the choice of technique and materials should be made by women in consultation with their surgeon.

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# Post Traumatic Lower Lid Reconstruction by Wolfe Graft: A Case Report

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## Abstract

In this modern area where cosmetic and aesthetic sense prevails, every reconstructive surgeon needs various skills to meet the challenges to bring back the former structure and function of the area involved. Eyes are an integral part of the face and hence more challenging for the surgeon. Eyelid tumor excision and trauma are two common causes of eyelid defects requiring surgical reconstruction. Nowadays, there are a wide variety of techniques available for various types of construction. This case report is on lower lid reconstruction for an anterior lamellar defect using full-thickness skin graft (FTSG). FTSG is easy to perform and gives very good results.

**Keywords:** Eyelids, Reconstructive procedures, Skin transplantation

## INTRODUCTION

Eyelids are like protective shutters for the eye. Not only do they impart aesthetic appeal to the face, it imparts several purposes like protecting the eye from dust, foreign body, trauma, maintaining moistness, draining the tears, etc.

Eyelid reconstruction is an art of its own. Many a times, it is warranted following excision of tumors, in congenital anomalies and following trauma. Uncorrected wounds can later go for cicatricial ectropion and entropion, scarring, symblepharon and cosmetic disfigurement and hence correction is imperative.

The choice of procedure for the reconstruction will depend upon the degree of anterior or posterior lamellar involvement. The principles guiding upper and lower reconstruction are also different. There are several methods now available which include primary closure of wound, free skin grafts, myo-cutaneous advancement

flaps, tarsoconjunctival substitutes like hard palate mucoperiosteum, nasal septalchondromucosa, acellular human dermis etc.<sup>1</sup> In this article, we describe a case of post-traumatic lid reconstruction using Wolfe Graft.

## CASE REPORT

A 22-year-old male patient presented to our outpatient department with a history of injury to right lower eyelid following road traffic accident 10 days back. He had presented himself to the emergency department of a local hospital where immediate first aid was given. No history of loss of consciousness, vomiting or nausea. No history of blurring of vision, diplopia, floaters, etc.

General examination was normal. No signs of head injury or long bone fracture. Local examination revealed two deep lacerated wounds. One was on the forehead, 2 cm above lateral end of right eyebrow measuring 4.2 cm × 2.6 cm × 1 cm. There was a second anterior lamellar defect involving the lateral 2/3 of right lower lid and measured 5.3 cm × 2.4 cm × 1.7 cm (Figure 1). There was also a superficial abrasion over the upper eyelid just below the lateral end of right eyebrow.

Floor of the wound had red granulation tissue and wound margins were healthy.

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Anterior segment examination was normal. Visual acuity was 6/6 OU and dilated fundus examination was normal.

Patient was taken up for wound reconstruction by full thickness graft under general anesthesia. The donor site was skin of inner brachium (Figure 2). After measuring both the defects, full thickness graft was taken from both inner arms and the site was sutured back using 5-0 chromic catgut for deep sutures and 4-0 vicryl for skin. The grafted skin was meticulously placed over the wound sites and sutured with 5-0 vicryl (Figures 3 and 4).

Non-adhesive dressing was placed after the suturing and patient shifted out from the operation theater. Adequate coverage of injectable antibiotics and anti-inflammatories were given. In the serial follow-ups, the graft was well taken up.

## DISCUSSION

Once the eyelid anatomy is compromised, only surgical repair will help restore the integrity of the eyelid. Eyelid

reconstruction will help restore the anatomy and function, normalize the eyelid position and movements.<sup>2</sup> Hence sound knowledge of eyelid anatomy is required. Each eyelid has an anterior and posterior lamella. The anterior lamella consists of skin and orbicularis muscle and posterior lamellae consisting of the tarsal plate, layer of smooth muscle and conjunctiva.

There are several methods for eyelid reconstruction. The methodology adopted will vary depending upon whether the upper or lower lid is involved, whether the anterior or posterior lamella is involved and also with the extent of the defect.

Free skin grafts are helpful in covering areas of anterior lamellar defects of the lower lid especially that cannot be covered with myo-cutaneous flaps.

Skin grafts, which can be used are of two types: Full thickness skin grafts (FTSG) and split thickness skin grafts (STSG).



Figure 1: Pre-operative photo

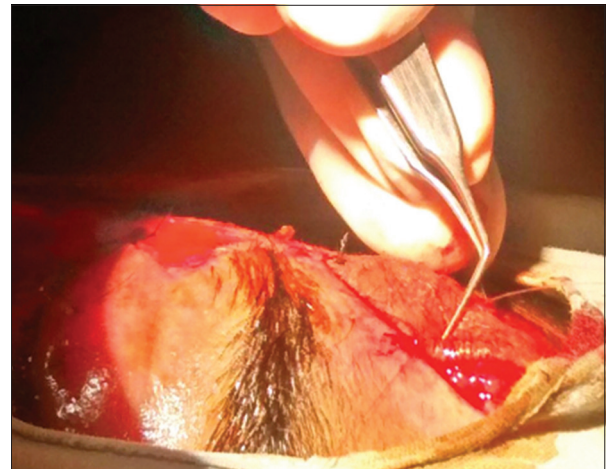


Figure 3: Graft being sutured to the site



Figure 2: Skin graft harvested from inner arm



Figure 4: Post-operative day 1



STSGs involve the epidermis and partial thickness of the dermis. It is used to cover large areas of defect and the rate of auto rejection is also low. Also these grafts tend to be fragile and appear paler when compared to the adjoining skin. Humpy's knife, dermatome, etc. are used to take a STSG. Split thickness grafts however are usually not used in lid reconstruction.

FTSGs are also known as Wolfe Graft. It consists of the entire thickness of the epidermis as well as the dermis. They are harvested by sharp dissection with a scalpel. They are mostly used for small wounds and on the visible parts of the body like face. They provide excellent color match and cosmetically also they look excellent.

The donor site for the FTSG should be matched well in terms of thickness and texture. Retro-auricular skin, supraclavicular area, inner arm skin, groin (children), upper eyelid if lax are the preferred sites.<sup>3</sup>

In the upper and lower eyelids, the underlying orbicularis provides excellent vascular bed for the graft and if it's absent, muscle should be moved in from around the defect.

If the posterior lamella is involved, skin graft cannot be used as there must be a tarso-conjunctival substitute. Many different materials can be used like ear cartilage, temporalis fascia, nasalseptal cartilage etc.

Early complications include infection, hematoma or seroma collection under the graft which will result in difficulty for the graft to be taken up. Long-term complications include graft hypertrophy, partial graft failure, long time

to vascularization, rarely graft contracture and its sequelae such as ectropion and lid retraction.<sup>4</sup> Graft hypertrophy can be managed in the same lines of hypertrophic scars and keloids.

Contra-indications for performing skin graft include infection at the donor and recipient site, wounds contaminated with foreign body, inadequate blood supply to sustain a graft etc.

## CONCLUSION

Today, there are several methodologies available to correct anomalies and defects of the lid. Reconstruction of the lid and peri-ocular area using free skin grafts is an easy procedure without any steep learning curve and gives cosmetically and functionally very good results. The complications seen with this technique is also very less. Hence, it should be a part and parcel of every reconstructive surgeons skill.

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# A Rare Case Report on Unilateral Optic Nerve Sheath Meningioma

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## Abstract

Optic nerve sheath meningiomas (ONSM) are rare, slow-growing benign tumors, which approximately constitute 2% of all orbital tumors of the anterior visual pathway and 1-2% of all meningiomas. The middle-aged females are primarily affected. The primary orbital meningiomas originate from the optic nerve sheath or from the extension of an intracranial meningioma into the orbit. ONSM left untreated always leads to progressive defective vision, color blindness and complete loss of vision, which is often associated with optic atrophy. Most of the time management is conservative in long-standing ONSM, as there is no much of visual improvement after the surgery. Here, we present a case of a 55-year-old female with unilateral optic nerve sheath meningioma. The diagnosis was delayed more than 6 years from initial symptoms.

**Keywords:** Contrast-enhanced computed tomography, Meningioma, Optic nerve, Optic nerve sheath meningiomas

## INTRODUCTION

Optic nerve sheath meningiomas (ONSM) are slow growing benign, and typically unilateral tumors that arise from the arachnoid cap cells around the intraorbital portion of the optic nerve and are intimately associated with the optic nerve. The natural history of primary ONSM involves indolent growth during a period of many years. Intracranial extension is rare. ONSM is confined to the dura matter and hence it often appears as a well-defined, tubular thickening of the optic nerve on computed tomography (CT) or magnetic resonance imaging. Definitive treatment of ONSMs is challenging, however, because of the lesions intimate circumferential relationship with the optic nerve and its vascular supply. Surgical excision has almost always resulted in post-operative blindness in the affected eye and is reserved for patients with intra cranial extension of tumor.<sup>1</sup>

## CASE REPORT

A 55-year-old south Indian female presented to ophthalmology outpatient Department complaining of gradual decrease in vision in the left eye and drooping of upper eyelid since 5 years with a history of mild intermittent headache. During this period, she has been treated elsewhere with different topical medications, details not provided. She did not give any previous history of eye pain, eye trauma or projectile vomiting. Patient is not a known diabetic or hypertensive.

Patient underwent detailed examination, ocular, medical and neurological from which the following observations were made. The best-corrected visual acuity was a perception of light in left eye without showing any improvement. The pupillary reaction was sluggish to direct light in left eye. Extraocular eye movements were restricted in all directions (Figure 1). Anterior segment examination under slit lamp was normal. The fundusoscopic examination showed optic atrophy with retino-choroidal collaterals in the left eye, and the right eye optic disc showed mild temporal pallor (Figure 2). Contrast-enhanced CT (CECT) brain study revealed evidence of hyper-dense mass lesion showing foci of calcification arising from left optic nerve sheath, suggestive of optic nerve sheath meningioma (Figure 3). The tumor had an intracranial extension along the

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**Figure 1: Nine cardinal positions of gaze**

optic nerve, so the case was referred to neuro center for intracranial approach for excising the tumor, as the optic nerve showed signs of atrophy. Thou the tumor is benign it is necessary to approach it intracranial and excise, since it may produce complications of space occupying lesions.

## DISCUSSION

ONSM are rare benign tumors of the optic nerve. 60-70% of cases occur in middle age females, and is more common in older adults (mean age 44.7 years). It is also seen in children, but this is rare. The tumors grow from cells that surround the optic nerve, and as the tumor grows, it compresses the optic nerve. This causes loss of vision in the affected eye. Rarely, it may affect both eyes at the same time.

It is typically a slow growing tumor and has never been reported to cause death. However, there is concern that the tumor can grow into the brain and cause other types of neurological damage. In some patients, the tumor grows so slowly that the treatment is not necessary.<sup>2-5</sup>

## CONCLUSION

Often meningiomas show homogenous and well-defined mass on CECT. CECT is the procedure of choice for diagnosis of ONSM. The findings in optic nerve sheath meningioma in this case are quite typical. The benign non-invading, well-defined growth pattern, the clinical manifestation strongly suggests the possibility of meningioma. As the patient's age is relatively advanced,



**Figure 2: Primary gaze**



**Figure 3: (a and b) Hyperdense mass lesion showing foci of calcification arising from left optic nerve**

aggressive procedure such as biopsy was considered unnecessary.

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# Sudden Onset of Loculated Hemothorax: An Uncommon Complication of Anticoagulant Therapy in Stroke

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## Abstract

Hemothorax is a collection of blood in the pleural cavity with hematocrit at least half of the peripheral blood hematocrit. Spontaneous or non-traumatic hemothorax is rarely encountered than traumatic hemothorax. We are reporting a case of anticoagulant-induced hemothorax that was a sudden onset and loculated on the left side. Our case was an acute embolic stroke who presented late in our hospital in intubated state, started on clopidogrel and warfarin. Routine daily chest X-ray showed sudden appearance of loculated pleural effusion, which was managed by discontinuation of anticoagulants and intercostals tube drainage. Anticoagulant-induced sudden-onset of loculated hemothorax in a stroke patient is very rarely reported.

**Keywords:** Anticoagulants, Hemothorax, Intercostal tube drainage, Stroke, Warfarin

## INTRODUCTION

Hemothorax in simple word is the presence of blood in the pleural cavity or by definition pleural fluid hematocrit is at least 50% of the peripheral blood hematocrit.<sup>1</sup> Majority of cases of hemothorax is due to open or closed chest trauma or procedure related. Spontaneous hemothorax is much less common.<sup>2</sup> Hemothorax associated with a coagulopathy is predominantly a result of anticoagulants administered in the setting of thromboembolic disease.<sup>3,4</sup> Our case was an old-age patient who presented with right middle cerebral artery (MCA) infarct and he was started on anticoagulant therapy and he suddenly developed isolated and loculated left sided pleural effusion which was confirmed as hemothorax on diagnostic aspiration.

## CASE REPORT

A 70-year-old male patient was referred from a local hospital with a diagnosis of right MCA embolic infarct. On arrival, patient was intubated, on mechanical ventilator support, and he was on antiplatelet agent and warfarin therapy along with other supportive treatments.

On examination, patient's Glasgow Coma Scale (GCS) was six; bilateral chest was clear with bronchovascular breath sounds and maintained oxygen saturation 100% at FiO<sub>2</sub> of 30%. Patient was continued on antiplatelet and warfarin therapy, prophylactic antibiotic were started, his vitals remained stable though his GCS was still six.

His routine investigations showed hemoglobin - 12.5 gm %, packed cell volume - 38, platelet counts 16,000/mm<sup>3</sup>, international normalized ratio (INR) - 1.3 and within normal limit of kidney function tests and liver function tests. Patient's chest X-ray (CXR) did not show any abnormality (Figure 1), but his brain imaging confirmed the right MCA infarct and he was continued on the same treatment.

Next day morning patient's routine CXR was performed which revealed left sided loculated collection in pleura

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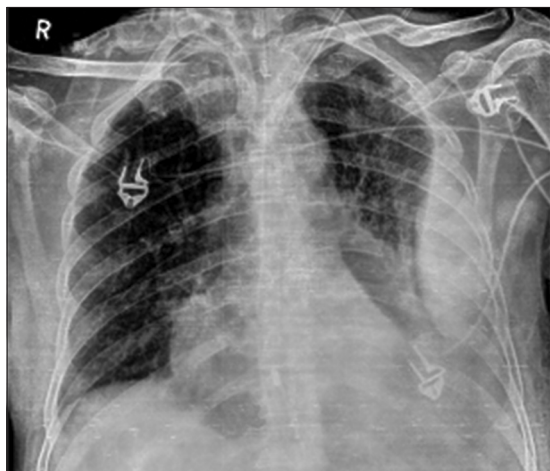
(Figure 2), ultrasonography guided diagnostic aspiration was done, which showed reddish color fluid with hematocrit 27%, consistent with diagnosis of hemothorax. Patient's repeat platelet counts and INR was done, which were  $15,600/\text{mm}^3$  and 1.2 respectively. Patient was evaluated for pulmonary embolism, and it was ruled out. Intercostal tube was inserted in the left side of the pleural cavity, and fluid was drained completely. There was no other site of the body, which showed any evidence of bleeding complications. Patient was tracheostomized and weaned off from ventilator and sent home in stable condition.

## DISCUSSION

Hemothorax is the presence of blood in the pleural space, specifically when the hematocrit of the pleural fluid is at least 50% that of the peripheral blood.<sup>1</sup> When bloody pleural fluid is obtained with a diagnostic thoracentesis, the hematocrit should always be measured. Frequently,



**Figure 1: Chest X-ray on June 22, 2014 does not show any effusion**



**Figure 2: Chest X-ray on June 23, 2014 showing left sided loculated pleural effusion**

even though the pleural fluid appears to be pure blood, the hematocrit of the fluid will be  $<5\%$ .<sup>1</sup> Most common cause of hemothorax is the traumatic hemothorax, which includes penetrating and non-penetrating chest trauma, iatrogenic hemothorax due to central venous catheterization, pleural biopsy, thoracentesis, and the translumbar aortography. The suspicion of hemothorax should be concerned in any individual with thoracic trauma and a pleural effusion on the chest radiograph. The vast majority of hemothoraces are due to bleeding from the low-pressure, pulmonary parenchymal vessels; they stop bleeding spontaneously when the hemothorax is evacuated, and the pleural surfaces are reapposed.<sup>5</sup> Both penetrating and non-penetrating hemothoraces are managed by immediate intercostals tube drainage, which evacuate the blood from the pleural cavity and provide the quantitative measure of blood loss. Intercostal drainage also stops the further bleeding by apposing the pleural surfaces to create a tamponade.<sup>5</sup> In the rare case of hemothoraces where continued bleeding, immediate thoracotomy indicated.

Non-traumatic or spontaneous hemothorax is uncommon. Most common cause of spontaneous hemothorax is malignancy, followed by anticoagulant therapy, other causes includes vascular ruptures, endometriosis, pulmonary infarctions, complication of spontaneous pneumothorax, and hematologic abnormalities such as hemophilia and thrombocytopenia.

Anticoagulant therapy associated hemothoraces are very rare and present in setting of treatment of thromboembolic diseases and most cases occur within the 1<sup>st</sup> week of therapy.<sup>6</sup> Most of the cases of anticoagulants associated hemothorax in thromboembolic diseases are pulmonary in origin, and they are probably due to rupture of pulmonary infarct. Few cases of hemothorax with anticoagulation in the non-pulmonary embolic setting were reported, one case was after angioplasty,<sup>7</sup> and the other case was in the setting of anticoagulation for an artificial heart valve.<sup>8</sup> Hemothorax secondary to anticoagulant therapy in stroke patients thoroughly searched, but no case report was found.

Treatment of anticoagulant-induced hemothorax is the correction of the coagulopathy and drainage. If the rupture of a pulmonary infarct is suspected, a surgical consultation should be obtained for possible thoracotomy and resection.<sup>9</sup>

## CONCLUSION

Hemothorax secondary to anticoagulant therapy is very rarely reported, and most of the reported cases are pulmonary thromboembolic diseases. In setting of

thromboembolic diseases, stroke patients are in a rare category that developed spontaneous hemothorax. Interestingly in our case, hemothorax was loculated rather than free flowing as in other cases. Hence, all thromboembolic diseases, including stroke patients who receiving anticoagulant therapy and sudden appearance of pleural effusion in CXR, hemothorax should always be first suspicion.

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# Infiltrating Angiolipoma: A Rare Benign Soft Tissue Neoplasm with Malignant Potential

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## Abstract

Angiolipomas are benign neoplasms of adipose tissue with a rich vascular component and are classified as infiltrating and non-infiltrating. Non-infiltrating angiolipomas are seen in young individuals, presents as painful, soft, subcutaneous nodules and are treated by simple enucleation. Infiltrating angiolipoma is a rare neoplasm with only 23 previously reported cases. The lesions are usually non capsulated or rarely encapsulate partially and tends to infiltrate bony, neural, muscular and fibrocartilagenous tissues. Treatment of infiltrating angiolipoma aims at wide local excision with radiotherapy indicated for cases of recurrence. A case study of infiltrating angiolipoma of a 10-year-old girl presented with symptomatic painful swelling over right lower one-third of the thigh on posterior aspect involving popliteal fossa, extending up to middle 1/3<sup>rd</sup> of leg causing discomfort while walking. Magnetic resonance imaging and histopathology confirm the diagnosis of infiltrating angiolipoma and treated with wide local excision.

**Keywords:** Angiolipoma, Infiltrating, Soft tissue neoplasm

## INTRODUCTION

Infiltrating angiolipoma is a benign lipomatous lesion that mainly occurs in the soft tissues and frequently presented in the extremities and the trunk in a locally aggressive manner.<sup>1,2</sup> The nature of these lesions was first documented in 1960 by Howard and Helwig<sup>1</sup> who reported a large series of cutaneous angiolipomas, described as small, painful, completely encapsulated subcutaneous nodules, which could be easily and completely shelled out. In 1974 Lin and Lin reviewed angiolipomas and divided them into infiltrating and non-infiltrating groups based on their biologic behavior.<sup>3</sup> Tumors with similar benign histology were capable of infiltrating into and between skeletal muscle planes.<sup>2,4,5</sup> They differ clinically and histologically from the pure primary angiomata of skeletal muscle. Here, we describe infiltrating angiolipoma of right lower extremity.

## CASE REPORT

A 10-year-old girl presented to our out-patient department with complaints of a progressively increasing painful subcutaneous swelling over right lower 1/3 of the posterior aspect of thigh involving the popliteal fossa causing little discomfort to the patient while walking since 6-8 months (Figure 1).

Ultrasonography (USG) reveals small hyperechoic lesions (Figure 2) and in color and power Doppler study multiple small vessels with predominant arterial flow are seen (Figure 3). Magnetic resonance imaging study of right leg shows a 13 cm × 4 cm, large, ill-defined intramuscular and inter-muscular lesion almost nearly replacing flexor compartment muscles at distal 2/3 of the thigh on right side showing extensive fatty tissues interposed between the vascular channels appearing hyperintense on T1W images (Figure 4). The vessels are draining into dilated superficial subcutaneous veins, short saphenous vein and popliteal vein. Histopathological findings consistent with angiolipoma showing a non-epithelial neoplasm made up of adipose tissues without any intervening septae deep to reticular dermis with several thin and thick walled capillaries interspersed in between the adipocytes (Figure 5). Our case was diagnosed and confirmed on the basis of histopathology, USG and radiological findings.

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## DISCUSSION

Lipomas are most common cutaneous soft tissue tumors and trunk and extremities are the most common sites. Angiolipoma is a variant of lipoma, with a prominent vascular component, constituting only 6-17% of all lipomas.<sup>3</sup> They usually present as painful or tender subcutaneous mass in young adults. Infiltrating angiolipomas can lead to muscular pain and neural deficits.<sup>1,3</sup>



Figure 1: Ill-defined subcutaneous swelling

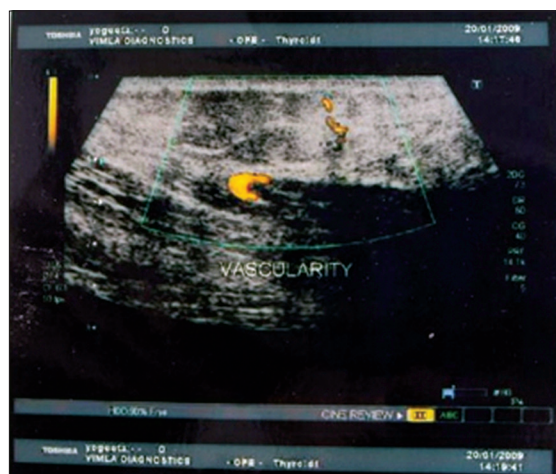


Figure 2: Ultrasonography

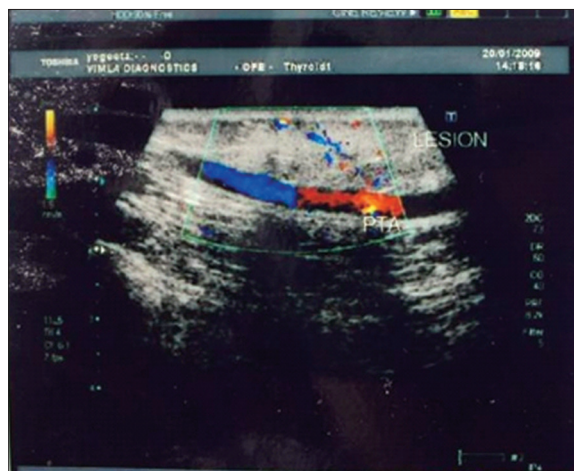


Figure 3: Doppler study

Histological finding of our patient shows the tumor was infiltrating angiolipoma predominantly composed of mature adipose tissues with angiomatous infiltrations. Blood vessels often contain fibrin rich thrombi.<sup>1</sup> Infiltrating angiolipoma is a non-capsulated mass that tends to involve the deeper tissues.<sup>2,3</sup> Infiltrating is a non-capsulated mass that tends to involve the underlying plane.<sup>3</sup> Symptoms like muscle pain and neural deficit these characteristics.<sup>1,6</sup>

Surgical excision is the treatment of choice for both infiltrating and non-infiltrating angiolipomas.<sup>7</sup> Carbon dioxide laser and liposuction may be alternative options for treatment of single and multiple angiolipomas. In the present case we performed surgical excision. Wide local

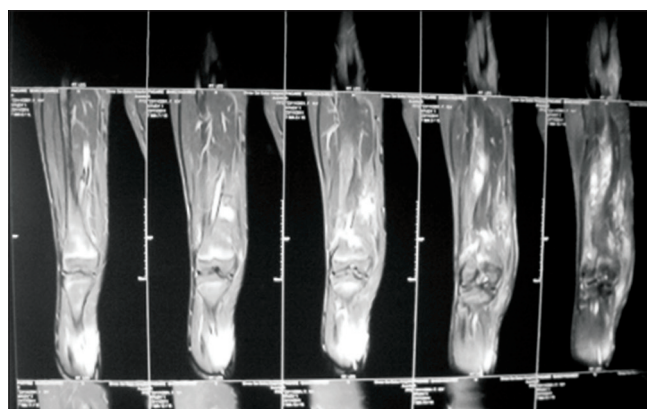


Figure 4: Magnetic resonance imaging

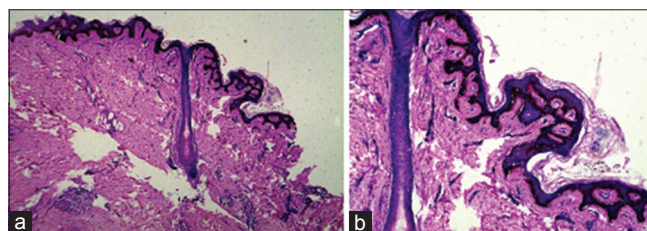


Figure 5: (a and b) Histopathological findings



Figure 6: (a and b) After wide local excision

excision, beta-blockers and interferon alpha has been successfully tried in many cases.<sup>5</sup> Our patient successfully treated with wide local excision (Figure 6a and b) and no recurrence after 3 years follow-up.

## CONCLUSION

The above case is reported due to its rarity, often misdiagnosis, long follow-up requirement and very infrequent literature documentations. Infiltrating angiolipoma has locally malignant potential that involves underline dipper planes leading to neuromuscular deficient features. Wild local excision is the treatment of choice for infiltrating angiolipoma.

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# Orbital Reconstruction of a Severely Contracted Socket Using Autogenous Derma-Fat Graft: A Case Report

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## Abstract

Severely contracted sockets pose problem to all oculoplastic surgeons. All sockets have a tendency to contract after enucleation or evisceration, and the etiologies are varied. Earlier methods employed to correct were use of mucous membrane and skin grafting. Derma-fat graft (DFG) supplies orbital volume, eliminates the risk of implant extrusion, preserves the existing conjunctiva and advances it into the fornices. This case report describes the management of DFG in an 18 years old for the management of a severely contracted socket. Post-operatively after the reconstruction, a prosthetic eye was kept, which was well-accepted.

**Keywords:** Anophthalmos, Artificial eye, Orbital implants

## INTRODUCTION

Anophthalmic eye and contracted socket pose a problem to all ophthalmologists. There are several etiologies resulting in contracted socket and varies from infections like endophthalmitis and panophthalmitis, tumors like retinoblastoma, scarring of conjunctiva, especially after chemical injuries, improper or not using artificial eye etc.<sup>1</sup>

Autogenous derma-fat grafts (DFG) can be used as primary as well as secondary orbital implant to recreate a socket and volume augmentation and hence that a prosthetic implant can be kept.<sup>2</sup> There is a variety of artificial implants available nowadays but the significance of autogenous grafts should not be discounted as the rate of complications is significantly lower. This case report describes a case of an 18-year-old who underwent enucleation for a phthisical eye following penetrating eye

injury and underwent orbital reconstruction with DFG and a prosthetic eye implantation.

## CASE REPORT

An 18-year-old girl presented with a phthisical left eye with a contracted socket following penetrating ocular injury at the age of 14 years. She had undergone placement of artificial left eye over her existing phthisical eye, but got rejected 2 months prior to presentation. Examination revealed an unaided snellen visual acuity of 6/60-6/6 in the right eye with refraction correction of -2.5D Sph and no light perception in the left eye. Anterior segment and fundus examination of the right eye were unremarkable. Examination of the left eye showed phthisical eye (Figures 1 and 2).

After obtaining informed consent, the girl underwent socket reconstruction with gluteal DFG under general anesthesia. As the first step, the phthisical eye was enucleated and hemostasis was obtained (Figure 3).

The graft was obtained from the left gluteal region. A 20 mm × 20 mm area of dermis with underlying fat was harvested (Figure 4). The gluteal wound was closed with interrupted 4-0 vicryl sutures. The epidermis was stripped

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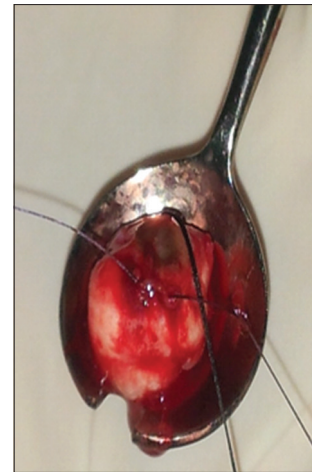
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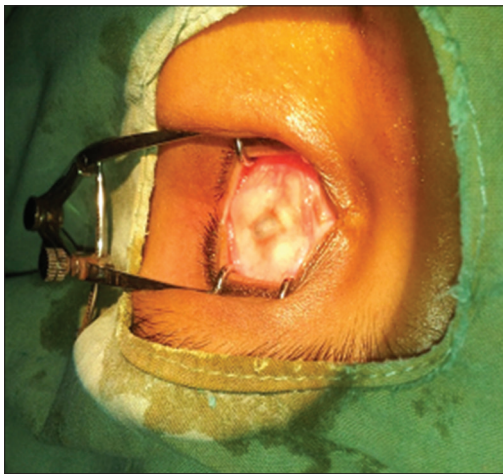




**Figure 1: Left phthisical eye**



**Figure 3: Enucleated left eye**



**Figure 2: Pre-operative picture**



**Figure 4: Derma-fat being taken from gluteal region**

off from the graft. The DFG was then inserted into the orbital socket cavity with the dermis layer anteriorly, and the fatty side posteriorly oriented. The extraocular muscles and conjunctiva were sutured into the border of the DFG using 6-0 vicryl sutures for the former and 5-0 interrupted vicryl sutures for the latter (Figure 5). After instillation of antibiotic eye drops, the eye was patched with a light pressure pad.

The extraocular muscles and conjunctiva was sutured into the border of the dermis fat graft using 6-0 vicryl sutures for the former and 5-0 interrupted vicryl sutures for the latter.

On the 1<sup>st</sup> post-operative day, examination showed the graft tissue well apposed with the host tissue. Thus, the patient was discharged with instructions to use antibiotic eye drops. When seen in the clinic a month later, the DFG was well integrated with the orbital tissue. The graft-host junction was healthy, with epithelialization of the surface of the graft. There was no evidence of necrosis or infection.

After 6 weeks of the primary surgery a prosthetic eye was implanted (Figures 6 and 7).

## DISCUSSION

The first use of DFG was by Smith and Petrelli in 1978.<sup>3</sup> It can be used as primary implant after enucleation or as a secondary implant following rejection of artificial implants.

DFG as the name suggests is composed of dermis and subcutaneous fat. The epidermis is stripped off from the graft. The dermis is retained as it supposedly enhances graft vascularization and decrease the incidence of fat atrophy. Most common sites, which are used to harvest the graft is the gluteal area, but other areas such as the abdomen, hip, inner thigh and the periumbilical region can be used.

The most important factor pertaining to the acceptance of the graft is the vascular supply of the orbit. Thus, in case of compromised vascular supply, such as after severe trauma,





**Figure 5: Graft implanted into the socket**



**Figure 6: Different sizes of artificial eye**



**Figure 7: Prosthetic eye in situ**

chemical burns, irradiation, systemic vascular disease, etc. it is contra-indicated. Other factors to minimize the complications

**Table 1: Indications and contra-indications of autogeneous grafts**

Indications	Contra-indications
Primary implantation after post enucleation, post evisceration	Severely contracted socket
Secondary implantation post irradiation	Compromised orbital vascular supply
	Multiple orbital surgeries

are to avoid the following: Excessive cautery of the graft bed, use of oversized grafts, excessive handling of the graft and excessive pressure on the graft following implantation. Indications and contra-indications are in Table 1.<sup>4</sup>

DFG helps not only to replace lost orbital volume but also preserves the conjunctival surface area. This is achieved by partially covering the implanted dermis with conjunctiva and leaving an exposed area of dermis similar to the diameter of the cornea. Normal fornix depth is also maintained.

Complications are usually minor. They include hematoma, infection, central graft ulceration, granulomas, fat atrophy, and volume loss. Most complications can be avoided by employing the careful surgical techniques. The problems associated with the management of ophthalmic sockets such as implant extrusion, implant migration and conjunctival shrinkage resulting in contracted sockets are more commonly seen with the traditional methods of reconstruction.<sup>5</sup>

## CONCLUSION

DFG after primary enucleation demonstrates a good maintenance of orbital soft tissue volume and periorbital symmetry. There are very little complications encountered. Autogenous implants are effective in maintaining orbital volume while preserving the fornices and conserving the conjunctiva. It is associated with low morbidity and a satisfactory cosmetic result.

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# Spinal Myoclonus Following Intrathecal Anesthesia with Bupivacaine for Elective Appendicectomy

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## Abstract

Involuntary movements under anesthesia are a less recognized phenomenon. In this report, we describe a case of myoclonus in a 22 years female patient undergoing elective appendicectomy under spinal anesthesia with 0.5% hyperbaric bupivacaine. Surgery was uneventful and completed in approximately 45 min from the start of surgical incision. Myoclonic movement that appeared in the lower extremities in the early post-operative period was controlled with intravenous midazolam. Despite all biochemical and imaging tests performed, an apparent cause was not detected. After ruling out all possible causes, the diagnosis of spinal myoclonus after spinal anesthesia with bupivacaine was made by exclusion. She was finally discharged on 4<sup>th</sup> post-operative day. The patient was followed up for 3 months during which she remained asymptomatic. The case warrants awareness about its occurrence, and anesthetists must watch out for and recognize it.

**Keywords:** American Society of Anesthesiologists 1, Bupivacaine, Spinal myoclonus

## INTRODUCTION

Spinal myoclonus is defined as involuntary, rhythmic or dysrhythmic movements characterized by rapid contractions in the extremities, developing as a result of the stimulation of medulla spinalis.<sup>1,2</sup> The onset of myoclonus can be shortly after the stimulus of the spinal cord or after hours or days.<sup>3</sup> Restricted to a few somatic regions, it is usually caused by diseases including the spinal cord such as spinal cord compression, tumors, vascular myelopathy, infections, demyelinating diseases, paraneoplastic syndromes, and trauma to the spinal cord.<sup>4</sup> Spinal myoclonus has been reported in studies following intrathecal administration of local anaesthetics,<sup>2-11</sup> opioids,<sup>12-14</sup> radiocontrast agents,<sup>15,16</sup> tranexamic acid,<sup>17-19</sup> and even placement of intrathecal

catheter<sup>20</sup> though the incidence is relatively uncommon. We report a case of spinal myoclonus in a patient following hyperbaric bupivacaine subarachnoid anesthesia for elective appendicectomy.

## CASE REPORT

A 22-year-old unmarried female patient scheduled for elective appendicectomy was categorized as American Society of Anesthesiologists physical status 1 during pre-anesthetic checkup. With a weight of 49 kg and height of 161 cm, she had no previous history of hypertension, diabetes mellitus, chronic obstructive pulmonary disease, seizure disorder or any other major medical disease. There was no previous history of any major operative procedure carried out on her nor any exposure of general or neuraxial anesthesia. There was no history suggestive of allergy to any specific food or drugs. Her menstrual cycle was regular. On examination, central nervous system, peripheral nervous system, respiratory system and cardiovascular system showed no obvious abnormalities. She had a good effort tolerance. Institutional based routine investigations were carried out. A written consent was taken.

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The patient was advised to be nil per orally after 10 pm on the previous night as per our institutional protocol. Alprazolam 0.5 mg was prescribed to her at bedtime. On the day of operation, no premedication was given. Monitoring consisted of non-invasive blood pressure, pulse oximetry, electrocardiogram and temperature recording. Preloading with 500 ml of balanced salt solution was done. Spinal puncture was performed using a 25G quincke needle in the L3/L4 space with the patient in the left lateral position. 3 ml (15 mg) of 0.5% hyperbaric bupivacaine was injected in the subarachnoid space after backflow of clear cerebrospinal fluid (CSF). The injection was easily administered without discomfort. She was then placed in horizontal dorsal decubitus. Maximum height of sensory block achieved was T6 dermatome with accompanying motor block. Surgery was uneventful and completed in approximately 45 min from the start of surgical incision. Patient was shifted to post anesthesia care unit. After an hour, she was shifted to ward. After about 30 min following her shifting to ward, she developed involuntary contractions in the muscles of the lower limbs that recurred every 45-60 s and lasted for 5-10 s. These jerky myoclonic movements were accompanied with unbearable pain in the pelvic region. The patient became agitated and started crying. She complained that she could not stop the movements. No such movements were noted in the upper extremities. Her mental functions were intact and muscle power was normal in all the four limbs. Her hemodynamic status also did not show many alterations except a slight increase in the heart rate. An arterial blood sample was drawn and analyzed, which almost showed normal acid-base status and electrolytes. We then administered 2 mg intravenous midazolam followed by another 1 mg after 15 min. Finally, after about 25 min, the involuntary movements stopped. She was referred to a neurologist for detailed examination. Magnetic resonance imaging (MRI) of the brain and spinal column that were done subsequently were also normal. Unexpectedly, CSF reports and electroencephalogram (EEG) examinations were also within normal limits. During her stay in hospital for next 3 days, no such involuntary movement recurred. She was finally discharged on 4<sup>th</sup> post-operative day. The patient was followed up for 3 months during which she remained asymptomatic.

## DISCUSSION

Spinal myoclonus that includes both segmental and propriospinal myoclonus seems to be due to abnormal hyperactivity of the local dorsal horn interneurons, with the loss of inhibition of suprasegmental descending pathways. Contractions are repetitive, usually restricted to a muscle or a group of muscles. They appear in varied time intervals, always corresponding to specific spinal innervation. The

most striking characteristic is that the patient remains conscious. The episodic rhythmic nature of the movements in our patient was diagnostic of myoclonus. The frequency of attack, occurrence only during the waking hours, normal EEG, normal MRI scan of brain and spinal column and absence of neurological deficit pointed towards the diagnosis of spinal myoclonus.

We have gone through various literatures pertaining to spinal myoclonus following spinal anesthesia. According to these previous reports, onset, duration, and recurrence of spinal myoclonus are not predictable and are not related to the type of local anesthetic, dose, baricity and concomitant drugs in spinal anesthesia. Spinal myoclonus have been reported following spinal anesthesia with tetracaine,<sup>10</sup> prilocaine<sup>6</sup> and bupivacaine.<sup>2-5,7-9,11</sup> Regarding baricity, all the three forms of bupivacaine have been reported to produce spinal myoclonus. There is also no predilection for any specific age group, sex or the type of operation. Spinal myoclonus has also been reported to occur in the upper extremities<sup>5</sup> though majority of the reports have reported its occurrence in lower extremities. Even the severity is not fixed. In the case report by Abrão *et al.*,<sup>3</sup> patient was intubated and kept under mechanical ventilation for 2 days, whereas in other case reports, spinal myoclonus either resolved spontaneously or with benzodiazepines or other anticonvulsants. However, the question that arises in our mind is whether spinal anesthesia can be safely re-administered subsequently to the same patient for any other procedure. In the case report by Lee *et al.*,<sup>11</sup> spinal myoclonus recurred after two episodes of spinal anesthesia with bupivacaine at a 1-year interval in a 35-year-old woman. They recommended that spinal anesthesia should not be repeated in a patient having previous history of spinal myoclonus under spinal anesthesia.

## CONCLUSION

- Anesthesiologists and surgeons must be aware of the potential for this very rare phenomenon to occur as a result of spinal anesthesia
- Also, anesthesiologists should carefully take past anesthetic histories and consider the recurrence when planning anesthetic technique for the patients who had an episode of spinal myoclonus
- More awareness regarding this event is needed since there is a possibility of the anesthesiologist being blamed of a faulty technique.

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# Total Dystrophic Onychomycosis Caused by *Syncephalastrum recemosum*: A Case Report

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## Abstract

Onychomycosis is a common nail infection caused by two groups of pathogenic fungi, dermatophyte and yeast. However in a small portion of the cases, the etiological agents are non-dermatophyte molds, belonging to different genera and species. The present study reports a case of total dystrophic onychomycosis associated with *Syncephalastrum recemosum*, belonging to the family zygomycetes, in a 24-year-old male patient. Samples were taken and examined under potassium hydroxide mount and fungal culture was done. Growth appeared within 48 h, lactophenol cotton blue was done and identified the fungi by morphological characteristics. Identification of the causative agent is indispensable to select the proper treatment for onychomycosis.

**Keywords:** Onychomycosis, *Syncephalastrum recemosum*, Zygomycetes

## INTRODUCTION

Onychomycosis is a common fungal infection of the toe or finger nails, which is caused by dermatophytes, yeast and non-dermatophyte molds. The non-dermatophyte fungi are normally seen in soil and decayed plant debris. These are generally considered as the secondary pathogens of onychomycosis. Onychomycosis affects approximately 5% population worldwide,<sup>1</sup> but variable frequency depending on different climatic, occupational and socioeconomic conditions.

*Syncephalastrum recemosum* is a fungus belonging to the order mucorales with very low human pathogenicity. To the best of our knowledge, only few cases are reported in the medical literature. We report a case of total dystrophic onychomycosis caused by *S. recemosum*.

## CASE REPORT

A 24-year-old male patient presented with a history of nail dystrophy in the hands for the past 6 months. On

examination of the nail were yellowish brown in color and complete destruction of the nail and signs of inflammation (Figure 1). The patient is working as a building construction labor since 2012. The nail clipping and scrapings were collected and sent to the microbiology laboratory.

Direct wet mount examination of the nail sample at 40% of potassium hydroxide showed thick walled aseptate hyphae. The nail sample cultured on to sabouraud dextrose agar and incubated at 37°C for 48 h. The colony were cottony to fluffy, white to gray in colour. After 72 h of incubation, the colonies become dark gray in color (Figure 2). Lactophenol cotton blue mount showed aseptate hyphae branching sporangiospores with terminal ovoid vesicle, which bear finger like merosporangia. Based on the above morphological features, the isolate was identified as *S. recemosum*. The fruiting body of *S. recemosum* are similar to *Aspergillus* sp. But *S. recemosum*, the spores were confined within the merosporangia around the entire circumferences giving “daisy head” appearance and the hyphae were broad and aseptate (Figure 3). The patient was started on fluconazole 150 mg orally for 4 week and is under follow-up.

## DISCUSSION

Onychomycosis is caused by three types of fungi, dermatophytes cause 90% of cases, yeast causes 8% of

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Figure 1: Dystrophic onychomycosis in right index finger



Figure 2: Fungal growth on sabouraud dextrose agar plate

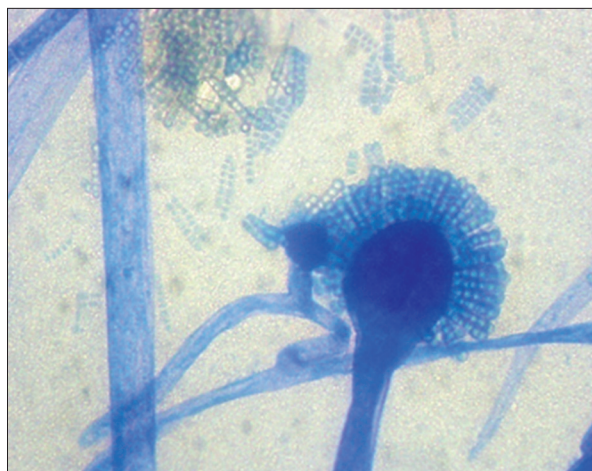


Figure 3: Lactophenol cotton blue preparation of *Syncephalastrum racemosum*

cases and non-dermatophyte molds cause 2% of cases. During the recent years, there has been an increase in the reporting of onychomycosis caused by non-dermatophyte molds and yeast. The common non-dermatophyte molds are *Scopulariopsis*, *Aspergillus*, *Acremonium*, *Fusarium* and *Alternaria* sp.<sup>2</sup> *Syncephalastrum* is a saprophytic fungi belonging to Zygomycetes with very low pathogenicity. Only few cases of onychomycosis caused by *S. racemosum* have been reported worldwide. A case of great toenail onychomycosis has been described in a 45-year-old man by Pavlovic and Bulajic<sup>3</sup> The other published case of *Syncephalastrum* are cutaneous infection,<sup>4</sup> intra-abdominal zygomycosis, successfully treated with partial surgical debridement and high dose amphotericin B lipid complex,<sup>5</sup> sino-orbital infection in chronic hepatorenal disease,<sup>6</sup> mycetoma such as lesion,<sup>7</sup> subcutaneous zygomycosis,<sup>8</sup> rhino orbital cerebral infection,<sup>9</sup> and subcutaneous infection in anterior chest wall.<sup>10</sup>

## CONCLUSION

Onychomycosis is caused by the dermatophyte and non-dermatophyte molds. *Syncephalastrum* is a rare isolate. Onychomycosis is a not life-threatening, but it can be a source of pain and discomfort. It is a disease of considerable value that can generate many psychological and occupational problems impairing patient's quality of life.

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# Imaging of Nasopharyngeal Carcinoma with Intracranial Extension

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## Abstract

Nasopharyngeal carcinoma (NPC) is unique in its clinical behavior, epidemiology and histopathology from that of other squamous cell carcinomas of the head and neck. Most NPC originates in the lateral pharyngeal recess, also known as the fossa of Rosenmuller. Magnetic resonance imaging is the imaging modality of choice. However, computed tomography (CT) has a major role in the assessment of bony skull base involvement and for radiotherapy planning. Positron emission tomography-CT using 18F-FDG is used primarily for the detection of distant metastasis. An understanding of its patterns of spread is important to relay the relevant information to the referring clinician so that appropriate management may be made.

**Keywords:** Base of skull, Cavernous sinus, Intracranial, Multislice computed tomography, Nasopharyngeal cancer

## INTRODUCTION

The clinical behavior, epidemiology, and histopathology of nasopharyngeal carcinoma (NPC) are unique and different from other squamous cell carcinomas of the head and neck. NPC is common in southern Chinese population. The male-to-female ratio is 3:1 and is commonly seen in 40-60 year age group.<sup>1-5</sup> NPC is caused by the interaction of environmental factors (e.g., exposure to chemical carcinogens), genetic susceptibility and infection with Epstein-Barr virus.<sup>2-5</sup>

Management of NPC patients, from diagnosis to treatment and follow-up, involves imaging. In a minority of patients (6%) with NPC, the disease is submucosal and cannot be seen on endoscopy.<sup>6</sup> Hence, cross-sectional imaging studies, such as magnetic resonance imaging (MRI) and computed tomography (CT), are required for diagnosis and accurate assessment of the tumor extent- including pharyngeal wall involvement and invasion into adjacent

structures. MRI is currently the imaging modality of choice for NPC; however, CT has a major role in the assessment of skull base involvement for sclerotic and lytic lesions.<sup>7,8</sup> Positron emission tomography (PET)-CT using 18F-FDG is primarily used for the detection of distant metastasis and NPC recurrence.<sup>9</sup>

We report two case studies of NPC with skull base invasion and intracranial extension and the role of imaging in making a positive diagnosis and pre-treatment assessment of tumor extent.

## CASE REPORTS

### Case 1

A 60-year-old male came with complains of headache and nasal block for 1 month. On examination, mass noted in right nasal cavity, middle meatus and nasopharynx that bleeds on touch. Contrast-enhanced computed tomography (CECT) for neck showed an ill-defined heterogeneously enhancing soft tissue lesion centered in the nasopharynx with anterior extension into the nasal cavity and posterior extension to involve the long us muscle (Figure 1a). The lesion is seen extending superiorly with destruction of the petrous apex, right medial pterygoid, greater wing of sphenoid and basisphenoid with invasion into the sphenoid sinus

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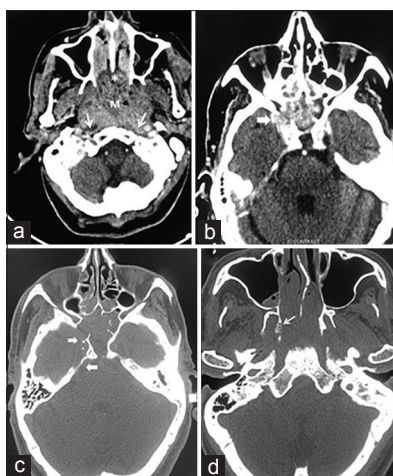
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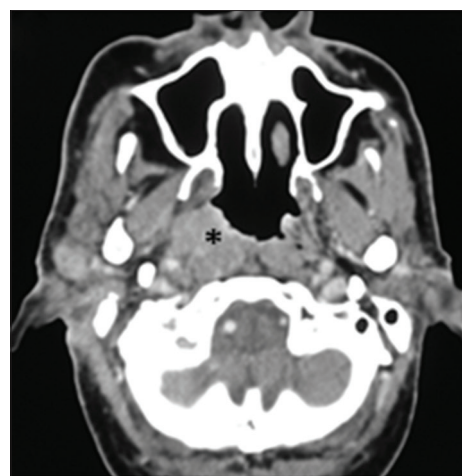
**Figure 1:** (a) Axial contrast-enhanced computed tomography image shows heterogenous nasopharyngeal mass lesion (m) with anterior extension into the nasal cavity (\*) and posterior extension to the longus muscle (arrows). (b) Axial contrast-enhanced computed tomography image shows heterogenous mass with Superior extension and invasion of the sphenoid sinus (straight arrow). (c) Axial computed tomography window shows erosion of the basisphenoid and petrous apex of temporal bone (arrow) (d) Axial computed tomography window shows erosion of right medial pterygoid plate (arrow)

(Figures 1b-d). Bilateral heterogeneously enhancing retropharyngeal and cervical lymph nodes with central necrosis are seen. (Biopsy taken from the mass lesion showed a picture of squamous cell carcinoma and awaited follow-up)

## Case 2

A 55-year-old male came with complaints of right ear discharge, hard of hearing and right-sided facial pain for 1 month. On examination, tender swelling seen in the right side of the neck.

CECT neck showed an ill-defined heterogeneously enhancing soft tissue mass lesion in the region of right fossa of Rosenmuller, extending laterally to involve the para-pharyngeal space (Figure 2). The mass extends superiorly, causing destruction of the petrous apex and basisphenoid (Figure 3). Note made of intracranial extradural tumor extension into the right cavernous sinus. The mass is seen to encase the right internal carotid artery with mass effect on the right temporal lobe (Figures 4 and 5). Multiple heterogeneously enhancing necrotic right retropharyngeal and bilateral cervical lymph nodes seen (Figure 6). Note also made of right middle ear effusion and mastoiditis with intact ossicular chain (Figure 3). Apical sections of the thorax show a spiculated mass lesion in the left side (Figure 7). Histopathology report of the right cervical lymph node showed a picture of metastatic undifferentiated NPC.



**Figure 2:** Axial contrast-enhanced computed tomography image shows a heterogeneously enhancing mass filling the right fossa of rosenmuller (\*) with parapharyngeal involvement on the right side



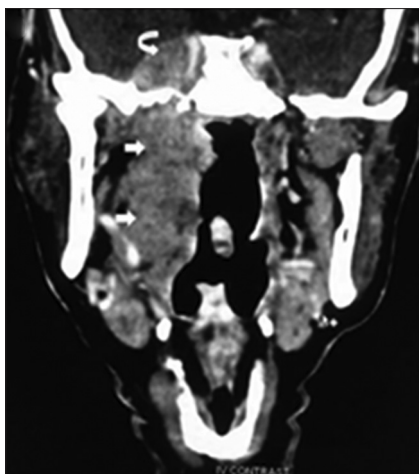
**Figure 3:** Axial computed tomography bone window shows erosion of the basisphenoid and petrous apex of temporal bone (arrow)

## DISCUSSION

Most NPCs originate in the lateral pharyngeal recess, also known as the fossa of Rosenmuller. They tend to spread sub-mucosally with early infiltration into deeper neck spaces. The mass shows a preference for superior spread to the skull base, rather than inferior spread to the oropharynx.<sup>10</sup>

Patients present with clinical symptoms, such as pain, trismus, otitis media due to eustachian tube dysfunction, hearing loss, nasal block and nasal regurgitation due to paresis of the soft palate. The nasopharynx is a relatively clinically silent area, and the most common presentation may be with cervical nodal or distant metastasis.<sup>1-5</sup> Depending





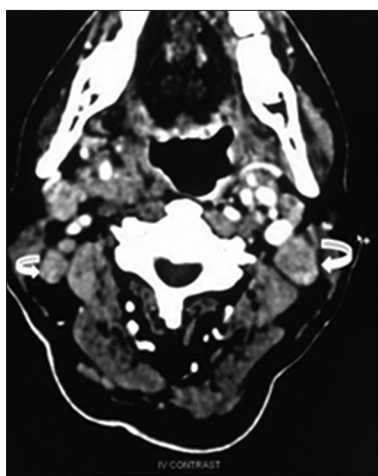
**Figure 4:** Coronal contrast-enhanced computed tomography image shows heterogenous mass (straight arrows) with skull base invasion and extension into right cavernous sinus (curved arrow). Note encasement of internal carotid artery



**Figure 7:** Axial computed tomography image-lung window, at the level of the lung apices shows a spiculated lesion on the left side (arrow)



**Figure 5:** Axial contrast-enhanced computed tomography image shows cephalad extension of the mass lesion with skull base invasion and extension into middle cranial fossa (straight arrow)



**Figure 6:** Axial computed tomography image shows bilateral enlarged level II lymph nodes (curved arrows)

on the degree of local infiltration, patients may also suffer from cranial nerve dysfunction and headache. Distant metastatic spread may result in organ dysfunction or bone pain. Tumor confined to the nasopharynx is only found in one-fifth of patients.<sup>1</sup> Invasion of the para-pharyngeal space carries an increased risk of distant metastases and tumor recurrence. It can lead to compression of the eustachian tube with middle ear and mastoid effusion.<sup>11</sup>

The anatomical location of the nasopharynx and early invasiveness of NPC, facilitates the adjacent skull base erosion and intracranial extension, thus making locally advanced disease a common clinical presentation at diagnosis. This means that the base of the skull is involved in 25-35% of the cases, with intracranial invasion occurring in 3-12% of the cases.<sup>12</sup> The pterygoid bones, clivus, body of the sphenoid and petrous temporal bones are most commonly invaded. CT reveals erosive or permeative bone changes of the skull base and spread along foraminal pathways. There is involvement of the paranasal sinus as a result of direct extension. Up to 25% of patients have tumor extension superiorly into the floor of the sphenoid sinus, and further into the sphenoid sinus cavity.<sup>8,13</sup>

Unchecked, NPC can extend superiorly into the cavernous sinus with extra dural involvement while direct invasion of the brain is rare at diagnosis.<sup>1</sup>

Features denoting intracranial extension include meningeal involvement (especially if seen as nodular enhancing masses), masses within the middle or posterior cranial fossa and peritumoral spread. Carotid artery encasement is defined as tumor tissue surrounding  $>270^\circ$  of the vessel circumference. In these cases, the patient is deemed inoperable as the surgeon cannot remove all the tumor

tissue. Other potential issues that may result from the encasement include vessel invasion and potential carotid artery blow-outs post-radiotherapy.

Imaging studies suggest that nodal spread is seen in 60-90% of cases, in an orderly fashion beginning with the retropharyngeal nodes, and then to levels II, III and IV and are found to have a tendency for bilateral spread. Necrosis, if identified is considered 100% specific if present, can only be reliably identified in tumor foci larger than 3 mm. In CT images, necrosis is seen as a focal central area of hypoattenuation with or without peripheral rim enhancement.

Extranodal spread carries a grave prognostic significance, in which there is an extension beyond the capsule into the adjacent soft tissues. It is recognized radiologically as loss or irregularity of the nodal margins, with or without adjacent fat stranding.

Among head and neck malignancies, NPC has the highest incidence of distant metastasis, with a rate of 11% at diagnosis.<sup>14,15</sup> The most common sites are skeletal (20%), thoracic (mediastinal lymph nodes and pulmonary deposits) (13%), hepatic (9%), and distant lymph nodes. PET-CT is sensitive to detect soft-tissue and bony metastatic deposits.<sup>9</sup>

## CONCLUSION

Understanding of the unique clinical behavior of NPC, together with its pattern of spread, is important while imaging NPC. NPC most commonly arises in the lateral pharyngeal recess and has a tendency to invade widely and metastasize. Cervical lymphadenopathy is very common at presentation. Diagnosis and effective treatment of NPC requires an accurate mapping of tumor extent with imaging. MRI is the best tool for assessing tumor extent, while high-resolution CT has a definitive role in places where MR equipment is not readily available. CECT can accurately

assess the extent of the tumor especially extension to the para-pharyngeal space, cortical bone erosion, and intracranial extension. PET/CT is the modality of choice for accurate assessment of distant metastases and recurrence.

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# Invasive Pituitary Macroadenoma: A Rare Case Report

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## Abstract

Pituitary adenomas constitute approximately 10% of all intracranial tumors. Pituitary adenomas are the most common tumors of the sellar region. They show slow but severe impact on vision due to compression of the optic nerves, optic chiasm, and cavernous sinus. We are presenting this case report of 47-year-old patient with chief complaints of headache for 3 months and disorientation. Patient was subjected to computed tomography brain – plain + contrast and magnetic resonance imaging-T1 T2 fluid-attenuated inversion recovery and diffusion sequences. The report highlights the extension of mass into suprasellar region postero-inferiorly into clivus with compression of optic chiasma and encasement of cavernous sinus bilaterally suggestive of the invasive nature of macro adenoma.

**Keywords:** Clivus erosion, Invasive, Macroadenoma

## INTRODUCTION

Pituitary adenomas are the most common tumors of the sellar region. They constitute approximately 10% of all intracranial tumors. They tend to have slow but severe impact on vision due to compression of the optic nerves, optic chiasm and cavernous sinus. Grossly, depending on the size they are classified as microadenomas if their diameter is <10 mm or as macro adenomas if it is >1 cm.<sup>1</sup>

Tumor is called invasive when it extends into the suprasellar cistern, not by invading but simply by stretching and fenestrating the diaphragma sellae, and arachnoids layer that separates the cerebrospinal fluid-containing subarachnoid space above from the intrasellar space below.

In some patients, a dumbbell-like extension of a pituitary tumor reaches through the small opening in the diaphragm traversed by the pituitary stalk.<sup>2</sup>

The few reports published to date have not reported series of sufficient size to establish the characteristic clinical, pathologic, and imaging attributes of clival invasion by pituitary adenoma.<sup>3</sup> Pituitary adenomas are almost always benign with no malignant potential.

In general, pituitary lesions can be subdivided into nonsecretory and secretory tumors of the pituitary gland, other intrasellar tumors, and parasellar tumors.

Nonsecretory tumors occur in and around the sellae turcica and can mimic the pituitary tumors clinically.

## CASE REPORT

A 47-year-old male presented with headache of gradual onset slowly progressive increasing in severity since 3 months with recent onset of disorientation of sudden onset. On advice, patient was evaluated using plain and contrast computed tomography brain and magnetic resonance imaging (MRI).

### CT Brain Plain

Well defined lobulated mixed density mass lesion (Figures 1-3) approximately having measure 5 cm × 4 cm × 4.7 cm. Noted arising from sella and invading into suprasellar region bone window shows widening/

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ballooning of sella (Figures 4 and 5) with clivus erosion. Mass lesion appears to compress optic chiasma and displaces suprasellar cisterns anteriorly. Mass seems to invade the optic chiasma anteriorly.

### MRI Brain with Contrast

Non homogenous heterogeneous mass lesion measuring: 5 cm × 4 cm × 4.7 cm with few cystic areas, noted arising from sella with extension into suprasellar region mass seems to compress optic chiasma anteriorly and extend posteroinferiorly into clivus (Figures 6-8). Lesion causes diffuse ballooning of sella tursica with a classical figure of 8 appearance superiorly into suprasellar cistern.

Clivus involvement is evident by loss of normal T1 hyperintense signal of fatty marrow which appears to be replaced with hypointense signal.

Post contrast study shows intense heterogenous enhancement of the mass lesion with few non-enhancing cystic areas (Figures 4, 8, 9).

Mass lesion seen to encase both intracavernous internal carotid arteries left cavernous sinus more than right.

Lesion appears hyperintense on T2W and few areas of blooming s/o calcification.

### Histopathology

H and E stained multiple sections show diffuse shunts and few nests of monomorphic cells obliterating the normal architecture.

Cells are oval to polygonal with fairly large amount of eosinophilic cytoplasm and normal central nuclei with fine chromatin and inconspicuous nucleoli separated by thin fibrovascular connective tissue.

No e/o mitosis or hemorrhage noted.

Reticulin stain showed absence of normal nested architectural pattern of pituitary adenohypophysis. Features suggestive of invasive pituitary macroadenoma.

## DISCUSSION

Truly aggressive pituitary tumors are uncommon, with the incidence of not more than 2%. Such tumors prove their atypical behavior by invading adjacent tissues, by proliferating rapidly.

Nonsecretory pituitary tumors are called null-cell tumors measuring a few millimeters are common and found in up to 25% of autopsies. These may grow slowly, destroying

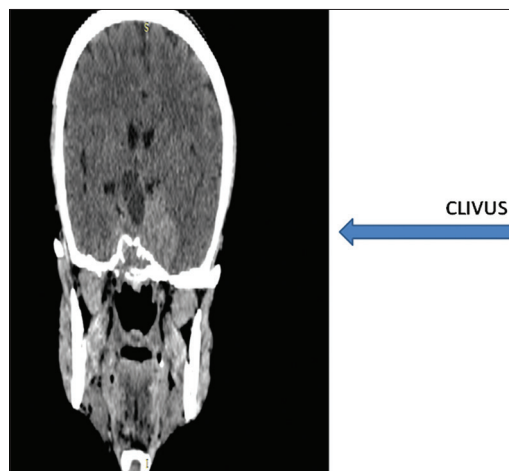
normal pituitary function (hypopituitarism), or they may compress nearby structures and cause neurologic problems.<sup>4</sup>



**Figure 1: NECT (sagittal view) Bone window demonstrating sellar widening with clivus destruction**



**Figure 2: NECT axial section brain showing invasive mass in suprasellar region**



**Figure 3: NECT coronal view demonstrating clivus erosion**



MRI has proven to be the best imaging modality in the evaluation of pituitary tumors. Contrast MRI using gadolinium played an important role in diagnosis. Its role in detection and characterization of micro and macro adenoma has been well described.<sup>5</sup>

Dynamic Imaging is technically has emerged for the evaluation of pituitary adenomas, particularly inaccurate delineation of those microadenomas with no contour abnormality and in differentiating residual/recurrent adenoma from surrounding post-operative tissue. It is

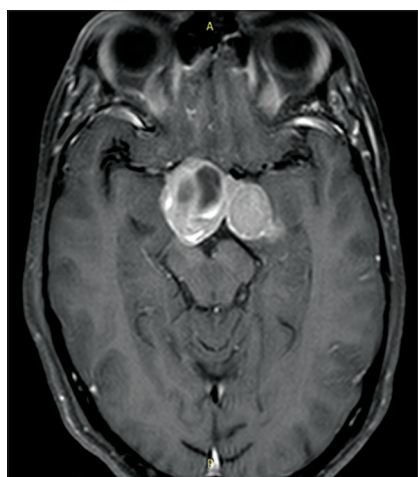


Figure 4: MRI axial view

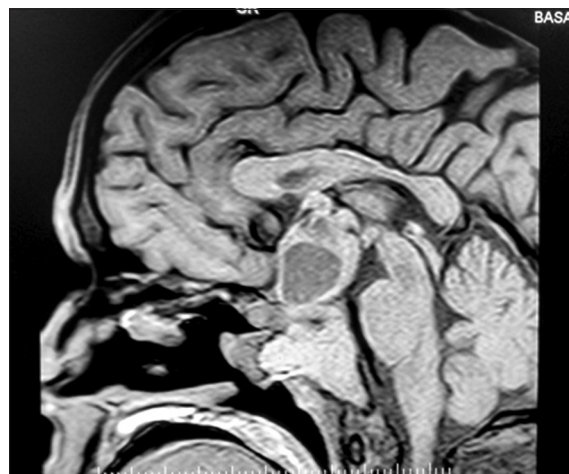


Figure 7: MRI 3 mm thin section sagittal view demonstrating cystic areas within the mass

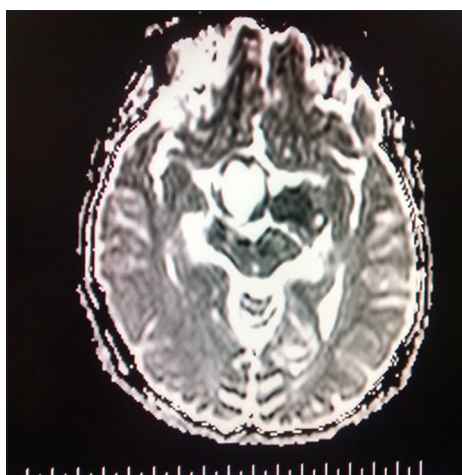


Figure 5: Diffusion weighted MRI images



Figure 8: MRI coronal view demonstrating extent of mass lesion

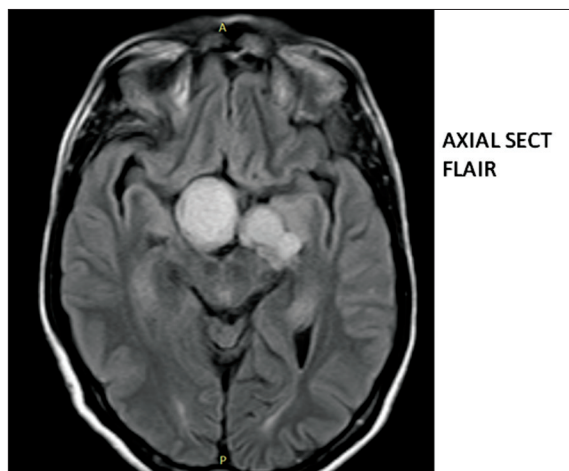


Figure 6: Axial fluid attenuated inversion recovery sequence

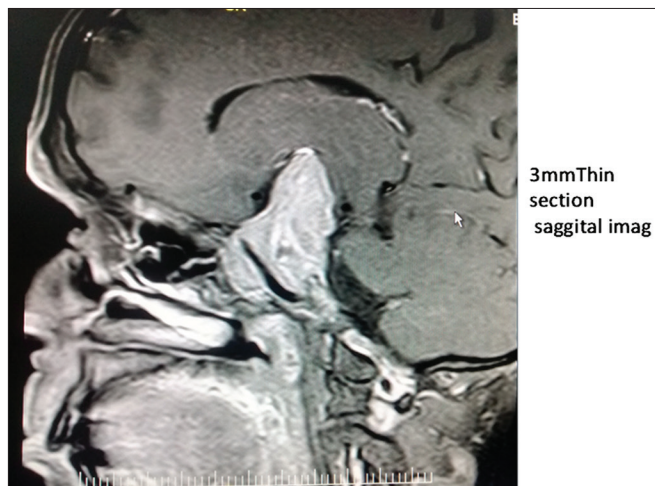


Figure 9: 3 mm thin section sagittal image

useful in the evaluation of pituitary microadenomas as well as assessment of macro adenoma.

The use of intraoperative MRI (IMRI) and intraoperative real-time ultrasonography during endoscopic pituitary surgery is the most recent advancement in pituitary imaging.

IMRI provides better visualization of intra- and parasellar anatomy facilitating complete resection of the tumor.

In the near future, the use of plasma screen has a promising role as it can provide a sufficient high-quality image to demonstrate the nerve compression and the residual tumor.

The use of intraoperative real-time ultrasonography has proven to be very useful in localizing the intracranial neoplasm, particularly the deep skull base lesions and facilitating their resection. It also assists in guiding needles for biopsy and aspiration of pituitary lesions.<sup>6</sup>

## CONCLUSION

The study highlights the extension of mass into suprasellar region, posteroinferiorly into clivus, with compression of

optic chiasma and encasement of cavernous sinus bilaterally suggestive of the invasive nature of macroadenoma.

The invasive nature of pituitary macroadenoma is well-documented, but while invasion of the cavernous sinuses and carotid arteries and along the dura is common, invasion of the clivus is relatively rare.

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