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# A Study on Critical Review of Drug Promotional Literature Using the WHO Guidelines

Archanababen Chaudhari<sup>1</sup>, Jitendra Zaveri<sup>2</sup>

<sup>1</sup>Assistant Professor, Department of Pharmacology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India,

<sup>2</sup>Professor and Head, Department of Pharmacology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India

## Abstract

**Background:** Drug promotion refers to all the informational and persuasive activities of the pharmaceuticals, which include the activities of medical representatives, drug package insert, provision of gift and samples, conducting or organize seminar, etc. However, promotion of drug by ethical way is important because it may influence the irrational drug prescriptions.

**Objective:** The objective of this study was to evaluate and analyze the drug promotional literature distributed by pharmaceutical companies to physicians using the World Health Organization (WHO) criteria for ethical medicinal drug promotion.

**Materials and Methods:** A total of 100 drug promotion literatures were evaluated collected from the various outpatient departments and evaluated according to the WHO criteria for drug promotion.

**Results:** Among 100 drug promotional literatures (DPLs), a total of 109 drugs were promoted. However, only 33% of DPLs gives side effect, precaution, contraindication, and warning and only 10% of DPLs gives drug interaction information. None of the DPLs fulfills all criteria of who drug promotion.

**Conclusion:** Information on the DPLs given only focus on the positive aspect of the drugs and not fulfill all the WHO criteria of drug promotion.

**Key words:** Drug promotional literature, Review, WHO

## INTRODUCTION

According to the World Health Organization (WHO), drug promotion refers to “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drugs” (WHO 1988).<sup>[1]</sup> For the promotion of many new drugs, pharmaceutical companies are using drug promotional literatures (DPLs).<sup>[2]</sup> Many studies conducted previously concluded that increased promotion is usually associated with increased sales.<sup>[3]</sup>

All promotion making claims about drugs should be accurate, informative, up to date, and ethical.

They should not contain misleading, false and biased statements (WHO 1988). Pharmaceutical companies promote their products as best and better to existing to which physician are familiar. However, many times due to inadequate, inaccurate, and false information from DPLs lead to irrational drug prescription and for physicians, many times DPLs are only source for updating their knowledge about the existing and novel drugs.<sup>[4,5]</sup>

## MATERIALS AND METHODS

An observational cross-sectional study conducted by the Department of Pharmacology at Ananta Institute of Medical Sciences and Research Centre from January 2019 to March 2019. DPLs were collected from the outpatient department (OPD) of a tertiary care center attached Ananta institute of medical sciences and Research Centre from January 2019 to February 2019. Printed DPLs promoting allopathic drugs were collected from OPDs of medicine, pediatrics, skin, psychiatry, ophthalmology, obstetrics and gynecology, otorhinolaryngology, and orthopedics. 100 drug promotional literature included in the study according

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**Corresponding Author:** Jitendra Zaveri, Ananta Institute of Medical Sciences, Rajsamand, Rajasthan, India.

to exclusion criteria. DPLs were evaluated using the WHO criteria by the following parameters:

1. The names of the active ingredients using either international non-proprietary names or approved generic names of the drugs.
2. The brand names.
3. Amount of active ingredients per dose.
4. Other ingredients known to cause problems, i.e., adjuvant.
5. Approved therapeutic uses.
6. Dosage form or dosage schedule.
7. Safety information including side effects and major adverse drug reactions, precautions, contraindications, and warnings and major drug interactions.
8. Name and address of manufacturer or distributor.
9. References to scientific literature appropriate.

Exclusion criteria: DPLs promoting:

- Drugs other than allopathic drugs,
- Medicinal devices.
- Equipment.

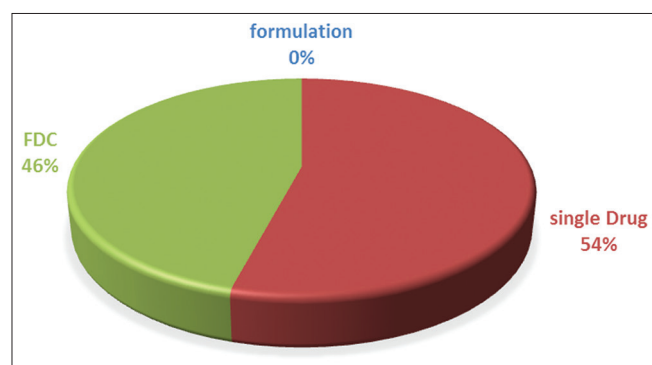


Figure 1: Distribution according to drug formulation

## RESULTS

A total of 100 DPLs evaluated. A total of 109 drugs were promoted from 100 DPLs. Among them, 59 (54%) were prompted as single drug formulations and 50 (46%) promoted as fixed drug combinations [Figure 1].

Majority of drug promoted in collected DPLs were from drug act on endocrine system 36 (33%) followed by cardiovascular system 20 (18%). There were only 3% DPLs of drugs acting on kidney and 4% of respiratory system [Figure 2].

Of 100 DPLs, 63 (63%) DPLs promoted one active compound formulation and 37 (37%) DPLs promoted >1 active compound formulation [Figure 3].

None of the DPLs fulfilled all the WHO criteria. Active ingredient generic name, brand name, and dosage detail were presented in all DPLs (100%). Only 33 (33%) DPLs showed side effect and 33 (33%) showed precaution, contraindication, and warning. Few of total collected DPLs showed drug interactions 11 (11%) [Table 1].

Of 100 DPLs, 30 DPLs had not shown any references for their claim and 70 DPLs showed their references. Among 70 DPLs which provide references for their claim where consider from various National and International Journals. Some of the DPLs also had given more than 1 references. Journal references about 40% were before 2010 [Figure 4].

For attractive presentation of DPLs, companies are using picture on drug promotional literature. Of 100 DPLs, 23 (23%) DPLs not given any picture, but majority of 77 (77%) were given the picture on DPL. Among these

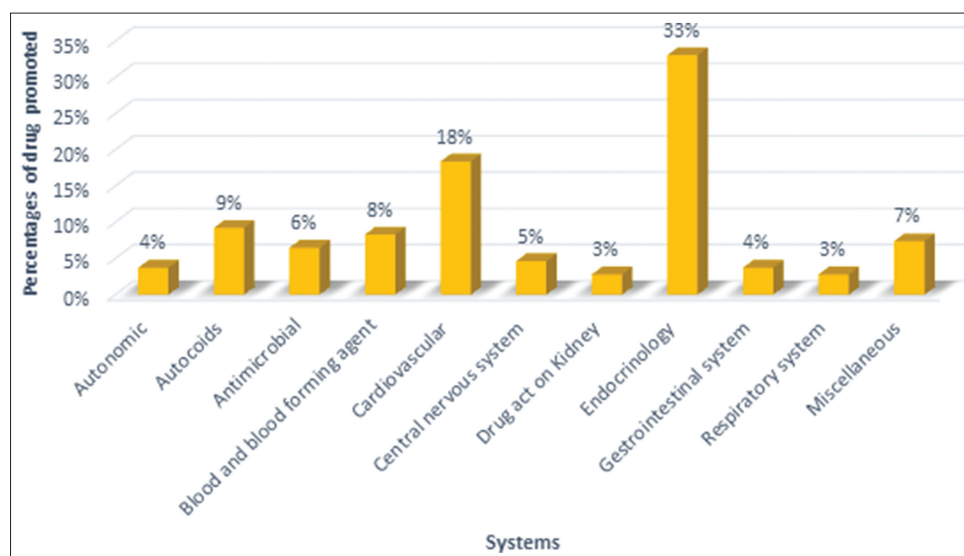


Figure 2: System-wise classification of drugs promoted in drug promotional literatures

77 literature, majority of picture were not relevant to disease and promoted drug 59 (77%). Only 18 (23%) DPLs presented with disease or drug-related picture.

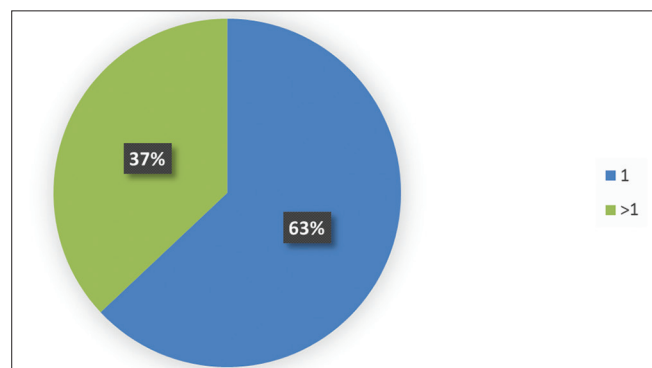
## DISCUSSION

The pharmaceutical industries have the right to promote its products, but it should do in ethical manner and promotional

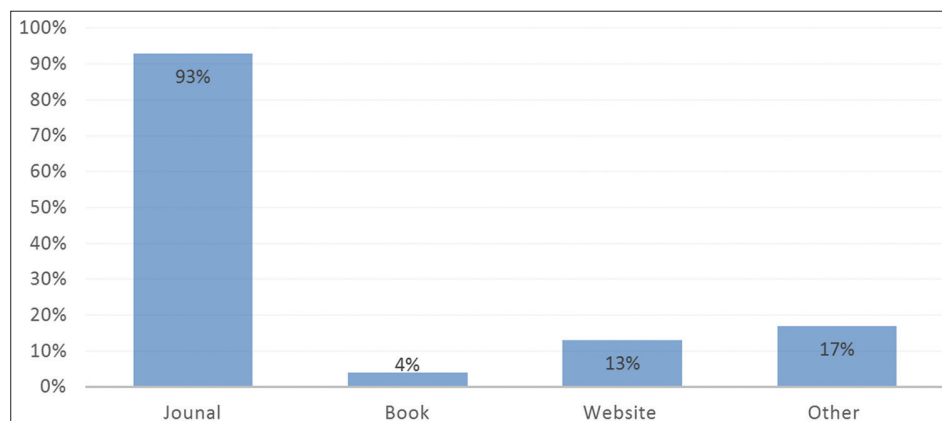
**Table 1: WHO criteria for drug promotional literature**

WHO criteria for drug promotional literature	Information available in DPL n=100 (%)
Active ingredient-generic name of drug	100 (100)
The brand names	100 (100)
Amount of active ingredients per dose	100 (100)
Other ingredients known to cause problems, i.e., adjuvant	5 (5)
Approved therapeutic uses	89 (89)
Dosage form or dosage schedule	100 (100)
Side effects	33 (33)
Drug interaction	11 (11)
Precautions, contraindications, and warnings	33 (33)
Name of manufacturer or distributor	93 (93)
Address of manufacturer or distributor	42 (42)
References to scientific literature appropriate	70 (70)

WHO: World Health Organization, DPLs: Drug promotional literatures



**Figure 3: Distribution according to the number of drugs promoted in drug promotional literatures**



**Figure 4: References given in drug promotional literatures**

claims need to be reliable, truthful, informative, balanced, and up to date. However, while promoting their products, pharmaceutical industries do not adhere to these ethical principles it may influence irrational use of drugs.<sup>[6]</sup>

In the present study, 100 DPLs evaluated. A total of 109 drugs were promoted from 100 DPLs. Of 109 drugs, 59 (54%) were prompted as single drug formulations and 50 (46%) promoted as fixed drug combinations which are similar finding as the study conducted by Jadav *et al.*, of 224 drug promoted, 54% were single component and 46% FDCs.<sup>[4]</sup>

In the present study, drug promoted from collected DPLs, majority of drug promoted in from drug act on endocrine system 36 (33%). In other studies, chemotherapy agents and cardiovascular drugs are promoted more which was different from the present study.<sup>[2,7]</sup>

In our studies show that none of the DPLs fulfill the WHO criteria which is similar finding as other studies.<sup>[2,7,8,9]</sup> Active ingredient that is generic name, brand name, and dosage detail were presented in all DPLs (100%), but other prescription information such as side effect precaution, contraindication, and warning were presented only on 33% of DPLs, drug interaction presented only in 11% of DPLs. This information is very important for rational use of drug but not available in majority of the DPLs. The study conducted by Sonwane *et al.* same shows that side effect, major drug interaction, precaution, contraindication, and warning were mentioned in only 31% which is also match with other studies.<sup>[8]</sup>

Of 100 DPLs, among 70 DPLs, majority of reference are from journal articles (93%), but among them 40% of references from before 2010. Hence, recent data about product are not given. Moreover, catchy words such as “best one” and “the only” are not available in given references. DPLs are colorful and attractive, but the picture provided on it majority were not related with disease and promoted drug.

## CONCLUSION

None of the Drug promotional literatures fulfilled all criteria of WHO for drug promotion. Promotion mainly focuses on the positive aspect of drug not the negative aspect such as side effects, contraindications, and drug interaction.

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# Effect of Liquid Paraffin Gauze Dressing In Burn Wounds: A Prospective Study

Ashish Singh<sup>1</sup>, Lalmani Singh<sup>2</sup>, Rachna Gupta<sup>3</sup>, Saurabh Saxena<sup>4</sup>, Rajeev Kaneria<sup>5</sup>

<sup>1</sup>Post Graduate Student, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, <sup>2</sup>Associate Professor, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, <sup>3</sup>Professor, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, <sup>4</sup>Assistant Professor, Department of General surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, <sup>5</sup>Senior Resident, Department of General surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

## Abstract

**Introduction:** Burn injury causes a considerable amount of disability, prolonged hospital stay, and burden on the public health sector. Main requirement in burn wound management is an economical, easy to apply, readily available dressing, or method of coverage that will provide good pain relief, protect the wound from infection, promote healing, prevent heat and fluid loss, be elastic, non-antigenic, and adhere well to the wound while waiting for spontaneous epithelialization of superficial partial thickness burns. The sterilized paraffin gauze dressing is non-adherent and non-allergenic and helps in speedy recovery of burn wounds.

**Materials and Methods:** A prospective study of 90 patients with partial thickness burns who were salvageable ( $\leq 40\%$  body surface area), admitted to Burn unit of Shyam Shah Medical College and associated Sanjay Gandhi Memorial Hospital, Rewa from June 1, 2017, to May 31, 2018. The autoclaved liquid paraffin gauze was applied over burn wound. Patients were assessed on the basis of subsidence of pain, time of epithelialization if occurred after liquid paraffin gauze dressing. Patients' blood investigations were noted and the assessment of the effect of hemoglobin (anemia) and platelet counts in burn wound healing in terms of mean epithelialization time were done.

**Results:** Mean epithelialization time was 16 days. In 25% of cases epithelialization developed in 10–12 days. Post-burn pain subsided in 4–6 days in maximum in 54.44% cases. Mild and moderate anemia had no significant effect on wound healing time (mean epithelialization time). Patient with less than normal platelet counts ( $< 1.5$  lakh/cumm) had more epithelialization time and with normal platelet count had less epithelialization time. 15 patients developed complications and most common complication was hyper granulation (11.11%).

**Conclusion:** Burn wounds pose a great burden on health-care infrastructure and burn units. We can conclude that liquid paraffin gauze dressing has good patient acceptability and less painful, it is easily available and relatively less expensive. In developing and resource-poor countries, most of the patients are from the rural background so these patients will need a dressing that is relatively less expensive and easily available such as liquid paraffin gauze dressing.

**Key words:** Burn wound, Epithelialization time, Liquid paraffin gauze

## INTRODUCTION

Burn injury causes a considerable amount of disability, prolonged hospital stay, and burden on the public health sector. Previous studies showed that the incidence of burn injury in different parts of the world is high and proper

treatment and rehabilitation of burn patients is an uphill task for public health systems. For survivors, the most common problem is scarring, so the process of wound healing and the final outcome of this process is under investigation with the hope of decreasing the complications related to scar.

Burn wound healing is a complex process including inflammation, granulation, and remodeling of the tissue.<sup>[1]</sup> Burn patients have many problems during the stages of recovery from a burn injury. Majority of patients have associated problems of healing and final outcomes of healing in terms of scarring. It is, therefore, appropriate that the process and problems of wound healing

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**Corresponding Author:** Dr. Ashish Singh, Haripujan Singh, Panchayat Inter College, Gauramehnagar, Azamgarh, Uttar Pradesh - 276 204, India



should be vigorously addressed by all practitioners and investigators involved in the treatment of burn patients and the development and use of new wound repair material. Irrespectively, the main requirement in burn wound management is an economical, easy to apply, readily available dressings or method of coverage that will provide good pain relief, protect the wound from infection, promote healing, prevent heat and fluid loss, be elastic and non-antigenic, and adhere well to the wound while waiting for spontaneous epithelialization of superficial partial thickness burns.

Liquid paraffin also known as paraffinum liquidum. It is a highly refined mineral oil used in cosmetics and for medical purposes. Paraffin is a mixture of hydrocarbons derived from petroleum and coal. Paraffin has many properties, but the best and most demanded is its moisturizing properties, which are why it is used a lot in beauty treatments and has therapeutic uses. Liquid paraffin gauze has interlocking threads which minimize fraying when the dressing is cut to shape.

Paraffin gauze dressings are used to dress denuded areas and burn wounds, and hence, these gauzes are especially coated with soft paraffin. The paraffin gauze dressing is non-adherent, non-allergenic, and sterilized, which helps in speedy recovery of wounds used in the treatment of ulcers, burns, skin grafts, and various traumatic injuries.

## MATERIALS AND METHODS

A prospective study of 90 patients with partial thickness burns who were salvageable ( $\leq 40\%$  body surface area), admitted in Burn unit of Shyam Shah Medical College and associated Sanjay Gandhi Memorial Hospital, Rewa from June 1, 2017, to May 31, 2018.

Patients were admitted to the burn unit from surgery outpatient department (OPD) or emergency department. A detailed history was recorded regarding name, age, sex, religion, occupation, education, date and time of admission and discharge, referral, and final outcome. On admission, the patient was initially resuscitated with intravenous fluid (crystalloid/colloid) along with analgesic, tetanus toxoids and antibiotics were given. A thorough general and systemic examination were done and burn area was examined for extent and type of burn wound and the total percentage of the burn was calculated by Lund and Browder charts and rule of nine and superficial, and deep burns were classified according to the depth of burn and degree of burn.

Local care of wound was done by cleaning of the wound. Sterile gauze was soaked with liquid paraffin and then autoclaved. This autoclaved liquid paraffin gauze was

applied over burn wound. Patients were assessed with subsidence of pain, time of re-epithelialization if occurred in days after liquid paraffin gauze dressing. Patients' blood investigations were noted and the assessment of the effect of hemoglobin (anemia) and platelet counts over burn wound healing in terms of mean re-epithelialization time were done.

During treatment patient was monitored for any local and systemic complications and managed accordingly. Patients were discharged after recovery with advice for follow-up in surgery OPD with an oral antibiotic, analgesic, and liquid paraffin dressing. Patients were also encouraged for skin grafting and physiotherapy.

## RESULTS

It is evident from Table 1 that maximum of patients developed epithelialization in 10–12 days (25%) followed by 13–15 and 16–18 days. 10 patients were excluded because they did not develop re-epithelialization. Mean duration of development of epithelialization tissue was 16 days.

It is evident from Table 2 that pain was relieved in maximum (54.44%) of patients in between 4 and 6 days.

It is evident from Table 3 that mild and moderate anemic patients had no significant effect on mean epithelialization time. Patients with less than normal platelets ( $<1.5$ ) had more mean epithelialization time (19.86 days) and normal (1.5–3) or more ( $>3$ ) had less mean epithelialization time (15.6 days) and (13.35 days), respectively.

It is evident from Table 4 that in out of 90 patients, 16.66% patients developed various types of complications. The most common complication was hypergranulation.

## DISCUSSION

Burn is a serious traumatic wound produced by excessive heat on the protective covering of the body, damaging the underlying tissues causing circulatory disturbances, and mild or severe constitutional disturbances. If untreated burn injuries result in intense suffering and protracted course of illness, possible disfigurement with physiological and psychological trauma to patients, huge cost and suffering to the patients family.

Burn wounds pose a great burden on health-care infrastructure and burn units, although morbidity and mortality has been decreased with a better understanding of the pathophysiology and greater stress on correction of fluid loss and electrolyte imbalance, improved methods of



**Table 1: Distribution of cases according to the development of epithelialization tissue in patients with liquid paraffin gauze dressing (n=80)**

S. No.	No. of days	Total cases	Percentage (%)
1	7–9	11	13.75
2	10–12	20	25
3	13–15	13	16.25
4	16–18	13	16.25
5	19–21	09	11.25
6	22–24	04	5
7	25–27	05	6.25
8	28–30	04	5
9	31–33	01	1.25
Total		80	100

**Table 2: Distribution of cases based on the subsidence of post-burn pain in patients with liquid paraffin gauze dressing (n=90)**

No. of Day	Total cases	Percentage
0–3	25	27.78
4–6	49	54.44
7–9	12	13.33
10–12	04	4.44
13–15	00	0.0
Total	90	100

resuscitation. The mesh paraffin gauze dressing has been the primary choice for the coverage of partial thickness burns, given its ease of application, conformability, low risk of infection, and minimal cost. The mean time to re-epithelialization was 16 days, and ranging from a minimum of 7 days to 33 days. Frequent inspections of the wound to assess epithelialization may damage the regenerating tissue. Overall wound healing, as measured by the percentage of the epithelialized dermis, was faster with paraffin gauze dressing than with dry dressing. The faster re-epithelialization rate that had been seen with the paraffin gauze dressing can partially be explained by its physical properties. Paraffin gauze dressing was found to form a fibrin layer between the dressing and the wound, creating a physical barrier that retains cytokines, particularly intrinsic growth factors.<sup>[2,3]</sup> Furthermore, epithelial cell proliferation and migration are believed to be optimal in a moist environment.<sup>[4]</sup> This concept seems to be supported by evidence from many skins graft donor site studies which have shown faster re-epithelialization rates when moist environment dressings are compared with the traditional dry dressing.<sup>[2]</sup> A paraffin gauze dressing helps in keeping the wound moist, inducing a favorable environment that facilitates recruitment of vital host defenses and necessary cell population for better wound healing.<sup>[2,5]</sup>

In the present study, we found that 15 patients (16.66%) developed complications. In the present study 15 patients (16.66%) were found to have developed complications

**Table 3: Distribution of cases according to the effect of blood investigation on epithelialization tissue in patients with liquid paraffin gauze dressing (n=80)**

Blood investigation	Values	Total cases	Mean time (Days)
Hb	<6 (severe)	3	23
	6–9 (moderate)	25	17.04
	9–12 (mild)	36	15.58
Platelet (lakh/cumm)	<1.5	15	19.87
	1.5–3	45	15.6
	>3	20	13.35

**Table 4: Distribution of cases according to the development of complications**

S. No.	Complications	Total no. of patients	Percentage (%)
1	Contracture	1	1.11
2	Hypergranulation	10	11.11
3	Infection	3	3.33
4	Gangrene	-	-
5	Bedsore	1	1.11
Total		15	16.66

of which 10 patients (11.11%) had hypergranulation, 3 patients developed infection, 1 patient complicated with contracture and 1 patient had developed bedsore. There was no significant role of paraffin gauze dressing in the reduction and management of local complication. Anemia is a common factor assigned to poor wound healing. However, clinical studies have shown over and over again, that in healthy normovolemic patients, mild to moderate anemia alone was not associated with impaired wound healing. Conditions which might accompany anemia such as malnutrition, impaired blood supply, and inflammation have a more dominant impact on wound healing abnormalities.<sup>[6]</sup> In the present study, results are the same to previous studies that mild and moderate anemia patients did not have a significant effect on burn wound healing time (mean epithelialization time). In mild anemia, patients had re-epithelialization, time was 15.58 days and in moderate anemia, it was 17.04 days. Platelets had a negative relation with mean epithelialization time. Patients with more platelets had less mean re-epithelialization time and patients with less than normal (<1.5 lakh/cumm) had more epithelialization time.

## CONCLUSION

Burn wounds pose a great burden on health-care infrastructure and burn units. Although morbidity and mortality has been decreased with a better understanding of the pathophysiology and greater stress on correction of fluid loss and electrolyte imbalance, improved methods of resuscitation. We can conclude that liquid paraffin gauze

dressings has good patient acceptability and less painful; it is easily available and relatively less expensive. In developing and resource-poor countries, most of the patients are from the rural background so these patients will need a dressing that is relatively less expensive and easily available such as liquid paraffin gauze dressing. Liquid paraffin gauze dressing leads to early epithelialization of wound and also it provides a relatively less painful mode of wound coverage and helps in early healing of wounds.

On the basis of results of this study, it can be concluded that liquid paraffin gauze dressing can be an acceptable and cost-effective method of wound coverage in burn patients. It provides a good alternative for wound coverage in resource-poor countries where other types of dressings are not readily available and are not cost-effective.

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# Nature of Disordered Sleep in Patients with Moderate to Very Severe Chronic Obstructive Pulmonary Disease

Piyush P Gupta<sup>1</sup>, Amol B Fuladi<sup>2</sup>

<sup>1</sup>Assistant Professor, Department of Respiratory Medicine, Government Medical College and Hospital, Akola, Maharashtra, India, <sup>2</sup>Professor and Head, Department of Respiratory Medicine, Government Medical College and Hospital, Akola, Maharashtra, India

## Abstract

**Introduction:** Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death in the world. Comorbidities occur frequently in COPD patients.

**Aim:** The present study was an observation based cross-sectional prospective study carried out with an aim to evaluate the breathing disorders during sleep in patients with COPD and to correlate this disorder with the stage of the disease.

**Materials and Methods:** A total of 50 patients were eligible for participation in our study. 18 patients had moderate COPD, 19 patients had severe COPD, and 13 patients had very severe COPD as per the global initiative for chronic obstructive lung disease guidelines.

**Results:** Mean sleep efficiency was low at  $53.25 \pm 18.15$ . Sleep latency was normal in three patients only. We found abnormal sleep architecture in all three groups with decreased duration of stage N3 and stage rapid eye movement. Obstructive sleep apnea (OSA) was present in 23 of 50 subjects of COPD (Overlap syndrome).

**Conclusion:** In present study, it was found that OSA is highly prevalent in patients with moderate to very severe COPD. Sleep quality is also poor among this selected group.

**Key words:** Apnea-hypopnea index, COPD, Sleep

## INTRODUCTION

Chronic obstructive pulmonary disease (COPD), the fourth leading cause of death in the world,<sup>[1]</sup> represents an important public health challenge that is both preventable and treatable. Globally, the COPD burden is projected to increase in the coming decades due to continuous exposure to COPD risk factors and aging of the population.<sup>[2]</sup>

COPD often coexists with other diseases (comorbidities) that may have a significant impact on prognosis.<sup>[3-7]</sup> Some of these arise independently of COPD whereas others

may be causally related, either with shared risk factors or by one disease increasing the risk of another.

Comorbidities that occur frequently in COPD patients include cardiovascular disease, skeletal muscle dysfunction, metabolic syndrome, osteoporosis, depression, lung cancer, and sleep-related breathing disorder.<sup>[8]</sup>

Obstructive sleep apnea (OSA) is a form of sleep-disordered breathing (SDB) clinically recognized four decades ago and defined by the total or partial intermittent collapse of the upper airway resulting in nocturnal hypoxemia and arousals from sleep. Recent data indicate an increasing trend, with 26% of adults estimated to have mild-to-severe OSA (apnea-hypopnea index [AHI] >5/h).<sup>[9]</sup>

COPD and OSA syndrome (OSAS) are highly prevalent disorders, so the possibility of both occurring together in the same patient is relatively high by chance alone. Current estimates for the prevalence of COPD are in the region

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**Corresponding Author:** Dr. Amol B Fuladi, Damle Marg, Ramdaspeth, Akola - 444 001, Maharashtra, India.

of 10% and the prevalence of OSAS is at least 10%. The coexistence of both disorders, termed the overlap syndrome, carries additional prognostic implications relating to worsening respiratory failure, cardiovascular, and other comorbidities, and ultimately survival.<sup>[10]</sup>

Early small studies showed a high prevalence of OSA in COPD and vice versa.<sup>[11,12]</sup> However, these studies may have had selection bias. The more recent Sleep Heart Health Study (SHHS), a large community-based cohort study, showed no increase in the prevalence of OSA in mostly mild obliterative airway disease patients compared to the general population.<sup>[13]</sup> Similar results were shown by Bednarek *et al.*<sup>[14]</sup> in a Polish cohort with predominantly mild COPD.

Little is known about the path physiological and clinical consequences of having concomitant COPD and OSA. Recent studies have demonstrated that patients with COPD-OSA have a high risk of death as well as increased risk of exacerbations if OSA remains untreated. Therefore, evaluating the presence of OSA in patients with advanced COPD seems logical.<sup>[9]</sup>

To that end, we investigated sleep characteristics of patients enrolling in a respiratory medicine department of a tertiary care center to determine the nature of disordered sleep in patients with advanced COPD.

## METHODS

The present study was an observation based cross-sectional prospective study carried out in a well-equipped sleep laboratory of the Department of Respiratory Medicine, R D Gardi Medical College, Ujjain, India. The aim of the study was to evaluate the breathing disorders during sleep in patients with COPD and to correlate this disorder with the stage of the disease.

The study cohort was constituted by patients of COPD registered into chest OPD or admitted in Indoor Units of the hospital from July 2012 to July 2014.

A total of 50 consecutive COPD patients who consented to be enrolled into the study were classified into moderate, severe, and very severe stages based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for the management of COPD, i.e., Mild COPD: Forced expiratory volume in 1 s (FEV1)/Forced vital capacity (FVC) <70%, FEV1 >80% predicted; Moderate COPD: FEV1/FVC <70%, FEV1 50–80% predicted; and Severe COPD: FEV1/FVC <70%, FEV1 30–50% predicted; very severe COPD: FEV1/FVC <70%, FEV1 <30% predicted.

The inclusion criteria followed for enrolling the patients in the study were age >40 years; clinical history consistent with COPD; irreversible airflow obstruction, i.e., FEV1/FVC <70% and post-bronchodilator change in FEV1 <15% (or) if FEV1 <1.5 L, change in FEV1 <200 ml.

Patients with active tuberculosis, congestive heart failure, chronic renal failure, morbid obesity (Body mass index [BMI] >40), pregnant women, age <40 years and >80 years were excluded from the study.

All COPD patients were subjected to detailed clinical history, thorough physical examination, ear, nose and throat examination, Mallampati grading to rule out upper airway obstruction. All patients were asked to fill up the Epworth Sleepiness questionnaire. BMI was recorded (BMI = weight in kg/height in m<sup>2</sup>). Neck circumference (cm) was measured at the level of the cricothyroid membrane.

For each enrolled subject, spirometry was done using international protocols by Computerized Spirometry Machine (MIR-Spiro lab III) for confirmation and staging of COPD.

All patients underwent polysomnography (Level 1 using Alice 5 Respirationics) to diagnose OSA along with sleep quality (include total sleep time, sleep efficiency, sleep latency, percentage of sleep stage N<sub>1</sub>, N<sub>2</sub>, N<sub>3</sub>, and rapid eye movement [REM]), arousal index (AI) (i.e., average number of arousal per hour of sleep), periodic leg movement index (PLMI) (i.e., the average number of periodic limb movement in an hour of sleep), desaturation index, and AHI (The average number of apneas and hypopneas in an hour of sleep). The AHI grading was done according to the American Academy of Sleep Medicine guidelines. Patients were classified according to the severity of OSA as mild (AHI 5–15), moderate (AHI 15–30), and severe (AHI >30). Correlation of all outcomes with the severity of COPD was studied.

Qualitative data were collected, and results were arranged into tables, and statistical test-Chi-square test, regression correlation, and Mann–Whitney non-parametric test were applied for the tables. *P* value for significance was taken out for all the tables. Test was considered significant when *P* < 0.05.

Microsoft Excel 2010 software and SPSS version-20 was used for data entry and analysis.

## RESULTS

A total of 58 patients were eligible for participation in our study. Eight studies (13.7%) were not suitable for analysis:

sleep duration <4 h ( $n = 2$ ), loss of EEG signal ( $n = 2$ ), and lost raw data in a hardware malfunction ( $n = 4$ ). A final sample of 50 subjects was included in the analysis.

Eighteen (36%) patients had moderate COPD, 19 (38%) patients had severe COPD, and 13 (26%) patients had very severe COPD as per GOLD guidelines. Majority of the patients 44 (88%) were in the age group of 55 years and above (range 45–80 years, mean 61.12 years). 49 (98%) males and one (2%) female participated in the study.

On physical examination, there were no risk factors for OSA such as deviated nasal septum, high arched palate, macroglossia, and retrognathia. The mean BMI was  $18.12 \pm 3.92$ . The mean neck circumference was  $34.64 \pm 3.71$  cm. However, both BMI and neck circumference were not significantly different in the compared groups ( $P = 0.72$  and  $P = 0.97$ , respectively). All the patients had mallampati score of <3, signifying no additional risk factor for OSA.

Most of the patients enrolled in the study were heavy smokers with a mean pack year of 33.9. Smoking history was not significantly different across the three groups ( $P = 0.56$ ).

Baseline demographic, anthropometric, and spirometric data are presented in Table 1 for all subjects who completed the study. There were no significant demographic differences in patients of all the three study groups [Table 1].

**Table 1: Demographic, anthropometric, and spirometric data in COPD**

Parameters	Moderate COPD ( $n=18$ )	Severe COPD ( $n=19$ )	Very severe COPD ( $n=13$ )	P value
Age, year	$59.8 \pm 16.5$	$60.5 \pm 0.0$	$63.8 \pm 10.0$	0.16
Male/Female, %	94.4/5.6	100/0	100/0	0.0001
BMI, kg/m <sup>2</sup>	$18.6 \pm 3.4$	$18.3 \pm 0.8$	$17.15 \pm 1.2$	0.72
Smoking, pack-years	$31.6 \pm 10.0$	$31.15 \pm 15.0$	$41.0 \pm 17.5$	0.56
Neck circumference	$35.2 \pm 1.2$	$34.5 \pm 0.7$	$34.1 \pm 0.0$	0.97
FVC%	$72.3 \pm 1.0$	$60.4 \pm 4.5$	$51 \pm 3.5$	0.001
FEV1%	$61.3 \pm 0.5$	$37.3 \pm 0.0$	$23.8 \pm 0$	0.0001
FEV1/FVC%	$64.45 \pm 10.0$	$56.6 \pm 8.3$	$48.2 \pm 13.5$	0.004

COPD: Chronic obstructive pulmonary disease, FVC: Forced vital capacity, FEV1: Forced expiratory volume in 1 s, BMI: Body mass index

The average FEV1/FVC of the cohort was  $57.23 \pm 19.5$ . Subjects with very severe COPD had a mean FEV1/FVC of  $48.2 \pm 13.5$ . There was a significant difference in FEV1, FVC, and FEV1/FVC across all the three groups [Table 1].

Epworth Sleepiness Scale was in the normal range in 34 (68%) patients. Ten (20%) patients had score between 8 and 9 suggesting the average amount of daytime sleepiness and only 6 (12%) had score ranging from 10 to 15 suggesting excessive sleepiness depending on the situation. Not a single patient had scored higher than 16 suggesting excessive daytime sleepiness.

Mean sleep efficiency was low at  $53.25 \pm 18.15$ . Sleep efficiency differed significantly between severe and very severe COPD groups ( $P = 0.01$ ).

Sleep latency was normal in three patients only, 47 (94%) patients had sleep latency above normal (range 5–209 min).

Furthermore, we found abnormal sleep architecture in all three groups with decreased duration of stage N3 and stage REM, with no significant difference across the three groups ( $P = 0.08$  and  $P = 0.45$ , respectively) [Table 2].

OSA was present in 23 of 50 subjects (46%) of COPD (Overlap syndrome). Mild OSA was seen in 7 (14%) patients, moderate in 13 (26%) patients, and severe OSA in 3 (6%) patients. There was a significant correlation between OSA and FEV1, FVC ( $P = 0.01$  and  $P = 0.01$ , respectively). The severity of OSA increased with the severity of airflow obstruction.

Thirty (60%) patients had high AI. The severity of AI increased with the severity of disease ( $P \leq 0.0001$ ).

Forty (80%) patients had high (>5) desaturation index. 26 (52%) patients had mild desaturation index,<sup>[5-15]</sup> 10 (20%) patients had moderate desaturation index,<sup>[15-20]</sup> and 4 (8%) patients had severe desaturation index (>30). Desaturation index increased with the severity of COPD with a significant difference in moderate and severe, very severe COPD. On comparing desaturation index with

**Table 2: Polysomnography data in COPD patients**

Sleep quality	Moderate COPD ( $n=18$ )	Severe COPD ( $n=19$ )	Very severe COPD ( $n=13$ )	P value
Sleep efficiency	$74.1 \pm 2.9$	$81.2 \pm 11.5$	$68.27 \pm 18.9$	0.09
Sleep latency	$28.5 \pm 3.2$	$52.65 \pm 3.0$	$65.86 \pm 17.5$	0.2
Sleep stage N1%	$21.9 \pm 3.8$	$21.5 \pm 0.0$	$21.5 \pm 9.9$	0.50
Sleep stage N2%	$58.7 \pm 5.1$	$55.6 \pm 1.8$	$58.9 \pm 3.9$	0.39
Sleep stage N3%	$6.8 \pm 0.7$	$11.1 \pm 1.3$	$9.6 \pm 8.6$	0.08
Sleep stage REM%	$12.5 \pm 0.6$	$12.0 \pm 0.6$	$9.8 \pm 5.3$	0.45

COPD: Chronic obstructive pulmonary disease, REM: Rapid eye movement



**Table 3: AHI, AI, desaturation index, and PLMI in moderate to very severe COPD**

Sleep study findings	Moderate COPD (n=18)	Severe COPD (n=19)	Very severe COPD (n=13)	P value
AHI	7.9±10.6	15.9±0.9	19.4±6.7	0.003
AI	3.6±5.2	9.6±1.9	14.1±7.1	0.001
Desaturation index	7.3±3.8	15.1±5.9	15.4±5.8	0.005
PLMI	2.8±1.6	8.5±0.9	15.5±3.5	0.0001

AHI: Apnea-hypopnea index, AI: Arousal index, PLMI: Periodic leg movement index, COPD: Chronic obstructive pulmonary disease

severity of COPD, the data were significant ( $P = 0.04$ ,  $P = 0.0008$ , respectively).

Periodic limb movement index was above normal in 20 (40%) patients. It significantly increased with the severity of disease ( $P \leq 0.0001$ ) [Table 3].

## DISCUSSION

The literature regarding sleep in COPD is somewhat mixed. The SHHS, for example, found no major increase in OSA risk among patients with COPD compared with matched control subjects.<sup>[13]</sup> However, they studied a community sample of patients with mild subclinical disease, and thus the findings may not generalize to clinical cohorts. On the other hand, Sharma *et al.* found a high risk of OSA in patients with COPD, but the authors failed to use GOLD standard polysomnography, and thus the results may be biased by misclassification.<sup>[15]</sup>

In studies by Bradley *et al.*<sup>[16,17]</sup> and by Chaouat *et al.*,<sup>[12]</sup> in which consecutive patients with SAHS were investigated (n = 50 and 265, respectively) the prevalence of an associated COPD, was, respectively, of 14%<sup>[17]</sup> and 11%.<sup>[12]</sup> These figures were considered as high, suggesting that the prevalence of COPD in SAHS exceeded that observed in the general population.

Our study, which consisted of COPD in different stages of severity, observed a high prevalence of SDB in patients with moderate to very severe COPD referred to our OPD. OSA was present in 23 of 50 subjects (46%). There was a significant correlation between OSA and FEV1, FVC ( $P = 0.01$  and  $P = 0.01$ , respectively). Thus, the severity of OSA increased with the severity of airflow obstruction.

We found abnormal sleep architecture in all the groups with decreased duration of stage N3 and stage REM, with no significant difference across the three groups ( $P = 0.08$  and  $P = 0.45$ , respectively). We have further identified poor sleep quality and low sleep efficiency in full polysomnography in COPD patients. Other studies

confirmed that patients with COPD experience poor sleep quality with diminished amounts of slow-wave and REM sleep.<sup>[18,19]</sup>

Pathophysiologically sleep has a number of adverse effects on breathing that include negative effects on respiratory control, respiratory muscle function, and lung mechanics.<sup>[10]</sup> These effects produce negligible adverse consequences in normal subjects but may result in profound disturbances of gas exchange in patients with COPD and they may experience profound oxygen desaturation, particularly during REM sleep, in addition to carbon dioxide retention, and the oxygen desaturation encountered during sleep may exceed that during maximum exercise.<sup>[10]</sup> Therefore, people with COPD-OSA have more profound hypoxemia (both day and night) than patients having either condition alone and may be predisposed to pulmonary hypertension.<sup>[9]</sup> Our study confirmed a significant increase in desaturation index with increasing severity of COPD.

Thus, the study findings point toward the important causative risk factors among patients with COPD (e.g., increased cardiovascular events and reduced quality of life) in afflicted individuals increasing morbidity and mortality. Previous studies also showed that the presence of COPD with OSA increases the risk of death seven-fold.<sup>[9]</sup>

Furthermore, our study demonstrated that the majority of subjects were naive to the OSA diagnosis, which may be clinically important. Poor sleep has classically been reported among both COPD and asthma patients. Therefore, many practitioners may attribute sleep difficulties or sleep symptoms to these respiratory diseases rather than investigate for OSA. Patients, too, may have a tendency to under-report poor sleep symptoms (possibly attributing them to underlying lung disease), or there may be a tendency among pulmonologists not to pay close attention to sleep-related symptoms in general.<sup>[20]</sup>

Our study suggests that OSA is common in COPD patients in outpatient pulmonary clinics, and pulmonologists should consider screening for OSA symptoms in these patients.

We acknowledge some limitations of our study. The sample size was modest compared with some prior reports in more general COPD populations. We studied a relatively sick homogeneous cohort of moderate to very severe COPD patients and thus our findings cannot be generalized to all patients with COPD, specifically those having mild disease. Therefore, larger-scale studies are warranted in COPD patients.

## CONCLUSION

To summarize, in this study, we found that OSA is highly prevalent in patients with moderate to very severe COPD. Sleep quality is also poor among this selected group. These patients have greater-than-expected sleep-disordered breathing, which could be an important contributory factor to morbidity and mortality. There was a significant difference in both efficiency and quality of sleep according to the severity of COPD. Thus, sleep disorders as a comorbid condition need to be studied in COPD to reduce mortality and morbidity in these patients.

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# Clinical Study on Acute Inflammatory Inguinoscrotal Lesions

Naveen Patidar<sup>1</sup>, Yogesh Kailasia<sup>2</sup>, Priyank Sharma<sup>3</sup>, Rajeev Kaneria<sup>4</sup>

<sup>1</sup>Post Graduate Student, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, <sup>2</sup>Associate Professor, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, <sup>3</sup>Professor, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, <sup>4</sup>Senior Resident, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

## Abstract

**Introduction:** Acute inguinoscrotal swellings are the most common swellings affecting both children and adults. Although these swellings are frequently encountered, many times correct diagnosis is not made and testes have been sacrificed. A wide variety of acute inflammatory conditions affects inguinoscrotal region and testes such as inguinal abscess, funiculitis, inguinal lymphadenitis, primary infections of scrotum, and/or secondary infection of testes such as epididymo-orchitis and scrotal abscess, pyocele, and Fournier's gangrene. Knowledge of the risk factors, prevention, and early detection with prompt treatment of inguinoscrotal lesions, which leads to reduction in morbidity and mortality associated with these lesions.

**Materials and Methods:** In this prospective study carried out in 195 patients in the Department of Surgery, Shyam Shah Medical College and associated Gandhi Memorial and Sanjay Gandhi Memorial Hospitals, Rewa, Madhya Pradesh, during the period of 1 June 2017 to 31 May 2018. All male patients with complaints of acute painful inguinoscrotal swelling and ulcer with a history of <2 weeks were included in the study. Presenting complaints and detailed history were recorded in a predesigned pro forma. Thorough general examination and local examination were done. Patients were investigated and final diagnosis was established. Then, treatment was initiated according to diagnosis.

**Results:** Acute epididymo-orchitis (42.6%) was the most common cause for acute inguinoscrotal pathology followed by Fournier's gangrene (19.5%) and scrotal abscess (17.9%). Majority patients belong to the age group of 31–40 years, 22.6% and in the age group of 41–50 years, 20.5%. The most common predisposing factor was lower urinary tract syndrome present in 47.1% followed by poor personal hygiene (43.07%). Conservative treatment was given in 80 patients. All, except eight cases of epididymo-orchitis (83), two cases of scrotal cellulitis and four cases of inguinal lymphadenitis were treated conservatively. All 38 cases of Fournier's gangrene and one case of scrotal cellulitis were treated by debridement and daily dressings. Incision and drainage of pyocele was carried out in five patients. Scrotal exploration with drainage of testicular abscess was done in three cases. Orchidectomy was required in two cases of testicular abscess.

**Conclusion:** Acute inguinoscrotal lesions are common in younger and middle age individuals with variable symptomatology. Such conditions presenting to emergency department need careful examination, proper evaluation, and prompt treatment. Conservative treatment with rest, scrotal support, antibiotics, and analgesics is effective in case of epididymo-orchitis. Emergency surgical exploration proved to be the best in case of scrotal abscess, Fournier's gangrene, pyocele, and hematocele. Various predisposing factors can be minimized by proper health education and developing good primary health-care system.

**Key words:** Acute inguinoscrotal lesions, Epididymo-orchitis, Fournier's gangrene

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## INTRODUCTION

The inguinoscrotal region is an important anatomical region of body as it contains inguinal canal which poses spermatic cord and nerve and vessels. Scrotum along with the indwelling testes is not only male reproductive organs but also has been considered as “Tool of Manhood” since man

**Corresponding Author:** Dr. Naveen Patidar, Post Graduate Student, Department of General Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh - 466651, India.

learned the very differentiation between male and female.<sup>[1]</sup> Rightly the precise diagnosis and treatment of various scrotal and testicular pathologies with available recent technological means is very important for both physical and psychological health of the men. A wide variety of acute inflammatory conditions affects inguinoscrotal region such as inguinal abscess, funiculitis, inguinal lymphadenitis, primary infections of scrotum, and secondary infection of testes such as epididymo-orchitis and scrotal abscess, pyocele, and Fournier's gangrene. Filariasis scrotum and epididymo-orchitis are highly prevalent in this region. Fournier's gangrene is an aggressive necrotizing cellulitis of scrotal region often presented with shock. Early diagnosis and resuscitation with extensive debridement and antibiotic coverage reduces mortality significantly. Due to poverty, illiteracy, and social stigma patient and their relatives are relying on treated by indigenous methods without examination of patient, which prevent the patient from reporting early in the course of their disease which further worsen the situation because patient presents with advanced disease and complications. Thorough clinical examination and early intervention plays important role in the management of inguinoscrotal lesion. Proper education, hygiene, early diagnosis, and management will help in reducing complication and psychosocial burden of the disease. The benefit of the study will be that it will help in knowing the risk, prevention, and early detection with prompt treatment of inguinoscrotal lesions, which leads to reduction in morbidity and mortality associated with these lesions.

## MATERIALS AND METHODS

A prospective study carried out in 195 patients in the Department of Surgery, Shyam Shah Medical College and associated Gandhi Memorial and Sanjay Gandhi Memorial Hospitals, Rewa, Madhya Pradesh, during the period of June 1, 2017–May 2018. All male patients with complaints of acute painful inguinoscrotal swelling and ulcer with a history of <2 weeks were included in the study.

Patients with painless inguinoscrotal swelling due to inguinal hernia, hydrocele, testicular tumors, torsion testis, and history of >2 weeks and female patients were excluded from the study. Presenting complaints and detailed history were recorded in a predesigned pro forma. Thorough general examination and local examination were done. Patients were investigated and final diagnosis was established. Then, treatment was initiated according to diagnosis.

Conservative treatment includes rest, scrotal support, appropriate antibiotic, analgesic, and antifilarial treatment for 7–21 days. Patient with septicemic shock treated

with intravenous (IV) fluid resuscitation, IV antibiotics, symptomatic, and supportive treatment. Patient with uncontrolled diabetes treated with insulin/hypoglycemic drugs. Patients requiring surgical intervention were operated under anesthesia. Surgical intervention includes incision and drainage of abscess with antibiotic coverage and incision drainage with aggressive debridement with antibiotic coverage.

Pus culture of aspirated contents was sent, antibiotic sensitivity will be advised and treatment reviewed accordingly. Post-operative treatment was continued.

Patients were examined daily for clinical improvement. Recovery was defined as clinical improvement in signs and symptoms, decrease in WBC count and follow-up ultrasonography if required.

Patients were discharged and mean hospital stay was recorded. All information was recorded in predesigned pro forma as per plan. Patients were followed up in surgical outpatient department.

## RESULTS

In our study of 195 cases, the following results were obtained.

### Type of Lesions

Acute epididymo-orchitis (42.6%) was the most common cause for acute inguinoscrotal pathology followed by

**Table 1: Distribution of cases according to the type of lesions**

Diagnosis	Number of cases (%)
Epididymo-orchitis	83 (42.6)
Fournier's gangrene	38 (19.5)
Scrotal abscess	35 (17.9)
Inguinal abscess	24 (12.3)
Pyocele	5 (2.6)
Inguinal lymphadenitis	4 (2.1)
Testicular abscess	3 (1.5)
Scrotal wall cellulitis	3 (1.5)
Total	195 (100)

**Table 2: Distribution of cases according to age**

Age (in years)	Number of cases (%)
0–10	8 (4.1)
11–20	21 (10.8)
21–30	2 (14.9)
31–40	44 (22.6)
41–50	40 (20.5)
51–60	26 (13.3)
61–70	18 (9.2)
>70	9 (4.6)
Total	195 (100.0)

Fournier's gangrene (19.5%) and scrotal abscess (17.9%) [Table 1].

### Distribution of Cases According to Age

Majority of the patients were in the age group of 31–40 years, 44 cases (22.6%). The youngest patient was of 9 months old with the right inguinal abscess and oldest patient was of 83 years old with Fournier's gangrene [Table 2].

### Distribution of Cases According to Occupation

Majority of patients were laborer accounting for 35.8% (70 cases) of the total cases and next common group was of farmer 28.8% (56 cases).

### Distribution of Cases According to Residence

Majority of the patients belongs to rural area comprising 66.2% of total case and 33.8% of patients belongs to urban area.

### Distribution of Cases According to Presenting Symptoms

All patients presented with symptom of scrotal swelling and pain. Burning micturition and difficulty in passing urine accounted for 25.1% and 11.7%, respectively [Table 3].

### Distribution According to Various Predisposing Factors (n= 195)

Majority of patients have lower urinary tract syndrome in 92 cases (47.1%) and the second common predisposing factor was poor personal hygiene in 84 cases (43.07%). 54 cases had a history of comorbidities, of which 41 cases had diabetes mellitus and four had AIDS and three patients had pulmonary tuberculosis [Table 4].

### Investigations

Eighty-two cases (46.07%) were found anemic, majority of patients had their leukocyte count lying in the range of >11,500 (48.87%). The most common organism cultured was *Escherichia coli* (27.61%) followed by *Staphylococcus aureus* (20.95%). Polymicrobial was caused by *Proteus*, *Pseudomonas*, *Klebsiella*, *E. coli*, *S. aureus*, and *Streptococcus* found in 12.39% cultures.

### Distribution According to Treatment

Eighty cases were managed conservatively. All, except eight cases of epididymo-orchitis (83), two cases of scrotal cellulitis and four cases of inguinal lymphadenitis were treated conservatively with rest, scrotal support, antibiotics, and analgesics. Conservative treatment was given for 7–21 days.

All 38 cases of Fournier's gangrene were treated by extensive debridement and daily dressings. Similarly, one patient of scrotal cellulitis was treated by debridement and dressing. Incision and drainage of pyoceles was carried

**Table 3: Distribution of cases according to presenting symptoms**

Presenting complaints	Number of cases (%)
Inguinoscrotal swelling	195 (100)
Pain	195 (100)
Burning micturition	49 (25.1)
Fever	48 (24.6)
Ulcer	23 (11.8)
Difficulty in passing urine	23 (11.7)
Discharge	19 (9.75)

**Table 4: Distribution of predisposing Factors (n=195)**

Predisposing factors	Number of cases (%)
LUTS	92 (47.1)
Poor personal hygiene	84 (43.07)
Comorbidities (DM, immunosuppression, and TB)	54 (27.6)
Skin lesions	46 (23.5)
Similar complaints in the past	28 (14.3)
Perianal/perirectal infections	20 (10.25)
Exposure to STD	18 (9.2)
Trauma	15 (7.6)
Instrumentations	13 (6.6)
H/O recent catheterization	4 (2.05)
Congenital abnormality	1 (0.5)

LUTS: Lower urinary tract syndrome, DM: Diabetes mellitus, TB: Tuberculosis, STD: Sexually transmitted diseases

**Table 5: Distribution according to treatment**

Treatment	Number (%)
Conservative	80 (44.1)
Incision and drainage	68 (32.8)
Debridement	40 (20.5)
Scrotal exploration with drainage of testicular abscess	3 (1.6)
Orchidectomy	4 (1)

out in all cases (5). Scrotal exploration with drainage of testicular abscess was done in three cases. Orchidectomy was required in two cases of testicular abscess [Table 5].

## DISCUSSION

Evaluation of patients of inguinoscrotal lesions is not only important but also difficult task due to being male genital organs and often associated with feeling of shame and secrecy. Patients not only require proper diagnostic and therapeutic facilities but also proper psychological support. Making the people aware of the predisposing factors and problems of their reproductive organs is an important part in prevention and management of these lesions.

Ingale *et al.*<sup>[2]</sup> stated that incidence for acute epididymo-orchitis and Fournier's gangrene was maximum in 30–50 years. In our study, majority of the patients were in the adult age group of 31–40 years (22.6%) and in the age

group of 41–50 years (20.5%), respectively, followed by younger age group of 21–30 years which was accounted for 29 cases (14.9%). Mean age for acute epididymorchitis was 35.8 years and for Fournier's gangrene and scrotal abscess were 49.7 years and 41.6 years, respectively.

Paul *et al.*<sup>[3]</sup> stated that the most common cause of acute scrotal swelling was acute epididymo-orchitis (30%) followed by Fournier's gangrene (24%). In a case study by Abul *et al.*<sup>[4]</sup> of 40 patients, the most common lesion was epididymitis (60%). In our study, acute epididymo-orchitis (42.6%) was the most common cause for acute inguinoscrotal pathology followed by Fournier's gangrene (19.5%) and scrotal abscess (17.9%).

In Sharma<sup>[5]</sup> [2003] study, majority of patients were of farmers (32.9%) and next common group were of laborers (30.9%). Malikarjun<sup>[6]</sup> (2005) series of 30 cases stated that 63.33% of cases were manual laborers and only 37.67% were sedentary workers. In our study, majority of patients were laborers accounting for 35.8% (70 cases) of the total cases and next common group was of farmer 28.8% (56 cases).

In a study was conducted by Ghanghoria,<sup>[1]</sup> the incidence of scrotal lesion was more in rural population (68.4%) as compared to urban (31.6%). Another study was conducted by Sharma<sup>[5]</sup>, incidence was found to be in rural population (64.5%) and urban population (35.4%). In our study, the majority of the patients belong to rural area comprising 66.2% of total case and 33.8% of patients belongs to urban area.

In a study conducted by DelVillar *et al.*<sup>[7]</sup> of 45 cases, a history of similar complaints in the past was found in two cases of epididymitis. Furthermore, there was a history of trauma in seven cases of epididymitis. Dysuria was present in seven cases of epididymitis. In Hazarika *et al.*<sup>[8]</sup> study of 90 cases, there was a history of urinary symptoms in 22 cases of epididymo-orchitis, two cases epididymitis, and one case of pyocele. There was a history of similar complaints in the past in six cases with epididymo-orchitis. In our study, the most common predisposing factor was a history of urinary symptoms present in 92 cases, followed by poor personal hygiene present in 84 cases. There was a history of similar complaints in the past in 28 cases. 40 cases had a history of comorbidities. There was a history of trauma in 15 cases.

Paul *et al.*<sup>[3]</sup> study found that all cases had swelling of scrotum, associated with pain, 60% fever, 18% burning micturition, 14% of patients had a history of trauma, and 2% had difficulty in micturition. Malikarjun<sup>[6]</sup> stated that all cases had swelling of scrotum, associated with pain at the time of presentation, 73.33% had a history of fever

while 16.67% had a history of burning micturition. In our study, all the cases present with swelling and pain at inguinoscrotal region. Burning micturition and difficulty in passing urine accounted for 25.1% and 11.7%, respectively. Fever, discharge, and ulcer were accounted for 24.6%, 9.75%, and 11.8%, respectively, as presenting symptoms.

Gislason *et al.*<sup>[9]</sup> showed that leukocytosis was present in 44% of cases. Hazarika *et al.*<sup>[8]</sup> study, increase in total leukocyte count in 54 (60%) cases was found, out of 90 cases. Khandelwal *et al.*<sup>[10]</sup> reported polymicrobial infection experienced in 44.4% of patients, 20.4% had *Pseudomonas aeruginosa*, 12.9% suffered *Klebsiella* species, 9.3% had *Proteus mirabilis*, and 12.9% of cases had contaminants in the cultures. Ingale *et al.*<sup>[2]</sup> study, wound swab culture was reported monomicrobial in 68% and polymicrobial growth in 28%. In our study, the most common organism cultured was *E. coli* (27.61%), followed by *Staphylococcus aureus* (20.95%), *Klebsiella aeruginosa*, *P. aeruginosa*, and *Streptococcus* were found in 13.33%, 10.48%, and 3.80% culture, respectively. The least common organism was *Proteus* (1.91%) cultures.

Eskitaşcioğlu *et al.*<sup>[11]</sup> reported the average debridement in their study to be  $1.55 \pm 1.15$  with a range of 1–8 debridements. Serial debridement was done in 30% patients. In our study, all, except eight cases of epididymo-orchitis (83), two cases of scrotal cellulitis and four cases of inguinal lymphadenitis were treated conservatively with rest, scrotal support, antibiotics, and analgesics. Conservative treatment was given for 7–21 days. All cases of Fournier's gangrene and one patient of scrotal cellulitis were treated by debridement and dressing. Incision and drainage was done in all cases of pyocele and three cases of testicular abscess. Orchidectomy was done in two cases of testicular abscess.

## CONCLUSION

The primary objective of the management of acute scrotal pathologies is to avoid testicular loss. Acute inguinoscrotal lesions are common in younger and middle age individuals with variable symptomatology. Such conditions presenting to the emergency department need careful examination, proper evaluation, and prompt treatment. Since the scrotal disease may represent inherent disease of testis, epididymis, and other intrascrotal structure which may affect the entire life of the patient in the form of sterility, so they need aggressive treatment. The most common cause for acute inguinoscrotal lesion is epididymo-orchitis followed by Fournier's gangrene. Routine investigation such as urine analysis, hemogram, blood sugar, urine culture/sensitivity (C/S), and wound swab C/S and



special investigations like USG are not always very much conclusive to the final diagnosis but are supportive to clinical diagnosis. Conservative treatment with rest, scrotal support, antibiotics, and analgesics is effective in case of epididymo-orchitis. Emergency surgical exploration proved to be the best in case of scrotal abscess, Fournier's gangrene, pyocele, and hematocele. Various predisposing factors can be minimized by proper health education and developing good primary health-care system.

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# A Clinical Audit: Intrapartum Care in Third Stage of Labor

S Harshitha<sup>1</sup>, R Nagarathnamma<sup>2</sup>, M P Sailakshmi<sup>3</sup>

<sup>1</sup>Post Graduate, Department of Obstetrics and Gynaecology, Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India,

<sup>2</sup>Professor, Department of Obstetrics and Gynaecology, Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India,

<sup>3</sup>Professor and Head, Department of Obstetrics and Gynaecology, Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India

## Abstract

**Introduction:** The third stage of labor is the time from the birth of the baby to the expulsion of the placenta and membranes. Management is normally categorized into two types; active management and physiological management. Active management of the third stage involves a package of care comprising the following components: Routine use of uterotonic drugs, deferred clamping, and cutting of the cord controlled cord traction after signs of separation of the placenta. Most common complications of the third stage of labor are postpartum hemorrhage and retained placenta.

**Aims and Objectives:** The present clinical audit aims to improve the care of healthy women and their babies during the third stage of child and to review the practices regarding the third stage of labor and to develop and implement action plan regarding management strategies.

**Materials And Methodology:** The audit was carried out on 218 pregnant women admitted in Rajarajeswari Medical College and Hospital from April 2018 to September 2018. The inclusion criteria, exclusion criteria, and data collection on the excel sheet were based on the National Institute for Health and Care Excellence (NICE) guidelines.

**Results:** Among 218 cases, vaginal blood loss was recorded in 181 (83%) cases whereas the color, respiration, and general condition were recorded in all 218 cases. In all 218 cases, active management of the third stage was carried out, and decision regarding the same was recorded. The time of cord clamping was recorded in only 6% of the cases. The management of postpartum hemorrhage and retained placenta met audit standard in all 218 cases.

**Conclusion and Recommendations:** The present clinical audit suggests that there is a need to follow specific guidelines and treatment strategies to avert the complications. Recording of vaginal blood loss in all cases, instructions for the compulsory recording of the cord clamping time following the birth of a baby and continue to follow the remaining steps according to the NICE guidelines to reduce the complications of the third stage of labor.

**Key words:** National Institute for Health and Care Excellence guidelines, Postpartum hemorrhage, Uterotonics

## INTRODUCTION

The third stage of labor is the time from the birth of the baby to the expulsion of the placenta and membranes. "This indeed is the unforgiving stage of labor, and in it, there lurks more unheralded treachery than in both the other stages combined. The normal case can, within a min to, become

abnormal and successful delivery can turn swiftly to disaster." Management of the third stage is categorized into two types: Active management and physiological management.

Active management of the third stage involves the following components: Routine use of uterotonic drugs, deferred clamping, and cutting of the cord controlled cord traction after signs of separation of the placenta.<sup>[1]</sup> Physiological management of the third stage involves the following components: No routine use of uterotonic drugs, no clamping of the cord until pulsation has stopped, delivery of the placenta by maternal effort.

Most common complications of the third stage of labor are postpartum hemorrhage, retained placenta, and uterine

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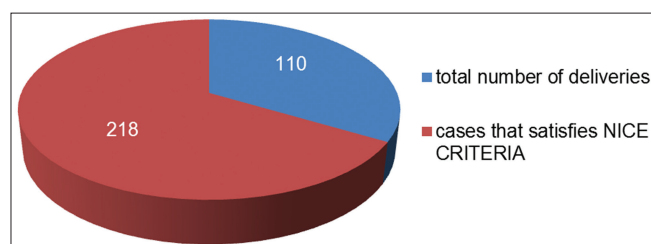
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**Corresponding Author:** Dr. S Harshitha, Rachana Nilaya, 5<sup>th</sup> Cross, Shankarmutt Road, K R Puram Hassan – 573201, Karnataka, India.

inversion. Postpartum hemorrhage (PPH) is the loss of >500 ml of blood following delivery of the baby. Most bleeding comes from where the placenta was attached to the uterus and is bright or dark blood and usually thick. PPH occurs when the uterus fails to contract well, usually due to partially or completely separated placenta or atonic uterus. Retained placenta is when placenta remains inside the uterus for longer than 30 minutes after the delivery of baby. Uterine inversion when the uterus is pulled “inside out” as the baby or the placenta is delivered and partly emerges through the vagina.

Active management of the third stage of labor (AMTSL) involves interventions to assist in the expulsion of the placenta with the intention to prevent or decrease blood loss and minimize the complications of the third stage of labor. Advise the woman to have active management of



**Figure 1: Total number of deliveries and number of cases included in the study**

**Table 1: Audit results**

Audit standards	Audit results	
Observations in the third stage		
1. All women in the third stage of labor have the following observations recorded: Their general physical condition, as shown by their color, respiration, and their report of how they feel vaginal blood loss	83%	181/218
Active and physiological management of the third stage		
2. All women have documented in their records the decision that is agreed with the woman about active or physiological management of the third stage of labor	100%	218/218
3. All women who have active management of the third stage of labor have 10 IU of oxytocin	100%	218/218
4. All women have the time the cord was clamped recorded in their records	6%	14/218
5. All women who have active management of the third stage of labor have the cord clamped no earlier than 1 min from the birth of the baby and no later than 5 min	0%	0/218
Retained placenta		
6. All women with a retained placenta have intravenous access secured	100%	11/11
7. Women are given intravenous oxytocic agents to deliver a retained placenta only if they are bleeding excessively	82%	9/11
8. All women for whom uterine exploration is necessary to have arrangements made for urgent transfer to an obstetric unit	%	0/0
9. All women undergoing uterine exploration or manual removal of the placenta are given anesthesia	100%	2/2

the third stage, because it is associated with a lower risk of a PPH and/or blood transfusion. For active management, administer 10 IU of oxytocin by intramuscular injection with the birth of the anterior shoulder or immediately after the birth of the baby and before the cord is clamped and cut. Use oxytocin as it is associated with fewer side effects than oxytocin plus ergometrine. After administering oxytocin, clamp and cut the cord: Do not clamp the cord earlier than 1 min from the birth of the baby unless there is concern about the integrity of the cord or the baby has a heart rate <60 beats/min that is not getting faster. Clamp the cord before 5 min to perform controlled cord traction as part of active management.

After cutting the cord, control cord traction performed as a part of active management of labour. It is performed only after administration of oxytocin and witnessing signs of placental separation. Record the timing of cord clamping in both active and physiological management.

In case of postpartum hemorrhage, bolus of one of the following as first-line treatment for PPH oxytocin (10 IU intravenous) or ergometrine (0.5 mg intramuscular) or combined oxytocin and ergometrine (5 IU/0.5 mg intramuscular) as the first line of treatment. If the bleeding persists, repeat bolus dose of intravenous oxytocin or intramuscular ergometrine or combined oxytocin and ergometrine intramuscularly. Other drugs such as misoprostol, oxytocin infusion, and carboprost (intramuscular) are also used. Adjuvants such as tranexamic acids can also be administered. If the hemorrhage still persists then evaluation under anesthesia should be considered. Balloon tamponade is considered before proceeding with surgical options.

In case retained placenta, vaginal examination to assess the need for manual removal of placenta and manual removal of the placenta under anesthesia is carried out. All the above-mentioned steps, pf active management is as per the National Institute for Health and Care Excellence (NICE) guidelines.<sup>[1]</sup>

## MATERIALS AND METHODOLOGY

The audit was carried out on 218 pregnant women admitted in the Department of Obstetrics in Rajarajeswari Medical College and Hospital from April 2018 to September 2018. The inclusion and exclusion criteria were based on the NICE guidelines for clinical audit in intrapartum care in the third stage of labor.

### Inclusion Criteria<sup>[1]</sup>

1. Healthy women receiving intrapartum care during the third stage of labor.



### Exclusion Criteria<sup>[1]</sup>

The following criteria were excluded from the study:

1. Women in suspected or confirmed preterm labor (before 37 weeks of gestation)
2. Women with an intrauterine fetal death
3. Women with coexisting severe morbidities such as pre-eclampsia (high blood pressure of pregnancy) or diabetes.
4. Women who have multiple pregnancies
5. Women with intrauterine growth restriction of the fetus.
6. Women with labor induced
7. Women who have cesarean birth
8. Women with breech presentation.

Data collection was done using a printed form, and the findings were tabulated into the excel sheet of clinical audit tool third stage of labor from NICE guidelines.

The tool includes:

1. Clinical audit standards based on the NICE guideline for intrapartum care.
2. A data collection sheet in which audit data can be entered.
3. A clinical audit report that provides basic information about the audit and automatically displays the audit results.
4. An action plan template.
5. An appendix containing a printable data collection form.

The data collection sheet includes recording of the general physical condition, as shown by their color, respiration, and their report of how they feel and vaginal blood loss. The vaginal blood loss was estimated by placing a shallow bedpan below the mother's buttocks and then weighs the collected blood, along with blood that has soaked into any pads and material. This is referred to as an indirect method.<sup>[1]</sup> The mode of management whether active or physiological was noted. If active the use of oxytocin or any other uterotonics were recorded. Timing of cord clamping and delivery of placenta noted. Complications such as PPH (postpartum hemorrhage) and retained placenta if observed were noted and mode of management was recorded. The above data were tabulated into the clinical audit tool on an excel sheet. The results were generated automatically on the excel sheet provided by NICE.

Below is the printable data collection sheet used for recording patient details and steps during the third stage of labor.<sup>[1]</sup>

### RESULTS

Out of 1010 deliveries conducted in Rajarajeswari Medical College during the study period of 6 months, 218 cases satisfied the criteria for clinical audit tool according to the NICE guidelines.

Among the 218 deliveries, the woman's general physical condition, as shown by her color, respiration and her report of how she feels was recorded in all the 218 cases. Vaginal blood was recorded by the indirect method in 181 cases which were 83% of the study population. Thus, only 83% of the patient care met audit standards 1. The decision about the management of the third stage of labor was recorded in all 218 cases which were 100% and met the standards of audit 2. All 218 patients had AMTSL and 218 of them were given injection oxytocin 10 IU intramuscularly immediately after delivery of anterior shoulder. 100% of the cases met audit standard 3. The time of cord clamping was recorded only in 14 cases which accounted for 6% of the cases. Thus, only 6% of the cases met audit standards 4. As only early cord clamping in cases of Rh-negative pregnancy were recorded, none of the cases met audit standards of 5. The third stage of labor was completed within 30 min in 211 cases that are in 95% of the cases. The remaining 11 cases needed further intervention and the intravenous line was secured in all 11 cases. In 82% of the above cases, intravenous oxytocin was given whereas in the remaining 2 cases methylergometrine was given. Among the 11 cases, 9 of them had excessive bleeding and needed oxytocics for further management. The remaining 2 cases had retained placenta and needed manual removal of the placenta under anesthesia. Hence, the audit standards of 6, 7, and 9 were met in all the 11 cases with complications. The audit standards of 8 were met in all the cases as the patients were already in the obstetric unit [Table 1 and Figure 1].

### DISCUSSION

The main aim of care during the third stage of labor is to prevent PPH and retained placenta. In the present audit, the audit one standards were met in 83% of the patients. Among the 218 deliveries, the woman's general physical condition, as shown by her color, respiration and her report of how she feels was recorded in all the 218 cases. Vaginal blood was recorded in 181 patients. Hemorrhage remains one of the leading causes of maternal mortality. In developing nations, where the vast majority of maternal deaths occur, the problem is exponentially greater. Postpartum hemorrhage has traditionally been defined as an estimated blood loss exceeding 500 mL. Underestimation of peripartum blood loss and delayed blood component therapy seems to be common factors

in many cases of avoidable hemorrhage-related maternal mortality. Inaccurate blood loss assessment can result in significant adverse sequelae and delay in the management of postpartum hemorrhage. In the present audit recording of the vaginal blood loss was missed in 13% of the patients. This can be improved by strict documentation and teaching the proper and convenient method of estimating the blood loss for the nurses, interns, and residents in the delivery room. This can help to achieve the target of 100% for audit standard 1.

The decision regarding the management of the third stage of labor was recorded in 100% of the cases. All 218 patients consented for active management of labor with intramuscular oxytocin injection after delivery of anterior shoulder and placental expulsion by controlled cord traction. Active management is preferred due to shortening of the third stage of labor and reduces the risk of postpartum hemorrhage and the need for blood transfusion. In a study conducted by Prendiville *et al.*<sup>[2]</sup> in 4709 women in the third stage of labor reduction in the incidence of PPH from 7 to 5% under physiological management to 5% under active management and also it shortened the third stage of labor and need for blood transfusion. In another study conducted by Begley *et al.*<sup>[3]</sup> in 2010, on 6486 women active management reduced the average risk of maternal primary hemorrhage (>1000 ml) (risk ratio [RR] 0.34, 95% confidence interval (CI) 0.14–0.87, three studies, 4636 women) and of maternal hemoglobin <9 g/dl following birth (RR 0.50, 95% CI 0.30–0.83, two studies, 1572 women) for women irrespective of their risk of bleeding. Intramuscular oxytocin was administered in all 218 cases, and hence audit three standards were met. In a study conducted by Elbourne *et al.*<sup>[4]</sup> in 2001, on 3000 women in the hospital, prophylactic oxytocin showed benefits reduced blood loss (relative risk RR for blood loss >500 ml 0.50; 95% CI 0.43, 0.59) and need for therapeutic oxytocics compared to no uterotonic. Furthermore, oxytocin has fewer side effects compared to other uterotonic.

The time of cord clamping was recorded in only 14 (6%) of the cases and failed to meet the audit standard 5. The timing of cord clamping is very important. Early cord clamping in term newborns results in a decrease of 20–40 mL/kg of blood, which is equivalent to 30–35 mg of iron. A delay in clamping, causing increased neonatal blood volume, may lead to complications such as respiratory distress, neonatal jaundice, and polycythemia. According to the NICE guidelines, cord clamping should be after 1 min and before 5 min after the birth of the baby. A systematic review and meta-analysis comparing cord clamping done early (<1 min after delivery of the infant) and late (at least 2 min after delivery) showed that late

clamping conferred a physiological benefit to the newborn that extended up to 6 months into infancy. Advantages included prevention of anemia over the first 3 months of life and enhanced iron stores and ferritin concentration for up to 6 months. There was no increase in respiratory distress, defined as tachypnea, or grunting. Neonates were at increased risk of asymptomatic polycythemia. There was no significant difference between the early and late groups in bilirubin levels and proportions of infants receiving phototherapy. A 2004 Cochrane Review by Rabe *et al.*<sup>[5]</sup> and a prospective study by Ibrahim *et al.* demonstrated that delaying cord clamping by 30–120s resulted in less need for transfusion due to anemia and less intraventricular hemorrhage. Therefore, the residents and nurses working in the delivery room should be given instructions for cord clamping as per the NICE guidelines that are all women who have active management of the third stage of labor have the cord clamped no earlier than 1 min from the birth of the baby and no later than 5 min and document the same in the patient records. This helps in reducing the neonatal complications as mentioned in the above studies. Exception being when there is concern about the integrity of the cord or the baby has a heartbeat <60 beats/min that is not getting faster and where a woman requests that the cord is clamped and cut later than 5 min.

In the present study out of 218 cases, in 207 cases AMTSL lasted for >30 min. Among the 11 cases, 9 of them had postpartum hemorrhage and 2 of them had retained placenta. Out of 9 cases, 7 of them were given intravenous oxytocin to reduce PPH and the remaining 2 cases were given methylergometrine. The intravenous access was secured in all 11 cases. The cases with retained placenta were managed under anesthesia by manual removal of placenta. The present study met with the audit standards 6, 7, and 9. The audit standard 8 was an exception as the patient was already in obstetric unit. According to the NICE guidelines, if a woman has a PPH call for help and gives immediate clinical treatment. First by emptying of the bladder followed by a uterine massage, uterotonic drugs, intravenous fluids, and controlled cord traction if the placenta has not yet been delivered. Continuously assess blood loss and the woman's condition, and identify the source of the bleeding and give supplementary oxygen. Administer a bolus of one of the following as first-line treatment for PPH: Oxytocin (10 IU intravenous) or ergometrine (0.5 mg intramuscular) or combined oxytocin and ergometrine (5 IU/0.5 mg intramuscular). Offer second-line treatment for PPH if needed. No particular uterotonic drug can be recommended over any other; options include repeat bolus of oxytocin (intravenous)/ergometrine (intramuscular, or cautiously intravenously)/combined oxytocin and ergometrine (intramuscular)/misoprostol/

oxytocin infusion/carboprost (intramuscular). Adjuvants like tranexamic acid can also be used. If the hemorrhage continues examination under anesthetic should be considered to ensure that the uterus is empty and repair any trauma consider balloon tamponade before surgical options.

## CONCLUSION

A major strength of regular clinical audits is that they bring practitioners together frequently to discuss the management of severe cases and to define relevant improvement objectives appropriate to the local context and based on the audit's findings. The present clinical audit suggests that room for improvement exists. There is a need to follow specific guidelines and treatment strategies to avert the complications during the third stage of labor. Severe PPH can lead to poor health for the mother (maternal morbidity), and sometimes even death, particularly in low- and middle-income countries. If excessive blood loss is identified early, interventions to help stem the blood flow can be started sooner, and improve health outcomes for the mother.

## RECOMMENDATIONS

Recording of vaginal blood loss in all cases in the third stage of labor by the indirect method and managing the cases based on the NICE guidelines. Instructions to the residents and midwives for the compulsory recording of the timing of cord clamping following the birth of the baby. Updating the residents and midwives regarding the newer recommendations and strategies to prevent complications of the third stage of labor and for the safe delivery of the baby.

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# Role of Diffusion-weighted Imaging, Perfusion Magnetic Resonance Imaging, and Magnetic Resonance Spectroscopy in Evaluating Histopathologically Confirmed Brain Tumors in 3-Tesla Magnetic Resonance Imaging

Deepak Jain<sup>1</sup>, Satya Bhuwan Singh Netam<sup>2</sup>, Vivek Patre<sup>3</sup>, Dnyanesh Amle<sup>4</sup>, Rajiv Sahu<sup>5</sup>, Renuka Gahine<sup>6</sup>

<sup>1</sup>Assistant Professor, Department of Radiology, Pt. Jawahar Lal Nehru Memorial Medical College, Raipur, Chhattisgarh, India, <sup>2</sup>Professor, Department of Radiology, Pt. Jawahar Lal Nehru Memorial Medical College, Raipur, Chhattisgarh, India, <sup>3</sup>Professor, Department of Radiology, Pt. Jawahar Lal Nehru Memorial Medical College, Raipur, Chhattisgarh, India, <sup>4</sup>Assistant Professor, All India Institute of Medical Sciences, Nagpur, Maharashtra, India, <sup>5</sup>Associate Professor, Department of Neurosurgery, Pt. Jawahar Lal Nehru Memorial Medical College, Raipur, Chhattisgarh, India, <sup>6</sup>Professor and Head, Department of Pathology, Pt. Jawahar Lal Nehru Memorial Medical College, Raipur, Chhattisgarh, India

## Abstract

**Objective:** Our aim was to evaluate the diagnostic capabilities of physiological magnetic resonance imaging (MRI) in differentiating type and grades of tumor and correlation with prospective histopathology results.

**Materials and Methods:** We evaluated 70 patients in 3-tesla MRI preoperatively using conventional and physiological MR sequences (diffusion, perfusion, and spectroscopy) of common brain tumors who were prospectively confirmed by histopathology. Post-imaging analysis was done by available software and ratio was calculated. Data were expressed as mean  $\pm$  standard deviation and median (range) and Kolmogorov–Smirnov analysis was used to check distribution. Multiple statistical tests were applied and receiver operating characteristic (ROC) curve was plotted wherever feasible.

**Results:** We obtained a significant difference in spectroscopic parameters, relative cerebral blood volume, and apparent diffusion coefficient values between different tumor groups and also between different tumor grades. ROC curve plotted among groups showed sensitivity and specificity of diagnostic capability. Time-intensity curve showed a significant difference between different tumor groups and correlation with grades of tumor.

**Conclusion:** We propose an algorithm for differentiating different types and grades of common brain tumor using physiological MRI in addition to conventional MR sequences.

**Key words:** 3-tesla magnetic resonance imaging, Apparent diffusion coefficient, Magnetic resonance spectroscopy, Perfusion magnetic resonance imaging

## INTRODUCTION

Imaging plays a crucial role in the management of brain tumors. Magnetic resonance imaging (MRI) has the most

potential of any imaging technique to allow a complete and accurate diagnosis and initial management strategy to be formulated for a brain tumor. Although MRI has delivered remarkable advances in the information available from the vast array of pulse sequences and MRI techniques, the radiologist still relies most heavily on more fundamental criteria's, such as location in the neuraxis and the age of the patient, for specific pathologic diagnoses.

Apart from conventional sequences, physiological MRI such as diffusion-weighted (DW) imaging, perfusion MRI (pMRI), and proton MR spectroscopy, provides additional

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**Corresponding Author:** Dr. Deepak Jain, Department of Radiology, Pt. Jawahar Lal Nehru Memorial Medical College, Raipur - 492 001, Chhattisgarh, India.



**Table 1: General characteristics of study subjects**

Characteristics	Value (Mean $\pm$ SD) n (%)
Age (Years)	38.67 $\pm$ 17.79
Gender	
Male	33 (47.14)
Female	37 (52.86)
Volume (cc)	95.09 $\pm$ 127.57
2D MR NAA/Cr	0.70 $\pm$ 0.57
2D MR Cho/Cr	4.29 $\pm$ 3.18
SVS NAA/Cr	1.55 $\pm$ 1.80
SVS Cho/Cr	3.94 $\pm$ 3.45
SVS lac/Cr	2.76 $\pm$ 5.22
SVS Mi/Cr	1.65 $\pm$ 3.01
SVS Glu/Cr	0.82 $\pm$ 1.94
ADC value	1041.43 $\pm$ 257.51
rCBV	3.95 $\pm$ 2.59
% regain in signal intensity	
21–40	28 (39.91)
41–60	21 (30.00)
61–80	18 (25.71)
81–100	3 (4.29)
Tumor type	
Astrocytic tumors	30 (42.86)
Cranial nerve tumors	9 (12.86)
Meningothelial tumors	15 (21.43)
Metastasis	5 (7.14)
Oligodendroglial tumors	3 (4.29)
Others	8 (11.43)
Grade of tumor	
I	33 (47.14)
II	17 (24.29)
III	5 (7.14)
IV	10 (14.29)
Metastasis	5 (7.14)

information regarding grade, type of tumor, vascularity, and composition. This is a study to find out the utility of physiological MRI in brain tumors, in 3-tesla (3T) MRI with an emphasis on its capabilities to differentiate the type of tumor, grade of tumor, and to some extent prognosis of the tumor and its histopathological correlation.

## MATERIALS AND METHODS

We did our study at the Department of Radiology, Pt. Jawahar Lal Nehru Memorial Medical College, Raipur, Chhattisgarh, for a period extending from July 2014 to March 2018. Patients having primary brain neoplasm or metastasis who are later confirmed histopathologically are selected for the study. Informed consent was taken from all the patients who were enrolled for the study. Patients who are unwilling to take part in the study or who are histologically proven non-tumorous intra-cerebral lesion or patients who are already treated for brain tumors were excluded from the study. The data for the study were collected through a uniform pro forma. We used Magnetom Skyra MRI machine and accessories having 3-T field strength with 70 cm open bore design and 173 cm system length. Radiofrequency Tim

(204  $\times$  48) (204  $\times$  64) (204  $\times$  128) was used with gradient strength – XQ Gradients (45 mT/m at 200T/m/s) and zero Helium boil-off technology. The contrast was given through pressure injector.

DW images were obtained using an axial echo-planar spin echo (SE) sequence (4700/98 ms (repetition time [TR]/echo time [TE]), on average, 4-mm section thickness, 288  $\times$  360 matrix size, 220  $\times$  220-mm FOV) in 22 s. DW images and apparent diffusion coefficient (ADC) maps were acquired at b values 0, and 1000 s/mm<sup>2</sup>. No obvious post-processing was required. Solid appearing tumoral areas were sampled manually. Standard mean ADC values were calculated by the manual drawing of the region of interest (ROI) circle and expressed in 10<sup>-3</sup> mm<sup>2</sup>/s. Control ADC values were obtained from normal-appearing white matter from contralateral normal brain tissue.

The contrast was administered using 18–20 gauge intravenous catheter through pressure injector. We used a susceptibility T2\*-weighted multi-slice multi-shot fast field echo-echo-planar imaging (EPI) sequence with water selective excitation pre-pulse. The imaging parameters were as follows: 1650/30 ms TR/TE; 90° flip angle; 1 excitation; 221  $\times$  221 mm FOV; 4 mm section thickness; 128  $\times$  128 reconstruction matrix; 1.7  $\times$  1.7  $\times$  4.0 mm voxel size; 0% intersection gap; 1220 signal intensity bandwidth in EPI readout direction; and 128 EPI factor; keeping phase Fourier transformation off. 25 sections were obtained without intersection gap to cover the entire lesion volume identified on T2-weighted images. A series of 50 multi-section acquisitions were acquired at 1.84 s intervals, the total acquisition time is 1 min 32 s. The first six acquisitions are performed before the contrast agent injection to establish a pre-contrast baseline. At the seventh acquisition, 0.2 mmol/kg of body weight of gadodiamide (Omniscan; GE Healthcare Pvt. Ltd. IDA Business Park, Carrigtohill. Cork, Ireland) was injected with a power injector at a rate of 4 mL/s through an 18- or 20-gauge intravenous catheter, immediately followed by a bolus injection of saline at the same rate for a total of 20 ml. Axial contrast-enhanced T1-weighted images were obtained after the perfusion images, using the same parameters as for the pre-contrast images.

The DSC perfusion images were transferred to Syngo through (workstation-Siemens Medical Systems). Image analysis and measurements were performed with T2\* perfusion tool software. The raw data were processed off-line. A motion correction of 3 mm was applied to raw images before integration. During the first pass of the bolus of paramagnetic contrast material, the signal intensity in T2\*-weighted sequence decreased, whereas the signal intensity partially restored directly after the passage.

**Table 2: Comparison of various radiological parameters between subjects with a different type of tumor**

Radiological characteristics	Mean $\pm$ SD	Std. error	f/Chi-square	P Value
Volume				
Astrocytic tumors	124.26 $\pm$ 163.56	34.10	26.99 <sup>#</sup>	<0.0001
Cranial nerve tumors	52.91 $\pm$ 16.74	5.58		
Meningothelial tumors	45.43 $\pm$ 22.71	6.07		
Metastasis	13.52 $\pm$ 7.37	3.29		
Oligodendroglial tumors	363.88 <sup>a, b, c, d, f, g</sup> $\pm$ 14.58	8.42		
Others	95.86 $\pm$ 98.44	37.21		
2D MR NAA/Cr				
Astrocytic tumors	0.63 $\pm$ 0.28	0.05	4.107 <sup>*</sup>	0.003
Cranial nerve tumors	1.35 <sup>a</sup> $\pm$ 0.76	0.25		
Meningothelial tumors	0.63 <sup>b</sup> $\pm$ 0.29	0.07		
Metastasis	0.31 <sup>b</sup> $\pm$ 0.18	0.08		
Oligodendroglial tumors	0.25 <sup>b</sup> $\pm$ 0.06	0.03		
Others	0.75 $\pm$ 1.10	0.39		
2D MR Cho/Cr				
Astrocytic tumors	3.13 $\pm$ 1.53	0.28	3.144 <sup>*</sup>	0.013
Cranial nerve tumors	3.45 $\pm$ 0.62	0.21		
Meningothelial tumors	6.46 <sup>a</sup> $\pm$ 4.82	1.24		
Metastasis	3.93 $\pm$ 0.06	0.03		
Oligodendroglial tumors	6.69 $\pm$ 0.03	0.02		
Others	4.88 $\pm$ 4.85	1.72		
SVS NAA/Cr				
Astrocytic tumors	0.99 $\pm$ 0.82	0.20	9.244 <sup>#</sup>	0.10
Cranial nerve tumors	3.28 $\pm$ 3.70	1.31		
Meningothelial tumors	1.01 $\pm$ 0.83	0.23		
Metastasis	1.60 $\pm$ 0.05	0.02		
Oligodendroglial tumors	0.62			
Others	1.92 $\pm$ 1.36	0.48		
SVS Cho/Cr				
Astrocytic tumors	3.02 $\pm$ 3.22	0.81	16.54 <sup>#</sup>	0.005
Cranial nerve tumors	3.14 $\pm$ 1.64	0.58		
Meningothelial tumors	6.15 $\pm$ 3.00	0.83		
Metastasis	0.64 $\pm$ 1.43	0.64		
Oligodendroglial tumors	5.82			
SVS Iac/Cr				
Astrocytic tumors	2.88 $\pm$ 3.17	0.79	11.80 <sup>#</sup>	0.038
Cranial nerve tumors	0.00 $\pm$ 0.00	0.00		
Meningothelial tumors	1.88 $\pm$ 1.75	0.50		
Metastasis	1.98 $\pm$ 0.04	0.02		
Oligodendroglial tumors	0.62			
Others	7.05 $\pm$ 11.39	4.03		
SVS Mi/Cr				
Astrocytic tumors	0.63 $\pm$ 1.15	0.30	17.207 <sup>#</sup>	0.002
Cranial nerve tumors	5.47 $\pm$ 3.14	1.11		
Meningothelial tumors	1.28 $\pm$ 3.78	1.09		
Metastasis	0.00 $\pm$ 0.00	0.00		
Oligodendroglial tumors				
Others	1.31 $\pm$ 2.19	0.77		
SVS Glu/Cr				
Astrocytic tumors	0.03 $\pm$ 0.09	0.03	15.643 <sup>#</sup>	0.004
Cranial nerve tumors	3.83 $\pm$ 2.61	0.99		
Meningothelial tumors	0.81 $\pm$ 2.00	0.58		
Metastasis	0.00 $\pm$ 0.00	0.00		
Oligodendroglial tumors				
Others	0.03 $\pm$ 0.09	0.03		
ADC value				
Astrocytic tumors	1053.63 $\pm$ 285.39	52.11	2.309 <sup>*</sup>	0.054
Cranial nerve tumors	1064.78 $\pm$ 98.39	32.80		
Meningothelial tumors	1084.13 $\pm$ 178.56	46.10		
Metastasis	685.60 <sup>a, c, g</sup> $\pm$ 13.18	5.90		
Oligodendroglial tumors	1079.67 $\pm$ 150.34	86.80		
Others	1097.38 $\pm$ 367.34	129.87		

(Contd...)

**Table 2: (Continued)**

Radiological characteristics	Mean±SD	Std. error	f/Chi-square	P Value
rCBV				
Astrocytic tumors	3.82±2.05	0.38	2.521*	0.038
Cranial nerve tumors	2.91±0.41	0.14		
Meningothelial tumors	5.79±3.89	1.00		
Metastasis	2.58±0.08	0.04		
Oligodendroglial tumors	2.77±0.12	0.07		
Others	3.49±2.66	0.94		

\*f, #Chi-square, \*P<0.05 versus Astrocytic tumors, <sup>b</sup>P < 0.05 versus Cranial nerve tumors, <sup>c</sup>P < 0.05 versus Meningothelial tumors, <sup>d</sup>P < 0.05 versus Metastasis, <sup>e</sup>P < 0.05 versus Oligodendrogloma, <sup>f</sup>P < 0.05 versus others, rCBV: Relative cerebral blood volume, Adc: Apparent diffusion coefficient, ROI: Region of interest, EPI: Echo-planar imaging, TSIC: Time signal intensity curve, SVS: Single-voxel spectroscopy, 2D-MVS: 2D multivoxel spectroscopy, NAA: N-acetyl aspartate, Cho: Choline compounds, Cr: Creatine, : Alanine, Mimyo-inositol, Glu: Glutamine, lac: Lactate

**Table 3: Comparison of various radiological parameters between subjects with different grade of the tumor**

Radiological characteristics	Mean±SD	Std. error	f/Chi-square	P value
Volume				
I	77.60±70.74	12.71	14.49	0.006
II	119.29±128.04	32.01		
III	101.45±36.54	16.34		
IV	227.83±388.14	194.07		
Metastasis	13.52±7.37	3.29		
2D MR NAA/Cr				
I	0.87±0.73	0.13	2.062	0.096
II	0.64±0.35	0.09		
III	0.33±0.27	0.12		
IV	0.62±0.14	0.05		
Metastasis	0.31±0.18	0.08		
Total	0.70±0.57	0.07		
2D MR Cho/Cr				
I	4.79±4.31	0.75	0.816	0.519
II	4.46±2.00	0.49		
III	3.81±0.04	0.02		
IV	2.78±0.80	0.25		
Metastasis	3.93±0.06	0.03		
Total	4.29±3.18	0.38	11.84	0.019
SVS NAA/Cr				
I	1.95±2.31	0.44		
II	0.63±0.72	0.25		
III	0.66±0.29	0.17		
IV	1.45±0.90	0.32		
Metastasis	1.60±0.05	0.02		
SVS Cho/Cr				
I	5.34±3.79	0.73	14.11	0.007
II	3.43±2.82	1.00		
III	4.01±1.33	0.77		
IV	1.79±1.19	0.42		
Metastasis	0.64 <sup>a</sup> ±1.43	0.64		
SVS lac/Cr				
I	2.69±6.66	1.33	9.49	0.05
II	1.71±4.05	1.43		
III	2.12±3.14	1.81		
IV	4.80±3.03	1.07		
Metastasis	1.98±0.04	0.02		
SVS Mi/Cr				
I	2.77±3.68	0.72	14.29	0.006
II	0.03±0.07	0.03		
III	2.50±1.95	1.38		
IV	0.24±0.69	0.24		
Metastasis	0.00±0.00	0.00		

(Contd...)



**Table 3: (Continued)**

Radiological characteristics	Mean±SD	Std. error	f/Chi-square	P value
SVS Mi/Cr				
I	2.77±3.68	0.72	14.29	0.006
II	0.03±0.07	0.03		
III	2.50±1.95	1.38		
IV	0.24±0.69	0.24		
Metastasis	0.00±0.00	0.00		
SVS Glu/Cr				
I	1.52±2.47	0.50	7.665	0.105
II	0.04±0.10	0.04		
III	0.34			
IV	0.00±0.00	0.00		
Metastasis	0.00±0.00	0.00		
ADC value				
I	1201.33±214.14	37.28	13.245	<0.0001
II	1005.53 <sup>a</sup> ±234.32	56.83		
III	846.20 <sup>a</sup> ±76.33	34.14		
IV	850.30 <sup>a</sup> , <sup>b</sup> ±129.51	40.95		
Metastasis	685.60 <sup>a</sup> , <sup>b</sup> ±13.18	5.90		
rCBV				
I	4.65±3.21	0.56	1.685	0.164
II	3.32±2.04	0.49		
III	2.28±0.05	0.02		
IV	4.09±1.32	0.42		
Metastasis	2.58±0.08	0.04		

rCBV: Relative cerebral blood volume, Adc: Apparent diffusion coefficient, ROI: Region of interest, EPI: Echo-planar imaging, TSIC: Time signal intensity curve, SVS: Single-voxel spectroscopy, 2D-MVS: 2D multivoxel spectroscopy, NAA: N-acetyl aspartate, Cho: Choline compounds, Cr: Creatine, Ala: Alanine, Mimyo-inositol, Glu: Glutamine, lac: Lactate

**Table 4: Comparison of various radiological parameters between astrocytic tumors and non-astrocytic tumors**

Radiological characteristics	Tumor	Mean±SD	Std. error mean	t/Mann–Whitney U-test	P value
Volume	Astrocytic tumors	124.26±163.56	34.10	236.0 <sup>b</sup>	0.003
	Other tumors	77.44±98.15	15.92		
2D MR NAA/Cr	Astrocytic tumors	0.63±0.28	0.05	-0.851 <sup>a</sup>	0.398
	Other tumors	0.75±0.71	0.11		
2D MR Cho/Cr	Astrocytic tumors	3.13±1.53	0.28	-1.530 <sup>a</sup>	0.007
	Other tumors	5.17±3.79	0.60		
SVS NAA/Cr	Astrocytic tumors	0.99±0.82	0.20	222.0 <sup>b</sup>	0.239
	Other tumors	1.81±2.06	0.35		
SVS Cho/Cr	Astrocytic tumors	3.02±3.22	0.81	207.0 <sup>b</sup>	0.138
	Other tumors	4.36±3.52	0.59		
SVS lac/Cr	Astrocytic tumors	2.88±3.17	0.79	210.5 <sup>b</sup>	0.246
	Other tumors	2.71±6.02	1.05		
SVS Mi/Cr	Astrocytic tumors	0.63±1.15	0.30	207.5 <sup>b</sup>	0.314
	Other tumors	2.11±3.47	0.60		
SVS Glu/Cr	Astrocytic tumors	0.03±0.09	0.03	169.0 <sup>b</sup>	0.162
	Other tumors	1.15±2.22	0.39		
ADC value	Astrocytic tumors	1053.60±285.39	52.11	0.341 <sup>a</sup>	0.734
	Other tumors	1032.30±237.81	37.60		
rCBV	Astrocytic tumors	3.82±2.05	0.38	-0.370 <sup>a</sup>	0.713
	Other tumors	4.05±2.94	0.47		

<sup>a</sup>: t-value, <sup>b</sup>: Mann–Whitney U-test, rCBV: Relative cerebral blood volume, Adc: Apparent diffusion coefficient, ROI: Region of interest, EPI: Echo-planar imaging, TSIC: Time signal intensity curve, SVS: Single-voxel spectroscopy, 2D-MVS: 2D multivoxel spectroscopy, NAA: N-acetyl aspartate, Cho: Choline compounds, Cr: Creatine, Ala: Alanine, Mimyo-inositol, Glu: Glutamine, lac: Lactate

**Table 5: Association of percentage regain in signal intensity with different characteristics of the tumor**

Characteristics	Chi-square	P value
Astrocytic tumors and other tumors	9.063	0.06
Different classes of tumors	38.22	0.008
Grade of tumors	46.95	<0.0001

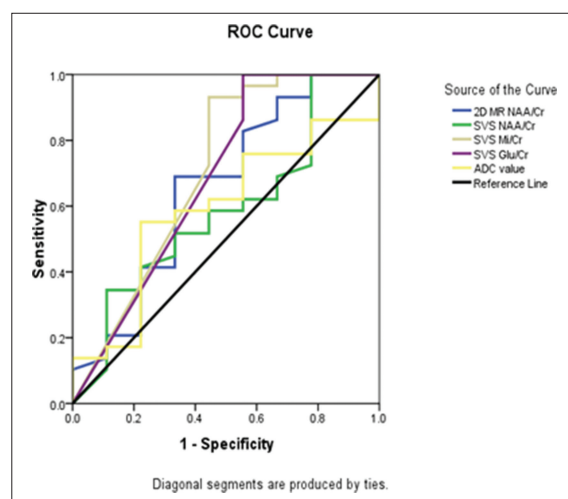
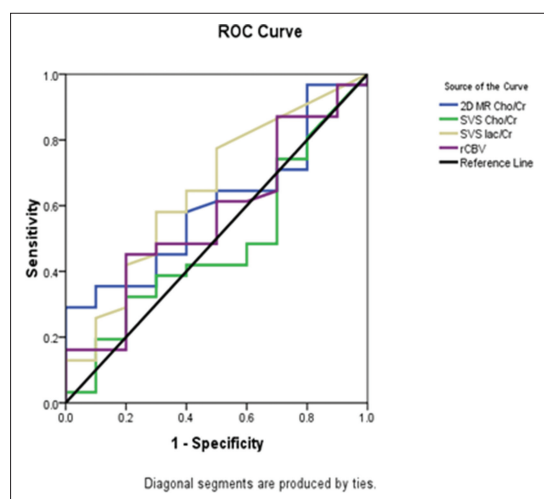
The relative measure of contrast agent concentration can be calculated from the time signal intensity curve (TSIC).

Single-voxel spectroscopy (SVS) data were obtained using a double SE point-resolved spectroscopy (PRESS) sequence with one-pulse water signal suppression mainly from contrast-

**Table 6: ROC curve analysis of primary brain tumors to assess the diagnostic significance of various parameters in identifying intraaxial tumors from extraaxial tumors**

AUC								
Test result variable (s)	Area	Std. error <sup>a</sup>	Asymptotic sig. <sup>b</sup>	Asymptotic 95% confidence interval		Cutoff	Sensitivity	Specificity
				Lower Bound	Upper Bound			
2D MR Cho/Cr <sup>a</sup>	0.598	0.095	0.354	0.411	0.786	5.95	29	100
SVS Cho/Cr <sup>a</sup>	0.481	0.105	0.855	0.276	0.685	5.28	32.3	80
SVS lac/Cr <sup>a</sup>	0.650	0.101	0.158	0.452	0.848	0.97	58.1	70
rCBV <sup>a</sup>	0.569	0.102	0.514	0.369	0.770	3.46	45.2	80
2D MR NAA/Cr <sup>b</sup>	0.655	0.115	0.164	0.431	0.880	068	69	66.7
SVS NAA/Cr <sup>b</sup>	0.584	0.111	0.450	0.367	0.801	0.77	34.5	88.9
SVS Mi/Cr <sup>b</sup>	0.705	0.118	0.066	0.474	0.936	2	93.1	55.6
SVS Glu/Cr <sup>b</sup>	0.684	0.119	0.099	0.452	0.916	5.32	100	44.4
ADC value <sup>b</sup>	0.590	0.105	0.420	0.383	0.797	1003	55.2	77.8

<sup>a</sup>: Positive if more than, <sup>b</sup>: Positive if less than, rCBV: Relative cerebral blood volume, Adc: Apparent diffusion coefficient, ROI: Region of interest, EPI: Echo-planar imaging, TSIC: Time signal intensity curve, SVS: Single-voxel spectroscopy, 2D-MVS: 2D multivoxel spectroscopy, NAA: N-acetyl aspartate, Cho: Choline compounds, Cr: Creatine, Ala: Alanine, Mimyo-inositol, Glu: Glutamine, lac: Lactate, ROC: Receiver operating characteristic, AUC: Area under the curve



enhanced areas of the lesions, while avoiding contamination. Spectroscopic data from cubic volumes of  $2 \times 2 \times 2 \text{ cm}^3$  were obtained using the PRESS sequence with 2000/30 ms (TR/TE), 80 averages, 1024 data points, and 1200 Hz spectrum width. The acquisition time was approximately 2 min 50 s. 2D multivoxel spectroscopy (2D-MVS) data were obtained using a chemical shift imaging with a water suppression pulse sequence mainly from metabolically active fleshy parts of the lesions, while avoiding contamination from scalp fat. Spectroscopic data from cubic volumes of  $8 \times 8 \times 1.5 \text{ cm}^3$  were obtained by using the PRESS sequence (csi\_slaser: Siemens) containing 64 voxels and each voxel measuring  $1 \times 1 \times 1.5 \text{ cm}^3$  with 1700/135 ms (TR/TE), 3 averages, 1024 data points, and 1200 Hz spectrum width. The acquisition time was approximately 6 min 53 s. Appropriate automatic shimming and water suppression were achieved using 50 Hz bandwidth, no spectral width, and the automated software developed by the manufacturer for SVS and 2D-MVS both. The time domain signal intensity was optimized and processed to remove the residual water signal. Post-processing of the spectroscopic data consisted of frequency shift and phase and

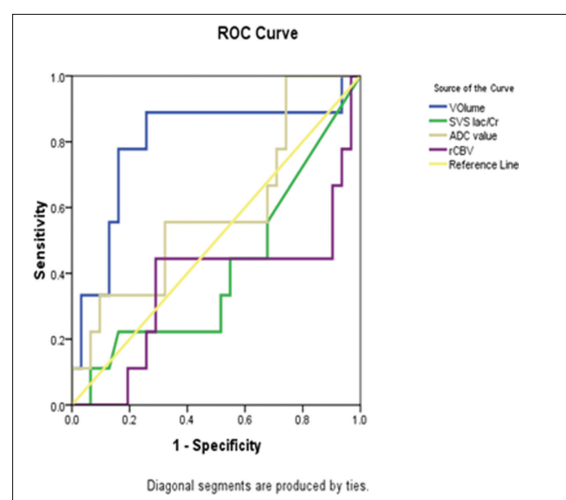
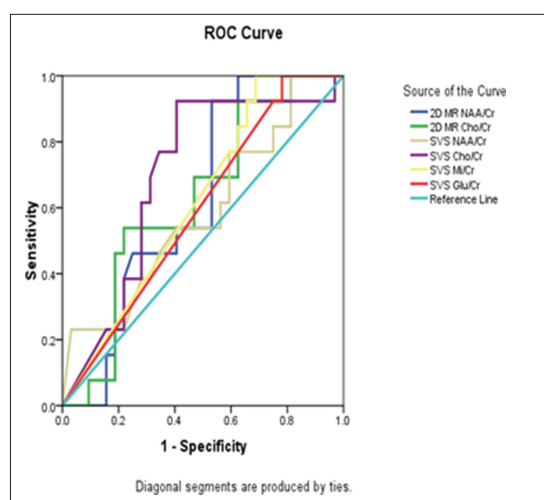
linear baseline corrections after Fourier transformation. These processes were automatic mostly, but manual processing was done whenever needed. Frequency domain curve was fitted to Gaussian line shape using the software provided by the manufacturer to analyze different metabolic peaks. Metabolic peaks used in the differentiation of the different tumor types were as follows: N-acetyl aspartate (NAA) at 2–2.1 parts per million (ppm), Choline (Cho) at 3.2–3.3 ppm, Creatine (Cr) at 3–3.1 ppm, and lipid-containing compounds in the range of 0.9–1.3 ppm. Other metabolic peaks, if any, were also calculated as alanine (Ala) at 1.4–1.6 ppm, myo-inositol (Mi) at 3.6–3.8 ppm, glutamine (Glu) at 2.1–2.3 ppm, and lactate (lac) at 1.3 ppm. Metabolite values were calculated automatically from the area under each metabolite peak using the standard commercial software program provided by the manufacturer. Peak integral values were normalized to the internal Cr peak. Metabolite ratios of NAA/Cho, NAA/Cr, Cho/Cr, and if possible, Mi/Cr, Ala/Cr, lac/Cr, and Glu/Cr were calculated.

We evaluated relative cerebral blood volume (rCBV) and TSIC of pMRI and drew all ROI with consensus

**Table 7: Diagnostic potential and diagnostic cutoff of various radiological parameters to diagnose meningo epithelial tumors from astrocytoma**

Test result variable (s)	AUC	Std. error <sup>a</sup>	P value	95% CI		Cutoff	Sensitivity	Specificity
				Low	High			
Volume <sup>b</sup>	0.448	0.089	0.617	0.273	0.624	17.86	100	24.1
2D MR NAA/Cr <sup>b</sup>	0.649	0.100	0.150	0.454	0.844	0.61	81.8	62.1
2D MR Cho/Cr <sup>b</sup>	0.746	0.103	0.017	0.545	0.947	4.69	81.8	79.3
SVS Cho/Cr <sup>b</sup>	0.793	0.073	0.005	0.650	0.936	4.675	90.9	72.4
SVS lac/Cr <sup>b</sup>	0.636	0.089	0.188	0.462	0.811	0.37	90.9	51.7
ADC value <sup>b</sup>	0.607	0.090	0.303	0.430	0.783	845	100	34.5
rCBV <sup>b</sup>	0.671	0.114	0.099	0.447	0.895	5.98	54.5	93.1
SVS NAA/Cr <sup>a</sup>	0.691	0.084	0.053	0.526	0.856	1.11	91.7	60.6
SVS Mi/Cr <sup>a</sup>	0.576	0.095	0.441	0.389	0.762	1.54	91.7	30.3
SVS Glu/Cr <sup>a</sup>	0.518	0.098	0.857	0.325	0.710	4.29	91.7	15.2

<sup>a</sup>: positive if lesser than or equal to, <sup>b</sup>: Positive if greater than or equal to, AUC: Area under the Curve, CBV: Relative cerebral blood volume, Adc: Apparent diffusion coefficient, ROI: Region of interest, EPI: Echo-planar imaging, TSIC: Time signal intensity curve, SVS: Single-voxel spectroscopy, 2D-MVS: 2D multivoxel spectroscopy, NAA: N-acetyl aspartate, Cho: Choline compounds, Cr: Creatine, Ala: Alanine, Mimyo-inositol, Glu: Glutamine, lac: Lactate, ROC: Receiver operating characteristic



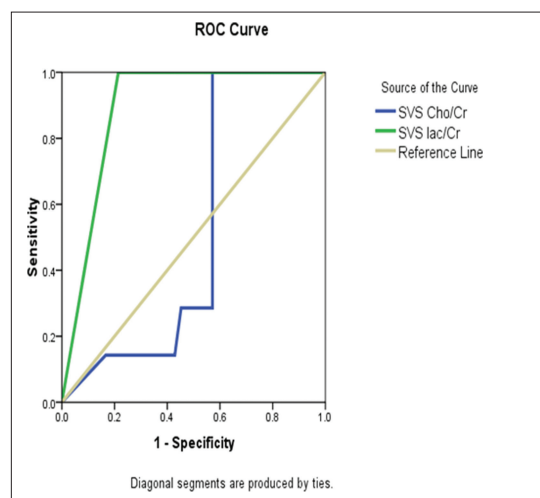
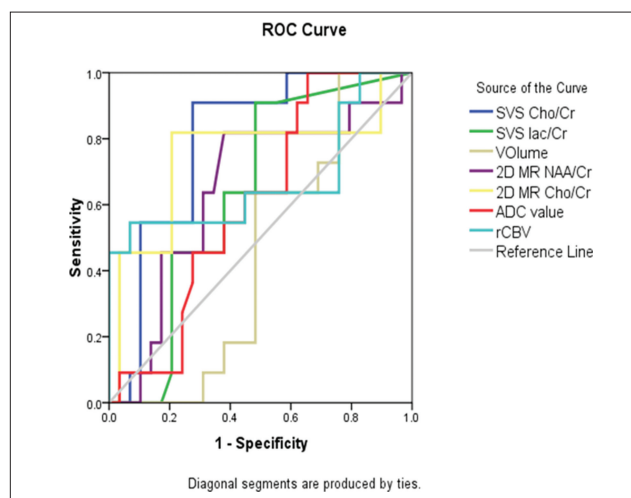
from different areas of tumoral, and normal-appearing mirrored areas showing the greatest visually identifiable CBV values on color maps. The regions were defined as<sup>[1]</sup> normal tissue-an area containing no enhancement, normal signal intensity on T2/fluid attenuated inversion recovery (FLAIR) images;<sup>[2]</sup> tumoral area-a region containing clearly well-defined solid portion, preferably uniform contrast enhancement, and high signal intensity on T2/FLAIR images; and to provide the highest reproducibility in CBV measurements, macroscopic cystic/necrotic areas, cerebrospinal fluid-filled sulci or cisterns, and major vessels were avoided. The area of regions of interest was kept nearly constant to minimize confounding factors in the rCBV analysis. The highest CBV value out of five regions of interest was recorded for each area. It was necessary to express the measurement relative to a standard reference, which was called rCBV. The values obtained from tumoral and normal areas were recorded for statistical analysis. We did correlation with histopathology results to compare, benign versus malignant, low grade versus high grade, and different tumor types.

Data were expressed as mean  $\pm$  standard deviation (SD) and median (range) and Kolmogorov-Smirnov analysis were used to check distribution. Fischer exact test or Chi-square test was used to check the significance of the difference between the frequency distribution of data in different groups. Kruskal-Wallis test followed by *post hoc* Bonferroni's tests was used to study the significance of the difference between more than two groups in case of nonparametric data. ANOVA followed by *post hoc* Tukey's honestly significant difference test was used to study the significance of the difference between more than two groups in case of parametric data.  $P < 0.05$  was considered to be statistically significant. Sample size exceeded the required sample size calculated for the power of the study 0.8,  $\alpha$  error to be 0.05, and the population means as seen in the previous study. SPSS<sup>®</sup>14 (IBM Corp. NY, USA) and MS Excel<sup>®</sup> (Microsoft Corp. New Mexico, USA) were used for statistical calculations. Receiver operating characteristic curve was plotted to check for diagnostic significance.

**Table 8: Diagnostic potential and diagnostic cutoff of various radiological parameters to diagnose astrocytoma from non-astrocytic intraaxial tumors**

Test result variable (s)	AUC	Std. error <sup>a</sup>	P value	Asymptotic 95% CI		Cutoff	Sensitivity	Specificity
				Low	High			
2D MR NAA/Cr <sup>a</sup>	0.626	0.083	0.189	0.464	0.788	0.73	92.3	40.6
2D MR Cho/Cr <sup>a</sup>	0.625	0.087	0.193	0.454	0.796	2.95	53.8	78.1
SVS NAA/Cr <sup>a</sup>	0.587	0.095	0.367	0.401	0.772	0.045	23.1	96.9
SVS Cho/Cr <sup>a</sup>	0.697	0.085	0.040	0.531	0.864	3.78	92.3	59.4
SVS Mi/Cr <sup>a</sup>	0.620	0.085	0.211	0.454	0.787	1.96	100	31.2
SVS Glu/Cr <sup>a</sup>	0.594	0.088	0.329	0.421	0.766	1.81	100	21.9
Volume <sup>b</sup>	0.796	0.099	0.008	0.602	0.989	47.82	88.9	74.2
SVS Iac/Cr <sup>b</sup>	0.410	0.111	0.418	0.192	0.628	3.955	22.2	83.9
ADC value <sup>b</sup>	0.591	0.112	0.409	0.372	0.810	745.5	100	25.8
rCBV <sup>b</sup>	0.366	0.121	0.225	0.128	0.604	3.32	44.4	71.0

<sup>a</sup>: Positive if lesser than or equal to, <sup>b</sup>: Positive if greater than or equal to, rCBV: Relative cerebral blood volume, Adc: Apparent diffusion coefficient, ROI: Region of interest, EPI: Echo-planar imaging, TSIC: Time signal intensity curve, SVS: Single-voxel spectroscopy, 2D-MVS: 2D multivoxel spectroscopy, NAA: N-acetyl aspartate, Cho: Choline compounds, Cr: Creatine, Ala: Alanine, Mimyo-inositol, Glu: Glutamine, Iac: Lactate, ROC: Receiver operating characteristic, AUC: Area under the curve



## OBSERVATIONS AND RESULTS

In this study, we assessed 70 patients having primary or metastatic brain tumors. We classified tumors into two major groups, primary and metastatic brain tumors out of which primary is again classified into two groups, i.e., intraaxial and extraaxial tumors. Intraaxial tumors were again differentiated into three groups as astrocytoma oligodendroglioma and other intraaxial tumors. Central neurocytoma, choroid plexus tumors, and hemangioblastoma were included in other intraaxial tumors. The extraaxial tumors were further divided into meningeothelial and non-meningeothelial tumors.

The study included 33 male and 37 female subjects. The mean age is 38.67 years (SD. 17.79). Out of 70, there were 30 astrocytic tumors, three oligodendroglioma, nine cranial nerve tumors, 15 meningeothelial tumors, and five metastatic tumors which were assessed in terms of ADC value, spectroscopic ratios in relation to Cr, rCBV, and TSIC as shown in Table 1.

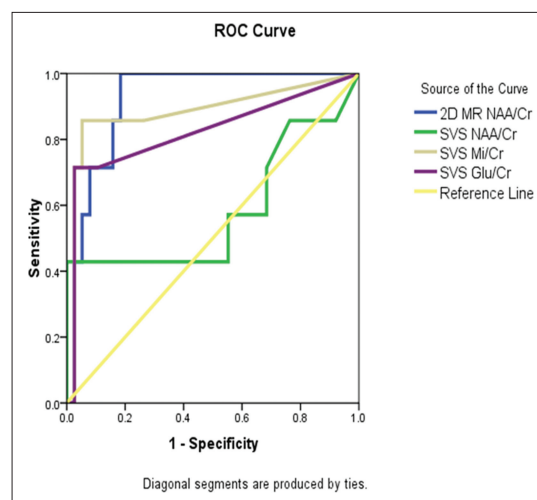
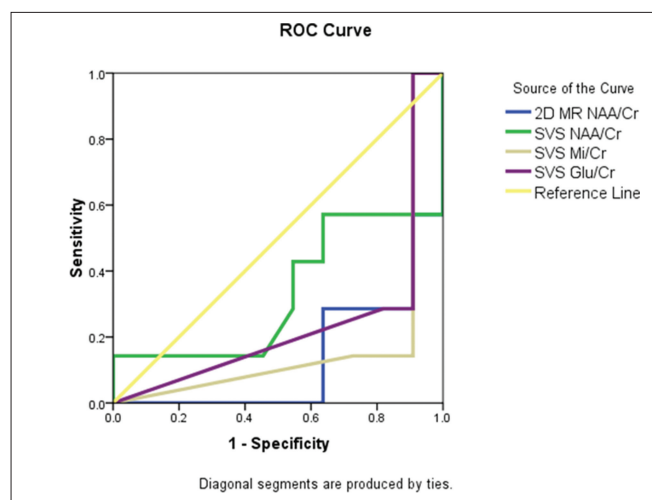
When different parameters were compared between types of tumors, significant difference was noted between tumors regarding Volume, 2D MR NAA/Cr, 2D MR Cho/Cr, SVS Cho/Cr, SVS Iac/Cr, SVS Mi/Cr, SVS Glu/Cr, ADC value, and rCBV [Figure 1]. On further *post hoc* analysis, volume was found to be significantly higher in oligodendroglioma tumors compared to all other tumors [Table 2]. 2D MR NAA/Cr was found to be significantly lower in astrocytic tumors, meningeothelial tumors, metastasis, and oligodendroglioma tumors compared to cranial nerve tumors. 2D MR Cho/Cr was found to be significantly lower in Astrocytic tumors compared to meningeothelial tumors. ADC value was found to be significantly lower in metastasis compared to astrocytic tumors and meningeothelial tumors.

Comparison of various radiological parameters between subjects with different grades of the tumor showed a significant difference was noted in volume, SVS NAA/Cr, SVS Cho/Cr, SVS Mi/Cr, and ADC value [Table 3]. On *post hoc* analysis, SVS Cho/Cr was found to be significantly less in

**Table 9: Diagnostic potential and diagnostic cutoff of various radiological parameters to differentiate schwannoma from meningo epithelial tumors**

Test result variable (s)	Area	Std. error <sup>a</sup>	Asymptotic sig. <sup>b</sup>	Asymptotic 95% confidence interval		Cutoff	Sensitivity	Specificity
				Lower bound	Upper bound			
Volume <sup>a</sup>	0.557	0.150	0.696	0.263	0.851	40.40	71.4	70
2D MR NAA/Cr <sup>b</sup>	0.143	0.092	0.015	-0.038	0.324	0.73	100	63.3
2D MR Cho/Cr <sup>a</sup>	0.800	0.126	0.040	0.552	1.048	4.49	100	80
SVS NAA/Cr <sup>b</sup>	0.307	0.144	0.188	0.025	0.590	5.65	42.9	100
SVS Cho/Cr <sup>a</sup>	0.914	0.083	0.005	0.751	1.078	4.69	100	90
SVS lac/Cr <sup>a</sup>	0.950	0.059	0.002	0.835	1.065	0.255	100	90
SVS Mi/Cr <sup>b</sup>	0.171	0.117	0.025	-0.057	0.400	2.17	85.7	90.9
SVS Glu/Cr <sup>b</sup>	0.243	0.131	0.079	-0.014	0.500	4.29	71.4	90.9
ADC value <sup>a</sup>	0.643	0.143	0.329	0.362	0.923	1022	85.7	60
rCBV <sup>a</sup>	0.629	0.148	0.380	0.339	0.918	5.255	100	60

The test result variable (s): SVS NAA/Cr, SVS lac/Cr, SVS Mi/Cr, and SVS Glu/Cr have at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased. <sup>a</sup>: Under the nonparametric assumption, <sup>b</sup>: Null hypothesis: True area = 0.5, AUC: Area under the Curve, CBV: Relative cerebral blood volume, Adc: Apparent diffusion coefficient, ROI: Region of interest, EPI: Echo-planar imaging, TSIC: Time signal intensity curve, SVS: Single-voxel spectroscopy, 2D-MVS: 2D multivoxel spectroscopy, NAA: N-acetyl aspartate, Cho: Choline compounds, Cr: Creatine, Ala: Alanine, Mito: inositol, Glu: Glutamine, lac: Lactate, ROC: Receiver operating characteristic



metastasis lesions compared to Grade I tumor. ADC value was found to be significantly less in Grade II, Grade III, Grade IV, and metastasis tumors compared to Grade I also Grade IV and metastasis was found to be having significantly lower ADC value compared to Grade II tumor.

Comparison of various radiological parameters between astrocytic tumors and non-astrocytic tumors is shown in Table 4. Volume was found to be significantly larger ( $P = 0.003$ ) and 2D MR Cho/Cr was found to be significantly lower ( $P = 0.007$ ) in case of Astrocytic tumors. Significant associating was detected between different classes and grades of tumors in relation to TSIC [Table 5].

## DISCUSSION

Our study demonstrated that with the variable combination of mean ADC value, rCBV and MR spectroscopy can

significantly differentiate types and grades of brain tumors. Starting with a primary and metastatic tumor, our study shows a significant difference in ADC values between the two groups ( $P < 0.05$ ) [Table 2]. Primary brain tumors have higher ADC value as compared to metastasis,<sup>[1]</sup> but cannot differentiate high-grade gliomas from lymphoma or lymphoma from metastasis.<sup>[2]</sup>

A significant difference ( $P < 0.05$ ) [Table 2] was also noted in NAA/Cr and Cho/Cr ratios, which were significantly lower in metastasis than primary brain tumors. Cho/Cr ratio in the tumoral area was significantly lower in low-grade tumors than in high-grade tumors and metastasis; no significant difference was seen between primary high-grade tumors and metastasis.<sup>[3,4]</sup>

Extraaxial tumors are characterized by a near complete absence of neuronal marker NAA<sup>[5]</sup> [Table 6]. There is a significant difference with short TE as well as long TE while



comparing Cr, Gly, Mi, choline, and lipid between metastasis and gliomas.<sup>[6]</sup> At short TE, intratumoral Cr suggestive of glioma while its absence favors metastasis.<sup>[7]</sup> A significant difference was present in the spectroscopic value of NAA/Cr, Cho/Cr, and Cho/NAA ratios between low-grade gliomas, high-grade gliomas, and metastasis in tumoral and peri-tumoral region.<sup>[8]</sup> Moreover, the peri-tumoral soft tissue shows altered spectroscopic patterns in case of glioma as compared to metastasis as these lesions have peri-tumoral infiltration, which is not seen in metastasis.<sup>[9]</sup> We found a significant difference ( $P < 0.05$ ) in Mi/Cr and Glu/Cr ratios on SVS between extraaxial and intraaxial brain tumors, where those ratios were significantly low in subjects with intraaxial brain tumors compared to extraaxial tumors [Table 6]. A significant difference in the form of higher Mi/Cr ratio in extraaxial lesions such as hemangiopericytoma and meningioma compared to intraaxial tumors.<sup>[10]</sup> Very low Mi and Cr were noted in meningioma as compared to astrocytic tumors.<sup>[11]</sup> Significant differences were noted in terms of Ala, glycine, Gly, Mi, and Cr.<sup>[6]</sup>

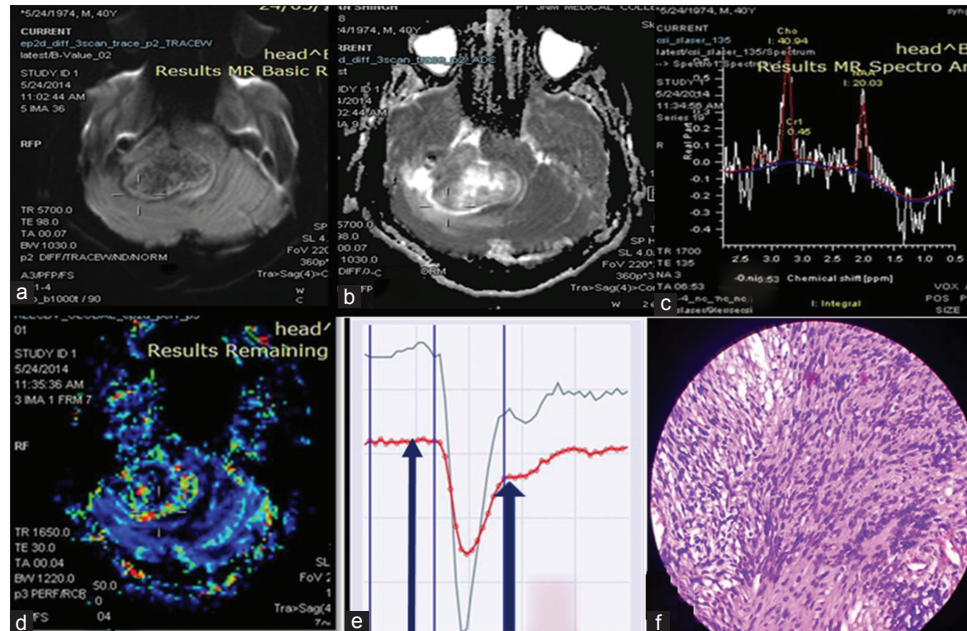
A separate analysis of radiological parameters of astrocytoma and meningioma was done which showed significantly reduced 2D MR Cho/Cr in astrocytic tumors compared to meningotheial tumors. Strongest predictors were found to be SVS Cho/Cr and 2DMR

Cho/Cr. Cho/Cr value  $\leq 3.78$  suggest astrocytoma at a sensitivity and specificity of 92.3% and 59.4%, respectively [Table 7]. A lower Cr and inositol in meningiomas than in astrocytomas were observed and also found that malignant astrocytomas are more regionally heterogeneous than meningiomas or benign astrocytomas.<sup>[12]</sup>

Overall comparison of rCBV among all categories of tumors showed a significant difference ( $P = 0.038$ ) [Table 1] but comparing rCBV between any two groups including a comparison of astrocytoma with non-astrocytic intraaxial tumors showed no significant difference and needs to be assessed with larger sample size. One study showed a significant difference in rCBV between astrocytoma and oligodendroglioma with cutoff value of 3.0 at a sensitivity and specificity of 100% and 87.5%, respectively.<sup>[13]</sup>

The NAA/Cr ratios were found to be significantly higher ( $P < 0.05$ ) [Tables 4 and 8] in non-astrocytic intraaxial tumors in comparison to astrocytoma. Shah *et al.* found very high levels of choline surpassing gliomas in central neurocytomas along with the presence of glycine and Ala with the absence of lipids.<sup>[14]</sup>

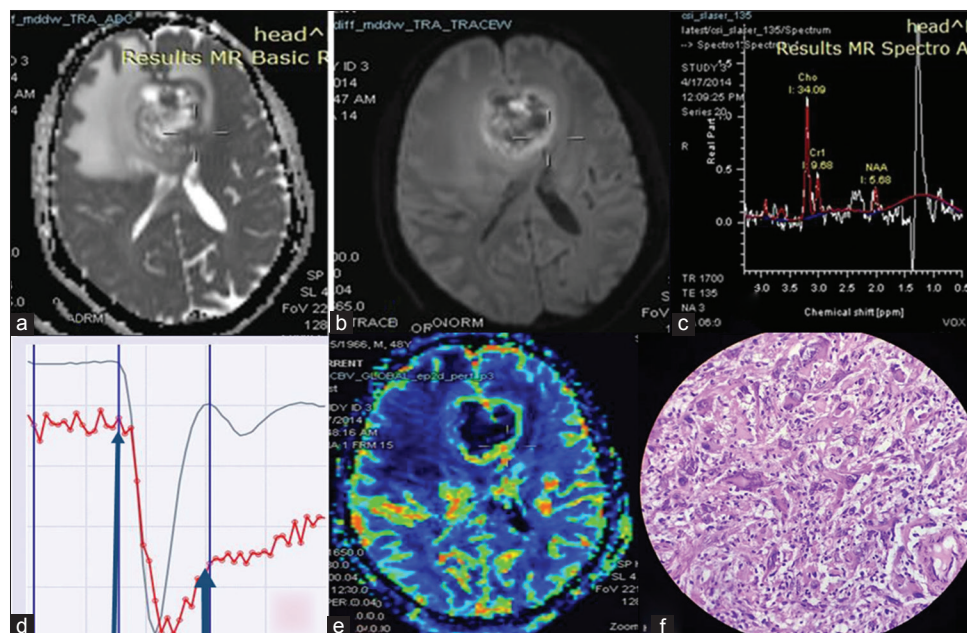
ADC values were  $P < 0.05$  [Table 3], significantly lower in Grade III astrocytoma as compared to Grades I and II. Similar



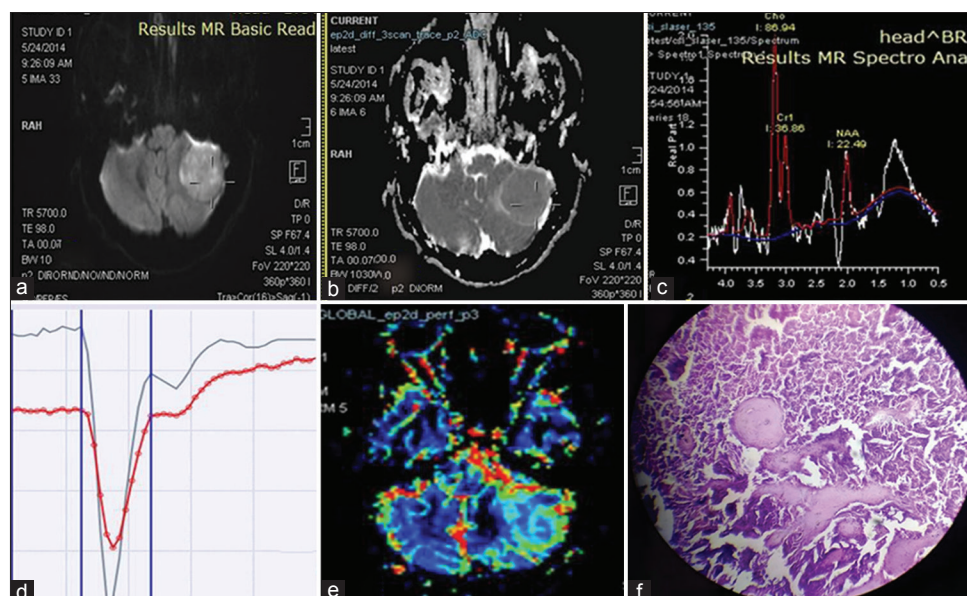
**Figure 1:** A 40-year-old male patient presented with progressive hearing loss. Figure 1 shows pre-operative magnetic resonance imaging (MR) of the patient. (a) Diffusion weighted image at b value 1000 show focal areas of diffusion restriction with corresponding low apparent diffusion coefficient (b). (c) 2D proton MR spectroscopy shows markedly increase choline with a decrease in N-acetyl aspartate. (d) Relative change in relative cerebral blood volume (rCBV) of tumor tissue as compared to the normal appearing parenchyma in the form of color code maps (rCBV = 2.1). (e) Time signal intensity mean curve in which red line shows approximately 80% regain in signal intensity of tumoral tissue. Histopathology shows predominantly hypercellular area (Antoni A area). Cells are narrow, elongated, and wavy with tapered ends interspersed with collagen fibers. (f). Nuclear palisading around the fibrillary process (Verocay bodies) is seen (hematoxylin-eosin,  $\times 400$ ) suggestive of Schwannoma

findings were observed in one study which also concluded that minimum ADC and ADC difference helps in accurate

diagnosis of grades of astrocytoma.<sup>[15]</sup> We also found ADC values were found to be significantly lower in Grade IV



**Figure 2:** A 48-year-old male patient presented with progressively increasing headache. Pre-operative magnetic resonance (MR) imaging of the patient shows the peripheral area of diffusion restriction (a) at b value 1000 with corresponding low apparent diffusion coefficient (b) and also differentiating it from perilesional edema. (c) 2D proton MR spectroscopy shows significantly increase Choline/Creatine ratio with markedly decrease N-acetyl aspartate and a large lipid peak at 1.3 ppm. (d) Perfusion time signal intensity curve showing 20–40% regain in the signal intensity (red line). (e) Tumor has higher relative cerebral blood volume than normal appearing parenchyma. (f) Histopathological section from excision biopsy shows malignant glial tumor having pleomorphic and bizarre tumor cell along with multinucleated tumor giant cells (hematoxylin-eosin,  $\times 400$ ) suggestive of gliosarcoma



**Figure 3:** A 45-year-old female having a history of Bidi (a kind of tobacco) smoking since 20 years presented with complaints of chronic headache and single episode of loss of consciousness. Cerebellar signs were present on clinical examination. Figure 3 shows pre-operative magnetic resonance (MR) imaging showing no obvious diffusion restriction (a) with normal apparent diffusion coefficient (b). (c) 2D proton MR spectroscopy showed Choline/Creatine ratio of 2.4 and N-acetyl aspartate/Creatine  $\sim 0.6$ . Time signal intensity curve (d) normal regain of signal intensity on first pass. (e) Mildly increased relative cerebral blood volume as compared to normal parenchyma. Histopathological examination shows meningeal tumor composed of spindle cell with indistinct cell boundaries arranged in a sheet such as architecture and whorling pattern. (f) (hematoxylin-eosin,  $\times 400$ ) suggestive of fibroblastic meningioma

tumors than Grades I and II tumors ( $P < 0.01$ ) [Table 2]. A significant negative correlation existed between ADC and astrocytic tumors of the World Health Organization grades 2–4 (Grade 2 vs. Grades 3 and 4, accuracy of 91.3% [ $P < 0.01$ ]; Grade 3 vs. 4, accuracy of 82.4% [ $P < 0.01$ ]) similar to other studies<sup>[16-18]</sup> The mean ADC value of normal brain was found to be  $0.85 \times 10^{-3} \text{ mm}^2/\text{s}$  with a significant difference from glial tumors.<sup>[19]</sup> Hu *et al.* reached a cutoff value of  $0.7 \times 10^{-3} \text{ mm}^2/\text{s}$  for differentiating high grade from low-grade gliomas at

sensitivity and specificity of 100% and 82.5%, respectively.<sup>[20]</sup> A cutoff value of  $1.47 \times 10^{-3} \text{ mm}^2/\text{s}$  for differentiating Grade I from higher grades.<sup>[15]</sup>

The Choline/Cr was significantly high ( $P < 0.05$ ) in Grade IV tumors compared to Grades I and II tumors [Table 2]. The NAA/Cr ratio was significantly higher ( $P < 0.05$ ) in Grade II tumors compared to Grade III tumors. One of the studies found that anaplastic astrocytomas (the WHO Grade III) are found to have higher choline levels compared to low-

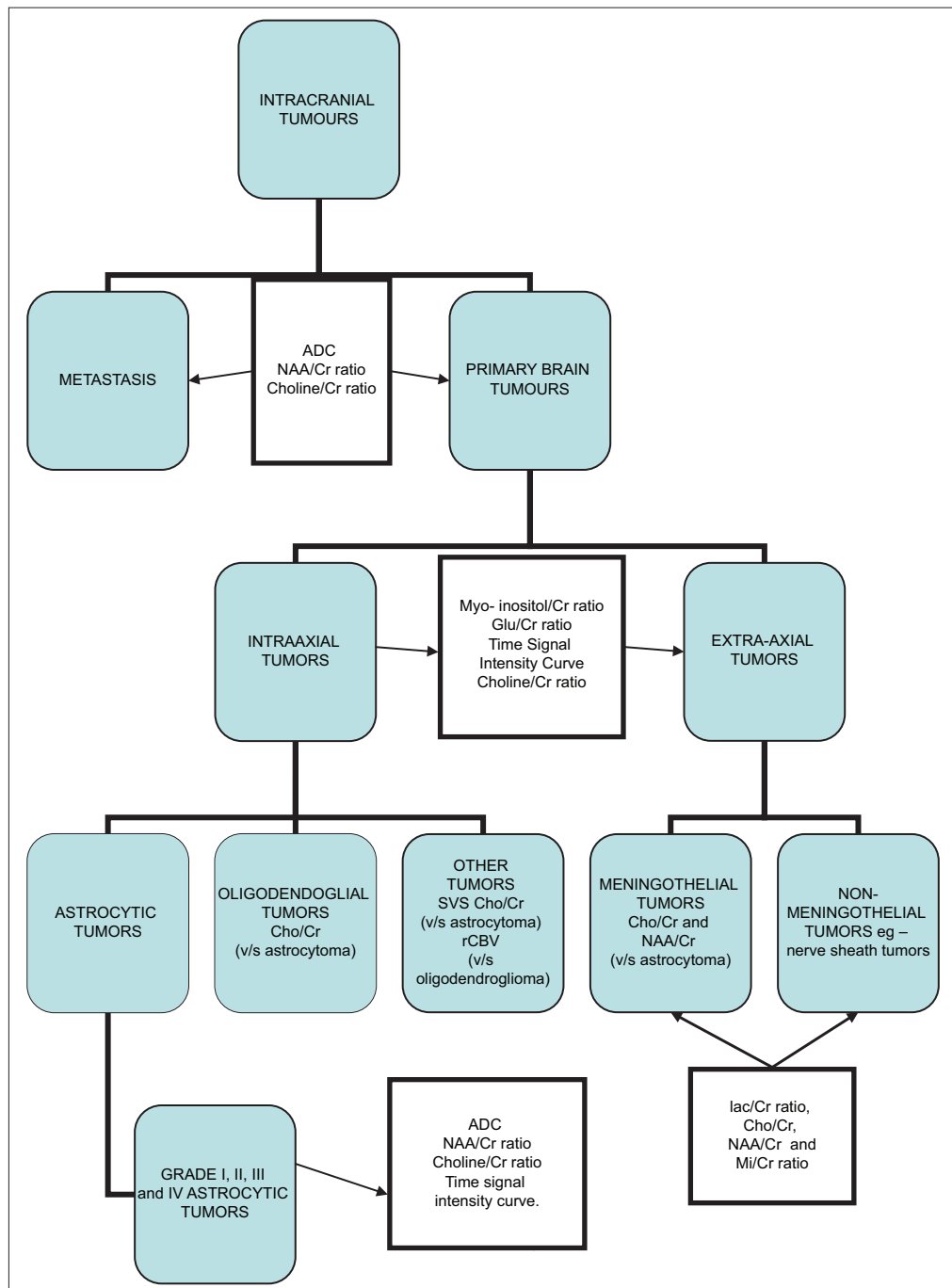


Figure 4: Here, we present an algorithm for approaching brain tumors and systematically approaching to differential diagnosis and obtaining grade of a particular tumor through these physiological magnetic resonance imaging



grade gliomas. A ratio of NAA/Cr has been suggested to accurately discriminate between low and high grade (Grade III) astrocytomas with ratio<1.6 predicting high-grade gliomas.<sup>[21]</sup> Cho/Cr ratio was also significantly higher in high-grade gliomas.<sup>[22]</sup>

Mean rCBV ratios were  $4.90 \pm 1.01$  for glioblastomas, [Figure 2]  $3.97 \pm 0.56$  for anaplastic gliomas and  $1.75 \pm 1.51$  for low-grade gliomas, and were thus significantly different.<sup>[23]</sup> In general, high-grade gliomas have higher rCBV ratios than their counterpart.<sup>[24,9]</sup> Our study was inconclusive between individual groups, and further evaluation is needed. Evaluation base on signal intensity ratios showed that all tumor spectra differed from spectra of healthy brain tissue similar to other studies.<sup>[3,25]</sup> TSIC in dynamic susceptibility contrast appears to be a parameter that helps in differentiating intracerebral malignant lesions such as GBM, metastases, and lymphoma.<sup>[26]</sup> Microvessels within tumors of extra-axial and non-glial origin do not form a blood-brain barrier (BBB) but glioma microvessels form a BBB that is impaired but not absent, the TIC returns toward the baseline in these tumors, but not as much as in the normal brain.<sup>[27]</sup> We obtained significant difference TSIC while comparing astrocytoma from others, intraaxial from extraaxial and different grades of tumors [Table 5].

The significant difference noted between meningioma and schwannoma [Figures 1 and 3] in terms of Mi/Cr, lac/Cr, Cho/Cr with a sensitivity of 85.7%, 100%, and 100% and specificity of 90%, 90%, and 90.9%, respectively [Table 9]. There is significantly increased Mi/Cr ratio in schwannoma as compared to meningioma in a similar study.<sup>[28]</sup> Various studies also showed significantly increased Ala in meningioma.<sup>[3]</sup>

We propose an algorithm with the help of physiological MR sequences for assessment of common brain tumors in addition to conventional MR sequences [Figure 4].

## CONCLUSION

Physiological MRI sequences significantly help in identifying type and grades of tumor thereby improving diagnosis and management.

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# Demographic and Clinical Profile of Children with Severe Acute Malnutrition – An Experience from Nutritional Rehabilitation Centre in Jammu

Sunil Dutt Sharma<sup>1</sup>, Pallavi Sharma<sup>2</sup>, Ashu Jamwal<sup>1</sup>, Ghanshyam Saini<sup>3</sup>

<sup>1</sup>Associate Professor, Department of Pediatrics, Government Medical College, Jammu, Jammu and Kashmir, India, <sup>2</sup>Registrar, Department of Pediatrics, Government Medical College, Jammu, Jammu and Kashmir, India, <sup>3</sup>Professor and Head, Department of Pediatrics, Government Medical College, Jammu, Jammu and Kashmir, India

## Abstract

**Background:** Childhood undernutrition remains a key public health challenge in India and is a significant contributor of Under-5 mortality as these children have significantly higher risk of mortality and morbidity. Nutritional rehabilitation centres have been set up by Government of India at facility level to provide medical and nutritional care to Severe Acute Malnourished children under the age of 5 years who have medical complications.

**Materials and Methods:** Retrospective record based observational study conducted in NRC located at SMGS Hospital, GMC Jammu. All the children upto 60 months of age, admitted in NRC during the study period, from September 2018 to February 2019 were included in the study.

**Aims and Objectives:** To know the demographic details and clinical profile of comorbidities in children with Severe Acute Malnutrition and to assess the outcome of these children.

**Results:** A total of 118 children were admitted in the Nutritional Rehabilitation Center during the study period 60% were females. 60% of the children were less than 12 months of age 20 % were between 13 and 24 months of life. Children belonged to all the districts, 22% from Jammu, 18% Reasi, 16% Udhampur, 15% Rajouri, 8% Kathua, 7% Poonch and 6% Samba. Bronchopneumonia (39.8%), Diarrhoea (30.5%) and skin infections (11%) were the commonest morbidities. 73.5% of the children had associated anemia. Other comorbidities were septicemia (10.1%), CSOM (5.9%), UTI (5%), measles (5%) and tuberculosis (2.5%).

**Conclusion:** Early diagnosis and standardized protocol based treatment in the NRCs has been very effective in reducing the morbidity and mortality in SAM patients.

**Key words:** Malnutrition, Wasting, Nutritional rehabilitation centre

## INTRODUCTION

Childhood undernutrition remains a key public health challenge in India and is a significant contributor of under-5 mortality as these children have significantly higher risk of mortality and morbidity.<sup>[1]</sup> The strongest and most consistent relation between malnutrition and an increased risk of

death has been observed for diarrhea and acute respiratory infection, although evidence also suggests a potentially increased risk of death from malaria and measles.<sup>[2]</sup> Data from developing countries indicate that 56% of child deaths are attributable to the malnutrition's potentiating effects, and 83% of these were attributable to mild-to-moderate malnutrition.<sup>[3]</sup> In India, National Family Health Survey-4 shows that about 35.7% of the children in India under 5 years of age are underweight, 38.4% are stunted, and approximately 21% are moderately to severely wasted.<sup>[4]</sup> Malnutrition not only increases the likelihood of acute and chronic diseases but also reduces long-term physical development, cognitive skills, and, consequently, has a negative effect on school enrollment and productivity in later life.<sup>[5]</sup>

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**Corresponding Author:** Dr. Pallavi Sharma, Registrar, Department of Pediatrics, SMGS Hospital, Government Medical College, Jammu - 180001, Jammu and Kashmir, India.

In the early 1990s, the mortality rate in severe acute malnutrition (SAM) was as high as 49%, which is now reduced due to trained staff and the presence of standardized World Health Organization (WHO) guidelines for the management of SAM.<sup>[6]</sup>

SAM is an important preventable and treatable cause of morbidity and mortality in children <5 years of age in India. Considering high mortality rate among malnourished children in India, Indian Academy of Pediatrics (IAP) undertook the task of developing guidelines for the management of SAM based on adaptation from the WHO guidelines in the year 2006. If these guidelines are carefully followed, the mortality rate can be brought down to <5%, even in areas with a high prevalence of HIV/AIDS.<sup>[7]</sup>

Government of India has initiated various programs to combat the challenges of malnutrition in the country. Nutritional Rehabilitation Centres (NRCs) have been set up at facility level to provide medical and nutritional care to severe acute malnourished children under the age of 5 years who have medical complications. In these centers, children with SAM receive therapeutic care following protocols based on the guidelines for the management of SAM by the IAP and WHO. In addition, counseling of the mothers/caregivers is done regarding proper feeding and once they are on the road to recovery, they are sent back home with regular follow-up.<sup>[8]</sup>

As a part of this initiative of Government of India, one such center was established in Sri Maharaja Gulab Singh (SMGS) Hospital, Government Medical College (GMC), Jammu, where the children with severe malnutrition from whole of Jammu Province are treated.

### Objectives

The objectives of this study were as follows:

1. To know the demographic details and clinical profile of comorbidities in children with SAM.
2. To assess the outcome of these children.

## METHODS

This is a retrospective record-based observational study.

The present study was conducted in NRCs located at SMGS Hospital, GMC, Jammu, from September 2018 to February 2019 after taking permission from the Institutional Ethical Committee. All the children up to 60 months of age admitted in NRC during the study period were included in the study. The criteria for admission for inpatient treatment in an NRC are as follows:

### Children 6–59 Months

Any of the following:

1. Mid-upper arm circumference <115 mm or 11.5 cm with or without any grade of edema.
2. Weight for height <−3 standard deviation (SD) with or without any grade of edema.
3. Bilateral pitting edema +/++ (children with edema +++ always need inpatient care).<sup>[8]</sup>

With any of the following complications:

- I. Anorexia (loss of appetite)
- II. Fever (39°C) or hypothermia.
- III. Persistent vomiting
- IV. Severe dehydration base
- V. Not alert, very weak, apathetic, unconscious, convulsions
- VI. Hypoglycemia
- VII. Severe anemia (severe palmar pallor)
- VIII. Severe pneumonia
- IX. Extensive superficial infection requiring intramuscular medications
- X. Any other general sign that a clinician thinks requires admission for further assessment or care.

### Infants <6 Months

Infant is too weak or feeble to suck effectively (independently of his/her weight for length)

Or

Weight for length <−3 SD (in infants >45 cm)

Or

Visible severe wasting in infants <45 cm

Or

Presence of edema both feet

At the NRC, a pediatrician conducts a clinical examination in children to detect the presence/absence of medical complications (altered alertness, respiratory tract infections, diarrhea/severe dehydration, high fever, tuberculosis, and/or severe anemia). Following tests were done in all patients such as blood glucose, hemoglobin/complete blood count, serum electrolytes (sodium, potassium, and calcium), kidney functions test, liver function tests, serum Vitamin B12 levels, and stool R/E. Screening for infections: Total and differential leukocyte count, erythrocyte sedimentation rate, C-reactive protein, blood culture, urine routine examination, urine culture, chest X-ray, Mantoux test, gastric lavage for acid-fast bacilli, and screening for HIV after counseling (only when suspected, based on history and clinical signs and symptoms). At NRCs, children with SAM receive therapeutic care following protocols based on the guidelines for the management of SAM by the IAP and the WHO.<sup>[5–7]</sup>

Children were discharged from the NRC when they met the following discharged criteria:

1. The child was active or alert;
2. The child had no signs of bilateral pitting edema, fever, and/or infection;
3. The child had completed all age appropriate immunizations;
4. The child was being fed 120–130 kcal/kg weight/day; and
5. The primary caregiver knew the care that the child needed to receive at home.

The data were entered into Microsoft Excel spreadsheet and results were calculated by percentages.

## RESULTS

- A total of 118 children were admitted in the Nutritional Rehabilitation Centre during the study period.
- 60% of the children were <12 months of age, 20% were between 13 and 24 months of life.
- Children belonged to all the districts, 22% from Jammu, 18% Reasi, 16% Udhampur, 15% Rajouri, 8% Kathua, 7% Poonch, and 6% Samba.
- 60% were female and 40% were male [Table 1].
- Bronchopneumonia (39.8%), diarrhea (30.5%), and skin infections (11%) were the most common morbidities. 63.5% of the children had associated anemia, while 10.1% had severe anemia with CCF. Other comorbidities were septicemia (10.1%), chronic suppurative otitis media (CSOM) (5.9%), urinary tract infection (UTI) (5%), measles (5%), and tuberculosis (2.5%).
- In the present study, investigations revealed anemia in 73%, serum Vitamin B12 deficiency 18%, hypothermia 10%, hyponatremia 10%, hypokalemia 8%, hypoglycemia 4%, hypernatremia 3%, and hyperkalemia 1%.
- Children stayed for inpatient treatment and nutritional rehabilitation in the hospital for 15–30 days. All the patients were kept in NRC and they were fed according to guidelines, play therapy was also encouraged during stay.
- 87% of the admitted patients were discharged, 5% defaulted, 5% left against medical advice, and 3% expired [Figures 1-3 and Tables 2-4].

## DISCUSSION

SAM cases from all the districts of Jammu Province report to the department of pediatrics with comorbidities.

In the present study, 118 children were admitted in NRC Department of Paediatrics, SMGS Hospital, Government Medical College, Jammu, over a period of 6 months. 60%

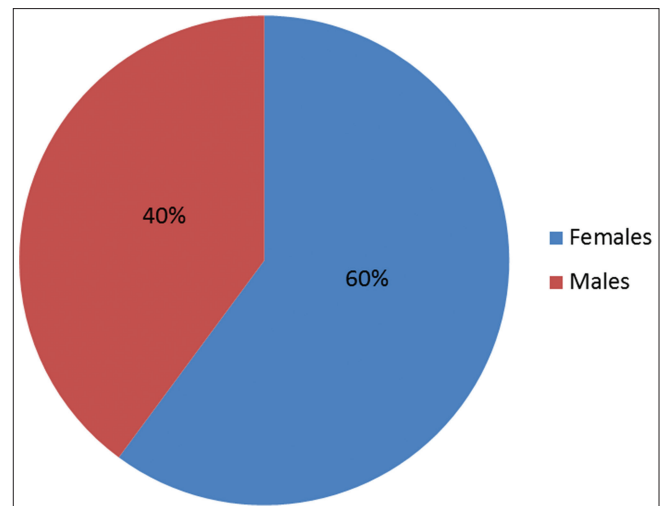


Figure 1: Male - Female ratio

Table 1: Sex-wise distribution of cases

Sex	Number of cases (n=118) (%)
Females	71 (60)
Males	47 (40)

Table 2: Comorbid conditions in children with SAM

Comorbidity	Number (n=118) of cases (%)
Anemia	75 (63.5)
Bronchopneumonia	47 (39.8)
Diarrhea	36 (30.5)
Skin infections	13 (11.0)
Anemia with CCF	12 (10.1)
Septicemia	8 (6.7)
CSOM	7 (5.9)
UTI	6 (5.0)
Measles	5 (4.2)
Tuberculosis	3 (2.5)

CSOM: Chronic suppurative otitis media, UTI: Urinary tract infection, SAM: Severe acute malnutrition

Table 3: Age-wise distribution

Age group (months)	Number of cases (n=118) (%)
<12	71 (60)
13–24	24 (20.3)
25–36	18 (15.2)
37–48	3 (2.5)
49–60	2 (1.6)

of the study groups were female and 40% of males. 60% of the total children belonged to 6–12 months of age, 30% to 13–24 months, and 10% were more than 25 months of age group. Our results are comparable to Shah *et al.*,<sup>[9]</sup> who observed that in their study group of SAM children, 80% were female. Majority of the children were aged <2 years and the predominant age group affected was 6–12 months. Our study is also comparable to Kumar

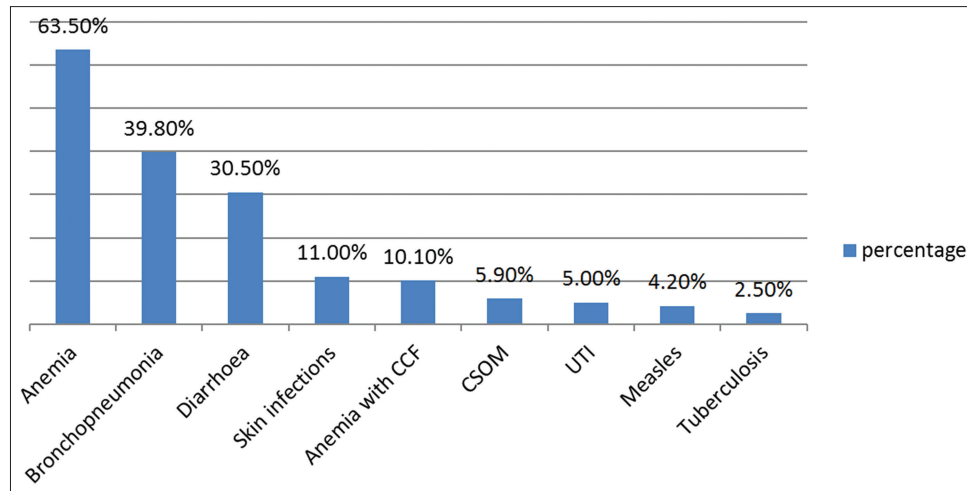


Figure 2: Comorbid conditions in children with Severe acute malnutrition

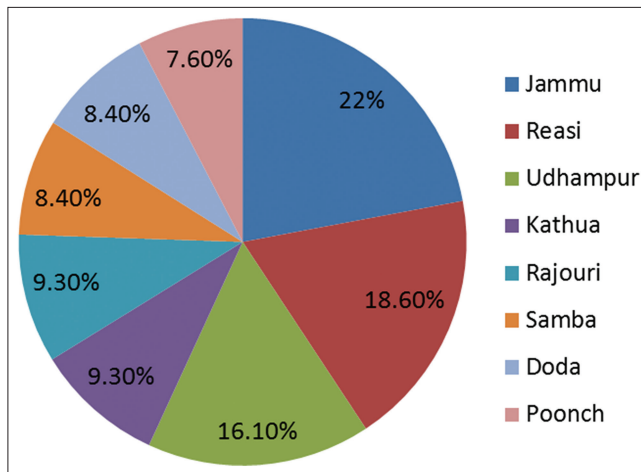


Figure 3: Demographic details of the patient

Table 4: Demographic details of the patients

District	Number of cases (n=118) (%)
Jammu	26 (22)
Reasi	22 (18.6)
Udhampur	19 (16)
Kathua	11 (9.3)
Rajouri	11 (9.3)
Samba	10 (8.4)
Doda	10 (8.4)
Poonch	9 (7.6)

*et al.*, who had reported 51.9% of females and 59.6% of children in the age group of 6–12 months.<sup>[10]</sup> The present study is also in conformity with Bernal *et al.* who had reported that 58% of SAM children were younger than 1 year old.<sup>[11]</sup> Patients presented to NRC with illnesses such as bronchopneumonia (39.8%), diarrhea (30.5%), and skin infections (11%). 87% of the children had associated anemia. Other comorbidities were septicemia, CSOM, UTI, and tuberculosis.

Baskaran *et al.* in a study of comorbidities in 200 children hospitalized with SAM observed that acute gastroenteritis was the most common (57.5%) followed by pneumonia (44.5%), anemia (27%), systemic illness (17%), worm infestation (13.5%), skin infection (8%), measles (6%), and tuberculosis (1%).<sup>[12]</sup> Kumar *et al.* in a study of 104 severe acute malnourished children observed that 54% had diarrhea and 27.8% had acute respiratory tract infections. Tuberculosis was diagnosed in 22% of cases, malaria and measles in 3.8% each, and HIV in 2.9%.<sup>[10]</sup> Syed *et al.* also reported acute gastroenteritis as the most common morbidity (30%) followed by respiratory tract infections.<sup>[13]</sup>

The present study is comparable with Shah *et al.*, they reported fever in 65%, diarrhea 40%, pallor 96.6%, and associated comorbidities such as bronchopneumonia followed by acute gastroenteritis. In the present study, investigations revealed severe anemia in 64%, serum Vitamin B12 deficiency 18%, hypothermia 10%, hyponatremia 10%, hypokalemia 8%, hypoglycemia 4%, hypernatremia 3%, and hyperkalemia 1%. Shah *et al.* had reported in their study hypoglycemia 5%, hypothermia 1.66%, severe dehydration 13.33%, hyponatremia 13.33%, hypokalemia 8.33%, hypernatremia 5%, hyperkalemia 1.66%, septic shock 11.6%, severe anemia 58.33%, and congestive cardiac failure 28.5%.<sup>[9]</sup> Syed *et al.* reported dehydration 31.5%, hypoglycemia 6.8%, hypothermia 11%, sepsis 15%, hyponatremia 11%, hypernatremia 8.2%, hypokalemia 9.58%, and hyperkalemia 0.68%.<sup>[13]</sup> All the patients were kept in NRC and they were fed according to guidelines, play therapy was also encouraged during stay. The hospital ranged from 15 to 30 days. 87% of the admitted patients were discharged, 5% absconded, 5% left against medical advice, and 3% expired. Patients expired of septic shock. Among three patients who

expired due to septic shock also had other morbidities such as hypothermia, hypoglycemia, bronchopneumonia, and severe anemia. According to the WHO, a case fatality rate of more than 20% is considered to be unacceptable in the management of severe malnutrition, 11–20% is poor, and 5–10% is moderate, 1–4% is good, and <1% is excellent.<sup>[6]</sup> Hence, in our study, the case fatality rate is 3% which shows effectiveness of NRC protocol-based management. Following the WHO/IAP guidelines is efficacious and cost effective in resource-limited settings. Early discharge of patients is possible with limited complication and mortality. Many authors have reported that mortality of SAM patients has been decreased by the following these guidelines.

## CONCLUSION

- SAM can be managed effectively in the NRCs.
- Early diagnosis and standardized protocol-based treatment in the NRCs has been very effective in reducing the morbidity and mortality in SAM patients.
- NRCs provide a very good platform for educating parents/caretakers to give frequent energy-rich locally available foods, proper immunization, and by maintaining hygienic lifestyle.
- Telemedicine and networking with the local community centers and Anganwadi centres should be made available in the NRCs as this can not only decrease further morbidity and mortality of SAM patients but also help mild-to-moderate malnourished children in the community.

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# Urban Load of Hepatitis B: A Kolkata Based Study

Abhra Banerjee<sup>1</sup>, Arup Bandyopadhyay<sup>2</sup>, Uttam Kumar Paul<sup>3</sup>

<sup>1</sup>Tutor, Department of Microbiology, R. G. Kar Medical College and Hospital, Kolkata, West Bengal, India, <sup>2</sup>Professor and Head, Department of Physiology, Agartala Government Medical College, Agartala, Tripura, India, <sup>3</sup>Professor, Department of Medicine, Mata Gujari Memorial Medical College and Hospital, Kishanganj, Bihar, India

## Abstract

**Background:** Kolkata is a populous and congested city prone to viral hepatitis of all types in general. Since hepatitis B is the most serious and also the most life-threatening among all types of hepatitis virus infections; a study was done for 1 year to find out the hepatitis B prevalence in a North Kolkata based medical college.

**Materials and Methods:** Blood was taken from all patients in the medicine outpatient department and indoor wards who were referred to get a blood test for detection of hepatitis B surface antigen (HBsAg) as also from pre-operative and ante-natal patients who needed routine testing for screening of HBsAg. They were tested 3 times with HBsAg card test method and a person testing positive for HBsAg on all the three tests were taken as positive.

**Results and Discussion:** Out of 8520 persons tested, 97 were found to be positive for HBsAg. Of them, 51 had a history of needle injury, 27 had multiple blood transfusions, 13 had tattoo markings or acupuncture, 4 had a family history of hepatitis B, and only one had concomitant HIV. 89.7% of the patients tested were married and 10.3% were unmarried.

**Conclusion:** Although Kolkata is an area prone to hepatitis virus infections in general, only 1.13% of the population in our study was positive for hepatitis B proving that Kolkata is a low epidemic area for hepatitis B. The culture here of using only new syringes, taking vaccinations and other education might be responsible for this low epidemic of this disastrous disease, in this region.

**Key words:** Epidemiology, Hepatitis B surface antigen, Hepatitis B, Urban load

## INTRODUCTION

As the name suggests, hepatitis B is an infectious disease of the liver caused by the hepatitis B virus (HBV). This disease is of two types: Acute and chronic. Usually, the disease starts in an asymptomatic manner. However, in some cases, jaundice starts early and is accompanied by nausea, vomiting, weakness, loss of energy, high colored urine, and abdominal pain along with yellow discoloration of the skin and mucous membrane. Mostly these symptoms run a course of 2–3 weeks, and the morbidity continues as mortality is very rare in the initial stages of the disease. In some cases, it has also been seen that the above-mentioned symptoms take even up to 6 months to be manifested completely. There is also a vertical way of

transmission of the disease in which 90% of the patients develop chronic active hepatitis. Hepatitis B is a DNA virus, in contrast to the other liver-related viruses such as hepatitis A, C, D, or E which are all RNA viruses.<sup>[1]</sup> Most of the time, a hepatitis B infection is a mono-infection, but often it is subservient to an infection with a delta hepatitis virus. The latter cannot work unless there is an infection concomitantly with hepatitis B.<sup>[2]</sup> Apart from going into a state of chronic active Hepatitis, infection with hepatitis B often leads to two major complications both of which are almost fatal, namely, cirrhosis of liver and hepatocellular carcinoma. It is reported that though hepatitis B is a preventable disease by following some simple precautions and taking the full course of its vaccine also, this is being observed as a progressively increasing infection in both Asia and sub-Saharan Africa.<sup>[2]</sup> Normally, HBV is transmitted horizontally from an affected person to a healthy victim through exposure to or contamination of blood or body fluid for that matter. It is most common in children, probably because they have less immunity.<sup>[2]</sup>

This disease hepatitis B affects, in a year, about 350–400 million people as measured globally.<sup>[3]</sup> As a result of that,

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**Corresponding Author:** Dr. Arup Bandyopadhyay, Department of Physiology, Agartala Government Medical College, Agartala, Tripura, India.

it gives rise to almost permanent morbidity and mortality, mostly due to cirrhosis of liver and hepatocellular carcinoma. Due to this, it is important to emphasize early detection and prompt treatment of hepatitis B as modern day treatment has grossly improved both morbidity and mortality of hepatitis B.<sup>[4,5]</sup> It has been outlined by recent international guidelines that the most important target to treat these patients is seroconversion of a positive hepatitis B e antigen to a negative state of serum to that antigen, i.e., to HBeAg, that is, a hepatitis B e antigen-free state of serum.<sup>[6-8]</sup> This gives a much more impactful prognosis in as much as it produces much less relapse and lesser rates of complications such as chronic active hepatitis, cirrhosis of liver, and hepatocellular carcinoma. It, therefore is regarded as the first-line treatment option in hepatitis B with a high e antigen in all international guidelines.<sup>[9,10]</sup>

Under these contexts, it is imperative that one should know the viral type, load, incidences, and prevalence of hepatitis B in an epidemic-prone area. Now that, Kolkata is often an epidemic-prone area in relation to the disease viral hepatitis in general, it has been decided by us to go for a study on the hepatitis-B burden in a North Kolkata based medical college. Even though it is a tertiary care super-specialty hospital and medical college, it basically caters to the health needs of urban low- to middle-income population and a huge number of slum dwellers. Kolkata, as is unfortunately known as a highly populous, congested, polluted and with a high infectious disease occurrence rate and one of the largest cities of the world, so an in-depth epidemiological study is definitely needed here.

## MATERIALS AND METHODS

### Study Period

From January 1, 2018, to December 31, 2018, that is one full calendar year covering all seasons of the year. 8520 patients (both male and female) who came for treatment of jaundice or suspected to be suffering from viral hepatitis, at least clinically, in the medicine outpatient department

**Table 1: Number of HBsAg positive cases compared to patients tested**

No. of samples received for suspected hepatitis	No. of HBsAg positive cases	Percentage of positive cases
8520	97	1.13

HBsAg: Hepatitis B surface antigen

**Table 2: Relationship of positive cases with risk factors**

Associated risk factors	Needle injury	Multiple blood transfusion	Family history	HIV/HCV present	Tattoo or Acupuncture	Total
No of +ve patients	51	28	4	1	13	97
Percentage (%) of the patients	52.57	28.87	4.12	1.03	13.4	100

(OPD) were tested for hepatitis B surface antigen (HBsAg), using a standard card test. Many pre-operative and antenatal patients are also routinely tested for HBsAg and so these patients were also included in our study.

Before the commencement of the study, permissions from college authorities and ethical committee were obtained. A signed informed consent form was also obtained from each patient or their nearest kin as the case may be. Apart from the OPD patients, the study was also done on the already admitted but relevant patients. The in patients in whom HBsAg detection was advised on the basis of clinical findings or risk factors, as a part of pre-operative screening and antenatal screening were included in the study irrespective of their age, sex, or marital status. The presence of HBsAg was taken as an indication of hepatitis B infection. However, the patients who were already immunized against the disease by hepatitis B vaccine were excluded from the study.

To 3 ml of blood was collected from each patient by aseptic venepuncture, and the said sample was transferred in a glass vial to the laboratory for detection of HBsAg using the standard card test. In cases where the delay was conjectured, serum was separated from the blood sample, and the separated serum was kept stored in a refrigerator at a temperature of 4–8°C. Serum was separated from the blood by allowing the latter to clot and then subjecting to centrifuge for ½ h at a speed of 3000 r.p.m. Analysis of the sera was done by an immunoassay method based on the antigen capture or sandwich principle using “one step HBsAg rapid card test” for the qualitative detection of HBsAg as per the manufacturers’ instructions. The kit has a sensitivity of 99.8% and a specificity of >99%. The samples which were positive for HBsAg consecutively for 3 times were regarded as positive. The finding were tabulated and analyzed.

## RESULTS

The following tables and figures give a glimpse of the results obtained in our study [Tables 1-3].

## DISCUSSION

Our study shows that out of 8520 patients tested for HBsAg in their blood, only 97 patients were found to be positive

**Table 3: Relationship of HBsAg positivity with marital status**

Marital status	Married (%)	Single (%)
Percentage of HBsAg positive cases	89.7	10.3

HBsAg: Hepatitis B surface antigen

for HBsAg. Percentage wise it was 1.13% of the population tested for such a purpose. Out of those 97 patients 51 (52.57%) had a history of needle injuries, 28 (28.87%) had multiple blood transfusions, 4 (4.12%) had family history of hepatitis B, 1 (1.03%) had HIV/HCV present, and 13 (13.4%) had undergone tattoo or acupuncture on them. Furthermore, 89.7% of the hepatitis-B sufferers were married and only 10.3% were single.

Geographically, however, the burden of HBV infection is different in different places. The reasons are that different modes of transmission are prevalent in different population and also the age matters.<sup>[11]</sup> Affection at an early age leads to the continuation of chronic active hepatitis B for a long period, increasing the prevalence rate. Furthermore, the epidemiology changes as time advances, particularly in a developed country, most importantly due to the advent of vaccines, peoples', education, and various programs. In countries such as the Asia Pacific and the sub-Saharan African countries, hepatitis B infection is maximum, that is, more than 8% of the population, compared to 1.13% in the case of ours. Majority of infections in those regions are interestingly infected at birth or in early childhood.<sup>[12]</sup> According to Mahoney,<sup>[13]</sup> 45% of the world's population lives in an area of high prevalence. Again, vertical transmission is more common in Asia than in Africa.<sup>[14]</sup> Regions of the world where there is an intermediate range of HBV prevalence (2–7%) include South Asia, the Middle East, North Africa, Eastern, and Southern Europe, and parts of Latin America. Rest of Asia, Northern and Western Europe, North America, and some countries in South America comprise the low prevalence (<2%) populations. Hepatitis B prevalence is maximum in the African region and the Western pacific region, where the disease prevalence is 6.2% and 6.1%, respectively, of the total adult population. The same in North America is 0.7%, European countries 1.6%, Southeast Asia region 2.0%, and Eastern Mediterranean Region is 3.3%. In 1982, the vaccine against hepatitis B was globally introduced. 37 years later also, it is not ubiquitous in practice. HBV is not 100% dependent for survival to our body environment. Even outside our body, it remains alive and active for at least 7 days. Hence, an injection needle used to inject an infected person will remain infective for days hereafter. Therefore, its' use in healthy persons subsequently might lead to infection of the latter. Strict rules of using disposable syringes and that also for once only and thereafter their

proper disposals without chances of harming a person accidentally which can cause incidences of hepatitis B. It is also to be noted that two important causes of infection are through vertical transmission during childbirths and also through vaginal and seminal fluids. Prompt diagnosis and treatment of hepatitis B and making prevalent the practice of safe sex could grossly, therefore, reduce the incidences of hepatitis B.<sup>[15]</sup> It is good to know from our studies that our region belong to the low prevalence area but that should not rest us assured, and we should go for education, vaccinations, and other preventive measures. However, it is not found through internet searches that such study was ever done in our region of the world, at least in the recent past. Ours is, therefore, possibly, a novel finding which says that Kolkata is placed among the low hepatitis B prone areas of the world, at least in the present days and within the context of our limited study. The reason for this could be our newer culture of using only new syringes and needles, proper vaccinations and following other related rules to prevent hepatitis B. However, a qualitative study on knowledge, culture, and practices of the general population in Kolkata regarding hepatitis B could reveal many actual points particularly when compared with similar studies done in disease-prone areas in the world.

## CONCLUSION

Kolkata is an area prone to frequent epidemics of hepatitis in general. Since hepatitis B is the most serious and threatening among all the different types of hepatitis a study was done to know the burden of hepatitis B in a tertiary care medical college in North Kolkata. It was found that though overall hepatitis incidences were pretty high, the prevalence of hepatitis B here is comparatively low. Further qualitative studies on knowledge, culture, and practice might throw deeper light on this issue.

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# A Comparative Study of Various Surgical Methods for Sacrococcygeal Pilonidal Disease at a Tertiary Care Hospital in India

S Lakkanna, K Aditi, S Vaishnavi

<sup>1</sup>Professor and HOD, Department of general surgery, ESIC medical college and PGIMSR and Model hospital, Rajajinagar, Bangalore, <sup>2</sup>Senior Resident, Department of general surgery, ESIC medical college and PGIMSR and Model hospital, Rajajinagar, Bangalore, <sup>3</sup>Intern, Department of general surgery, ESIC medical college and PGIMSR and Model hospital, Rajajinagar, Bangalore

## Abstract

**Introduction:** Pilonidal sinus disease is a very common anorectal problem without a clinical consensus on its optimal management.

**Objective:** The objective of this study was to compare the surgical methods used in our hospital and determine the outcomes in relation to hospitalization time, healing, post-operative complications and recurrence.

**Materials and Methods:** All patients with pilonidal sinus disease that was treated surgically at our hospital between January 2014 and March 2018 were considered.

**Results:** A total of 74 patients of whom 57 were male and 17 females. 12 were treated with simple excision, 25 with simple excision and closure, 26 with Limberg's flap, and 11 with Karydakis flap. Duration of surgery and duration of hospital stay were significantly larger for the flap procedures. Complications such as infection (11.5%) and seroma (24.5%) were common with flap procedures. Recurrence was common with simple excision with or without closure (82%) compared to flap procedures (24.5%).

**Conclusion:** The two flap techniques show no difference among each other.

**Key words:** Pilonidal sinus, Flap techniques, Recurrence, Follow up

## INTRODUCTION

The term pilonidal sinus originates from pilus Latin for hair (plural pili), nest from nidus. Sinus is a blind tract from an epithelial surface, lined by granulation tissue. The etiology and pathogenesis of sacrococcygeal pilonidal sinus are not clear.<sup>[1,2]</sup> The pathogenesis of the disease is hypothesized to be related to the accumulation of weak and lifeless hair in the intergluteal region, which overtime gives rise to foreign body reaction, causing abscess, and sinus formation.<sup>[3,4]</sup>

Pilonidal disease can appear as an acute abscess along with sinus tract formation. A more complex manifestation can be characterized by chronic or recurrent abscesses with

extensive, branching sinus tracts. The common form is an acute abscess characterized by the existence of a midline pit in the natal cleft typically identified 4–8 cm from the anus. The skin enters the sinus giving the opening a smooth edge. This primary tract leads into a subcutaneous cavity, which contains granulation tissue and usually a nest of hairs that are present in two-thirds of cases in men and in one-third of those in women and may be seen projecting from the skin opening. Many patients have secondary lateral openings 2–5 cm above the midline pit. The skin opening and the superficial portion of the tract are lined with squamous cell epithelium, but the deep cavity and its extensions are not.

The risk factors of pilonidal disease are young age, obesity, increased sacrococcygeal subcutaneous fat thickness, ingrown hair, depth and narrowness of natal cleft, driving/sitting for >4 h/day, positive family history, and taking bath <3 times/week.

A deep natal cleft with one of favorable factors enhance sacrococcygeal pilonidal sinus, for example, sweating,

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**Corresponding Author:** K Aditi, Senior Resident, Department of general surgery, ESIC medical college and PGIMSR and Model hospital, Rajajinagar, Bangalore



maceration, bacterial contamination, and penetration of hairs. Obesity, trauma, local irritation, and a sedentary lifestyle are usually associated with pilonidal sinus.<sup>[5,6]</sup> Although pilonidal sinus can be treated using various conservative and surgical methods, recurrence rate remains high. Complete surgical removal of the pilonidal sinus or sinuses and appropriate reconstruction can lead to successful recovery.<sup>[7-9]</sup> However, collection of the lifeless hair depends on the anatomy of the intergluteal area, and accompanying risk factors can lead to subsequent recurrence.<sup>[10-13]</sup>

This paper presents the outcome of 74 patients operated at our hospital. There are very few studies with long follow-up period.

## MATERIALS AND METHODS

It is a retrospective study. It was done in the department of general surgery. All patients with sacrococcygeal pilonidal sinus disease operated between January 2014 and April 2018 were considered in the study.

The variables included are age, sex, method of surgery, time of hospitalization, duration of follow-up, and recurrence.

The surgery was done by various surgeons in the different surgical units and the surgical procedure was chosen by the surgeon based on the procedure of their choice and after taking informed consent from the patients. All the patients were explained regarding both the procedures, and the risks and benefits associated with them.

### Surgical Procedure

Surgery was done under spinal anesthesia and in prone position. Injection ceftriaxone 1 g intravenous was given while parts were painted just before the incision. Both buttocks were retracted laterally using adhesive tapes.

- Simple excision – The sinus tract along with surrounding skin margin of 5 mm was excised and allowed to heal by secondary intention.
- Excision with primary closure – An elliptical incision was made around the sinus, wash was given to the wound and closed primarily using non-absorbable sutures.
- Limberg's flap procedure – A rectangular (rhomboid) tissue of full thickness, skin and subcutaneous fat is excised including the midline with its long axis in the midline. Angles of rhomboid should be 60 and 120° and are adjusted as shown in the pictures. Flaps are elevated, rotated, and sutured using 3-0 polypropylene. Suction drain is placed underneath. Skin is closed with polyethylene.

- Karydak's primary excision and closure – The excision is performed using an asymmetrical incision which deliberately removes much more skin on one side than the other. The pits in the presacral cavity are excised, the side of the excision closest to the midline is undermined so that when the skin is approximated to the other side (the wider skin excision area) the wound lies off-center.<sup>[14]</sup>

## RESULTS

The demographic details are shown in Table 1.

A total of 74 patients with Sacrococcygeal pilonidal sinus disease who underwent surgery between 2014 and 2018 at our institute were studied. The average age (in years) was 26. Male to female ratio was 10:3. The type of sinus i.e primary: primary + secondary was 5:2.

12 patients of total 74 underwent simple excision, 25 underwent excision with primary closure, 26 underwent limberg's flap and 11 underwent karydakis's flap procedure (Table 2). The recurrence rate in simple excision was 50%, in simple excision with closure was 32%, limberg's flap procedure was 15.4% and karydakis's flap procedure was 9.1% (Table 3). Total number of patients with primary pilonidal disease were 63 and total number of patients with recurrent pilonidal disease were 11. Total number of patients who had surgery for pilonidal sinus twice in the past were 2.

Coming to the post operative complications, it was found that flap techniques had more complications compared to the simple procedures as shown in Table 4. Duration of surgery and duration of hospital stay was longer in flap techniques compared with simple procedures and statistically significant (Table 5)

## DISCUSSION

The ideal method of the treatment of pilonidal sinus would be one with minimal tissue loss, minimal post-operative morbidity, excellent cosmetic results, rapid resumption of daily activities, low cost, and a low recurrence rate.<sup>[15]</sup> However, although numerous operative treatment methods have been described, no treatment comprises all of these features.<sup>[16]</sup>

**Table 1: Summary of patients and procedures (range)**

Average age (years)	26 (19–33)
Male-to-female ratio	10:3
Mean duration of disease before surgery- 6 to 8 months	
Type of sinus (primary: primary+secondary)	5:2

Horwood *et al.*<sup>[17]</sup> systematically reviewed, by two independent investigators, six relevant randomized controlled trials for pilonidal disease regarding primary suture/repair and Limberg's flap. A total of 641 patients were included in this systematic review. This literature supports the use of rhomboid flap excision and the Limberg's flap repair procedures over primary midline suture techniques for the elective management of primary pilonidal disease, but further high-quality studies are necessary to support this. The points of strength of this paper are being belonged to Level 1 as a systematic review of randomized trials or n-of-1 trials according to the latest oxford level of evidence and the randomized trials with poor methodology were excluded.

Tavassoli *et al.*<sup>[18]</sup> performed excision with primary repair as Group 1 and rhomboid excision with the Limberg's flap as

Group 2. The demographic characteristics of their patients, early and late complications, comfort and pain score on the 1<sup>st</sup> and the 4<sup>th</sup> post-operative day, hospital stay, time of return to work, and patient satisfaction were compared. There was no significant difference between the two groups in terms of demographic characteristics, operation time, early complication rate, and recurrence. However, significant difference was observed in return to work, first pain-free toilet sitting, pain score, and patient satisfaction. The authors concluded that the Limberg's flap has similar complications as the primary repair method, but earlier return to work and less hospital stay, lower pain score and higher comfort, and satisfaction were the advantages of the Limberg's flap method. Thus, this method is recommended for the treatment of primary pilonidal disease. The relatively smaller number of patients was a weak point of this paper; otherwise, the results were well tabulated and the probability values of significant were traced.

Roshdy *et al.*<sup>[19]</sup> performed rhomboid flap versus primary closure after excision of sacrococcygeal pilonidal sinus as prospective randomized study in 140 patients. The authors stated that goal for the treatment of pilonidal disease in 2-fold, the first is excising and healing with low rate of recurrence; the second is minimizing patient inconvenience and morbidity after surgical procedure. In conclusion, the excision and rhomboid flap is better than excision and

**Table 2: Surgery type distribution of patients studied**

Surgery type	Gender		Total (%)
	Female (%)	Male (%)	
Simple excision	3 (17.7)	9 (1.8)	12 (5.4)
Excision with primary closure	7 (41.2)	18 (45.6)	25 (44.6)
Limberg's	4 (23.5)	22 (38.6)	26 (35.1)
Karydakis	3 (17.6)	8 (14)	11 (14.9)
Total	17 (100)	57 (100)	74 (100)

**Table 3: Recurrence**

Recurrence	Surgery type				Total (n=74)
	Simple excision (n=12)	Simple excision with closure (n=24)	Limberg's (n=26)	Karydakis (n=11)	
No (%)	6 (50)	17 (68)	22 (84.6)	10 (90.9)	55 (74.3)
Yes (%)	6 (50)	8 (32)	4 (15.4)	1 (9.1)	19 (25.7)

**Table 4: Post-operative complications**

Post-operative complications	Surgery type				Total
	Simple excision (%)	Simple excision with closure (%)	Limberg's (%)	Karydakis (%)	
Seroma	0 (0)	0 (0)	4 (15.4)	1 (9.1)	5 (6.8)
Infection	1 (12.5)	0 (0)	3 (11.5)	0 (0)	4 (5.4)
Superficial wound dehiscence	1 (12.5)	0 (0)	0 (0)	1 (9.1)	2 (2.7)
Partial necrosis	0 (0)	0 (0)	0 (0)	1 (9.1)	1 (1.4)
Nil	10 (75)	25 (100)	19 (73.1)	8 (72.7)	62 (83.8)
Total	12 (100)	25 (100)	26 (100)	11 (100)	74 (100)

**Table 5: Comparison of clinical variables according to surgical type of patients studied**

Duration	Surgery type				Total	p-value
	Simple excision	Simple excision with closure	Limberg's	Karydakis		
Duration of surgery (min)	31.25±8.35	34.80±10.36	46.73±10.76	46.27±16.4	31.25±8.35	<0.001**
Duration of hospital stay (days)	7.88±3.40	6.60±2.04	8.92±3.52	10.45±4.87	7.88±3.40	<0.001**

primary repair in the treatment of pilonidal disease because it flattens the natal cleft avoid dead space, healing time is short, morbidity is low, shorter hospital stay, and low rate of recurrence. In this paper, the sample size was satisfying, the results were well written and well tabulated, and the probability values of significant were traced.

Points of the strength of this paper were the sample size and the operating surgeons.

This study was limited by the smaller sample size which was considered a weak point of this paper.

## CONCLUSION

The ideal procedure for treating pilonidal sinus disease is not clear, but complete excision of the affected areas, flattening of the natal cleft, avoiding midline scars, and a tension free repair of the wound with well vascularized tissue appear to be essential features of any treatment for this disease. It is now clearly showed better patients' satisfaction with wound closure primarily or using flaps after surgery rather than leaving it open. For simple non-recurrent pilonidal sinus, less invasive surgery with limited excision and primary closure could be enough. Different flap techniques showed no significant difference among each other. However, the advantages of Karydakiss cleft lift flap in recurrent and complicated cases are noticeable in different studies, although wound complication is similar to other flap methods.

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# Effect of Common Comorbidities on the Success Rate of Myringoplasty

M B Nishant<sup>1</sup>, A M Aneesa<sup>2</sup>, K B Rajamma<sup>3</sup>

<sup>1</sup>Assistant Professor, Department of ENT, Sree Gokulam Medical College and Research Foundation, Trivandrum, Kerala, India, <sup>2</sup>Resident, Department of ENT, Sree Gokulam Medical College and Research Foundation, Trivandrum, Kerala, India, <sup>3</sup>Professor and HOD, Department of ENT, Sree Gokulam Medical College and Research Foundation, Trivandrum, Kerala, India

## Abstract

**Objective:** The aim of the study was to study the effect of common comorbidities on the success rate of myringoplasty.

**Materials and Methods:** A retrospective evaluation of the 40 patients who have undergone myringoplasty for different sizes of central perforation with pure conductive hearing loss of <60 dB were done. Both males and females of age 15–60 years were included in the study. The comorbidities studied were hypertension, diabetes and nasal allergy. Temporalis fascia was used as the graft and grafting was done by underlay technique. Patients were followed up for 6 months. The influence of various comorbidities was assessed by comparing the rates of graft take up and graft retraction.

**Results:** Among the 40 patients we selected, the majority were in the age group of 30–45 years. We had 7 (17.5%) patients with diabetes mellitus and during the follow-up at 6 months, 28.6% of failure and 14.3% of retractions were observed. (significance?) Among the 9 (22.5%) patients who were hypertensives, we did not find any graft failure. 17 (42.5%) patients had a nasal allergy. We found failures in 23.5% by 6<sup>th</sup> month and retractions in 17.6%. *P* value was calculated and was found to be statistically not significant.

**Key words:** Myringoplasty, Allergic rhinitis, Chronic otitis media, Hearing loss

## INTRODUCTION

Chronic otitis media are the inflammation of the middle ear cavity that causes permanent damage to the tympanic membrane such as perforation, tympanosclerosis, atelectasis, and retraction pocket. It results either from eustachian tube dysfunction with poor aeration of middle ear space or can be from trauma to tympanic membrane. Eustachian tube dysfunction causes recurrent episodes of acute otitis media which leads to a persistent middle ear infection or chronic inflammations.<sup>[1]</sup>

Perforation of pars tensa causes hearing loss of varying degrees. It depends on the involvement of the different

quadrants of the tympanic membrane, and the size of perforation varies from the small, medium, large, and subtotal perforation. Hearing loss caused by the tympanic membrane perforation can be up to 60 dB.<sup>[2]</sup>

The perforation can be corrected by a surgical procedure which aims in the repair of the tympanic membrane perforation. This surgical procedure is called Type 1 tympanoplasty or myringoplasty. Myringoplasty aims at the repair of the perforation, improvement of hearing and protects the middle ear and inner ear from external factors such as pathogens or water entry or increased air pressure. The routinely used method of closure is using temporalis fascia, and the surgical technique of grafting is by underlay or overlay technique.<sup>[2-7]</sup>

Various factors are to be considered for a successful myringoplasty. In our study, we are investigating the effect of age, systemic diseases such as diabetes mellitus and hypertension, nasal pathologies such as deviated nasal septum and nasal allergy with the outcome of the surgery.

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**Corresponding Author:** Dr. M B Nishant, Assistant Professor, Department of ENT, Sree Gokulam Medical College, Trivandrum – 695 607, Kerala, India.



## MATERIALS AND METHODS

A retrospective study of the 40 patients who have undergone myringoplasty for different sizes of central perforation with pure conductive hearing loss of <60 dB was done. Both males and females were included in the study.

The pre-operative assessment included a thorough clinical examination of ear nose and throat and otoscopic examination to record the site and size of perforation. All findings were confirmed with a Carl Zeiss microscopic examination. Hearing loss was graded into mild (25–35 dB), mild-moderate (36–45 dB), and moderate-severe (45–60 dB). Patients were grouped based on whether they had no comorbidities, diabetes, hypertension, or nasal allergy. Diagnostic nasal endoscopy was done to assess the nasal anatomy. X-ray of paranasal sinuses was taken. Those patients with foci of infection in the upper respiratory tract which influence the patency of Eustachian tube were treated. Cortical mastoidectomy was done in patients with sclerotic mastoid to ensure a patent aditus and facilitate middle ear aeration. Wet ears were made dry with antibiotics for at least 6 weeks before surgery. Informed and written consents were obtained before surgery.

All patients were operated under general anesthesia. The temporalis fascia was used as a graft in all cases which was harvested through an extended post auricular incision or a separate 2 cm incision in the temporal region of the scalp after infiltrating with 2% lignocaine and 1:100,000 adrenalin.

Myringoplasty was done either through a post auricular approach or transcanal approach depending on the width of the external auditory canal (EAC).

A cortical mastoidectomy is done in cases with a sclerotic mastoid and aditus patency is ensured. This facilitates aeration of the middle ear and aids in the proper healing of the graft.

All patients were given a mastoid dressing.

### Post-operative Care

All patients were kept in the post-operative intensive care unit for 24 h. Patients were kept nil per oral for 4 h postoperatively. IV fluids, IV antibiotics, and IV analgesics were given. Mastoid dressing changed on the 1<sup>st</sup> post-operative day.

Patients were discharged on the 3<sup>rd</sup> post-operative day. All patients received antibiotic, analgesic, decongestants, and antihistamines for 1 week. Steroid nasal spray and mast cell stabilizers were continued in those patients with nasal

allergy. Patients were advised not to cough, strain or sneeze, and keep ears dry. All patients were instructed to avoid air travel and swimming for 1 month.

Postural suture removal was done on the 7<sup>th</sup> post-operative day. Antibiotic ear drops were continued to facilitate dissolution of gel foam and to promote healing. All patients were called for regular follow-up. The gel foam in the EAC suctioned out by 3<sup>rd</sup> week if persisting. On the 4<sup>th</sup> week, the graft was assessed for perforation or retraction. The same was done after 3 months and 6 months. Pure tone audiometry (PTA) was done at the end of the 6<sup>th</sup> month to assess the hearing.

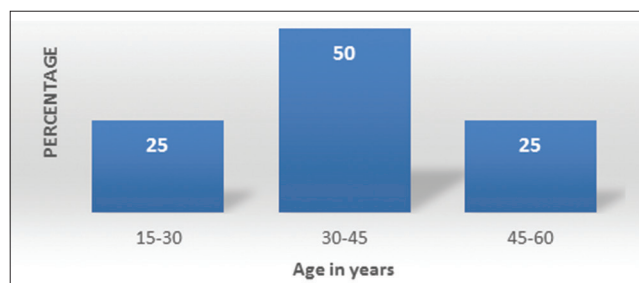
## RESULTS AND DISCUSSION

Patients between 15 and 60 years of age were included in the study. Patients were observed for 6 months for the take up of graft. Most of the patients were middle age group and they showed a good graft uptake [Table 1 and Graph 1].

A total of 40 patients, 7 had diabetes, 9 had hypertension, and 17 had a nasal allergy. The percentage distribution is as shown in Table 2.

Diabetes mellitus was present in 7 (17.5%) patients. We did not find any graft failure during the 1<sup>st</sup> month as patients at the time of surgery were put on insulin for better control of their diabetes. All patients also received systemic and local antibiotics in the immediate post-operative period. During the evaluation at a 6<sup>th</sup> month, failure of 28.6% and retraction of 14.3% were seen [Tables 3 and 4]. We observed this rise in failure rate probably due to the increased susceptibility to infection due to various reasons such as elevated blood sugar, suppressed immunity, and poor microvascular circulation which delays healing and elevates the failure rate or retraction of graft.

Among the 40 patients, 22.5% had hypertension, but none of them had graft failure [Table 5]. We observed an increase in bleeding during the surgery but was suitably controlled with local vasoconstrictors. During the immediate post-operative period, such patients required strict and close



Graph 1: Graphical representation of age.



**Table 1: Age distribution of the study population**

Age	Frequency (%)
15–30	10 (25.0)
30–45	20 (50.0)
45–60	10 (25.0)
Total	40 (100.0)

**Table 2: Distribution of patients with diabetes mellitus, HTN, and nasal allergy**

Factors	Absent	Present
Diabetes mellitus	33 (82.5)	7 (17.5)
HTN	31 (77.5)	9 (22.5)
Nasal allergy	23 (57.5)	17 (42.0)

HTN: Hypertension

**Table 3: Percentage distribution of graft uptake in diabetic patients in the 1<sup>st</sup> month**

T2DM	Follow-up at 1 month		Total
	Graft intact	Graft failure	n (%)
Absent	32 (97.0)	1 (3.0)	33 (100.0)
Present	7 (100.0)	0 (0.0)	7 (100.0)

 $\chi^2=0.218$ ,  $df=1$ ,  $P=0.641$ . T2DM: Type 2 diabetes mellitus**Table 4: Percentage distribution of graft uptake in diabetic patients in the 6<sup>th</sup> month**

T2DM	Follow-up at 6 months			Total
	Graft intact	Graft failure	Graft retracted	n (%)
Absent	26 (78.8)	4 (12.1)	3 (9.1)	33 (100.0)
Present	4 (57.1)	2 (28.6)	1 (14.3)	7 (100.0)

 $\chi^2=0.693$ ,  $df=2$ ,  $P=0.707$ . T2DM: Type 2 diabetes mellitus

monitoring of blood pressure to avoid any collection in the middle ear. We did not find any increased failures over the 6 months observation period [Table 6].

Nasal allergy was present in 17 (42.5%) patients. In the 1<sup>st</sup> month, none of them showed graft failure. During this period patients had good control of nasal allergy with medication. Over a period of 3–6 months, we observed a rise in failure probably because in spite of medications patients developed exacerbations of nasal symptoms and this lead to poor middle ear ventilation. By 3<sup>rd</sup> month failure was 11.8% and by 6<sup>th</sup> month it raised to 23.5%. We also observed a retraction in fascia graft among 17.6% of patients. However, the difference observed was not found to be statistically significant [Tables 7 and 8]. Cabra and Moñux found a success rate of 64% in the patients subjected to fascia tympanoplasty.<sup>[8]</sup>

**Table 5: Percentage distribution of graft uptake in hypertensive patients in the 1<sup>st</sup> month**

HTN	Follow-up at 1 month		Total
	Graft intact	Graft failure	n (%)
Absent	30 (96.8)	1 (3.2)	31 (100.0)
Present	9 (100.0)	0 (0.0)	9 (100.0)
Total	39 (97.5)	1 (2.5)	40 (100.0)

 $\chi^2=0.298$ ,  $df=1$ ,  $P=0.585$ . HTN: Hypertension**Table 6: Percentage distribution of graft uptake in hypertensive patients at 6<sup>th</sup> month**

HTN	Follow-up at 6 months			Total
	Graft intact	Graft failure	Graft retracted	n (%)
Absent	24 (77.4)	5 (16.1)	2 (6.5)	31 (100.0)
Present	8 (88.9)	0 (0.0)	1 (11.1)	9 (100.0)

 $\chi^2=1.766$ ,  $df=2$ ,  $P=0.413$ . HTN: Hypertension**Table 7: Percentage distribution of graft uptake in nasal allergic patients at 1<sup>st</sup> month**

Nasal allergy	Follow-up at 1 month		Total
	Graft intact	Graft failure	n (%)
Absent	22 (95.7)	1 (4.3)	23 (100.0)
Present	17 (100.0)	0 (0.0)	17 (100.0)
Total	39 (97.5)	1 (2.5)	40 (100.0)

 $\chi^2=0.758$ ,  $df=1$ ,  $P=0.384$ **Table 8: Percentage distribution of graft uptake in nasal allergic patients at 6<sup>th</sup> month**

Nasal allergy	Follow-up at 6 months			Total
	Graft intact	Graft failure	Graft retracted	n (%)
Absent	19 (82.6)	3 (13.0)	1 (4.3)	23 (100.0)
Present	10 (58.8)	4 (23.5)	3 (17.6)	17 (100.0)
Total	29 (72.5)	7 (17.5)	4 (10)	40 (100.0)

 $\chi^2=0.776$ ,  $df=2$ ,  $P=0.678$ 

## CONCLUSION

Among the 40 patients selected for the study, 50% of them were in the middle age group. We had 17.5% of patients with diabetes mellitus who underwent myringoplasty and during the follow-up, at 6 months 28.6% had graft failure and 14.3% had graft retractions. Among 22.5% of hypertensives, we did not find any graft failure. 42.5% of patients had a nasal allergy. We found graft failure of 23.5% by the 6<sup>th</sup> month and graft retraction of 17.6%. However, the increased rate of graft failures in both diabetics and those with nasal allergy were found to be not statistically significant. A limitation of

this study is the small number of patients for each group. Further studies using larger groups of patients are needed for a better understanding of the effects of various diseases on the success rate of tympanoplasty.

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# Sale and Consumption on Smokeless Tobacco in Jammu and Kashmir, India: Attitude and Views of Jammu Adult Population

Paramjeet Singh<sup>1</sup>, Prateek Jain<sup>2</sup>, Gaurav Agarwal<sup>2</sup>, Sandeep Kumar Swarnkar<sup>3</sup>, Astha Chauhan<sup>4</sup>, Bhupendra Singh Rathore<sup>5</sup>

<sup>1</sup>Dental Surgeon, Directorate of Health Services, Jammu, Jammu and Kashmir, India, <sup>2</sup>Senior Lecturer, Department of Public Health Dentistry, Maharana Pratap College of Dentistry and Research Centre, Gwalior, Madhya Pradesh, India, <sup>3</sup>Senior Lecturer, Department of Pedodontics and Preventive Dentistry, Maharana Pratap College of Dentistry and Research Centre, Gwalior, Madhya Pradesh, India, <sup>4</sup>Senior Lecturer, Department of Public Health Dentistry, Index Institute of Dental Sciences, Indore, Madhya Pradesh, India, <sup>5</sup>Dental Surgeon, Department of Orthodontics, College of Dental Sciences, Indore, Madhya Pradesh, India

## Abstract

**Background:** Concerned over increasing cases of mouth cancer in the state, the Jammu and Kashmir Government has banned the smokeless tobacco (ST) products like gutkha and also increased the taxes in other tobacco-related products. Despite legislation, the effectiveness of this step is a matter of concern. The gutka users are able to get their regular supply and shopkeepers are still seen selling gutka pouches.

**Objective:** The objective of this study was to assess the attitude and views of Jammu adult population toward the sale and consumption on ST by Jammu and Kashmir Government.

**Materials and Methods:** A cross-sectional survey was carried out among the general adult population of Jammu city. 400 respondents completed a questionnaire on tobacco use, knowledge of existence of law, health warning, cost increase, and hazards related to ST.

**Results:** Half of the current users (51.6%) surveyed compared to the past users (61.4%) and non-users (69.7%) had knowledge about laws on gutka products. Significantly higher percentage of the current users (52.1%) and past users (57.9%) indicated that the actions against tobacco products would be slightly effective ( $P < 0.05$ ). 52.5–68.4% of respondents were aware of health warning signs printed on the tobacco packet. 59.1% of the current users reported easy availability of gutka. The past users (54.4%) reported an increase in black marketing of ST gutka.

**Conclusion:** The sale and consumption ban and increased taxes by the government are an effective measure for the improvement of health and reduce consumption. They demonstrate that there is a need for greater public education and the policy has been lagging behind to curb the black market sale.

**Key words:** Health, Legislation, Policy, Smokeless tobacco, Tobacco control

## INTRODUCTION

Today, tobacco is the foremost cause of preventable deaths in world.<sup>[1]</sup> Tobacco use has assumed the dimension of an

epidemic resulting in about 1.3 million deaths each year in the Southeast Asia region. India is among the top 10 tobacco producing and consuming countries in the world.<sup>[2]</sup>

Global Adult Tobacco Survey (GATS) India (GATS 2009–2010) revealed that more than one-third of adults in India use tobacco in some form or the other.<sup>[3]</sup> Among them, 21% of adults use only smokeless tobacco (ST), 9% only smoke, and 5% smoke as well as use ST. The prevalence of tobacco use is highest in Mizoram (67%) and lowest in Goa (9%). Jammu and Kashmir tobacco consumption is higher than the national average. 32% of

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**Corresponding Author:** Dr. Astha Chauhan, Department of Public Health Dentistry, Index Institute of Dental Sciences, Nemawar Road, NH - 59A, Indore, Madhya Pradesh, India.

ST users purchased tobacco products from kiosks, which included roadside pan shops.<sup>[3]</sup>

ST is a blanket term that refers to a number of tobacco products that are used by means other than smoking. Gutka in India is one example. It is a generic name for a product that contains tobacco, areca nut, and several other substances in powdered or granulated form and is sold in small aluminum foil sachets.<sup>[4]</sup>

ST contains more nicotine than smoked. Danger of ST may go beyond the mouth. It might also play a role in other cancers, heart disease, and stroke.<sup>[5]</sup> Food and Safety Standards Authority of India under its Food Safety and Standards (Prohibition and Restriction on Sales) Regulations 2011 restricts the use of products that contain any substance which may be injurious to health, and according to them, tobacco and nicotine should not be used as ingredients in any food products.<sup>[6-8]</sup>

There have been some attempts to curb and regulate gutka promotion and use. In response to a public interest litigation filed in a state high court, the Central Committee on Food Standards duly conducted hearings and investigations and concluded that gutka was a dangerous food product.<sup>[4]</sup> The committee recommended an outright ban.

Concerned over increasing cases of mouth cancer in the state, the Jammu and Kashmir Government has banned all ST products like gutka and also increased the taxes on other tobacco products.<sup>[6-8,15]</sup> The ST Association has been questioning the health ministry notification as to why the ban is imposed only on gutka and not on cigarette.<sup>[9,10]</sup> The lobby claims that 4 crore farmers would lose their livelihood due to gutka ban.<sup>[11]</sup>

Despite legislation, the effectiveness of this action was a matter of concern. According to many reports in print media, ban on gutka will not create problem for gutka users as they have their own chain of getting them. Majority of pan shopkeepers are still seen selling gutka pouches.<sup>[11,12]</sup> Some believe that only gutka pouches are banned, and it can be prepared mixing pan masala with tobacco.

Jammu and Kashmir Government banned chewable tobacco products in the state. Minister for Finance, Abdul Rahim Rather while presenting his 13<sup>th</sup> budget in the state Assembly said, “the use of products containing chewable tobacco is much more dangerous. Many deaths in very miserable circumstances are caused every year due to consumption of these products.”<sup>[13,14]</sup>

The Minister said, “to save the society from the dangerous consequences of use of chewable tobacco, I propose

to impose a total ban on import, manufacturing, transportation, stocking, and sale of chewable tobacco and products like pan masala, gutka, khanini, and other similar products which contain chewable tobacco as one of its ingredients.”

He further said with a view to discourage the hazardous habit of smoking; taxation has been used as a tool from time to time. “I have proposed to increase the existing rate of value-added tax (VAT) from 30% to 40% on raw tobacco and in the rates of VAT on cigarettes and other related products,” Mr. Rather added.<sup>[15]</sup>

Hence, the present study was conducted with the objective to assess the attitude and views of Jammu adult population toward the sale and consumption ban on ST and increases tax on other tobacco products.

## MATERIALS AND METHODS

A cross-sectional survey was carried out among the general population of Jammu city. A two-stage random sampling was employed. First, five wards were randomly selected from the list of 75 wards obtained from the Municipal Authority. In the second stage, one major market place was randomly selected in each of the five wards. The survey was conducted from the center place of the market in any one direction. General adult population was randomly invited to complete a 16-item questionnaire. Only those subjects aged >15 years, willing to participate and providing consent were included. The response rate was 70%.

A sample size of 384 was calculated based on 50% prevalence of ST use among Jammu and Kashmir state and 95% confidence interval with a standard error of 5%. Assuming lower response rate, a final study sample of 400 was included in the study.

The study was approved by the Institutional Ethics Committee of Indira Gandhi Government Dental College. The 18-item survey instrument was developed and pretested on similar study subjects, keeping the study objective in mind. Reliability testing (Cronbach's alpha 0.7), construct and face validity were eliminated two questions. Finally, the questionnaire consisted of 16 questions that covered demographic variables, tobacco use, and knowledge of existence of law, health warning, cost increase, and hazards related to ST. They were also asked about their attitude toward the sales ban of ST and gutka.

Respondents were classified as non-tobacco user, smoker, and current and past ST user. Non-tobacco users were

those who had never smoked or chewed tobacco or gutka in their lifetime. Smokers were those who had smoked more than 100 cigarettes in their lifetime and who still smoked daily or occasionally. Respondents consuming ST or gutka daily or occasionally were classified as the current ST user and who had quit ST or gutka for minimum of the past 6 months were considered as the past users.

The data collected were entered into Microsoft Excel and subjected to statistical analysis using SPSS version 16. Data compilation showed response to one item was missing in each of two current smokers. The value of these missing responses was calculated by taking the average of response for that particular item in that group. Descriptive statistics and analytical test like Chi-square test were used to compare the responses.

## RESULTS

A total of 400 subjects participated in this cross-sectional study. Among these, 88.25% of respondents were men ( $n = 353$ ). The mean age was 36.7 (standard deviation  $\pm 12.2$ ) years. 23.5% of sample was uneducated, 40.5% had education level of schooling, and remaining 36% were college graduate and professionals [Table 1].

Most of the tobacco users were consuming 2–5 packets of tobacco product (45.8%) per day. Heavy consumers of tobacco of more than 10 packets accounted for only 11% [Table 2]. About two-third of the past ST users (66.7%) have reported to have experienced some health effects during the tobacco use compared to only 28.4% of the

**Table 1: Descriptive profile of the study sample**

Variables	Current ST user <i>n</i> =215	Past ST user <i>n</i> =57	Never a tobacco user <i>n</i> =99	Tobacco user in smoke form <i>n</i> =29	Total <i>n</i> =400
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Gender					
Male	189 (87.9)	54 (94.7)	81 (81.8)	29 (100)	353 (88.2)
Female	26 (12.1)	3 (5.3)	18 (18.2)	0 (0)	47 (11.8)
Age (years)					
15–20	8 (3.7)	3 (5.3)	7 (7.2)	0 (0)	18 (4.5)
21–30	70 (32.5)	10 (17.5)	48 (48.2)	8 (27.5)	136 (34)
31–40	61 (28.5)	15 (26.3)	28 (28.2)	10 (34.5)	114 (28.5)
41–50	39 (18.1)	23 (40.4)	7 (7.2)	9 (31)	78 (19.5)
51 above	37 (17.2)	6 (10.5)	9 (9.2)	2 (7)	54 (13.5)
Educational qualification					
Uneducated	67 (31.2)	6 (10.5)	10 (10.1)	11 (38)	94 (23.5)
Schooling	84 (39.1)	21 (36.9)	45 (45.4)	12 (41.4)	162 (40.5)
College	40 (18.6)	19 (33.3)	19 (19.2)	5 (17.2)	83 (20.8)
Professional	24 (11.1)	11 (19.3)	25 (25.3)	1 (3.4)	61 (15.2)

ST: Smokeless tobacco

**Table 2: Tobacco consumption among the study sample**

Variables	Current ST user <i>n</i> =215	Past ST user <i>n</i> =57	Tobacco user in smoke form <i>n</i> =29	Total <i>n</i> =400
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Duration of the use of tobacco products (years)				
<2	34 (15.8)	13 (22.8)	5 (17.2)	52 (17.3)
2–5	64 (29.8)	6 (10.5)	7 (24.3)	77 (25.6)
5–10	66 (30.7)	21 (36.9)	9 (31)	96 (31.9)
>10	51 (23.7)	17 (29.8)	8 (27.5)	76 (25.2)
Daily tobacco consumption				
One packet or less	47 (21.9)	8 (14)	11 (38)	66 (21.9)
2–5 packets	98 (45.6)	29 (50.9)	11 (38)	138 (45.8)
5–10 packets	50 (23.2)	11 (19.3)	3 (10.3)	64 (21.3)
>10 packets	20 (9.3)	9 (15.8)	4 (13.7)	33 (11)
Experienced any health effect during tobacco use				
Yes	61 (28.4)	38 (66.7)	11 (38)	110 (36.5)
No	115 (53.5)	10 (17.5)	9 (31)	134 (44.5)
Do not know	39 (18.1)	9 (15.8)	9 (31)	57 (19)
Ever thought of quitting tobacco				
Yes	80 (37.2)	48 (84.2)	13 (44.8)	141 (46.8)
No	135 (62.8)	9 (15.8)	16 (55.2)	160 (53.2)

ST: Smokeless tobacco



current users. Among the current users, only 37.2% have ever thought about quitting the habit.

The responses of different group of tobacco users and non-users were compared [Table 3] and it was found that significantly more respondents (52.5–68.4%) were aware of health warning signs printed on the tobacco packet ( $P < 0.05$ ). The respondents believed that pictorial warning signs such as “Tobacco kills” and “Tobacco causes cancer” on tobacco product were significantly effective in reducing tobacco use.

In comparison to non-users, the current users (25.1%) and past users (40.4%) always had a feeling that there is too much increase in cost of tobacco product by the government. The current users of ST (46%) and smokers (58.6%) have sometimes similar feeling ( $P < 0.05$ ). The tobacco users and non-users also indicated that the reason for government imposing heavy taxes on tobacco product is to reduce consumption and sale (44.8–59.7%).

In response to question relating to awareness about ST sale ban in Jammu and Kashmir, only half of the current users (51.6%) reported to be aware compared to the past users (61.4%) and non-users (69.7%). These differences were statistically significant ( $P < 0.05$ ).

When asked about the reason for government to bring this ban on ST/gutka sale, majority of the tobacco users and non-users had the feeling that it was to improve their health (77.1–94%). The attitude toward effectiveness of tobacco sales ban in Jammu showed statistically significant results

[Table 4]. Significantly higher ST current users (52.1%) and past users (57.9%) responded that it would be only slightly effective ( $P < 0.05$ ).

To assess the trend in market sales of ST or gutka, the respondents were asked about their availability in the shops and whether sales in black market with the knowledge of authority have increased. Many current ST users (59.1%) reported that ST or gutka was easily available. However, some 22.3% also reported that they have sometimes difficulty in getting it ( $P < 0.05$ ). The past users of ST (54.4%) reported that there was increase in sale of ST or gutka in black market. However, majority of the current users (53%) did not like to comment on this.

A significantly positive attitude was found among ST past users (82.5%) and non-users (80.8%) compared to the current users (54.3%) toward bringing out similar sales and consumption ban on smoking ( $P < 0.05$ ).

## DISCUSSION

This study reports knowledge and attitudes toward ST ban and increased taxes on other tobacco products in a representative sample of the Jammu population, Jammu and Kashmir. In April 2012, Jammu and Kashmir has increased the VAT on tobacco, magnesium carbonate, and nicotine-based gutka products following provisions of the Food Safety and Standards (Prohibition and Restriction on sales) Regulation 2013.<sup>[7,15]</sup>

**Table 3: Comparison of responses about awareness on tobacco-related legislation among tobacco users and non-users**

Variables	Current ST user <i>n</i> =215	Past ST user <i>n</i> =57	Never a tobacco user <i>n</i> =99	Tobacco user in smoke form <i>n</i> =29	Chi-square test <i>P</i> value
Have you noticed any health hazard message on tobacco products?					
Yes	116 (54)	39 (68.4)	52 (52.5)	17 (58.6)	$\chi^2=47.86$ $P=0.00$ (S)
No	62 (28.8)	14 (24.6)	5 (5.1)	8 (27.6)	
Not aware	37 (17.2)	4 (7)	42 (42.4)	4 (13.8)	
Is pictorial warning “tobacco kills” or “tobacco causes cancer” on tobacco product effective?					
Definitely yes	18 (8.4)	22 (38.6)	21 (21.2)	2 (6.9)	$\chi^2=44.14$ $P=0.00$ (S)
Yes	99 (46)	20 (35.1)	29 (29.3)	12 (41.4)	
Do not know	65 (30.2)	7 (12.3)	35 (35.3)	8 (27.6)	
No	16 (7.4)	3 (5.2)	7 (7.1)	4 (13.8)	
Definitely no	17 (8)	5 (8.8)	7 (7.1)	3 (10.3)	
Have you ever felt that government is increasing the cost of tobacco product too much					
Always	54 (25.1)	23 (40.4)	11 (11.1)	8 (27.6)	$\chi^2=89.25$ $P=0.00$ (S)
Sometimes	99 (46)	21 (36.8)	17 (17.2)	17 (58.6)	
Do not know	11 (5.1)	6 (10.5)	5 (5.1)	0 (0)	
No	50 (23.3)	7 (12.3)	66 (66.6)	4 (13.8)	
Never	1 (0.5)	0 (0)	0 (0)	0 (0)	
Reasons that government in imposing heavy taxes on tobacco product					
Increase revenue	30 (13.9)	9 (15.8)	20 (20.2)	3 (10.3)	$\chi^2=18.91$ $P=0.02$ (S)
Reduce consumption	104 (48.4)	34 (59.7)	57 (57.6)	13 (44.8)	
Discourage addict	37 (17.2)	4 (7)	4 (4.0)	3 (10.3)	
Burden people	44 (20.5)	10 (17.5)	18 (18.2)	10 (34.6)	

(S): Statistically significant, ST: Smokeless tobacco

**Table 4: Comparison of responses about awareness and attitude toward ST-gutka ban among tobacco users and non-users**

Variables	Current ST user n=215	Past ST user n=57	Never a tobacco user n=99	Tobacco user in smoke form n=29	Chi-square test P value
Are you aware of sale and consumption of ST/gutka ban in your state					
Yes	111 (51.6)	35 (61.4)	69 (69.7)	17 (58.6)	$\chi^2=24.9$ P=0.00 (S)
No	55 (25.6)	20 (35.1)	11 (11.1)	9 (31.1)	
Do not know	49 (22.8)	2 (3.5)	19 (19.2)	3 (10.3)	
Reason for government to impose this ban on ST/gutka					
Improve health	173 (80.5)	44 (77.1)	93 (94)	24 (82.8)	$\chi^2=22.31$ P=0.008 (S)
Increase sale	24 (11.2)	3 (5.3)	0 (0)	2 (6.9)	
Reduce burden	4 (1.8)	3 (5.3)	4 (4.0)	1 (3.4)	
Tobacco company	14 (6.5)	7 (12.3)	2 (2.0)	2 (6.9)	
Do you think this complete ban on sale or consumption is effective					
Definitely effective	17 (7.9)	13 (22.8)	30 (30.3)	0 (0)	$\chi^2=51.6$ P=0.00 (S)
Slightly effective	112 (52.1)	33 (57.9)	34 (34.3)	14 (48.3)	
Cannot say	37 (17.2)	5 (8.8)	24 (24.3)	6 (20.7)	
Slightly ineffective	10 (4.7)	1 (1.7)	1 (1.0)	3 (10.3)	
Definitely ineffective	39 (18.1)	5 (8.8)	10 (10.1)	6 (20.7)	
Are you finding difficulty in getting ST/gutka products					
Very difficult	9 (4.2)	6 (10.5)	7 (7.1)	1 (3.4)	$\chi^2=100.7$ P=0.00 (S)
Sometimes difficult	48 (22.3)	11 (19.3)	4 (4.0)	6 (20.7)	
Cannot say	25 (11.6)	16 (28.1)	54 (54.5)	2 (6.9)	
Available	6 (2.8)	4 (7)	10 (10.1)	3 (10.3)	
Easily available	127 (59.1)	20 (35.1)	24 (24.3)	17 (58.7)	
Do you think sale of ST/gutka has increased in black market with or without the knowledge of authority					
Definitely yes	35 (16.3)	18 (31.6)	24 (24.2)	5 (17.2)	$\chi^2=22.2$ P=0.03 (S)
Yes	55 (25.6)	13 (22.8)	10 (10.1)	7 (24.2)	
Do not know	114 (53)	21 (36.8)	57 (57.6)	15 (51.7)	
No	6 (2.8)	2 (3.5)	6 (6.1)	2 (6.9)	
Definitely no	5 (2.3)	3 (5.3)	2 (2.0)	0 (0)	
Do you think that similar ban on sale and consumption should be applicable on smoking					
Definitely yes	30 (13.9)	22 (38.6)	38 (38.4)	2 (6.9)	$\chi^2=68.94$ P=0.00 (S)
Yes	87 (40.4)	25 (43.9)	42 (42.4)	8 (27.6)	
Do not know	81 (37.7)	8 (14)	18 (18.2)	11 (37.9)	
No	10 (4.7)	2 (3.5)	1 (1.0)	6 (20.7)	
Definitely no	7 (3.3)	0 (0)	0 (0)	2 (6.9)	

(S): Statistically significant, ST: Smokeless tobacco

According to GATS India,<sup>[3]</sup> there are an estimated 275 million tobacco users in India, of whom 25.9% are ST users, while 5.7% smoke cigarettes and 9.2% smoke beedis. The present study reports daily ST consumption of 2–5 packets in 45% of the current users. This finding is higher compared to the percentage of the current users (15 years and above) daily consumption of ST in Jammu and Kashmir (31.4%) as reported by GATS India 2009–2010.

The ST/gutka consumption is more among the uneducated (31.2%) and school educated (39.1%) compared to professionals (11.1%). Similar trends are reported by GATS India 2009–2010 concluding that the prevalence of tobacco use decreases with increase in education among both males and females.<sup>[3]</sup>

GATS India 2009–2010 reports considerable variation in quit attempts across states/UTs. For users of ST, it ranges from 8% in Delhi to 54% in Jammu and Kashmir. In the present study, higher intention to quit was seen among the past users (84.2%). This may be expected as they have

succeeded in their quit attempts and the current user would be underreporting the unsuccessful events.

Singh *et al.* reported that in Rajasthan, India, every 10% increase in price of cigarette, bidi, and chewing tobacco leads to 8.0%, 6.2%, and 3.3% reduced consumption of these products, respectively.<sup>[13]</sup> The highest price increase was observed with chewing tobacco much more than the cigarettes and this led to the highest reduction in consumption and sales of chewing tobacco.

Despite the wide publicity and media campaign, the awareness about ST-gutka sales and consumption ban in Jammu and Kashmir was significantly low among the current users (51.6%). This may be due to easy availability of their daily dose of tobacco product. Even though the ST-gutka products are not on display, it is sold to regular customers may be at a higher price.

The respondents believe that the reason for government to impose heavy taxes and sale ban on tobacco product is

to reduce consumption and improve health. Majority of users and non-users consider this sale and consumption ban in Jammu and Kashmir would be effective if not, very effective. Similarly, Singh *et al.* reported that ban on production of various tobacco products is the most effective method to reduce tobacco use. Proper education on ill effects of tobacco, legal action, and increasing the cost of tobacco products is other effective measures.<sup>[13]</sup>

The black marketing, false branding, and easy availability of these ST-gutka products have been a major concern. The study subjects report that even after the ban, gutka products are easily available to the regular customers and many do not face any difficulty in getting them. Shopkeepers have been displaying pouches of mouth fresheners and been selling gutka to known customers via illegal sales.<sup>[11,12]</sup>

On the other side, the ST association and gutka producers started a country-wide campaign promulgating the proposition that ban of gutka brought under Food Safety Regulation Act is not correct and it is an act of strong cigarette lobby.<sup>[10]</sup> The gutka should not be considered as a food product and banning it may hamper the lives of many areca nut farmers. Their contention is that cigarette contains more tobacco as well as cancer-causing substances when compared to gutka and pan masala.

The generalization of results of the present study should be done carefully as more current users of ST responded compared to the past users and non-users. This may be due to the method of sample selection. The study also oversamples males (88%) likely due to willingness of participation is more in males than females. However, the findings of this study provide an insight into the effectiveness of legislation and baseline for study including different populations on a larger scale.

## CONCLUSION

The positive attitudes of the people of Jammu region of Jammu and Kashmir indicate that the increase sale tax and consumption ban by the government are an

effective measure for improvement of health and reduce consumption. They demonstrate that the policy has been lagging behind to curb the black market sale or false branding of gutka products, although they also identify the need for greater public education to counter common misunderstandings.

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# Effect of Sildenafil in the Management of Grade 2 Diabetic Foot Ulcers: A Prospective Study

R C Thampan<sup>1</sup>, P P Dineshan<sup>2</sup>, P P Lakshmanan<sup>3</sup>

<sup>1</sup>Associate Professor, Department of General Surgery, Malabar Medical College and Research Centre, Kozhikode, Kerala, India, <sup>2</sup>Assistant Professor, Department of General Surgery, Malabar Medical College and Research Centre, Kozhikode, Kerala, India, <sup>3</sup>Professor and HOD, Department of General Surgery, Malabar Medical College and Research Centre, Kozhikode, Kerala, India

## Abstract

**Background:** Diabetes mellitus has become a global epidemic. Mortality and morbidity due to this is increasing in alarming proportion. The financial burden to society by this is markedly increasing every year.

**Materials and Methods:** This randomized control study included 72 patients of age group 44–75 (36 studies and 36 control groups). The study group is provided sildenafil 25 mg daily orally for 36 days. The phase of the healing process is compared in both groups.

**Results:** In the study group, all 36 patients showed complete healing in 22 days but in control group, only 6 patients had complete healing on 36 days and other 30 patients are at various stage of healing. The difference was obvious statistically.

**Conclusion:** Although the sildenafil is mainly used for erectile dysfunction syndrome and other medical conditions its role in the management of diabetic foot ulcer is commendable.

**Key words:** Diabetic foot ulcers, Sildenafil, Wound healing

## INTRODUCTION

Diabetic mellitus has become a global epidemic with 387 million people harboring this problem. In India, 65 million people live with diabetic mellitus in the age group of 20–74 years.<sup>[1]</sup> Diabetic foot ulcers (DFU) is one of the lethal complications of untreated patients which is gradually increasing in the Indian sub-continent.<sup>[2]</sup> In the global scenario, one limb being lost in every 20 s. 10–15% of diabetic patients develop DFU mainly due to neuropathy, foot deformity, and ischemia.<sup>[3]</sup>

Multiple organ involvement in DM increases the morbidity and mortality if the glycemic profile is not maintained to normal values. Atherosclerosis, peripheral neuropathy, ischemia, low immune status, and high blood sugar level

predisposes the lower limb especially foot to ulcerate. Negligence leads to many of DFU. According to Wagner classification, diabetic foot is graded according to the intensity of pathology (six grades).

- Grade-0 At risk foot
- Grade-1 Superficial ulcer, not clinically infected
- Grade-2 Deep ulcer, often infected no bone involvement
- Grade-3 Deep ulcer, abscess formation, bone involvement
- Grade-4 Localized gangrene (toe or forefoot)
- Grade-5 Gangrene of whole foot.

Management of diabetic foot involves local and systemic measures. It needs judicious use of antidiabetic drugs, antibiotics, vasodilators, statins, platelets agglutination inhibiting drugs, and surgical toilet. Topical application of platelet-derived growth factor and granulocyte macrophage-colony stimulatory factors (GM-CSF) were tried but with limited success.<sup>[4]</sup> Many novel approaches to DFU are advocated in this decade such as bioengineered skin and tissue equivalent, negative pressure therapy,<sup>[5]</sup> hyperbaric oxygen therapy,<sup>[6-10]</sup> electrical stimulation,<sup>[11]</sup> ultrasound therapy,<sup>[12]</sup> and stem cell therapy<sup>[13]</sup> but the results are highly variable.

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**Corresponding Author:** Dr. R C Thampan, Associate Professor, Department of General Surgery, Malabar Medical College and Research Centre, Kozhikode, Kerala, India.



Proper meticulous cleaning of ulcer floor with copious flow of normal saline after desloughing is very important so as protection of the wound from environmental contamination. Sildenafil a phosphodiesterase inhibitors used widely for erectile dysfunction syndrome and pulmonary hypertension.<sup>[14]</sup> It dilates the vasculature by preventing the inactivation of cyclic guanosine monophosphate (GMP). Accumulation of cyclic GMP produces good vasodilation. Sildenafil is contraindicated in patients on vasodilators for coronary artery disease as this may lead to alarming hypotension.<sup>[15]</sup> Toxicity of this drug may be enhanced by taking drug such as macrolide antibiotics, imidazole, statins, and antiretroviral agents.

The principle behind the rationale is its vasodilator effect; hence, ulcer bed gets more blood and healing will be faster. Its effect on endothelium is reported by few authors prompted us to conduct this study.<sup>[16]</sup> All patient in the study group is given 25 mg of sildenafil for 36 days (study period).

## MATERIALS AND METHODS

A total of 72 patients were selected for this study [Table 1]. The study period was from 2013 to 2015 from a single institution. Patients were divided into two groups of 36 – one being the study group and other the control group. All the patients were given routine management including desloughing, antibiotics according to the culture study, rapid insulin (soluble), B complex factors and good nutrition.

### Selection Criteria

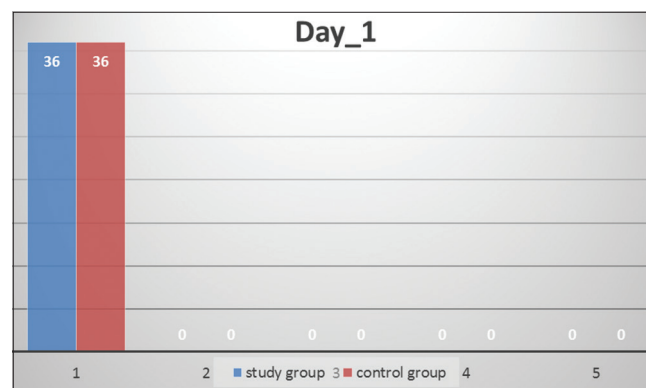
- Age group 45–70 years.
- Patient with severe coronary artery disease, chronic renal disease, and peripheral vascular disease with severe ischemia was excluded from the study.
- Diabetic foot with only Grade II is selected for the study.

Patients history, clinical examination with sex and age, duration of disease, treatment taken in the past, vascular and neurological factors, and disabilities are recorded. The average measurement of ulcer is done at the beginning of the study and is made into three categories of ulcer 10 cm<sup>2</sup>, 7 cm<sup>2</sup>, and 5 cm<sup>2</sup>, respectively. All the ulcers cleaned with normal saline irrigation and measurement is taken by tracing the outline on the butter paper and is transferred on graph paper. Figure 1 depicts first day of study. The procedure was done on beginning 8<sup>th</sup>, 15<sup>th</sup>, 22<sup>nd</sup>, 29<sup>th</sup>, and 36<sup>th</sup> days, respectively. Reduction in serous discharge and rate of granulation tissue presence and reduction in ulcer margin was meticulously recorded on the 8<sup>th</sup> day of the study. 20 (55.5%) case showed pale granulation tissue 14 (38.8%)

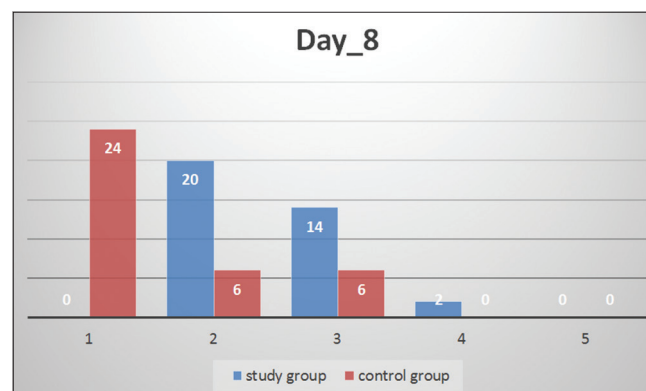
good granulation tissue and 2 (5.5%) case partially healed, whereas in control group 24 (66.6%) cases showed no change in ulcer floor 6 (16.6%) cases showed pale granulation tissue and another 6 (17%) showed good granulation tissue [Figure 2]. Even after 8 days, the improvement in the study group is remarkable. On the 15<sup>th</sup> day, 14 (38.8%) cases with pale granulation tissue and 16 (44.4%) cases with good granulation tissue and 2 (5.5%) cases completely healed in the study group whereas in control group 8 (22.2%) cases showed no change, 16 (44.4%) case with pale granulation tissue, 10 (27.7%) cases with good granulation tissue, and 2 (5.5%) cases partially healed [Figure 3]. After 3 weeks (on day 21) study group showed all 36 (100%) cases completely healed, whereas in control group 10 (27.7%) cases showed pale granulation tissue, 20 (55.5%) cases good granulation tissue, 2 (5.5%) cases partially healed, and 4 (11%) cases completely healed [Figure 4]. On the 29<sup>th</sup> day, control

**Table 1: Distribution of cases according to age and sex**

Age group	Male (%) n-40	Female (%) n-32	Total n-72
44–55	8 (20)	6 (18.75)	14 (19.4)
56–65	14 (35)	14 (43.75)	28 (38.8)
66–75	18 (45)	12 (37.5)	30 (41.6)
Total	40	32	72



**Figure 1: Bar diagram Day 1**



**Figure 2: Bar diagram showing result on Day 8**



group showed 8 (22.2%) case with pale granulation tissue, 12 (33.3%) cases with good granulation tissue, 10 (27.7%) with partial healing, and 6 (16.6%) cases with complete heal [Figure 5].

At the end of evaluation (36<sup>th</sup> day) control group showed 14 (38.8%) cases completely healed whereas 14 (38.8%) cases were healed 8 (22.2%) cases having only good granulation tissue [Figure 6]. The difference was found to be statistically significant [Table 2].

## DISCUSSION

Diabetic mellitus is a systemic disease involving all organs in the human body leading to a grave situation if the glycemic profile is not controlled properly. The morbidity related to a complication of diabetes mellitus (DM) in gradually increasing in urban, semi-urban, and rural population during the past few decades according to the studies done in the past by many authorities. DFU is one of the most common surgical complications of DM in the surgical outpatient department in our hospital.

In DFU healing is by secondary intention by granulation, contraction, and epithelialization. There is increased

inflammation and proliferation.<sup>[17]</sup> Prolonged inflammatory phase leads to overgrowth of tissue and heals by scarring. Here, the role of fibroblasts, platelets-derived growth factor, GM-CSF, insulin-like growth factors, transforming growth factors (TGF)- $\beta$ , and TGF- $\alpha$  is highly involved.

In the management of diabetic wound, two things are very important. It includes providing more blood to the affected area and wound care. Here, the blood supply to the lower limb is highly compromised due to progressing atherosclerosis. Our aim is to enhance the perfusion in the affected part so that the concerned growth factor and other anti-inflammatory

**Table 2: comparative analysis of study and control groups**

Duration	Outcome of patient analysis									
	Study group					control group				
Days	1	2	3	4	5	1	2	3	4	5
1	36	0	0	0	0	36	0	0	0	0
8	0	20	14	2	0	24	6	6	0	0
15	0	14	16	4	2	8	16	10	2	0
22	0	0	0	0	36	0	10	20	2	4
29	0	0	0	0	0	0	8	12	10	6
36	0	0	0	0	0	0	0	8	14	14

1. Granulation tissue absent, 2. Granulation tissue pale, 3. Granulation tissue good, 4. Partially healed, 5. Completely healed

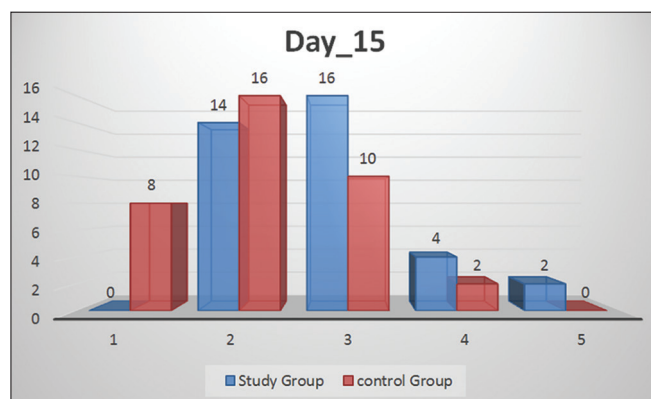


Figure 3: Bar diagram showing result on Day 15

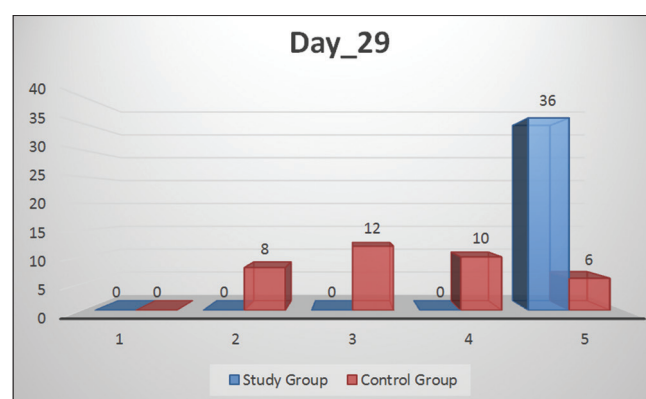


Figure 5: Bar diagram showing result on Day 29

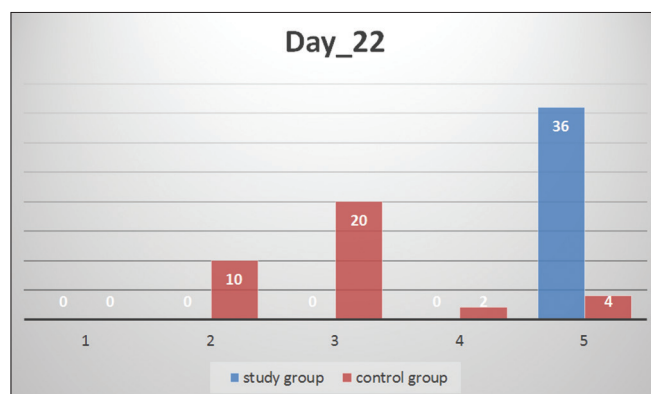


Figure 4: Bar diagram showing result on Day 22

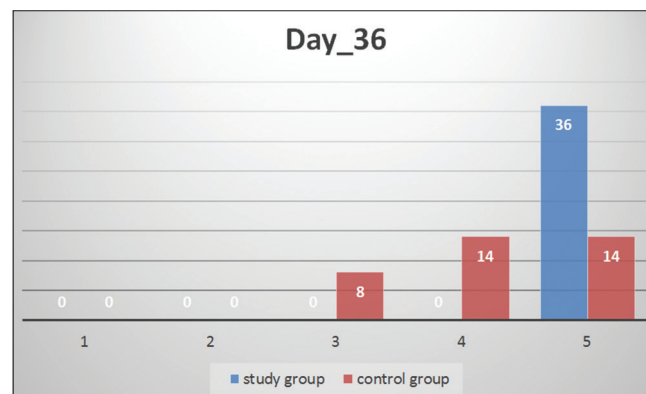


Figure 6: Bar diagram showing result on Day 36

mediators reach the wound site. Blood supply can be enhanced by many modalities such as dilating the lumen of arteries and decreasing the viscosity of blood, increase microcirculation, increase the flexibility of RBC; hence, it can go through the capillaries to provide more oxygen to the tissue. Drugs such as pentoxifylline (trental) and cilostazol are used for dilating the vessels aspirin used to prevent clumping of platelet, statins to control the atherogenesis.

In our study, sildenafil was given 25 mg/day for 36 days. It is a potent vasodilator. The study report is encouraging. Healing is very fast compared to the control group. Hence, apart from good wound care, providing more blood supply to the wound site is very important.

## CONCLUSION

Meticulous wound care with supplementation of sildenafil in DFU Grade II makes the wound reduction rate faster in comparison with wound care alone. The role of this phosphodiesterase inhibitors in the DFU management will be a boon to the diabetic patient. Our study is only limited to a small number of the patient; hence, study involving a large segment of the population with sildenafil is essential for further evaluation.

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# Prospective Analysis of Quality of Life in Patients with Inoperable Esophageal Carcinoma with Definitive Concurrent Chemoradiotherapy – A Single-center Study

K V S Latha<sup>1</sup>, T S Rahul<sup>2</sup>, Shehna A Khader<sup>3</sup>

<sup>1</sup>Assistant Professor, Department of Medical Oncology, Madras Medical College, Chennai, Tamil Nadu, India, <sup>2</sup>Senior Resident, Department of Medical Oncology, Madras Medical College, Chennai, Tamil Nadu, India, <sup>3</sup>Assistant Professor, Department of Radiation Oncology, Government Medical College, Thrissur, Kerala, India

## Abstract

**Introduction:** Cancer of the esophagus is a fatal disease and ranked the 6<sup>th</sup> most common cause of cancer-related death worldwide. Treatment for esophageal carcinoma is characterized as curative or palliative. Data from different studies show only 20% of patients present with cancer of the esophagus that is truly localized to the esophagus, indicating that at the time of diagnosis, approximately 80% of patients have either locally advanced or distant disease.

**Aim:** This study aims to study the clinical assessment of quality of life (QOL) before, during, and after treatment of concurrent chemoradiotherapy in inoperable esophageal cancers.

**Materials and Methods:** A single-arm prospective study of patients undergoing definitive chemoradiation treatment for locally advanced esophageal carcinoma was included in the study. All patients will have to undergo QOL assessment by the European Organisation for Research and Treatment of Cancer questionnaire before, during, and after treatment.

**Results:** A total of 40 patients were included in the study. Among the functional scales, emotional functioning, cognitive functioning, role functioning, physical functioning, and anxiety show a significant positive mean difference. This indicates a healthy level of functioning after treatment.

**Conclusion:** Definitive concurrent chemoradiation with cisplatin and 5-fluorouracil (FU) was well tolerated, promising a reasonable therapeutic option for patients with inoperable locally advanced esophageal squamous cell carcinoma.

**Key words:** Chemoradiotherapy, Esophageal cancer, Quality of life

## INTRODUCTION

Cancer of the esophagus is a highly lethal malignancy which is the 6<sup>th</sup> most common cause of cancer deaths worldwide and is more common in men than women.<sup>[1]</sup> It is an endemic in many parts of the world, particularly in the developing nations, where it is the 4<sup>th</sup> most common cause of cancer-related deaths.<sup>[1]</sup> In 2015, an estimated

16,980 people will be diagnosed with esophageal cancer and 15,590 people will eventually die of their disease in the United States.<sup>[2]</sup> High prevalence areas include Asia, Southern and Eastern Africa, and Northern France.<sup>[3]</sup>

According to the data from the US Surveillance, Epidemiology, and End Results Program, the 5-year survival for all patients with esophageal cancer improved only modestly over the past 30 years, from 5% in the years 1975–1977 to 19% during the period of 2001–2007.<sup>[2]</sup> These sobering figures were indicative of the advanced stage of disease (local-regional or metastatic) at diagnosis in most patients.<sup>[3]</sup>

The management of local-regional esophageal cancer has undergone a major evolution over the past 25 years.

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**Corresponding Author:** Dr. K V S Latha, Department of Medical Oncology, Madras Medical College, Chennai, Tamil Nadu, India.

The low cure rates after locoregional therapy alone prompted the inclusion of systemic chemotherapy (CRT) in multimodality treatment approaches, to control distant micrometastatic disease and enhance local radiation effects. The seminal Radiation Therapy Oncology Group (RTOG) 85-01 randomized controlled trial demonstrated a survival benefit for the addition of cisplatin-based CRT to radiation therapy in non-surgically treated patients.<sup>[4,5]</sup> Less than one-third of all patients were cured by multimodality therapy, and distant failure accounts for three-fourths of all recurrences.<sup>[6]</sup>

Despite many advances in both surgery and radiotherapy, the treatment of esophageal cancer remains a challenge for both surgeons and clinical oncologists. The biggest problems affecting patient outcomes are late presentation, as most symptomatic patients present with advanced disease and the lack of an effective screening program. Only a minority of patients is suitable for curative treatment, and 5-year survival for all patients remains poor at just 13% and surgical series report survival of 20%. This overview examines the role of definitive chemoradiotherapy (dCRT) in localized esophageal cancer.<sup>[5]</sup>

For patients with early localized and resectable disease, surgery, with or without neoadjuvant CRT, remains widely regarded as the gold standard treatment option, leaving dCRT as an alternative for those patients unsuitable for surgery due to medical comorbidities and extent of locoregional disease.<sup>[5-7]</sup> With the emergence of improved radiotherapy techniques with lower rates of morbidity, together with the development of more effective and targeted systemic therapy, the trend toward treating more patients with organ-preserving dCRT or as part of trimodality treatment is likely.

### Aim

This study aims to study the clinical assessment of quality of life (QOL) before, during, and after treatment of concurrent chemoradiotherapy in inoperable esophageal cancers.

## MATERIALS AND METHODS

A single-arm prospective study of patients undergoes definitive chemoradiation treatment for locally advanced esophageal carcinoma at the department of radiotherapy and oncology in a tertiary care hospital.

### Inclusion Criteria

The following criteria were included in the study:

1. Histologically confirmed, potentially unresectable squamous cell carcinoma of the esophagus.
2. Tumors of clinical stage T4N0 or T4 N1-3.
3. Inoperable or locoregionally advanced disease.
4. Age group 30–70 years.
5. Both male and female.
6. WBC count >4000 cells/mL.
7. Platelet count of >100,000 platelets/mL.
8. Serum creatinine <1.5 mg/dL.
9. Creatinine clearance >80 mL/min.

### Exclusion Criteria

The following criteria were excluded from the study:

1. Histology other than squamous cell carcinoma.
2. Operable carcinoma esophagus.
3. Presence of tracheoesophageal fistula.
4. Age >70 years.
5. WBC count <4000 cells/mL.
6. Platelet count <100,000 platelets/mL.
7. Creatinine clearance <80 mL/min.

### Initial Assessment

Staging including contrast-enhanced computed tomography scan of thorax, abdomen, and upper gastrointestinal (GI) endoscopy and biopsy for histological confirmation will be done along with routine blood examinations. All patients will have to sign informed consent forms. All patients will have to undergo QOL assessment by the European Organisation for Research and Treatment of Cancer (EORTC) questionnaire before, during, and after treatment.

### Radiotherapy

All patients will be irradiated by external beam radiation with megavoltage beams on telecobalt machine with a total dose of 50.4 Gy given in 28 fractions of 1.8 Gy per fraction, five fractions per week, starting the 1<sup>st</sup> day of the first cycle of CRT. The gross tumor volume (GTV) is defined by the primary tumor and any enlarged regional lymph node and will be drawn on each relevant CT slice. The GTV will be determined using all available information (physical examination, endoscopy, and CT thorax/abdomen). The planning target volume will provide a proximal and distal margin of 5 cm. A 2 cm radial margin around the GTV will be provided to include the area of subclinical involvement around the GTV and to compensate for tumor motion and set-up variations.

### CRT

5 fluorouracil (FU) (1000 mg/m<sup>2</sup>) × 4 days and cisplatin (75 mg/m<sup>2</sup>) will be given by intravenous infusion on weeks 1, 5, 8, and 11. All patients receiving cisplatin must be hydrated before, during, and post-drug administration. Usual approach is to give at least 1 l before and 1 l post-drug treatment of 0.9% sodium chloride. Mannitol diuresis may be used after hydration. They will also receive



premedication ½ h before the start of the cisplatin infusion. Standard antiemetic prophylaxis of 3 mg of granisetron and 16 mg of dexamethasone and 50 mg of ranitidine will be given as intravenous bolus as pre-medication. Antiemetic prophylaxis will be continued with granisetron orally 3 days after each cycle of CRT.

### Evaluation of Patients during Treatment

The regimen will be administered on an outpatient basis. During irradiation, all patients were scored weekly during the course of CRT for early toxicity skin reaction, GI toxicity, and neutropenia using the RTOG/EORTC acute radiation morbidity scoring scheme. Clinical examination, complete blood picture, and liver and kidney function tests were done before each cycle.

**Table 1: Comparison of EORTC QOL before and after treatment**

Dimensions	Mean±standard deviation of score			Z-value	P value
	Before	During	After		
Eating	11.6±1.97	13.08±1.53	8.92±1.63	5.263**	<0.001
Reflux	3.28±1.65	3.95±1.96	3.16±1.35	1.645 <sup>ns</sup>	0.100
Pain	5.73±2.23	8.49±2.35	3.84±0.89	4.416**	<0.001
Trouble swallowing saliva	1.88±0.69	2.62±0.78	1.26±0.45	4.234**	<0.001
Chalked when swallowing	1.7±0.88	1.9±0.94	1.18±0.39	3.275**	0.001
Dry mouth	1.3±0.46	1.74±0.59	1.26±0.45	1.000 <sup>ns</sup>	0.317
Trouble with taste	1.65±0.66	2.64±0.78	1.29±0.46	3.153**	0.002
Trouble with coughing	1.55±0.71	2.31±1	1.39±0.5	2.646**	0.008
Trouble with talking	1.1±0.3	1.62±0.67	1.08±0.27	1.000 <sup>ns</sup>	0.317
Dysphagia	9.25±1.43	7.36±1.4	12.53±16.5	3.329**	0.001

\*\*: Significant at 0.01 level, \*: Significant at 0.05 level, ns: Non-significant at 0.05 level. QOL: Quality of life, EORTC: European Organisation for Research and Treatment of Cancer

### Follow-up

The patients will require to follow-up at 6 weeks from completion of therapy to assess response, toxicity, and disease status. Subsequent follow-up visits will be scheduled at 3 monthly. At follow-up, patients will undergo thorough clinical examination for detection of locoregional disease. Patients who drop out or do not complete planned course of treatment will be excluded.

## RESULTS

The median age of the study population was 58.2 years that range from 45 to 70 years. Majority of the population were between 51 and 60 years. 8 of 38, 20% were female and 32 patients were male (80%). 26 patients (65%) were using both alcohol and smoking, 7 patients (17.5%) smoking only, and 4 patients (10%) were addicted to smoking, alcohol, and pan chewing.

Five patients (12.5%) had upper one-third of esophagus, as primary site of disease, 13 patients (32.5%) had lower one-third and majority of patients being affected at middle one-third as primary site (55%).

Seven patients had T<sub>2</sub> tumor, 25 patients had T<sub>3</sub> tumor, and eight patients being affected as T<sub>4</sub>. 19 patients with N<sub>1</sub>, 18 patients with N<sub>2</sub>, and 3 patients had N<sub>3</sub> nodal involvement of the disease [Figure 1].

Stage wise, 40% of the patients were Stage 3A and only 10% were Stage 2B. Stage 3B and Stage 3C constitute 25% each of the total number of the patients [Figure 2].

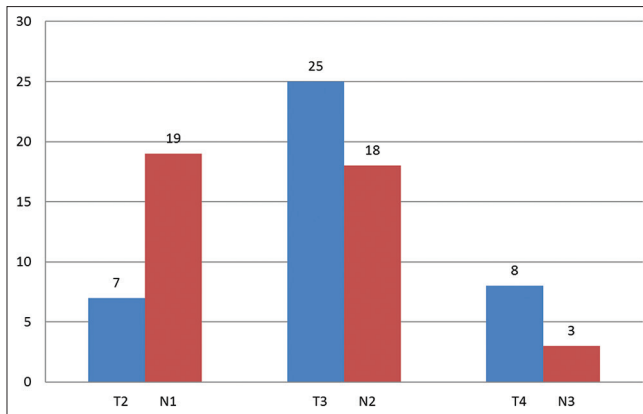
Neutropenia was absent for 40% of the total population, Grade 1 for 12 (30%) patients, Grade 2 for 6 (15%), Grade 3 for 5 (12.5%), and Grade 4 for one patient [Figure 3].

**Table 2: Comparison of QLQ before and after treatment**

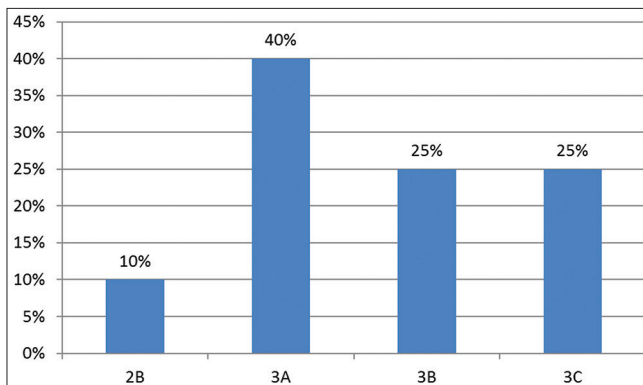
Dimensions	Mean±standard deviation of score			Z-value	P value
	Before	During	After		
Global health status	7±1.34	5.33±1.2	8.18±2.4	4.043**	<0.001
Physical functioning	9.85±1.56	11.51±1.54	9±2.11	4.134**	<0.001
Role functioning	5.45±1.13	6.23±1.11	5.26±1.22	2.041*	0.041
Emotional functioning	8.78±1.8	9.38±1.93	8.29±1.49	3.305**	0.001
Cognitive functioning	4.98±1.53	5.31±1.51	4.47±1.2	4.185**	<0.001
Social functioning	4.55±1.15	5.33±0.93	4.18±1.01	3.578**	<0.001
Fatigue	7.45±1.58	8.31±1.51	6.68±1.44	4.604**	<0.001
Nausea and vomiting	4.58±1.62	5.79±1.2	3.74±1.01	4.647**	<0.001
Pain	5.45±1.01	6.15±0.93	4.08±0.88	4.959**	<0.001
Dyspnea	1.85±0.74	2.38±0.85	1.76±0.71	2.000*	0.046
Insomnia	2.4±0.59	2.82±0.6	1.74±0.5	4.327**	<0.001
Appetite loss	2.48±0.6	2.79±0.8	1.58±0.55	5.014**	<0.001
Constipation	1.63±0.71	1.69±0.69	1.39±0.55	2.324*	0.02
Diarrhea	1.4±0.5	2.49±0.85	1.34±0.48	0.535 <sup>ns</sup>	0.593
Financial difficulties	1.68±0.62	2.62±0.78	1.53±0.56	1.508 <sup>ns</sup>	0.132

\*\*: Significant at 0.01 level, \*: Significant at 0.05 level, ns: Non-significant at 0.05 level. QOL: Quality of life





**Figure 1: Computed tomography tumor, node, and metastasis**



**Figure 2: Computed tomography stage**

Disease progression was seen in 14 patients (35%) of the total population that include death during the time of treatment and during follow-up. Disease progression was absent in 26 patients until the last follow-up [Figure 4].

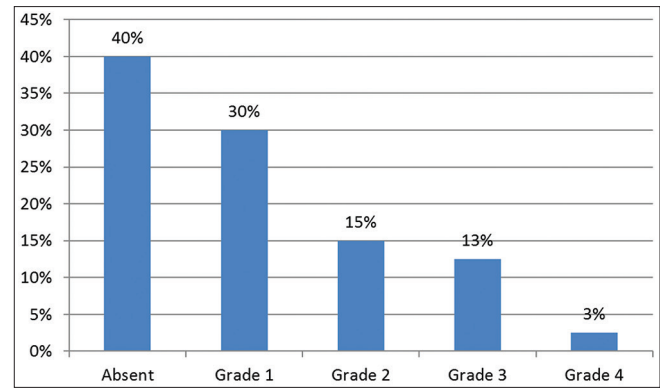
Among the functional scales, emotional functioning, cognitive functioning, role functioning, physical functioning, and anxiety show a significant positive mean difference. This indicates a healthy level of functioning after treatment.

Considering the symptom scale scores, except for financial difficulties and diarrhea, other symptoms show a significant mean difference.

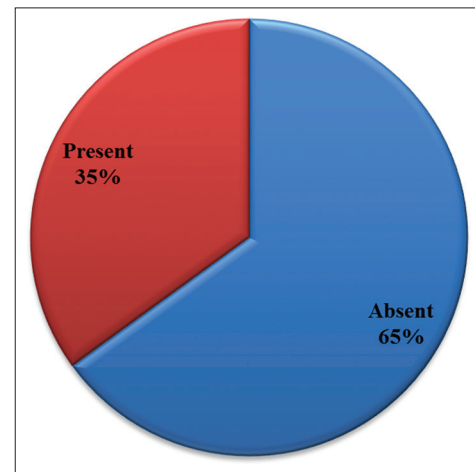
All other symptoms decreased after radiation, of which pain, trouble swallowing saliva, chalked when swallowing, trouble with coughing, trouble with talking, and dysphagia show a significant reduction. Global health score also shows a significant improvement after definitive concurrent chemoradiation [Tables 1 and 2].

## DISCUSSION

Esophageal cancer is usually associated with a poor prognosis due to a high local recurrence rate or distant



**Figure 3: Neutropenia grade**



**Figure 4: Disease progression**

metastasis.<sup>[8]</sup> Although surgery alone or chemoradiotherapy has been widely accepted as the standard treatment for esophageal cancer, the 5-year survival rate is only 20–30%.<sup>[9,10]</sup> The most efficient treatment remains uncertain as there are only a few clinical trials that have compared chemoradiotherapy and esophagectomy.<sup>[11,12]</sup> It is well known that radiotherapy can cause numerous complications including radiation esophagitis, radiation pneumonitis, and anorexia.<sup>[13,14]</sup> During radiotherapy, dysphagia of patients may become aggravated due to radiation edema of the esophagus, which induces a feeding disturbance. Patients who have undergone esophagectomy also suffer from continual problems associated with the function domains and specific symptoms. Particular studies have indicated that surgery also has an effect on the QOL.<sup>[15,16]</sup> QOL is one of the important factors for patients choosing to undergo therapy, particularly for older patients. Therefore, it is important to determine the variation in QOL for different treatments, and investigation of the factors that affect the QOL is necessary to provide a reference for clinicians to improve the QOL for patients. Since the 1990s, the potential contribution of the QOL for cancer therapy evaluation has gained increasing recognition. QOL assessment has been used to identify the optimal

therapy, estimate the efficiency of drugs and as one type of indicator for the prognosis of cancer.

QOL assessment using EORTC guidelines showed decrease in symptoms after completion of definitive chemoradiotherapy, even though there was an apparent increase in symptoms for the patients during the time of concurrent chemoradiation. Among the functional scales, emotional functioning, cognitive functioning, role functioning, physical functioning, and anxiety showed a significant positive mean difference. That indicates a healthy level of functioning after treatment and all other symptoms decreased after radiation, of which pain, trouble swallowing saliva, chalked when swallowing, trouble with coughing, trouble with talking, and dysphagia showed a significant reduction. Global health score also shows a significant improvement after definitive concurrent chemoradiation. All these findings were statistically significant, providing a clear advantage of concurrent chemoradiation in inoperable esophageal carcinomas.

## CONCLUSION

Definitive concurrent chemoradiation with cisplatin and 5-FU was well tolerated, promising a reasonable therapeutic option for patients with inoperable locally advanced esophageal squamous cell carcinoma. QOL assessment using EORTC guidelines showed decrease in symptoms after completion of concurrent chemoradiotherapy, even though there was an apparent increase in symptoms for the patients during radiotherapy.

Further studies with larger sample size are required to confirm the effect of definitive concurrent chemoradiation on QOL in inoperable disease status of carcinoma esophagus. The need of adjuvant treatment in reducing the progression of locally advanced disease should be evaluated. Carefully designed randomized clinical trials with more number of patients would be the answer to these issues.

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# Epidemiological Profile of Hospital-acquired Infection in a Tertiary Care Hospital of Eastern India

Rupali Dey<sup>1</sup>, Sayoni Datta<sup>2</sup>

<sup>1</sup>Associate Professor and Nodal Person Culture and Drug Sensitivity Test, Department of Microbiology, Burdwan Medical College, Burdwan, West Bengal, India, <sup>2</sup>Specialist Medical Officer, Department of Microbiology, Asansol District Hospital, Asansol, West Bengal, India

## Abstract

**Introduction:** "Hospital-acquired infection (HAI)" can be defined as an infection acquired in hospital by a patient who was admitted for a reason other than that infection.

**Purpose:** This study was done to observe the incidence of HAI (with bacteriological profile and their antibiotic susceptibility pattern) in the Orthopaedics Ward of Bankura Sammilani Medical College.

**Materials and Methods:** A total of 2062 patients admitted for more than 48 h were studied for 1 year for the detection of the development of any of the HAI during hospitalization. On suspicion of the development of an HAI, representative samples for the diagnosis of a site-specific HAI were collected, processed, and interpreted. A total of 158 patients admitted for more than 48 h showing clinical features of any one of the HAIs were selected for sampling.

**Results:** From the 158 samples collected during the study period, samples from 92 patients were positive in bacteriological culture.

**Conclusion:** The study attempts to understand the epidemiological profile of HAI in this tertiary care hospital in a non-urban region of eastern India to take necessary infection control measures.

**Key words:** Bacterial infections, Epidemiological profile, Hospital-acquired infections, Infection control, Methicillin-resistant *Staphylococcus aureus*

## INTRODUCTION

Hospital-acquired infection (HAI) or healthcare-associated infection or nosocomial infection refers to infection occurring in a patient in a hospital or other health-care facility in whom the infection was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge and also occupational infections among staff of the facility.<sup>[1]</sup>

These infections occur worldwide and affect both developed and developing countries pose a constant threat to patients and their families by causing illness, prolonged hospital stay, potential disability, excess costs, and sometimes death.<sup>[2,3]</sup>

In 2008, Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) published a document providing the terms and definition of infections acquired in the hospital. Urinary tract infections (UTIs) are the most common type of HAI reported to the NHSN.<sup>[4]</sup>

Infections can be of exogenous (which are acquired from the hosts' environment) or endogenous (when commensal flora from the hosts' own skin or mucous membrane originate transferred to another site and infect the same patient). The most common HAIs are UTI, surgical site infection (SSI), respiratory tract infection, and bloodstream infections.<sup>[5]</sup>

HAIs are a major global safety concern for both patients and health-care professionals.<sup>[6]</sup> In addition to increased morbidity and mortality, these HAIs contribute significantly to the financial burden borne by patients, their families, and the health-care system. The increasing occurrence of HAI with antibiotic-resistant bacteria makes the situation more complicated.

This study has been conducted at Bankura Sammilani Medical College serving the people of Bankura and adjacent districts of West Bengal. There is lack of proper

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**Corresponding Author:** Dr. Sayoni Datta, Mohini Apartment, BI-A, FI-B2, H/I-36, S. L. Sarani, Baguiati, Kolkata - 700 159, West Bengal, India.

epidemiological and microbiological data regarding HAI cases for this region. This study was conducted to study the occurrence of HAI (with bacteriological profile and susceptibility pattern) caused by pathogenic bacteria, which would be helpful for infection control measures.

## MATERIALS AND METHODS

This study was conducted in the Department of Orthopaedics and Department of Microbiology of Bankura Sammilani Medical College, from February 1, 2015, to January 31, 2016, after receiving approval from the ethical committee of Bankura Sammilani Medical College. A total of 2062 patients were admitted for more than 48 h in the male and female orthopedics ward during this period. These 2062 patients were followed up clinically for the detection of the development of any of the HAI during hospitalization until they were discharged. On suspicion of the development of an HAI, representative samples for the diagnosis of a site-specific HAI were collected, processed, and interpreted as per standard guidelines.<sup>[7]</sup>

A total of 158 patients, admitted for more than 48 h, who showed one or more symptoms and signs of any one of the HAIs – as per CDC guidelines<sup>[4]</sup> were selected for sampling. A pro forma designed for the study was used for data collection. A written informed consent was taken from each patient before collecting the samples.

A simplified diagnostic criterion for HAI by Mukherjee *et al.*<sup>[8]</sup> was used for categorizing the cases, which was as follows:

Hospital-acquired infections	Clinical features	Laboratory features
Urinary tract infection	Fever Lower abdominal pain Change in urinary characteristics	Leukocytosis Positive urine culture (10 <sup>5</sup> CFU/mL of urine)
Pneumonia/LRTI	Fever Pleuritic chest pain Decreased intensity of breath sounds Presence or increase in rales	Leukocytosis Sputum for Gram stain Positive sputum culture Positive chest X-ray
Bloodstream infection	Unexplained fever with chills and rigor Pain, tenderness, or purulent discharge at the site of insertion of I.V. access or CVP catheter	Leukocytosis Positive blood culture
Surgical site infection/skin and soft tissue infections	Pain, swelling, tenderness or inflammation, and warmth of skin Purulent drainage from skin Fever	Smear for gram stain Positive swab culture Leukocytosis

CFU: Colony-forming units

The samples collected from the department of orthopedics were labeled and transferred immediately to the laboratory of the department of microbiology for bacteriological examination. Urine, pus/wound swab, sputum, and blood were collected for suspected hospital-acquired UTI, SSI, hospital-acquired pneumonia, and bloodstream infections, respectively. Clean-voided midstream urine sample was collected in sterile, screw cap container with patient's identification number mentioned on it, by the clean-catch technique. In catheterized patients, samples were collected by aspiration in a sterile, screw cap container, after disinfection of catheter collection port. Pus/wound swabs were collected from patients who had developed post-operative wound infection with purulent discharge and clinically diagnosed as post-operative sepsis. Purulent materials were collected on sterile commercial cotton swabs aseptically and gently, before redressing and administration of antibiotic therapy. For superficial wounds, two swabs were taken, one for the preparation of a smear for microscopy and the other for the seeding of cultures. For deep wounds, the material was aspirated from the wall with a sterile syringe. Sputum was collected before any antibiotic therapy in a sterile, wide mouth plastic container with tightly fitted screw cap with laboratory number mentioned on it was given to the patient. Patient was instructed how to open and close the container and also on the proper collection of the sputum. Blood sample for culture was drawn before the use of systemic antibiotics, from two different venipuncture sites from the right and left arms. A blood volume of 10 mL was injected into each of two BacT/ALERT 3D blood culture bottles. All blood samples were inoculated into aerobic BacT/ALERT 3D bottles and sent to microbiology laboratory.

The samples were inoculated without delay. The culture media used were MacConkey agar (HiMedia, Mumbai), blood agar, and chocolate agar (for sputum samples). Identification of bacterial isolates grown was done by conventional biochemical tests for identification.<sup>[9]</sup>

For those patients who had a positive culture report, repeat culture was made every week till discharge for evidence of any new infection. Those patients who had same isolate with the same antibiotic susceptibility pattern were reported to have a single episode of infection. Antimicrobial susceptibility testing of the bacterial isolates was done on Mueller-Hinton agar (HiMedia Laboratories Pvt. Ltd., Mumbai, India) by disk diffusion technique using Kirby-Bauer's method<sup>[10]</sup> as per Clinical Laboratory Standards Institute guidelines.<sup>[11]</sup>

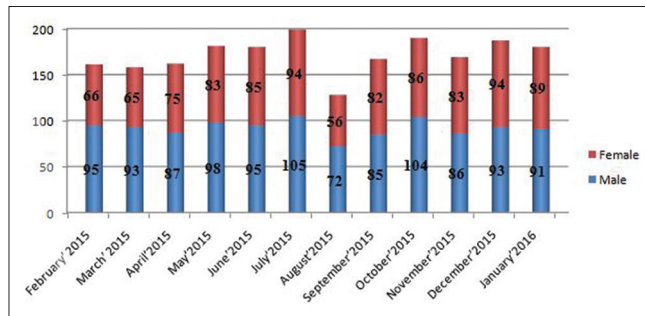
All the collected data from the study was compiled, analyzed, and finally interpreted statistically using the SPSS Statistics 19.0 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.).



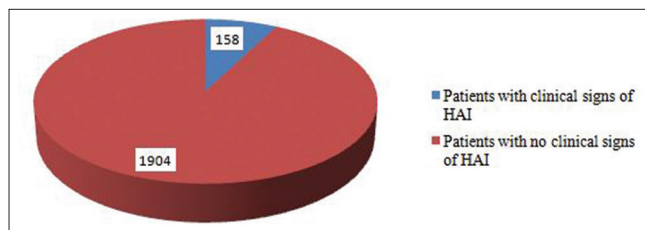
## RESULTS

The total number of patients who were admitted for more than 48 h during the study period of 1 year was 2062, which comprised 1104 male patients and 958 female patients [Figure 1].

Of the 2062 patients, a total of 158 patients were suspected to develop any of the HAI. Rest of the 1904 patients did not have any clinical sign of HAI [Figure 2].



**Figure 1: Distribution of the number of patients admitted for more than 48 h during the study period of 1 year along with gender-wise distribution**



**Figure 2: Distribution of patients based on the development of clinical signs of hospital-acquired infection**

**Table 1: Distribution of the study patients according to the presence or absence of infection (n=158)**

Total samples collected	Culture positive number (%)	Culture negative number (%)
158	92 (58.23)	66 (41.77)

**Table 2: Frequency distribution of patients included in the study according to the age group (n=158)**

Age group (in years)	Total (%)
11–20	22 (13.92)
21–30	24 (15.19)
31–40	28 (17.72)
41–50	33 (20.89)
51–60	26 (16.46)
61–70	25 (15.82)
Total	158 (100.00)

Figures in parenthesis indicate percentage

A total of 158 samples of blood, urine, sputum, and pus/wound swabs were collected from those patients for microbiological assessment.

Of the 2062 patients, a total of 158 patients were suspected of developing symptoms and signs of any of the HAI. A total of 158 samples of blood, urine, sputum, pus, and wound swabs were collected from the 158 patients for microbiological assessment during the study period. Therefore, the overall infection percentage was 7.66% over the study period of 1 year. From the 158 samples collected during the study period, samples from 92 patients revealed positive culture reports. The rest 66 cases showing clinical signs of suspected HAI were not detected as having healthcare-associated bacterial infection by laboratory methods [Table 1].

The mean age of the 158 patients (with clinical signs of HAI) included in the study was  $41.37 \pm 16.27$  years, with age groups ranging from 12 years to 70 years. Majority of the patients (20.89%) were of 41–50 years age group followed by 31–40 years age group (17.72%) and 51–60 years age group (16.46%). Percentage of patients in the age group of 61–70 years and 21–30 years were 15.82% and 15.19%, respectively. Patients in the age group of 11–20 years were least (13.92%) [Table 2].

Gender profile of the 158 patients (with clinical signs of HAI) included in the study was that 69.62% (110/158) were male and 30.38% (48/158) were female [Table 3].

From the 158 samples collected during the study period, samples from 92 patients were positive in bacteriological culture; they were considered as infected from HAI. The rest 66 cases with clinical signs of HAI were not detected of having hospital-acquired bacterial infection by laboratory methods, and these patients were considered as not infected from HAI caused by bacteria.

During the study period of 1 year, among the detected infections, SSI was most common (83.70%), followed by UTI (8.70%), bloodstream infection (5.43%), and pneumonia (2.17%) [Table 4].

The number of detected infection out of total collected samples was 58.22 (92/158) during the whole study period. During the study period of 1 year, the number of detected infection out of total samples for UTI, SSI, pneumonia, and bloodstream infection was 25.00% (8/32), 74.04% (77/104), 15.38% (2/13), and 55.56% (5/9), respectively.

A total of 92 bacterial isolates were identified during the study period of 1 year. *Staphylococcus aureus* was the



most frequently detected bacteria (28.26%) followed by *Escherichia coli* (19.57) and *Pseudomonas aeruginosa* (17.39%). Among *S. aureus* isolates, 17.39% (16/92) were methicillin-resistant *S. aureus* (MRSA) and 10.87% (10/92) were methicillin-sensitive *S. aureus* [Figure 3].

## DISCUSSION

HAIs are a problem of high concern in hospitals. Surveillance data regarding HAI are limited in India, especially from hospitals in non-urban settings. This study provides baseline data regarding HAI which will give direction to the infection control team to carry out their activities. The risk of HAI is 2–20 times higher in developing countries than the developed nations. The actual rates vary from 5% to 10% of all patients admitted in developed countries, whereas it may be as high as 25% in developing countries.<sup>[12]</sup> This study shows an infection rate of 7.33% in the orthopedic wards of our hospital.

A study by Coello *et al.*<sup>[13]</sup> showed that the overall increase in the duration of hospitalization for patients with SSI was 8.2 days, ranging from 3 days for gynecology to 9.9 for general surgery and 19.8 for orthopedic surgery. One significant aspect of this study lies in the fact that patients in orthopedics ward stay longer than the patients admitted in other wards of

the same hospital; thus, they are more exposed to the hospital-acquired drug-resistant pathogens and development of HAIs.

Therefore, bacteriological profile of the HAI in this study reflects the prevalence of drug-resistant pathogens. It was seen that of *S. aureus* isolated in this study almost 40% were MRSA. This is at par with national figures in a study done by INSAR group in 2013.<sup>[14]</sup>

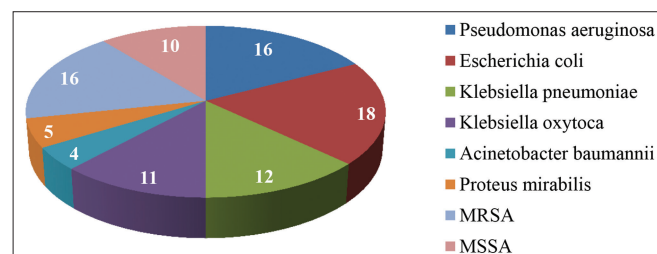
The mean age for patients with clinical signs of HAI included in the study was  $41.37 \pm 16.27$  years, with age groups ranging from 16 to 70 years. Most of the patients (53.17%) included in this study who had clinical signs of HAI were more than 40 years of age, which was similar to the finding of a study done by Mythri and Kashinath.<sup>[15]</sup>

During the study period of 1 year, among the detected infections, SSI was most common (83.70%), followed by UTI (8.70%), bloodstream infection (5.43%), and pneumonia (2.17%). In the previous studies by Green and Wenzel<sup>[16]</sup> and Haley,<sup>[17]</sup> SSIs are the most common HAIs. Therefore, this finding of the study was corroborative of other related studies.

Of the total 92 bacteria isolated from the samples collected from patients included in the study, Gram-negative bacteria isolated were 71.74% (66/92). Hence, the Gram-negative bacteria were the predominant organisms causing HAIs in this study. This finding was similar to other studies conducted in India. Some of the studies from India by Orrett<sup>[18]</sup> and Rajkumari *et al.*<sup>[19]</sup> also showed similar predominance of Gram-negative bacilli.

The most common bacteria causing UTI in the patients in the study was *E. coli* causing 19.57% (18/92) of total number of bacterial isolates. *P. aeruginosa* was the second common organism accounting for 17.39% (16/92) followed by *Klebsiella pneumoniae* which was 13.04% (12/92). This finding was consistent with the recent US data<sup>[20]</sup> indicating *E. coli* as the most common etiologic Gram-negative organism, followed in descending order of frequency by *P. aeruginosa*, *Klebsiella* Species, *Enterobacter* Species, and *Acinetobacter baumannii*.

Infections caused by Gram-negative bacteria have some epidemiological concern. These organisms are highly



**Figure 3: Distribution of bacteria isolated from the samples (n = 92)**

**Table 3: Frequency distribution of patients included in the study according to sex (n=158)**

Sex	Total
Male	110 (69.62)
Female	48 (30.38)
Total	158 (100.00)

Figures in parenthesis indicate percentage

**Table 4: Distribution of HAIs during the study period**

Type of HAI	Type of collected samples	Total number of collected samples	Number of detected infections (% of total samples)
Urinary Tract Infection (UTI)	Urine	32	8 (8.70)
Surgical Site Infection (SSI)	Pus/wound swab	104	77 (83.70)
Pneumonia/ LRTI	Sputum	13	2 (2.17)
Blood Stream Infection (BSI)	Blood	9	5 (5.43)
Total		158	92 (100.00)

SSI: Surgical site infection, UTI: Urinary tract infection, BSI: Bloodstream infection, HAI: Hospital-acquired infection, LRTI: Lower respiratory tract infection

efficient at upregulating or acquiring genes which code for the mechanisms of antibiotic resistance, especially in the presence of antibiotic selection pressure, which is a real concern in regular medical practice. Proper surveillance of HAI following standard methodology is required for the identification of the pathogen.

The advantage of this study was, we could identify potential bacterial pathogens, which are predominant in causing HAIs in this hospital. This should provide valuable inputs for formulating antibiotic stewardship guidelines for this hospital.

There were some limitations of this study. Due to limited resources, it was done in only orthopedics ward as a representative sample, but inclusion of few more areas of the hospital would have been more representative, thereby resulting in more effective infection control interventions.

## CONCLUSION

HAIs are a significant cause of morbidity and mortality of patients admitted in hospitals. These infections, often caused by drug-resistant pathogens, pose serious threat to the health-care system. Emergence of newer resistance patterns in both Gram-negative and Gram-positive bacteria further complicates the scenario. Proper surveillance of HAI following standard methodology is essential to implement any infection control program. Interventional programs to reduce the occurrence of HAIs should be planned based on the local epidemiological data.

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# Comparison of Functional and Radiological Outcome of Joshi's External Stabilization System Versus Volar Locking Compression Plate in Unstable Distal End Radius Fractures: A Short-term Prospective Study

Sandesh S Bobade<sup>1</sup>, Sharma Shyaji<sup>2</sup>, Bobade Satish<sup>3</sup>, Meena Pradeep<sup>4</sup>, Sonaje Jayesh<sup>5</sup>

<sup>1</sup>Junior Consultant, Department of Orthopaedics, Bobade Accident Hospital, Baramati, Maharashtra, India, <sup>2</sup>Professor, Department of Orthopaedics, SMS Medical College, Jaipur, Rajasthan, India, <sup>3</sup>Senior Consultant, Department of Orthopaedics, Bobade Accident Hospital, Baramati, Maharashtra, India, <sup>4</sup>Assistant Professor, Department of Orthopaedics, AIIMS Rishikesh, Rishikesh, Himachal Pradesh, India, <sup>5</sup>Consultant, Apollo Hospital, Madurai, India

## Abstract

**Purpose:** The purpose of this study was to compare the short-term functional and radiological outcome between Joshi's external stabilization systems (JESSs) with volar locking compression plate (LCP) in treatment of unstable distal end radius fractures.

**Materials and Methods:** A prospective study was conducted which included a total of 50 patients between the age group of 20–60 years with fresh closed unstable distal end radius fractures and was randomized into two groups of 25 patients each and their outcomes were compared.

**Results:** The average period of follow-up was 2 years after which range of motion of the two groups was compared and clinical and radiological evaluation was done. The functional result according to modified Gartland and Werley scoring was excellent in 8%, good in 40%, fair in 48%, and poor in 4% in JESS group while it was excellent in 8%, good in 84%, fair in 4%, and poor in 4% in volar LCP group. According to Stewart scoring system, the result was excellent in 8%, good in 40%, fair in 48% cases, and poor in 4% cases in JESS group while it was excellent-good in 88%, fair in 8%, and poor in 4% in the LCP group.

**Conclusions:** The mean time to union was 5.71 months in volar LCP group and 3.75 months in JESS group. The functional and anatomical evaluation of both the groups showed that fixation by volar LCP group had better result in comparison to external fixation by JESS with accurate maintenance of articular margin. Better functional results can be expected in the early post-operative period in association with open reduction and internal fixation, and this form of treatment should be considered for patients requiring a faster return to function after the injury, but in the long run, this is comparable with JESS fixation.

**Key words:** Closed reduction distal radius, Distal radius fractures, Joshi's external stabilization system fixator, Locking compression plate, Volar Barton's fracture

## INTRODUCTION

Distal radius fractures are very common injuries accounting for 16% of all fractures treated in emergency room and represent 74.5% of all fractures of the forearm.<sup>[1]</sup> Since Abraham Colles' original description of this injury in

1814,<sup>[2]</sup> more than 4000 articles have been published relating to distal radius fractures and their treatment. Many fixation techniques have been described including pin and plaster fixation,<sup>[3]</sup> percutaneous pinning and intramedullary pinning,<sup>[4]</sup> external fixation (bridging or non-bridging, static, or dynamic),<sup>[5]</sup> injectable bone cement,<sup>[6]</sup> and various forms of internal fixation with customized implants<sup>[7]</sup> and have their merits and demerits. Among external fixation and plating, none have been found to be superior than other in recent trials.<sup>[8]</sup> This has led us to directly compare the result of the two methods of treatment in intra-articular fractures of distal end of radius and compare their functional outcome, radiological outcome, and complications.

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**Corresponding Author:** Dr. Sandesh S Bobade, Harikrupa Nagar, Indapur Road, Opp. Market Yard, Baramati, Pune, Maharashtra, India.

## MATERIALS AND METHODS

### Study Group

The protocol was approved by the local ethics committee and written informed consent was obtained from each patient. This study was conducted in our hospital from January 2011 to July 2013 and included 50 patients with intra-articular distal radius fracture AO Type 23C3, with skeletal maturity (>18 years) and giving written informed consent, randomized into JESS and volar locking compression plate (LCP) with 25 patients each. The patients having old (>2 weeks), open fractures, pre-existing wrist disability, infection, or mental incompetence were excluded from the study. These patients were followed at 2 and 6 weeks, 3, 6, 9, and 12 months. Follow-up examination consisted of range of motion (ROM) measurements by Gartland and Werley demerit criteria<sup>[9]</sup> modified by Sarmiento<sup>[10]</sup> and radiographic evaluation by Stewart criteria,<sup>[11]</sup> respectively. The X-rays were evaluated for articular congruity of the distal radius, radial inclination, ulnar variance, volar—dorsal tilt, and osteoarthritic changes of the radiocarpal joint. Articular incongruity was arbitrarily defined as a step off or a gap of at least 2 mm.

### Surgical Technique

The patients were given a general anesthesia or regional anesthesia and were positioned in the supine position. We routinely used a pneumatic tourniquet, fluoroscopic imaging, and a pre-operative prophylactic intravenous antibiotic.

### JESS

The patient was placed supine on OT table with affected upper limb abducted and slightly flexed at elbow joint and forearm mid pronated. Two Schanz pins were inserted, first the proximal one on radius 90° to dorsal surface and the distal one through the base of the second metacarpal from dorsal surface. Fracture was reduced by giving traction by holding index finger and middle finger and keeping the wrist in slight dorsiflexion and ulnar deviation. JESS was fixed over the two pins and fixed by screw. Another proximal and distal Schanz pin fixed through the JESS and screws were tightened. Then, distraction of JESS was done by tightening the screw. Pin tract dressing was done and forearm slab was applied.

### Volar locking plate

The surgical approach was through the sheath of the flexor carpi radialis tendon. The LCP T-plate or oblique distal radius plate was used. The plate was applied to the volar aspect of the distal radius under direct vision and fixed proximally using the oblong hole to allow fine adjustment, the fracture was reduced and temporary fixation was maintained with K-wires. The reduction and plate position

were routinely checked under image intensification. Distal locking screws were subsequently sited so as to reach but not penetrate the dorsal cortex. A measurement of 2 mm was routinely subtracted from the distal screw length measurement to avoid penetration of the dorsal cortex and to minimize the potential for extensor tendon irritation. Distal locking screws were positioned aiming to site them 2 mm below the joint line to provide subchondral support.

### Statistical Analysis

The data were analyzed using computer statistical software (Microsoft Excel, SPSS 20 and primer). Descriptive statistics (mean, standard deviation, and proportions) were used to summarize the study variables. The 95% confidence intervals for difference of mean were used. Chi-square test was used to observe an association between the qualitative study and outcome variables. Unpaired *t*-test was used for analysis of quantitative data. Power analysis showed that the sample size able to detect an effect size of 0.75, with power and level of significance fixed at 80% and 5%, respectively, was minimum of 17 subjects in a group. The level of significance was set at  $P < 0.05$ .

## OBSERVATION AND RESULTS

The mean age was 42 (range 23–60) years and 38 (range 22–58) years in JESS group and LCP group, respectively, with 80% of males in JESS group and 88% in LCP group.

### Laterality

The right side was injured in 72% of patients in JESS group and 80% of patients in LCP group.

### Mechanism of Injury

Fall on outstretched hand from a standing height was the most common mechanism of injury, reported by 90% in JESS group and 88% in LCP group followed by road traffic accident.

### Union

The mean time to clinical and radiological signs of union was 3.75 months in JESS group and 5.71 months in LCP group.

### Fracture Type

According to AO classification, type C2 fracture was most common in both the groups followed by type C1 and type C3. The time to union was 2–3 months in 84% of cases in JESS group, while 52% of cases required 3–4 months and 40% required 2–3 months to unite in LCP group.

### ROM

The ROM at 1 year follow-up with respect to palmar flexion, dorsiflexion, supination, pronation, radial deviation, ulnar



deviation, and grip strength was  $66.96 \pm 6.95$ ,  $56.52 \pm 8.99$ ,  $79.04 \pm 9.16$ ,  $69 \pm 7.45$ ,  $13.76 \pm 3.07$ ,  $25.48 \pm 3.78$ , and  $78.84 \pm 9.84$ , respectively, in JESS group and  $67.48 \pm 8.54$ ,  $57.12 \pm 5.68$ ,  $80.76 \pm 8.19$ ,  $70.2 \pm 5.21$ ,  $14.12 \pm 2.5$ ,  $25.96 \pm 4.63$ , and  $79.88 \pm 11.72$ , respectively, in LCP group.

### Radiological Parameters at 1 Year Follow-up

The radial height, palmar tilt, and articular step off of  $11.28 \pm 2.44$  mm,  $4.08 \pm 6.1$  deg, and  $0.76 \pm 0.84$  were noted in JESS group compared to  $12.16 \pm 2.73$  mm,  $6.48 \pm 7.14$  deg, and  $0.66 \pm 0.60$  mm, respectively, in LCP group.

### Functional Outcome

The functional result according to modified Gartland and Werley scoring was excellent in 8%, good in 40%, fair in 48%, and poor in 4% in JESS group while it was excellent in 8%, good in 84%, fair in 4%, and poor in 4% in volar LCP group.

### Radiological Outcome

According to the Stewart scoring system, 2 (8%) cases showed excellent result with JESS, 10 (40%) cases having good result, 12 (48%) cases with fair, and 1 (4%) case with poor result while the LCP group showed 22 (88%) cases with excellent-good result and 2 (8%) cases with fair and 1 (4%) case with poor result.

### Distribution of Outcome According to Fracture Type

In JESS group, of seven cases with type C1 fracture, four had good and three had fair outcome; of 10 patients with type C2, five had good, four had fair, and one had poor outcome; of seven patients with type C3, two had excellent, one had good, and four had fair outcome while in LCP group, of eight cases with type C1 fracture, two had excellent and six had good outcome; of 12 patients with type C2, 10 had good, one had fair, and one had poor outcome; of three patients with type C3, all had good outcome.

### Complications

In JESS group, 4% of cases had pin tract infection, 2% had pin loosening, and 2% had neuropraxia of sensory branch of radial nerve. About 8% of patients had malunion after removal of JESS. About 10% of patients had finger and wrist stiffness in both JESS and volar LCP due to prolonged immobilization and inadequate physiotherapy, which was treated by regular exercises and these patients had fair result at 1 year follow-up.

## DISCUSSION

Intra-articular fractures of the distal end of radius represent complex, unstable injury and the treatment remains controversial.<sup>[12]</sup> The main objective of its treatment is the

reestablishment of anatomic integrity and functioning. Both external fixation and plating have shown to have satisfactory results.<sup>[13]</sup> A better understanding of wrist anatomy and functioning through the studies conducted in recent years,<sup>[14,15]</sup> as well as the increasing expectations of patients has expanded the borders of surgical treatment. Today, open reduction and plate fixation are the widely recognized surgical methods.<sup>[16,17]</sup> Locked plates are in the progress of replacing conventional support plates. While facilitating the positioning, those anatomical plates with screw plate interlocking feature have more biomechanical strength against forces applied on the fracture surfaces and work as internal fixator. Due to their biomechanical strength, locked plates are preferred in osteoporotic and/or multiple fractures.<sup>[18,19]</sup>

External bridging fixation is modality of treatment long before when plating came in scenario<sup>[20,21]</sup> and is still preferred by many surgeons as a familiar technique as it requires minimal exposure and is less time consuming with low learning curve.<sup>[22-24]</sup>

Various studies have been conducted using multiple measuring criteria to compare external fixation and plating and have shown comparable results.<sup>[8,25]</sup> Egol *et al.*,<sup>[8]</sup> in 280 patients, found an improved range of movement early after volar plating, but after 1 year, the range of movement between the groups was similar, as were the results for grip strength and DASH scores at all-time points. In our study, the LCP group showed advantage of early mobilization at 3-month follow-up as compared to JESS group but eventually at 9 months of follow-up both the groups showed comparable results. Patients in the open reduction and internal fixation group had greater ROM and strength than patients in the closed reduction and JESS at 6 and 9 months, and more patients in the open reduction and internal fixation group were very satisfied with the overall wrist function and motion. In our study, anatomical and radiological parameters were better restored in volar LCP group, but this was not significant when compared with JESS group. Moreover, the concept of anatomical restoration is still under debate as it has not been shown to have association with functional outcome.<sup>[26,27]</sup> Mean time for union was less in JESS group when compared to volar LCP group. In our study, despite complications such as pin loosening, infection JESS group showed to have comparable results with LCP group.

### Limitations

Our study had several limitations. Our study was focused and DALY and DASH score, workers' compensation were not taken into consideration, inclusion of which could have made this study better. Furthermore, sometimes while difficulties to apply scoring system accurately, particularly



for the radiological and subjective demerit points, might cause wide variance of results in groups with apparently comparable radiological and clinical findings. Another limitation of this study was difficulty in maintaining patient follow-up despite various protocols. However, the follow-up rates were comparable with other randomized controlled trials. Furthermore, the primary objective to compare functional and radiological outcomes did not show significant difference at 1 year follow-up, long-term changes such as radiocarpal arthritis could not be encountered which could further add to the outcome of the study.<sup>[28,29]</sup> A comparative trial with longer follow-up would allow evaluation of potential long-term sequelae.

## CONCLUSIONS

Better functional results can be expected in the early post-operative period in association with open reduction and internal fixation, and this form of treatment should be considered for patients requiring a faster return to function after the injury, but in a long run, this is comparable with JESS fixation.

## Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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# Prolonged Urinary Catheterization – A Risk Factor for Intensive Care Unit Infections and Mortality: A Clinical Study in Tertiary Teaching Hospital of Northern Kerala

P Muhammed Mushtaque, Anesh Ashok

Associate Professor, Department of Medicine, Kannur Medical College, Kannur, Kerala, India

## Abstract

**Background:** The major cause of mortality and morbidity in intensive care units (ICUs) are health care-associated infection (HCAI), especially nosocomial infection (NCI). HCAI and NCI are key factors determining the clinical outcome among patients admitted in critical care areas. Few hospitals in India perform regular surveillance for HCAI and NCI in ICUs.

**Aim of the study:** This study aims to study the incidence of HCAI and NCI as risk factors associated with mortality and morbidity ICUs.

**Materials and Methods:** A total of 624 patients hospitalized in six different ICUs of a large teaching hospital in Northern Kerala were assessed between April 2016 and March 2018. NCI was defined as the presence of clinical signs and symptoms of infection in patients at least 48 h after their hospitalization, confirmed by positive cultures of specimens taken from the patients' blood, urine, wounds, respiratory secretions, and other body fluids. A checklist comprising 109 questions were used to assess the presence of HCAI and NCI as factors of increased mortality and morbidity.

**Observations and Results:** Among the 624 patients, 364 (58.33%) were male and 260 were female (41.66%). The youngest patient was aged 16 years and the eldest one was aged 87 years with a mean age of  $49.78 \pm 11.30$ . The mean age of patients who had NCIs was  $57.68 \pm 09.45$  when compared to the mean age of  $52.39 \pm 8.20$  in patients without NCIs with  $P = 0.781$  (statistically not significant). The mean age of patients who died with NCIs was  $76.15 \pm 6.29$  and the mean age of patients with NCIs who survived was  $63.20 \pm 7.70$  with  $P = 0.021$  (statistically significant). Culture positivity of specimens collected and analyzed was observed in 195 (31.25%) patients. The overall rate of confirmed NCI in the studied patients was 241/624 (38.61%) (confidence interval 95% = 13.25–21.50). General ICU was the most crowded ward consisting of 237/624 admissions (37.98%) and had the highest rate of NCIs 72/159 (38.81%).

**Conclusions:** The patients with prolonged urinary catheterization were prone to NCIs and deaths in ICUs, and hence, they should be treated intensively.

**Key words:** Health care-associated infections and microorganism, Intensive care units, Nosocomial infections

## INTRODUCTION

Review of literature shows 30% of ICU patients suffer from one or the other kinds of infections and these patients

will encounter increased ICU length of stay, morbidity, mortality, and cost.<sup>[1]</sup> The most common pathogens isolated among NCIs were *Staphylococcus aureus* and *Acinetobacter* species with the rates of 30.9% and 26.8%, respectively.<sup>[2]</sup> *Acinetobacter* was considered as the most common Gram-negative organism colonized on the skin of hospital care providers, including ICU nurses and respiratory therapists.<sup>[3]</sup> Urinary tract infection (UTI) has been reported as the most common type of NCIs.<sup>[4,5]</sup> ICU infection was associated with multiple known risk factors such as prolonged ICU stay, different and multiple device insertions, prolonged mechanical ventilation, and colonization with micro-

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**Corresponding Author:** Dr. Anesh Ashok, Department of Medicine, Kannur Medical College, Anjarakandy, Kannur, Kerala, India.

organisms in the environment.<sup>[6]</sup> Meric *et al.* in their study proposed certain risk factors related to increased mortality which was as follows: age over 60, intubation, and central venous (CV) catheterization.<sup>[2]</sup> Reade *et al.* based on their study stated: "Anemia was associated with illness severity and more common in those with comorbid illnesses, female gender, and resulted in poor outcomes."<sup>[7,8]</sup> In the present study, the incidence of HCAs, NCIs, and deaths associated factors was assessed in ICUs of a large referral hospital complex in northern part of Kerala.

### Type of Study

This was a prospective, cross-sectional, and descriptive analytical study.

### Institute of Study

This study was conducted at Kannur Medical College, Anjarakandy, Kannur, Kerala, India.

### Period of Study

This study duration was from April 2016 to March 2018.

## MATERIALS AND METHODS

In this descriptive-analytical prospective study, 624 patients admitted to various ICUs were studied. An ethical committee clearance was obtained before the commencement of the study. An ethical committee approved consent form was used in this study.

### Inclusion Criteria

1. Patients hospitalized in six ICUs of Kannur Medical College Hospital were included in this study
2. Patients who were followed up from the time of admission to discharge/death were included
3. Patients of all age groups were included
4. Patients irrespective of their disease status or severity or critical illness were included
5. Patients who develop NCIs or HCAs 48 h after their admission were included.

### Exclusion Criteria

(1). Patients who are critically infected before the admission to the ICUs were excluded. (2). Patients who died after the first 24 h of admission to ICUs were considered as ICU mortalities during ICU hospitalization. (3). Critically ill patients who were not able to answer the questions at all and the patients who died during the first 24 h of admission to ICUs were excluded from the study due to the possibility of other causes of their mortality rather than infection. Kannur Medical College Hospital was tertiary teaching hospital with 750 beds located in a large hospital complex in a rural setting. It has 32 different types of wards and 250 physician/surgeon faculty members

affiliated to Kerala University of Health Sciences. The total number of beds including all the ICUs (general ICU, pre-operative surgical ICU, intensive coronary care unit, respiratory ICU, post-operative surgical ICU, and emergency medicine ICU) was 95. The study was carried out from April 2016 to March 2018. NCI was defined as the presence of clinical signs and symptoms of infection in the patients for at least 48 h after their hospitalization, confirmed by positive cultures of blood, urine, wounds, respiratory secretions, and other body fluid specimens. For all the patients, the data of the factors associated with NCIs and deaths were collected according to a 109-item researcher-administrated checklist including nine segments which are as follows: demographic factors (7 questions), hospitalization situations (6 questions), underlying diseases (10 questions), laboratory test results (12 questions), administered drugs (11 questions), usage of therapeutic instruments (15 questions), personal performance (9 questions), outcomes (7 questions), and environmental structure (32 questions). The other patients who died after the first 24 h of admission to ICUs were considered as ICU mortality during ICU hospitalization. The regular protocol for infection control in ICU wards included was as follows: hand washing before and after each visit, use of protective equipment such as surgical masks – gloves – goggles – shields and gowns in each visit, patient isolation in case of infectious state, environmental cleansing and disinfection (floors, walls, and roofs), use of antibiotics or probiotics based on physician prescription, use of non-silicon catheters, and periodic personnel education. By applying standard statistical methods, at the first descriptive statistics, was used to analyze the gathered data. Then, Chi-square and *t*-test were used, respectively, to test the associations between both qualitative and quantitative variables and outcomes.  $P < 0.05$  was considered statistically significant.

## OBSERVATIONS AND RESULTS

Among the 624 patients, 364 (58.33%) were male and 260 were female (41.66%). The youngest patient was aged 16 years and the eldest one was aged 87 years with a mean age of  $49.78 \pm 11.30$ . There was no statistically significant difference between patients' ages and their genders, according to NCI status. The mean age of patients who had NCIs was  $57.68 \pm 09.45$  when compared to the mean age of  $52.39 \pm 8.20$  in patients without NCIs with  $P = 0.781$  (statistically not significant). The mean age of patients who died with NCIs was  $76.15 \pm 6.29$  and the mean age of patients with NCIs who survived was  $63.20 \pm 7.70$  with  $P = 0.021$  (statistically significant). Culture positivity of specimens collected and analyzed was observed in 195 (31.25%) patients. The overall rate of confirmed NCI in the studied patients was 241/624 (38.61%)

(confidence interval [CI] 95% = 13.25–21.50). General ICU was the most crowded ward consisting of 237/624 admissions (37.98%) and had the highest rate of NCIs 72/159 (38.81%). The distribution of NCIs in other various ICUs was different from general ICU, as shown in Table 1.

According to univariate analysis, the patients' mean age and gender had no statistically significant relationship with NCIs ( $P > 0.05$ ), but the education level lower than diploma, increased length of stay in ICU, longer duration of antibiotic administration, combined antibiotic therapy, increased catheter stay, and the presence of chronic diseases had statistically significant association with increased rates of NCIs. The incidence of NCIs and mortality was significantly higher in 60 years and older age group [Table 2].

Among 195 positive cultures, *Acinetobacter* was isolated in 43/195 (22.05%) positive specimens. The most common site of infection was respiratory tract 86/195 (44.10%). The most common antibiotic prescribed for 74/195 (37.94%) culture positive cases was vancomycin. The overall mortality rate was 46/624 (7.69%) (CI 95% 5.3%–11.4%). The results of univariate analysis demonstrated that higher ages, education level lower than diploma, and combination antibiotic therapy were associated with the higher rate of mortality ( $P < 0.05$ ). Gender and the presence of NCIs showed no statistically significant association with mortality [Table 2]. According to multivariate logistic regression analysis, the statistically significant variables in the model for increased rate of NCIs were prolonged urinary catheterization (more than 7 days), combination antibiotic therapy, NG tube insertion, intubation, education level lower than diploma, and tracheostomy. Furthermore, the factors significantly associated with mortality in the model were the age more than 60, prolonged urinary catheterization (more than 7 days), CV line duration <7 days, education level lower than diploma, and NG tube insertion [Table 2].

**Table 1: The number of admissions in various intensive care units (n=624)**

Different ICUs	Positive culture, n (%)	CI 95%	Total, n (%)
General ICU	72 (38.81)	15.1–15.4	237 (37.98)
Pre-operative surgical ICU	54 (22.78)	08.2–10.3	127 (20.35)
Intensive coronary care ICU	33 (13.92)	04.1–07.5	096 (15.38)
Respiratory ICU	29 (12.23)	03–07.5	075 (12.01)
Post-operative surgical ICU	26 (10.97)	03.2–12.2	065 (10.41)
Emergency ICU	23 (09.70)	07.3–11.5	024 (03.84)
Total	237 (100)	-	624 (100)

ICU: Intensive care unit, CI: Confidence interval

## DISCUSSION

In this prospective study, NCI with culture positivity of specimens collected and analyzed was 195 (31.25%). The overall confirmed NCIs observed in the ICU patients was 241/624 (38.62%) (CI 95% = 13.25–21.50). In a similar study by Appelgren *et al.*, approximately 30% of patients admitted to ICUs were affected by NCIs.<sup>[9]</sup> The average of NCIs in this study was 26.28% which is less than the reported rate based on 95% CIs. Review of literature shows that immune suppression and other related changes to aging as the risk factors for increase in the incidence of NCIs in people older than 65.<sup>[10]</sup> However, in this study, patient's ages showed no statistical significance correlating with NCIs, in multivariate logistic regression analysis. However, in this study, patient's ages showed no statistical significance correlating with NCIs, in multivariate logistic regression analysis, although there was statistically significant increased rate of NCIs observed in patients 60 years old and above, in univariate analyses. This may be because the numbers of patients with younger age were more in this study in comparison with other studies. The average age of the patients in this study was <65. Like the other studies, there was no statistical significance in relationship between the gender and NCIs.<sup>[11]</sup> Although obesity and overweight were important factors associated with NCIs,<sup>[12]</sup> there was no measure to analyze these variables in the present study and it can be considered as a limitation to this study. The main reason of this limitation was that the height and weight could not be measured easily and accurately in critically ill patients. The findings showed that the education level lower than X<sup>th</sup> standard had statistically significant relationship with increased rate of NCIs and deaths, based on univariate and multivariate analyses. This may be due to better personal hygiene in patients with higher education or some other associated socioeconomic factors which play important roles in the higher rates of these outcomes. The present study showed that increased length of stay in ICUs to more than 7 days was associated with increased incidence of NCI similar to the study by Crooks *et al.*<sup>[11]</sup> However, multivariate analysis indicated that certain other factors also were associated with NCIs. Accordingly, one of the most important factors associated with both NCIs and ICU mortality was prolonged urinary catheterization (more than 7 days), which is compatible with the study by Rudman *et al.* study.<sup>[13]</sup> The mechanisms associated with UTIs and increased mortality was revealed in the past in literature.<sup>[14,15]</sup> In the present study, the most common isolated pathogen in patients with NCI was *Acinetobacter*. The findings of this study showed that 12% of isolated *Acinetobacter* were resistant to all routinely prescribed antibiotics.<sup>[16]</sup> This recent emergence of drug-resistant *Acinetobacter* has caused a great concern worldwide<sup>[16]</sup> and



**Table 2: Different associated factors with nosocomial infections and death (n=624)**

Variables	States (%)	Positive culture (%)	P	OR	Death	P	OR
Age							
>60	254 (40.70)	54 (27.69)	0.013	3.25	13	0.001	5.21
<60	370 (59.29)	52 (14.05)					
Gender							
Male	364 (58.33)	91 (25)	0.217	-	18	0.553	4.02
Female	260 (41.66)	48 (18.46)					
Education							
< tenth standard	297 (47.59)	84 (28.28)	0.010	-	17	0.023	4.28
> tenth standard	327 (52.40)	57 (17.43)					
CV line duration (days)							
>7	234 (37.50)	11348.29 ( )	0.031	-	24	0.001	-
<7	300 (48.07)	021 (07)					
ICU stay							
>7	240 (38.46)	128 (53.33)	0.005	-	29	0.020	-
<7	384 (61.53)	11 (02.86)					
Antibiotic duration							
>7	179 (28.68)	99 (55.30)	0.019	-	19	0.027	-
<7	445 (71.31)	21 (04.71)					
Urinary catheterization							
>7	221 (35.41)	118 (53.39)	0.028	-	129	0.001	-
<7	403 (64.68)	010 (02.48)					
Tracheostomy							
Yes	108 (17.30)	48 (45.37)	0.001	-	12	0.011	
No	516 (82.69)	103 (19.96)					
Intubation							
Yes	293 (46.55)	83 (28.32)	0.041	-	15	0.039	
No	331 (53.04)	44 (13.02)					
NG tube							
Yes	388 (62.17)	114 (29.38)	0.038	-	08	0.040	
No	236 (37.82)	126 (53.38)					
IV catheter duration							
Yes	119 (19.07)	61 (51.26)	0.021	-	06	0.017	
No	505 (80.92)	19 (03.76)					
Antibiotic therapy							
Combined	409 (65.54)	131 (32.02)	0.010	-	07	0.019	
Single	215 (34.45)	10 (04.65)					
Culture results							
Positive	195 (31.25)		0.001	-	14	0.001	
Negative	429 (68.75)						

CV: Central venous, ICU: Intensive care unit, OR: Odds ratio, NG: Naso gastric, IV: Intra venous

it seems that this matter should be paid special attention in these ICU settings. In this study, multiple antibiotics were prescribed for 192 patients and just 215 patients were treated using a single antibiotic. The statistical significance of association between combination antibiotic therapy and mortality indicates that increased drug resistance and ineffectiveness of different antibiotics may have inevitable role in mortality. In addition, certain special side effects of few antibiotics and immune system impairment may be another reason for the higher rate of mortality. The quality of prescribed antibiotics was also another important factor for increased mortality. Therefore, the effectiveness of antibiotics should regularly be investigated in both *in vitro* and *in vivo* settings. The UK Intensive Care Society has suggested that crowded ICUs, especially those with more than 8 beds, will face managerial problems,<sup>[17]</sup> and this fact may explain the higher rates of infections observed in general ICU. The most crowded ICU in the present study

was with 20 beds and it was general ICU. According to the above findings, NG tube insertion was associated with NCIs and deaths and this is consistent with the findings of the other studies in literature.<sup>[18]</sup> Lower gastric PH and aspiration during gavages and NG tube insertion may play roles in NCIs and the deaths subsequent to NCIs.<sup>[18]</sup>

## CONCLUSIONS

The patients with prolonged urinary catheterization were prone to NCIs and deaths in ICUs, and hence, they should be treated intensively.

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# Surgical Outcomes, Risk Factors, and Patterns of Recurrence in Endometrial Cancer

G Balamurugan<sup>1</sup>, A Suresh Venkatachalam<sup>2</sup>

<sup>1</sup>Associate Professor, Department of Surgical Oncology, Regional Cancer Centre, Government Coimbatore Medical College Hospital, Coimbatore, Tamil Nadu, India, <sup>2</sup>Professor, Department of Surgical Oncology, Regional Cancer Centre, Government Coimbatore Medical College Hospital, Coimbatore, Tamil Nadu, India

## Abstract

**Introduction:** Endometrial cancer (EC), being the third most common gynecologic cancer, is now increasing in prevalence among the developed countries. The morbidity and mortality rates are rising gradually in spite of available advancing treatment modalities. This study aims to brief on the patterns and risk factors of recurrence and surgical outcomes of EC.

**Aim:** This study aims to study the patterns of recurrence and surgical outcomes of EC based on surgical and adjuvant therapy.

**Materials and Methods:** The study was conducted among 60 women with EC in a tertiary care center. Disease staging was done by 2009 FIGO criteria. Post-operative adjuvant therapy in the form of pelvic radiation or vaginal radiation was offered along with chemotherapy to appropriate patients. The risk factors, surgical outcomes, and prognostic factors were studied by radiological imaging and blood parameters.

**Results:** The mean age of the occurrence of EC was 51.22 years and abnormal uterine bleeding was the common presenting symptom. About 86.6% of the patients underwent total abdominal hysterectomy and 52 of 60 patients required bilateral salpingo-oophorectomy (BSO). Pelvic lymph node dissection was done in 47 cases (61.6%) and 10 cases (16.6%) needed para-aortic node dissection. Laparoscopic vaginal hysterectomy with BSO was done in one patient due to associated comorbidity. One patient needed only vaginal hysterectomy due to early-stage disease. The complication rate in this series was found to be 15% (9/60 cases). Two recurrences and one reported death were noticed.

**Conclusion:** EC is common in postmenopausal women and comprehensive surgery, adjuvant radiotherapy and chemotherapy can help in reducing disease recurrence. Open surgery and minimally invasive surgery both have more or less equal outcomes.

**Key words:** Adjuvant therapy, Chemotherapy, Endometrial cancer, Hysterectomy, Perimenopausal, Radiation, Recurrence

## INTRODUCTION

Endometrial cancer (EC), also called uterine cancer, begins in the layer of cells that form the lining (endometrium) of the uterus. Other types of uterine cancer include uterine sarcoma, but they are much less common than EC.<sup>[1]</sup> The first sign of the disease is vaginal bleeding which is not associated with menstruation which prompts the women to meet the doctor. EC occurs most commonly in women who have crossed menopausal age.<sup>[2]</sup>

EC is the most frequent gynecologic cancer in developed countries that killed around 34,700 women in 2012 (Bogani *et al.*, 2016).<sup>[3]</sup> Although it primarily affects postmenopausal women, 25% are premenopausal and 3–5% are under 40 years.<sup>[4]</sup> A history of ovarian dysfunction, anovulation, infertility, and obesity is often found in this younger group with EC. In young women who have never been pregnant and have a strong desire to preserve fertility, endometrial carcinoma is an estrogen-dependent well-differentiated endometrioid carcinoma and does not tend to invade the myometrium and also exhibits good prognosis (Benshushan, 2004; Zivanovic *et al.*, 2009).<sup>[5]</sup> Therefore, these patients could be candidates to a conservative approach in preserving a potential fertility.<sup>[6]</sup>

EC has a favorable prognosis and women are often diagnosed at an early stage; therefore, they are managed by

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**Corresponding Author:** Dr. A Suresh Venkatachalam, Department of Surgical Oncology, Regional Cancer Centre, Government Coimbatore Medical College Hospital, Coimbatore, Tamil Nadu, India.

surgery alone and carry a low risk of recurrence. The 5-year overall survival rate is 80%.<sup>[7]</sup> For women with increased risk of recurrence, adjuvant radiotherapy and systemic treatment are other options. Women's age, histological type and grade, depth of myometrial invasion, cervical involvement, and lymphovascular space involvement (LVSI) status are predicting factors of recurrence and survival.<sup>[8]</sup> Although the prognosis of EC is good, about 13% can still recur and most EC-related deaths are due to recurrence.<sup>[9]</sup> The types of recurrence in EC have not been clearly defined till date although authors agree that the development of distant metastases to brain, lung, liver, bone metastases, and supradiaphragmatic nodal metastases can result in a significant reduction in overall survival rates.<sup>[10]</sup>

It is important to identify the prognostic factors that predict the development of recurrence and also improve the choice of adjuvant therapy subsequently. The risk groups for recurrence have been discussed in this study based on the clinicopathological prognostic factors to identify women with poor prognosis and high recurrence rates so that they may benefit from adjuvant therapy.

### Aims

The aims of this study are as follows:

1. Patterns of risk factors for recurrence in EC
2. Outcomes of EC based on surgical and adjuvant treatment.

## MATERIALS AND METHODS

This retrospective study was conducted in the Department of Surgical Oncology at a tertiary care center in EC patients. Data were collected from medical records such as baseline characteristics, disease profiles, surgical outcomes, complications, biopsy details, and adjuvant treatment. Patients were staged according to the 2009 FIGO criteria. Outcome measures included the use of blood and blood products and complications of the surgery such as infections, hemorrhage, wound breakdown, and lymphocysts. Recurrence was diagnosed based on clinical and radiological imaging. A local recurrence was defined as any disease confirmed by histopathologic examination at the vault region. Distant recurrence was defined as disease out of the pelvis as shown clinically or on imaging.

Pelvic lymph node dissection (PLND) involved the opening of the retroperitoneum and removing all fibrofatty tissues along the major pelvic vessels. The distal limit of the node dissection was up to the circumflex iliac vessels over the external iliac and the obturator nerve, leaving the pelvis at the obturator fossa. The upper limit was the common

iliac nodes at the bifurcation of the common iliac arteries. Para-aortic node dissection was performed up to the level of the inferior mesenteric artery. Completion surgery (post-hysterectomy) for patients operated elsewhere was offered if there was a deep myometrial invasion, or a Grade 3 tumor, or if high-risk histology and ovaries had been retained. Baseline imaging was performed, followed by a restaging laparotomy that included peritoneal washings, and pelvic and para-aortic node dissection as indicated. Patients were followed for 3 months.

## RESULTS

During the study period, a total of 60 women were operated on for EC. The mean age of the patients was 51.22 (standard deviation of 7.48). Most of the patients presented with postmenopausal bleeding (41 cases). Perimenopausal abnormal uterine bleeding was observed in 10 cases. The mean CA-125 (cancer antigen) levels were  $41.28 \pm 122.2$  IU/ml and the mean endometrial thickness measured by vaginal ultrasonography (TVS) was  $22.48 \pm 8.12$ . Of the 60 patients, 52 patients underwent total abdominal hysterectomy (TAH) (86.6%) and all 52 patients required bilateral salpingo-oophorectomy (BSO). PLND was done in 47 cases (61.6%) and 10 cases (16.6%) needed para-aortic node dissection. Laparoscopic vaginal hysterectomy (LAVH) with BSO was done in one patient due to associated comorbidity. One patient needed only vaginal hysterectomy due to early-stage disease. The complication rate in this series was found to be 15% (9/60 cases) [Table 1 and Figure 1].

Urinary tract infection, vessel injury, and post-operative ileus/intestinal obstruction were the most frequently encountered complications (two cases each). Post-operative fever and sepsis, deep venous

**Table 1: Operative Details**

Operative details	Frequency
Total abdominal hysterectomy+bilateral salpingo-oophorectomy	6
Total abdominal hysterectomy+bilateral salpingo-oophorectomy+pelvic lymph node dissection	37
Total abdominal hysterectomy+bilateral salpingo-oophorectomy+pelvic lymph node dissection+para-aortic node dissection	10
Laparoscopic vaginal hysterectomy+bilateral salpingo-oophorectomy	1
Vaginal hysterectomy	1
Others	5

thrombosis (DVT), and wound breakdown were the other complications observed [Figure 2]. Post-operative biopsy revealed that approximately two-thirds of the tumor were >2 cm (67%) and the rest were <2 cm. About 88.3% of the tumors were endometrioid and 11.6% was non-endometrioid. Most of the patients had Grade 1 disease (58.3%), 17 patients had Grade 2 disease (28.3%), and 8 patients had Grade 3 disease (13.3%). LVSI was positive in 16 cases (26.6%) and negative in 39 cases (65%). Twenty-two patients had >50% gross myometrial invasion which can be associated with a high prevalence of pelvic lymph node metastasis. Myometrial invasion of <50% was noticed in 36 cases. The mean PLND is 6 and the mean PAND is 4. Positive peritoneal cytology was seen in four patients and a positive parametrium was seen in two cases.

About 50% of the women (30 cases) had the early-stage disease (IA) and 13 cases were Staged I-B. Highly advanced and metastatic Stage IV disease was seen in 3 patients (5%)

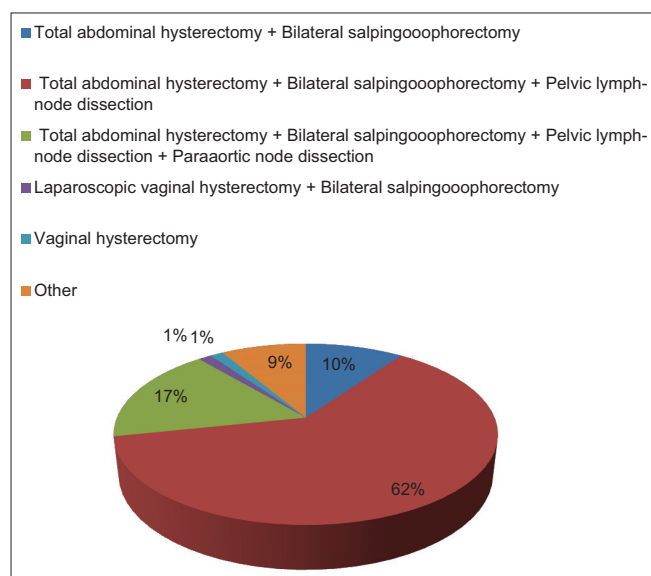


Figure 1: Distribution of procedures performed

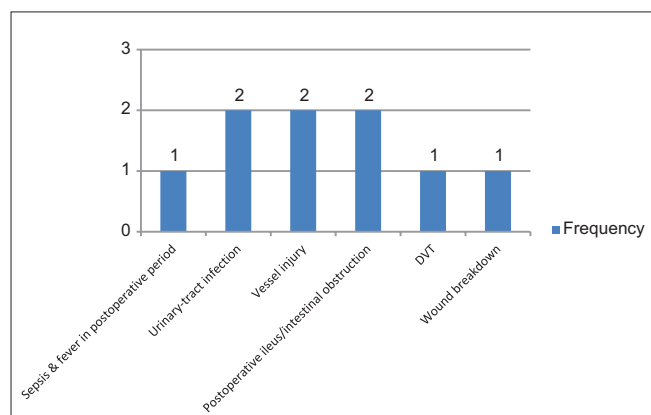


Figure 2: Complications

[Figure 3]. As most of the patients had Grade 1 early disease, they did not receive adjuvant therapy. Adjuvant therapy was given to 27 patients who were in the progressive phase and advanced stage of the disease. Twenty-three patients received radiation, 13 patients received chemotherapy, and 9 patients had a combination of both. Of the 23 patients who received radiation therapy, vaginal brachytherapy alone was administered to eight patients and abdominal radiation was given to three patients. Twelve patients received both vaginal and abdominal radiation. Chemotherapy was offered with a combination of paclitaxel+carboplatin to nine patients and carboplatin alone to one patient. For patients who were sensitive to these drugs, other platinum drugs were used. Combination of radiotherapy and chemotherapy was given to patients who had positive peritoneal cytology and other high-risk factors like pelvic node involvement [Figure 4].

In this case series, only two patients had a recurrence and one death was reported. An attempt was made to examine various factors that could have possibly affected survival. Logistic regression was computed for all these factors. Risk factors such as a deep myometrial invasion, higher grade of the tumor (G3), parametrium being positive, and adjuvant treatment were significant for disease-free survival (DFS) on univariate analysis.

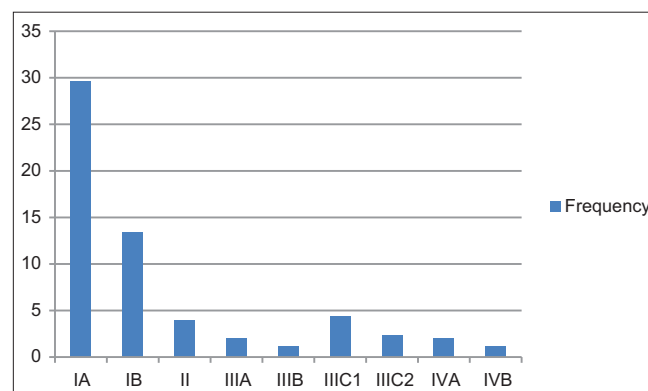


Figure 3: Stage of the disease

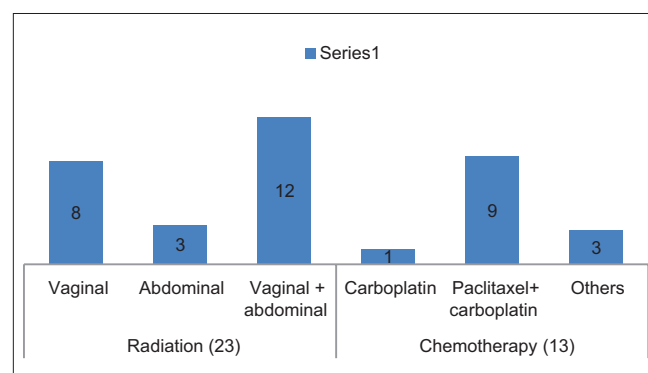


Figure 4: Adjuvant therapy



## DISCUSSION

EC is the third most commonly occurring gynecologic malignancies. The first sign of the disease is vaginal bleeding that is not associated with a menstrual period.<sup>[11,12]</sup> Other symptoms may include painful urination, pain during sexual intercourse, or pelvic pain.<sup>[13]</sup> EC occurs most commonly after menopause and over 40% of the cases are related to obesity.<sup>[14]</sup> The other risk factors include diabetes mellitus, high estrogen levels, use of tamoxifen, absence of pregnancy, and advancing age.<sup>[15,16]</sup> Genetics and environmental factors also contribute to 2–10% of EC.<sup>[17]</sup> The initial treatment for EC is some form of surgery which typically consists of hysterectomy and BSO.<sup>[18]</sup> For tumors above Grade II, PLND or PAND is performed.<sup>[16]</sup>

This retrospective analysis of surgical outcomes in EC emphasizes the importance of comprehensive surgical staging and the need to adhere to protocols based on which treatments are implemented for a better outcome. Our study results show that EC is more common in postmenopausal women, the mean age of occurrence being 51 years. Abnormal uterine bleeding was the most common presenting symptom. A study by Gao *et al.* among Chinese women in 2016 also states that the prevalence of both type I and type II EC is more likely to occur in postmenopausal women than before.<sup>[19]</sup> Around 86.6% of the patients in our study underwent TAH with BSO and the mean uterine thickness as measured by ultrasonography was 22.48 mm. Estrogen plays an important role in the development of EC and the risk increases with increased exposure to unopposed estrogen.<sup>[20]</sup> Here, the increased endometrial thickness can be attributed to increased estrogen levels. In obesity, the excess adipose tissue increases the conversion of androstenedione into estrone, an estrogen. This causes less or no ovulation and, in turn, exposes the endometrium to continuously high levels of estrogen.<sup>[21]</sup> Hence, obesity is one of the main risk factors for EC.

USG examination was routinely performed for all patients based on institutional protocols as pre-operative evaluation may assist the surgeon in deciding the extent of surgery and also to assess the grade, tumor size, and tumor extension. More than 90% of the patients underwent TAH in our study and the complication rate associated was 15% which is comparable to the quoted complication rate of open surgery by other researchers.<sup>[22]</sup> Urinary tract infection, vessel injury, and post-operative ileus/intestinal obstruction were the most frequently encountered complications. Post-operative fever and sepsis, DVT, and wound breakdown were the other complications observed. The recent advancement is laparoscopic hysterectomy which is associated with less hospital stay and less morbidity. Two

patients in this study series underwent an LAVH as they had the early-stage disease and to avoid a complicated open surgery. However, in general, removal of the uterus through the abdomen is recommended over the removal of the uterus through the vagina as it allows to examine and obtain washings of the abdominal cavity to detect any further evidence of cancer. Staging of the cancer is done during the surgery.<sup>[23]</sup>

Para-aortic and pelvic lymphadenectomy was required in many patients in our study (table) based on the operative character of the tumor. Post-operative biopsy was done and most of the tumors were >2 cm. Endometrioid tumors constituted 88.3% of the tumors in our study. Endometrioid adenocarcinoma is the most commonly occurring EC according to literature.<sup>[24]</sup> Most of the patients had Grade 1 disease (58.3%) and LVSI was positive in 16 cases (26.6%). Twenty-two patients had >50% gross myometrial invasion which can be associated with a high prevalence of pelvic lymph node metastasis. Positive peritoneal cytology was seen in four patients and a positive parametrium was seen in two cases. All these can be high-risk factors for disease recurrence even after extensive surgery.

About 50% of the women in our study had early-stage disease (IA) and 13 cases were Staged I-B. Highly advanced and metastatic Stage IV disease was seen in 3 patients (5%). As most of the patients had Grade 1 early disease, they did not receive adjuvant therapy. Adjuvant therapy was given to 27 patients who were in the progressive phase and advanced stage of the disease. Following risk stratification protocols, adjuvant radiation therapy, vaginal brachytherapy, or abdominal radiation were offered appropriately to high-risk patients. Chemotherapy was offered with a combination of paclitaxel + carboplatin to nine patients and carboplatin alone to one patient. For patients who were sensitive to these drugs, other platinum drugs were used. Combination of radiotherapy and chemotherapy was given to patients who had positive peritoneal cytology and other high-risk factors like pelvic node involvement.

Despite receiving pelvic radiation and vaginal brachytherapy, two patients had a recurrence in our study and one death was reported. CA-125 levels act as an important prognostic factor in determining disease progression and recurrence. Tumor recurrence is preceded by an increase in serum CA-125 levels.

The limitations of this study are its retrospective nature, small sample size, and the failure to obtain certain follow-up details. The compliance of advanced stage disease patients with further treatments was not satisfactory. If the follow-up period had been extended, the results would have been different.

## CONCLUSION

This study concludes that EC is common among postmenopausal women and the risk increases with advancing age. Combination of comprehensive surgery involving pelvic and para-aortic lymph node dissection followed by appropriate adjuvant radiation therapy or chemotherapy or a combination of both could result in better DFS rates. Endometrioid cancer is the most commonly occurring histologic type and most patients are diagnosed early. High-grade tumors, positive parametrium, deep myometrial invasion, and adjuvant treatments are risk factors of this disease. The outcomes of open surgery and minimally invasive surgery were more or less equal and more focus should be on developing adequate training skills to gynecologic surgeons and the need for referral of suspected cases to the oncologic set-up so as to make an early diagnosis.

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# Efficacy and Safety of Moxifloxacin 0.5% Eye Drops versus Tobramycin 0.3% Eye Drops in Pediatric Population with Purulent Bacterial Conjunctivitis

Prateek Koul<sup>1</sup>, Vijayta Gupta<sup>2</sup>

<sup>1</sup>Senior Resident, Department of Ophthalmology, Veer Chandra Singh Garhwali Government Medical College, Pauri Garhwal, Uttarakhand, India, <sup>2</sup>Senior Resident, Department of Ophthalmology, Government Medical College Jammu, Jammu and Kashmir, India

## Abstract

**Aims:** The study aims to determine the efficacy and safety of moxifloxacin 0.5% eye drops versus tobramycin 0.3% eye drops in pediatric population with purulent bacterial conjunctivitis.

**Study design:** Prospective, randomized, investigator-masked, clinical study was conducted on patients.

**Place and Duration of Study:** This study was conducted by the Department of Ophthalmology Veer Chandra Singh Garhwali Government Medical College, Srinagar, Uttarakhand, between March 2018 and February 2019.

**Methodology:** This study included 100 children with purulent discharge and bulbar conjunctival injection. Children either received moxifloxacin 0.5% 4 times a day for 5 days or received tobramycin 0.3% eye drops (every 2 h for 2 days and then 4 times for 5 days). Clinical signs were evaluated on days (D) 0, 3, and 7 and cultures on D0 and D7. The primary variable was the clinical cure (absence of bulbar injection and discharge) on D3 in the worst eye for patients with positive culture on D0.

**Results:** 100 culture-positive cases were included on D0. Moxifloxacin was superior to tobramycin in clinical cure rate on D3 (47.1% vs. 28.7%)  $P = 0.013$  and was non-inferior to tobramycin on D7 (89.8% vs. 78.2%, respectively). Moxifloxacin treatment eradicated causative pathogens, including resistant species with a similar resolution rate to tobramycin (89.8% vs. 87.2%).

**Conclusion:** Moxifloxacin 0.5% eye drops provided a more rapid and effective clinical cure than tobramycin 0.3% eye drops in the treatment of purulent bacterial conjunctivitis in children, with 4 times dosing.

**Key words:** Bacterial, Conjunctivitis, Moxifloxacin, Tobramycin

## INTRODUCTION

Conjunctivitis is one of the most common eye infections in childhood and a common cause of pediatric primary care visits and ocular complaints in pediatric emergency departments.<sup>[1]</sup> Bacterial infection accounts for up to 50% of all conjunctivitis cases in adults and as many as 70–80% of cases in children.<sup>[2]</sup>

Bacterial conjunctivitis is characterized by mucopurulent discharge and conjunctival hyperemia.<sup>[3]</sup> It is an extremely

contagious disease caused by one or more bacterial species and affects both sexes, all ages and countries. It can also cause epidemics among people close quarters, including nursery, school, and student populations.<sup>[4]</sup> Mild cases are generally considered to be self-limiting resolving in 5–10 days. However, current consensus supports the use of topical antibiotics as they provide significantly better rates of early clinical cure and microbiological resolution compared with artificial tears.<sup>[5]</sup> Topical antibiotics are also known to reduce the rate of reinfection and prevent the spread of infection.<sup>[6]</sup>

There are only a few available options for the treatment of purulent bacterial conjunctivitis with topical antibiotics in children as most available. Topical antibiotics have been approved based on clinical studies performed on adults. Although regulatory health authorities worldwide

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**Corresponding Author:** Dr. Vijayta Gupta, Room No 13, SR Hostel, HNB Base Hospital, Srikot Pauri, Srinagar – 246 174, Uttarakhand.

encourage pediatric clinical studies, the efficacy and safety in its population are still undertested.

The objective of this study was to determine the efficacy and safety of moxifloxacin 0.5% eye drops compared to tobramycin eye drops and also its rapidity of action to support its indication in children, notably in those younger than 2 years of age. Secondary objective included determination of infection bacteriological profiles and microbiological resolution rates.

## MATERIALS AND METHODS

This prospective, randomized, investigator-masked, clinical study was conducted on patients attending the eye OPD of Veer Chandra Singh Garhwali Government Medical College, Srinagar, Uttarakhand, India, during March 2018–February 2019.

Eligible patients were children from (1 day–18 years old) 100 in number with purulent bacterial conjunctivitis defined by mild-to-severe bulbar conjunctival injection and purulent discharge in at least one eye. Patients were excluded if they were premature newborns or had associated ocular pathologies [Table 1].

Systemic or ocular antibiotic, anti-inflammatory treatments were not authorized for use during the study.

### Treatment Administration

On D0, eligible patients were randomly allocated (1:1 ratio) to one of the two investigator-masked study treatments. The randomization was stratified by age group (<4, 4–12, and 12–18 years). Patients received either moxifloxacin 0.5% on drop 4 times a day from D0 to D2 or tobramycin 0.3% eye drops one drops every 2 h on D0 to 1, then 4 times a day on D2 to 6.

### Study Assessments and Outcomes

All patients were to attend three visits (D0, D3, and D7). An investigator who was masked to the treatment performed ophthalmologic examination, while other investigator was responsible for dispensing medications and assessing tolerance and safety.

### Clinical Efficacy and Assessments

Cardinal clinical signs of bacterial conjunctivitis were assessed for each eye under slit lamp and grading were done. The primary efficacy variable was clinical cure as defined by the absence of bulbar conjunctival injection and purulent discharge in worst eye on D3 in the microbiologically positive full analysis set, i.e., patients with positive culture on D0. Secondary efficacy variable included clinical cure on D7 and other ocular signs (folliculopapillary reaction of palpebral conjunctiva, eyelid

**Table 1: Patients characteristics at baseline**

Gender	Moxifloxacin (n=50)	Tobramycin (n=50)
Male	25	24
Mean age in years	2.7±3.0	3.2±3.9
Bulbar conjunctival injection in worst eye		
Absent	2 (4%)	2 (4%)
Mild	16 (32%)	18 (36%)
Moderate	25 (50%)	23 (46%)
Severe	7 (14%)	7 (14%)
Conjunctival purulent discharge in worst eye		
Absent	0	0
Mild	3 (6%)	2 (4%)
Moderate	26 (52%)	28 (56%)
Severe	21 (42%)	20 (40%)

erythema, and lid swelling) and symptoms were scored on a four-point scale (0 = absent, 1 = mild, 2 = moderate, and 3 = severe. Pre-verbal patients were not assessed for symptom scores.

### Microbiological Assessments

A conjunctival swabbing was taken from each infected eye on D0 and D7. Bacterial specimens were analyzed by a local laboratory. A bacteriological sample was considered positive if bacteria isolated after culture were above the threshold following Cagle's microbiological criteria. Microbiological resolution (i.e., absence of bacteria or their reduction below the pathogenic threshold) was assessed on D7.

### Safety Assessments

The safety analysis was based on the evaluation of adverse events, symptoms related to study medication instillation (i.e., burning/stinging/itching, stickiness, foreign body sensation, and blurred vision), ocular signs at slit-lamp examinations, visual acuity, and treatment tolerability by the investigator and patient or guardian. For preverbal children, unusual discomfort upon instillation was assessed by parent. If an exacerbated reaction was noted by the parents upon instillation of study medication to the child, the symptoms of itching/burning/stinging, stickiness, foreign body sensation, and blurred vision were recorded.

## RESULTS

### Clinical Efficacy

On D3, the clinical cure rate for the worse eye was significantly higher in moxifloxacin group compared with tobramycin group for patients in the Microbiologically positive full analysis set (47.1% vs. 28.7%;  $P = 0.013$ ). On D7, there was no statistically significant difference in clinical cure rates between treatment groups (89.2% vs. 78.2%;  $P = 0.077$ ), and non-inferiority of moxifloxacin to tobramycin was demonstrated [Table 2].



**Table 2: Clinical cure rates in worse eye**

	Moxifloxacin (n=50)	Tobramycin (n=50)	Between group difference	Superiority testing P value	Non-inferiority testing
Day 3	23 (47.1)	15 (28.7)	18.3	0.013	-
Day 7	45 (89.2)	39 (78.2)	11.0	0.077	-2.9 to 24.3

**Table 3: Bacterial resolution (day 7) in worst eye**

Organism	Cagle's category	Moxifloxacin (n=50)		Tobramycin (n=50)	
		Day 0	Day 7	Day 0	Day 7
<i>Staphylococcus aureus</i>	2	10	8/8	9	7/8
<i>Staphylococcus epidermis</i>	3	5	2/3	6	3/4
Coagulase-negative Staph	3	8	5/6	7	6/6
<i>Streptococcus pneumoniae</i>	1	15	12/13	16	13/14
Neisseria	1	1	1/1	1	1/1
<i>Branhamella catarrhalis</i>	2	1	1/1	1	1/1
Haemophilus	1	9	7/8	8	6/7
<i>Pseudomonas</i>	1	1	1/1	2	2/2
Overall resolution rate			89.8%		87.2%

Improvements of other ocular signs (eyelid erythema and lid swelling) were also noted on D3 and D7 but were not significantly different between groups (D3:  $P = 0.067$ ,  $0.662$ , and  $0.498$ , respectively; D7:  $P = 0.172$ ,  $0.421$ , and  $0.165$ , respectively).

### Bacterial Resolution

The most frequent causative microbes isolated from patients at inclusion were haemophilus (31.5%), *Staphylococcus aureus* (17.7%), *Streptococcus pneumoniae* (14.8%), and coagulase-negative staphylococcus (12.8%). Overall, the bacteriological resolution rate in worst eye on D7 was similar in both groups with no notable difference between treatments ( $P = 0.679$ ). A higher resolution rate was noted for *S. aureus* in patients treated with moxifloxacin (93.8%) versus 75% with tobramycin ( $P = 0.252$ ) [Table 3].

### Safety

Both treatments were well tolerated in all age categories, with no serious ocular AEs reported. Ocular AEs considered by the investigator as related to study drug were reported in 4 patients treated with moxifloxacin and 1 patient treated with tobramycin. These included erythema of eyelids, lid edema, and ocular hyperemia. All treatment-related ocular AEs were mild, except one case of severe ocular hyperemia in moxifloxacin group.

Itching/burning/stinging was the most common instillation-related ocular symptom reported on D3 in both treatment groups and was rated as “disturbing” or very disturbing for 7.6% of patients on moxifloxacin and 0.8% on tobramycin ( $P = 0.003$ ). Neither corneal inflammation nor active inflammation of anterior chamber was noted for any patient on slit-lamp examination.

Clinically significant superficial punctuate keratitis was found in one moxifloxacin patient on D3 but it resolved by D7.

## DISCUSSION

Randomized controlled studies with stratification by age group (i.e., neonates, infants, children, and adolescent) are designed to establish the efficacy and safety of medicinal products in the pediatric population which are strongly encouraged by the regulatory health authorities.<sup>[7]</sup> This study established the efficacy and safety of moxifloxacin 0.5% eye drops in children with average age of 3 years. Large proportion of patients younger than 24 months was seen in the study.

In this study, a short-term regimen (3 days) with moxifloxacin 0.5% drops 4 times daily provided a more rapid clinical cure in children with purulent bacterial conjunctivitis than did the tobramycin 0.3% eye drop regimen (every 2 h for 2 days and then 4 times for 5 days). When compared to tobramycin, efficacy of moxifloxacin was found to be significantly superior on D3 and non-inferior on D7. The clinical cure rates obtained for both antibiotics are very similar to those of previous studies that are 48% on D3 and 80% on D9 in moxifloxacin-treated children compared with 27% and 82% in tobramycin-treated children.<sup>[8]</sup>

The selection of patients with moderate-to-severe cardinal signs of acute conjunctivitis in this study may explain the relative high rate (71%) of positive bacterial culture noted at baseline. However, the bacteriological profile for patients in this study is similar to the one determined in the pediatric subgroup of an earlier randomized controlled study.<sup>[9]</sup>



Moreover, consistent with the causative microorganisms usually found in literature for acute conjunctivitis in young children.<sup>[10]</sup>

*Haemophilus influenzae* was the most frequently isolated pathogen, probably owing to the high incidence of associated otitis media in children with bacterial conjunctivitis as it is the most responsible pathogen.<sup>[11]</sup>

*Streptococcus pneumoniae* was also commonly detected in patients in this study.

Other pathogens, such as Gram-negative bacteria other than haemophilus, were found in new patients. Thus, a broad-spectrum antibiotic like moxifloxacin is justified for use as a first-line drug against purulent conjunctivitis in children. Most common causative agents differ from children than in adults, in which *Staphylococcus* species predominate. As most topical antibiotics are prescribed empirically without diagnostic bacteriological profile, these findings emphasize the importance of an etiological approach to determine best possible initial treatment.

The high rate of bacterial resolution noted in this study is consistent with the targeted efficacy of moxifloxacin 0.5% against bacterial spectrum found in children. Following moxifloxacin treatment, the bacteriological cure rate was about 90% (D7) ranging from 76.5% to 100% depending on the microbe. Moxifloxacin effectively eradicated all causative pathogens, including classically resistant species such as *Acinetobacteria*, *Corynebacteria*, and *Enterobacteria*.

Following moxifloxacin eye drop application, sustained antibiotic concentration in tears and conjunctival cells are usually higher than the plasma concentrations reached after oral moxifloxacin. This could explain why even bacteria resistant to plasma concentration of moxifloxacin are susceptible to eye drop treatment.<sup>[12]</sup> The pharmacokinetic properties of moxifloxacin justify the short-term treatment duration for 5 days for a rapid antibacterial action.<sup>[13]</sup>

In summary, moxifloxacin 0.5% eye drops are an effective and safe therapeutic option for purulent bacterial conjunctivitis in pediatric population notably in 0–2 years of age range.

Moxifloxacin provided a superior clinical cure rate on D3 compared to tobramycin, combined with a more convenient dosage regimen.

## CONCLUSION

The present study concludes that moxifloxacin 0.5% drops provided a more rapid clinical cure (47.1 vs. 28.7%  $P = 0.013$ ) and resolution rate (89.8% vs. 87.2%) than tobramycin 0.3% eye drops in the treatment of purulent bacterial conjunctivitis in children with 4 times dosing regimen.

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# Sturge-Weber Syndrome – A Case Report

Uthara Menon<sup>1</sup>, M S Aravind<sup>2</sup>, Lakshmi Prabha Das<sup>3</sup>

<sup>1</sup>Senior Lecturer, Department of Oral Medicine and Radiology, Malabar Dental College and Research Centre, Manoor, Kerala, India, <sup>2</sup>Reader, Department of Oral Medicine and Radiology, Amritha Dental College, Edappally, Kerala, India, <sup>3</sup>Senior Lecturer, Department of Oral Medicine and Radiology, Royal Dental College, Chaliserry, Kerala, India

## Abstract

Encephalo-trigeminal angiomas otherwise known as Sturge Weber syndrome is characterised by port-wine stain. Here we report a case with typical characteristics of the same and description about the patient's clinical presentations

**Key words:** Encephalotrigeminal angiomas, Sturge Weber syndrome, Port wine stain, Neurocutaneous disorder

## INTRODUCTION

Encephalotrigeminal angiomas commonly named as Sturge-Weber syndrome (SWS) is an uncommon neurocutaneous syndrome. It is characterized by unilateral facial nevus flammeus (or port-wine stain) with associated ipsilateral leptomeningeal angiomas. In the year 1860, first described by Schirmer and but more specifically in 1879 by Sturge. It is also known as Sturge-Weber disease, leptomeningofacial angiomas, and Sturge-Weber-Dimitri syndrome.<sup>[1,2]</sup> Though rare, this is the most frequent disease among the neurocutaneous syndromes.<sup>[2]</sup> It often follows the outline distribution of the trigeminal nerve.<sup>[3]</sup> Occurs in equal frequency in both the sexes. Intraorally, angiomas can involve lips causing macrocheilia, leading to hemihypertrophy of the buccal mucosa, palate, and the floor of the mouth. Gingival involvement varies from light vascular hyperplasia to severe overgrowth making it difficult for mouth closure or almost impossible.<sup>[4]</sup>

In 1992, Roach categorized SWS variants into three types:

- Type I: Individual has a facial port-wine stain, leptomeningeal angioma and may have glaucoma
- Type II: Individual has a facial port-wine stain, no leptomeningeal angioma and may have glaucoma
- Type III: Individual has leptomeningeal angiomas, no facial port-wine stain, and, rarely, glaucoma.<sup>[5]</sup>

Our aim with this case report is to present a case with classical signs of the disease being survived with this condition for 45 years.

## CASE REPORT

A 45-year-old female reported to the department with complaints of swollen and bleeding gums and loose tooth on the upper left side back tooth region. Her medical history revealed getting seizures on and off most frequently but was always manageable due to proper medication. She was on long-term multiple antiepileptic drugs (sodium valproate, clonazepam, and topiramate) for intractable seizures. Hematological and biochemical profile was within the normal range. The patient was apprehensive. She has no knowledge about the birth type or any uneventful birth events. No family histories relevant to her condition were elicited.

On extraoral examination, the patient had a unilateral port-wine stain centered around the right forehead, the right eye, over the nose, and the right side of upper lip. A reddish lesion similar to hemangioma was observed over the right side of the face. The entire lesion was centered toward one side without crossing midline.

Intraoral examination of the patient showed few missing teeth which patient reveals of being exfoliated on its and not being extracted by any dentist. No other obvious hard tissue abnormalities. Oral hygiene of the patient was poor with extensive calculus.

Gingiva in the upper right side region appeared inflamed, reddened with a tendency toward bleeding on probing.

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**Corresponding Author:** Dr. Uthara Menon, Department of Oral Medicine and Radiology, Malabar Dental College and Research Centre, Manoor, Kerala, India.



Figure 1: Extra oral view



Figure 2: Intra oral view

However, there was an absence of blanching on the application of pressure. The tongue also appeared stained. The palate showed marked port-wine stain over the entire right side without crossing midline. The buccal mucosa, floor of the mouth, and rest of the gingival appeared normal.

The ocular examination revealed the presence of suprascleral hemangiomas, indicative of glaucoma but the patient has not revealed any ocular checkup history for the same.

Radiographs did not show any relevant findings.

Based on the clinical features and vitropression execution, provisional diagnosis of SWS was made and the patient was advised to go for the ophthalmic examination and further medical evaluation for medical counseling in these specialties as a preventive measure.

## DISCUSSION

In our case, even though the patient has port-wine stain from birth onward, it remained asymptomatic till date. However, it is essential to be alert on having future complications as well. The lack of awareness about the disease among the dentist may lead to serious complication. This syndrome is associated with a port-wine stain in the face (naevus flammeus), ocular involvement leptomenigeal angiomas, ipsilateral gyriform calcification, convulsive crisis, hemiparesis, and hemiplegia.<sup>[3,6-8]</sup> Sturge-Weber oral manifestations occur in 38% of the patients, who may have hemangiomas lesion in lips, mucosa, gingiva, tongue, and palate.<sup>[9]</sup>

In this case report, the patient was identified with lesions resembling hemangioma, on the right side of the face extending from forehead covering cheeks, upper lip and clearly demarcated till the midline with intraoral findings involving gingiva and tongue.

## CONCLUSION

SWS is a neurocutaneous disorder. It includes the following triad port-wine stain involving the trigeminal nerve, ipsilateral leptomenigeal angiomas, and ipsilateral vascular malformation of the choroidal vasculature of the eye (Florine, 2011).

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# Apple-peel Atresia with a Twist: A Novel Case Report

Nandini Kaul Bedi<sup>1</sup>, Vishal Michael<sup>2</sup>, Samuel Paul Pradeep Konda<sup>3</sup>

<sup>1</sup>Associate Professor and Head, Department of Paediatric Surgery, Christian Medical College, Ludhiana, Punjab, India, <sup>2</sup>Student, Department of Paediatric Surgery, Christian Medical College, Ludhiana, Punjab, India, <sup>3</sup>Student, Department of General Surgery, Christian Medical College, Ludhiana, Punjab, India

## Abstract

Jejunoileal atresia is one of the more common causes of neonatal intestinal obstruction. Its incidence is up to 1 in 3000–5000 live births. The apple-peel deformity, Type IIIb according to Grosfeld's classification, forms about 5% of all jejunoileal atresia. It consists of a proximal jejunal bowel which ends blindly into a dilated segment; and a distal jejunoileum which exhibits a helical distribution around a central blood supply which usually arises from the ileocolic artery. We are presenting a novel case of jejunoileal atresia where the proximal bowel ends in an apple-peel formation, and the distal small bowel is supplied by a branch of the ileocolic artery. The baby was a full term, good weight, and otherwise well female baby with no major associated malformations.

**Key words:** Apple-peel atresia, Jejunoileal atresia, Neonatal intestinal obstruction

## INTRODUCTION

Jejunoileal atresia is one of the more common causes of neonatal intestinal obstruction which requires early, if not immediate, surgical management, and barring which it is incompatible with life. The incidence is up to 1 in 3000–5000 live births with a demographic variation.<sup>[1,2]</sup> It is antenatally diagnosed by fetal sonography which may show polyhydramnios, dilated small bowel loops and in some, fetal ascites if present. If antenatal bowel perforation occurs, it can be picked up, later in gestation, as calcification in the peritoneal cavity. Jejunoileal atresia has been classified by Grosfeld as follows, Type I has the presence of a mucosal web, Type II has a fibrous cord extending from the dilated proximal to the distal segment of gut, Type IIIa has a V-shaped mesenteric gap between the proximal dilated and distal micro gut, Type IIIb is the typical “apple-peel” deformity, and Type IV is the presence of multiple atresias, referred to as a “string of sausages.”<sup>[1,2]</sup>

The apple-peel deformity, Type IIIb, forms about 5% of all jejunoileal atresia,<sup>[3,4]</sup> consists of a proximal small bowel which ends in a typically blind and dilated jejunal or ileal segment which is supplied by the superior mesenteric artery (SMA) and the distal unused jejunoileum which is usually supplied by a branch from the ileocolic artery or sometimes from a branch of the right colic artery.<sup>[1,2]</sup> The name “apple-peel” comes from the fact that the distal small bowel is rotating around its arterial supply as the peel of an apple and the mesentery is not fixed to the posterior abdominal wall. The arterial supply enters the spiral of the small bowel from the distal end.<sup>[1,2]</sup> This deformity has the highest mortality out of all types of jejunoileal atresia followed by multiple atresia Type IV.<sup>[5]</sup> We are reporting a novel case of jejunoileal atresia with apple-peel deformity, where the apple-peel configuration is seen in the distal end of the proximal bowel.

## CASE REPORT

A full-term female baby weighing 3 kg with an antenatal diagnosis of polyhydramnios and dilated bowel loops had an abdominal X-ray [Figure 1a] suggestive of jejunoileal atresia. A gastrografin enema was given and the dye study observed under fluoroscope. Micro-colon was observed and the caecum was lying in subhepatic position [Figure 1b] with few loops of unused distal ileum seen bunched up around the caecum. The baby was kept nil by mouth, given

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**Corresponding Author:** Dr. Nandini Kaul Bedi, A – 273, Rajguru Nagar FF, Ludhiana - 141 012, Punjab, India.

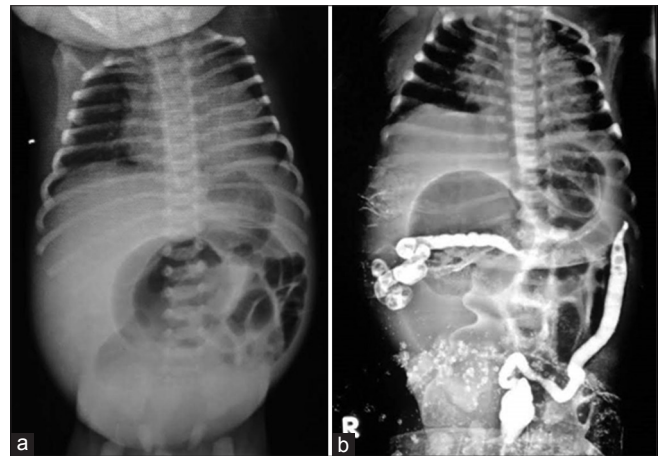


intravenous fluids, nasogastric tube was placed, aspirated and kept on the drain, antibiotics started, Vitamin K injection given and prepared for surgery.

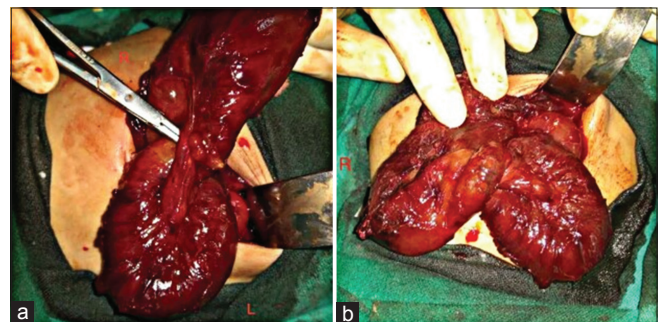
On laparotomy dusky loops of small bowel [Figure 2a] were seen at the start. When an attempt was made to deliver these loops, they were seen to be twisted [Figure 2b] and an effort to untwist the bowel led us to the large dilated blind end which was densely adherent to the under-surface of the liver and the superior surface of the bladder. This dusky small bowel was twisted around a leash of mesentery which was free and artery forceps could be passed under it [Figure 2a] freely. While attempting to untwist this loop, it was seen that the vessels in this mesentery were dusky and blackish in color. We decided to resect this gut as it did not improve on applying the warm sponge to the bowel and giving 100% oxygen in the respiratory circuit.

Proximally the bowel was resected about 1–2 cm away from the unhealthy margin but distally the grossly dilated blind end, seen as the large circular loop of gas-filled bowel in Figure 1a, was densely adherent to the liver and gall bladder superiorly and the urinary bladder inferiorly, indicating an antenatal perforation with fibrous adhesion. All attempts to separate, this adhesion was causing damage to the liver and the urinary bladder; hence, the parts which were adherent were left behind and the mucosa was peeled off. The resected specimen when held up showed the apple-peel configuration [Figure 3]. The proximal small bowel left behind was measured and was approximately 48–50 cm in length starting from the duodenojejunal junction. The distal small bowel was now seen more clearly as it had been lying jumbled up around the caecum, posterior to the dilated end of the proximal bowel [Figure 1b]. After injecting it with saline and confirming the distal patency, it was seen that the proximal 5–6 cm was a fibrous cord, which was excised. The remaining distal ileum was approximately 30 cm long. End to back anastomosis was done, mesenteric defect approximated.

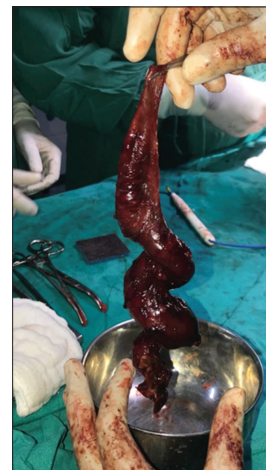
Postoperatively the baby had metabolic acidosis, was kept ventilated, and needed bicarbonate correction. She showed signs of sepsis with fall in platelets on the 3<sup>rd</sup> post-operative day. Aggressive management was continued. The baby passed a small amount of meconium per rectum. On the 5<sup>th</sup> post-operative day, there was a bilious leak in the surgical site and we decided to re-explore expecting a suture line leak which was the case. The bowel appeared pink and viable and except for a small leak, the rest of the repair was holding well. The distal gut had improved in caliber and contained meconium. We repaired the leak, inserted a central line, and kept the baby ventilated. On the 2<sup>nd</sup> post-operative day, the baby came off the ventilator, but at the same time, the leak reoccurred. We kept the baby nil by mouth, on total parenteral nutrition (TPN) and started a very low dose of octreotide,



**Figure 1: (a) Infantogram showing small bowel loops with dilated blind end and abrupt cut-off of bowel gas. The large bowel is not seen, gas in the stomach and a few loops of the small bowel are suggestive of jejunoileal atresia. (b) Gastrograffin enema showing unused "micro-colon" with caecum in sub-hepatic position. Dye is seen in loops of unused ileum which is bunched up in sub-hepatic region (there are artifacts in the lower region of the fluoroscope screen picture)**



**Figure 2: Dilated loops of small bowel proximal to the atresia, seen to loop around the mesenteric vessel forming an apple-peel configuration. The bowel is dusky with black patches all over. (a) An artery forceps eliciting a free mesentery around which the small bowel is rotating. (b) shows the apple-peel configuration of the proximal dilated small bowel. Gangrenous patches are visible in the dusky loops**



**Figure 3: Apple-peel configuration of the resected proximal gangrenous small bowel**

intravenously. Within 2 weeks the entero-cutaneous fistula had reduced in size and was draining a maximum of about 5–8 ml in 24 h, and the baby started passing small quantities of meconium about twice a day through anus. Postoperatively the weight had come down to 2.5 kg, and following TPN it had come up to 2.75 kg. We started oral feeds and gradually increased the quantity while reducing the TPN. The baby was now improving and was 30 days old. As we were gradually going up on feeds and had finally stopped the TPN, the parents, who were actively involved at this stage, insisted on taking the baby home, confident of being able to manage.

Within 6 days, the baby was brought back, severely dehydrated, in septicemia, with bradycardia, and in gasping condition. Although we resuscitated her and put her on life support measures, she succumbed to sepsis after 3 days.

## DISCUSSION

We are reporting a case of jejunoileal atresia with an apple-peel deformity at the end of the proximal gut. This is completely different from the Type IIIb jejunoileal atresia which has been described by Grosfeld.<sup>[1]</sup> The blood supply to this apple-peel segment was a distal jejunoileal branch of the SMA which ran through the center of the apple-peel configuration, entering it from the proximal end. The distal segment of ileum was supplied by arterial branches which appeared to be arising from the ileocolic branch of the SMA. The ascending colon was deficient and the caecum was in a sub-hepatic position. Alnosair *et al.*<sup>[4]</sup> have reported five cases, including their own, of a variant of apple-peel atresia where there is duodenal atresia, absence of 3<sup>rd</sup> and 4<sup>th</sup> part of duodenum, absence of SMA and the entire jejunoileum is in the form of an apple-peel deformity with a marginal arterial supply arising from the inferior mesenteric artery. To the best of our knowledge, we have not come across an anomaly similar to the one we are reporting, in the available literature.

Low birth weight, prematurity, and associated anomalies, mainly cardiac, are known to be the cause of death in the post-operative period.<sup>[1,2,4,5]</sup> None of these were present in our patient. The reason for an anastomotic leak, which is known to be a common post-operative complication,<sup>[1,2,6]</sup> could not be explained as the distal gut had moved a few times and the anastomosis itself was pink and patent showing no signs whatsoever of any vascular compromise on re-exploration. We can safely presume a functional obstruction of the distal ileal segment.<sup>[1,2,6,7]</sup>

The mortality and morbidity are higher with antenatal perforation of the bowel and vascular compromise. In

our patient, on exploration there were definite signs of an antenatal perforation and the blind end of the proximal bowel was densely adherent to the under-surface of the liver and the superior surface of the urinary bladder. There was no indication of an antenatal perforation on abdominal X-ray nor was there any indication of the gangrenous gut in the general condition or blood biochemistry of the baby. She appeared good weight, full term, active and well maintained, not giving us any warning of the gangrenous gut in the abdomen. Although we did not see it coming the baby was taken up for surgery at 24 h of age, so the delay was not the reason. We do feel that had the baby stayed in the hospital, we would have had a better chance to gradually shift her from parenteral to enteral feeds and attempted an early closure of the entero-cutaneous fistula. The major problems that we faced were the inability to maintain TPN for long due to the high cost and a high rate of hospital-acquired infections.

## CONCLUSION

We have reported a novel case of jejunoileal, apple-peel atresia and described the anatomy as we found it. It is a matter of further speculation and research as to what could be the developmental incidents which have led to this, as far as we know as yet, unreported form of intestinal atresia.

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# Management of a Case of Distal Ulna Giant Cell Tumor with Excision and Buttress Bone Grafting - A Case Report

Mahboobur Rahman<sup>1</sup>, Ritwika Nandi<sup>1</sup>, Sanjay Kumar<sup>2</sup>, Sujit Narayan Nandi<sup>3</sup>, Sanjay Kumar<sup>4</sup>

<sup>1</sup>Junior Resident, Department of Orthopaedics, Nil Ratan Sircar Medical College and Hospital, Kolkata, West Bengal, India, <sup>2</sup>Senior Resident, Department of Orthopaedics, Nil Ratan Sircar Medical College and Hospital, Kolkata, West Bengal, India, <sup>3</sup>Professor, Department of Orthopaedics, Nil Ratan Sircar Medical College and Hospital, Kolkata, West Bengal, India, <sup>4</sup>Associate Professor, Department of Orthopaedics, Nil Ratan Sircar Medical College and Hospital, Kolkata, West Bengal, India

## ABSTRACT

Giant cell tumor (GCT) of the distal ulna is an extremely uncommon entity. These tumors are generally managed by excision of the tumor without any reconstruction. Simple excision of the tumor mass without any reconstructive procedure leads to ulnar translation of the carpal bones and dynamic convergence of the ulna toward the radius. In our case, excision of GCT mass of the distal ulna in a 15-year-old boy was supplemented with reconstruction of the distal radioulnar joint by a 2 cm × 1 cm bone graft and tenodesis of extensor carpi ulnaris to the ulnar stump. The patient achieved painless range of motion of his wrist joint by 5 months without any post-operative complications.

**Key words:** Buttress bone grafting, Distal ulna, Giant cell tumor

## INTRODUCTION

Giant cell tumor (GCT) of the bone is an uncommon, benign, locally aggressive tumor arising usually in the epiphyseal region. GCT of distal ulna is an even rarer disease (0.45–3.2% of all primary bone GCTs).<sup>[1]</sup> This case report is that of a 15-year-old boy with GCT of his right distal ulna which was treated with wide excision and reconstruction of the wrist with buttress bone grafting.

## CASE REPORT

A 15-year-old boy came to the outpatient department with pain and swelling in his right wrist and distal forearm for 3½ months. The swelling 4 cm × 3 cm in size was initially small in size and had increased in size over the last 1 month. Standard anteroposterior and lateral radiographs showed

an expansile osteolytic lesion in the distal ulna [Figure 1]. A magnetic resonance imaging was done, and the impression was that of an expansile lytic locally aggressive SOL of the distal ulna, suggestive of a GCT [Figure 2]. Fine-needle aspiration cytology was done from the swelling, and the features were suggestive of GCT [Figure 3].

### Management: Surgery

The tumor was approached through a dorsal incision [Figure 4]. Distal ulna including the tumor and 3 cm of normal bone were excised [Figure 5]. A 2 cm × 1 cm iliac crest bone graft was harvested from the contralateral iliac crest. This graft was then fixed to the distal radius with two 4 mm cannulated screws [Figure 6]. The distal end of the remaining ulna was stabilized by tenodesis with the extensor carpi ulnaris muscle [Figure 7]. An immediate post-operative radiograph was obtained showing the graft being held in its place by 2 cannulated screws [Figure 8]. Post-operatively, the wrist was immobilized with a below elbow plaster of Paris slab for 2 weeks after which gentle range of motion exercises was started.

## DISCUSSION

GCT of the bone is an uncommon, benign, locally aggressive tumor usually arising in the epiphyseal region.

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**Corresponding Author:** Dr. Mahboobur Rahman, 16/2B Topsia Road, 2<sup>nd</sup> floor, Kolkata – 700 046, West Bengal, India.



GCT of distal ulna is a rare disease (0.45–3.2% of all primary bone GCTs).<sup>[1]</sup>

Recommended treatment of GCT of expendable bones like the distal ulna is en bloc excision of the tumor without any reconstruction. As per the study by Jamshidi *et al.*, for GCT of distal ulna, extended curettage with bone grafting is a better treatment modality when it is confined

to the bone. When the tumor breaches the cortex, they recommend tumor resection without reconstruction.<sup>[2]</sup>

However, excision of the distal ulna may lead to wrist and forearm instability and dynamic convergence of the ulnar



Figure 1: Anteroposterior and lateral radiographs showing an expansile osteolytic lesion in the distal ulna



Figure 2: Magnetic resonance imaging showing an expansile lytic locally aggressive SOL of the distal ulna

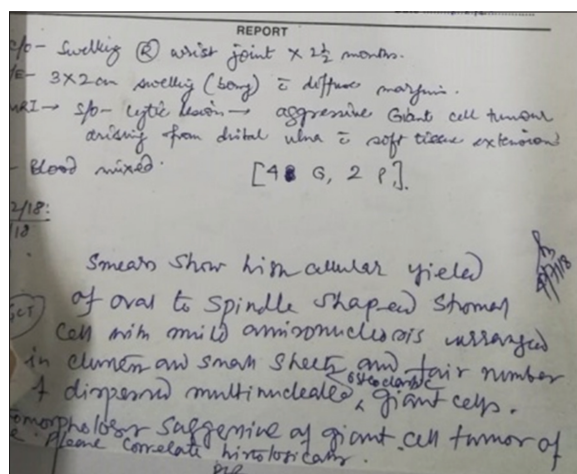


Figure 3: Fine-needle aspiration cytology report was suggestive of giant cell tumor



Figure 4: The tumor was approached through a dorsal incision



Figure 5: Distal ulna including the tumor and 3 cm of normal bone were excised

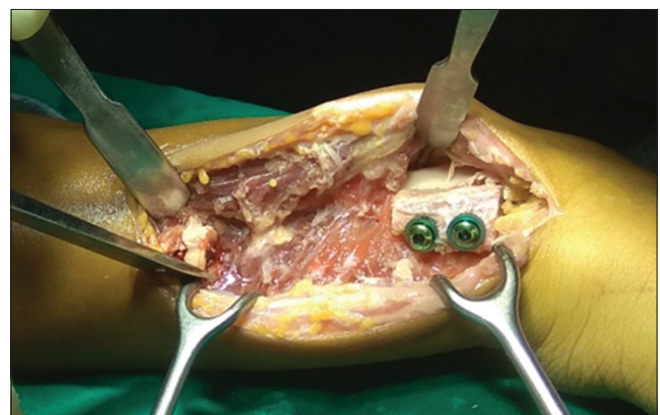
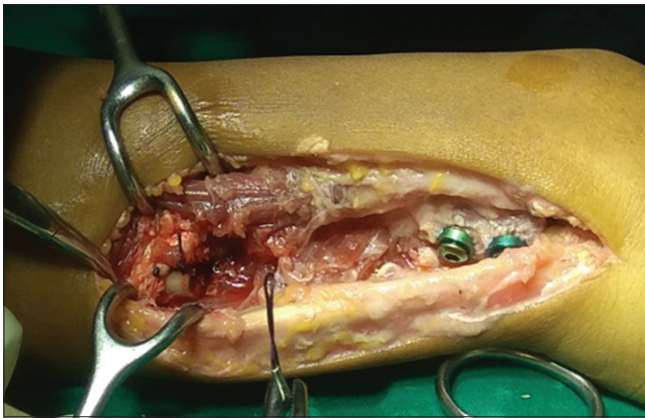


Figure 6: Bone graft fixed to radius with two 4 mm cannulated screws





**Figure 7: Tenodesis of extensor carpi ulnaris to the distal end of the ulnar stump**



**Figure 8: Immediate post-operative radiograph**

stump toward the radius.<sup>[3]</sup> Furthermore, there may be ulnar translation of the carpal bones.<sup>[4]</sup> This may cause pain and stiffness during wrist and forearm movements.

In our case, after tumor excision, we fixed a bone graft to the distal end of the radius to prevent ulnar translation of the carpal bones and to provide ulnar support at the distal radioulnar joint.<sup>[4]</sup> Moreover, to prevent the radioulnar convergence and ulnar instability, we did tenodesis of the extensor carpi ulnaris to the distal end of the ulnar stump.<sup>[5,6]</sup>

There were no post-operative complications. 3 months after surgery, there was bony fusion of the bone graft with distal radius, and after 5 months, the patient had painless range of motion of his right wrist joint.

## RESULT

There were no post-operative complications. 3 months post-surgery, there were bony fusion of the graft [Figure 9]



**Figure 9: Post-operative radiograph after 3 months showing union of the graft to the distal radius**



**Figure 10: Patient had painless range of motion 5 months after surgery**

and the distal radius, and after 5 months, the patient had painless range of motion of his right wrist joint [Figure 10]

## CONCLUSION

GCTs of the distal ulna are a rare entity. Mere excision of the tumor without any reconstruction may lead to wrist instability, ulnar translation of the carpal bones, and dynamic convergence of the ulna toward the radius during forearm movements. Hence, following excision of the distal ulnar GCT, reconstruction of the wrist can be done using a bone graft fixed to the distal radius, and radioulnar convergence can be prevented by tenodesis of extensor carpi ulnaris to the distal end of the ulnar stump. Painless range of motion of the wrist can be achieved without any post-operative complications.

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# Esophago-esophageal Intussusception: A Rare Presentation of Carcinoma Esophagus

Sagar Sonone, Vivek Murumkar, Jagneet Chatha, Amol Gawhale

Resident, Department of radiology, Seth G S Medical College and KEM Hospital, Mumbai, Maharashtra, India

## Abstract

Esophageal cancer is the third most common gastrointestinal malignancy and is among the ten most prevalent cancers worldwide. Common malignant neoplasms of esophagus include squamous cell carcinoma and adenocarcinoma. Squamous cell carcinoma is more common than adenocarcinoma, but the incidence of adenocarcinoma is on the rising trend nowadays and found to be predominant in newly diagnosed patients and in cases with Barrett's esophagus. Dysphagia and weight loss are the principal complaints in the patient with carcinoma esophagus. Intussusception causing acute obstruction of small bowel and colon is known. Few cases of gastroesophageal intussusception due to eating disorders, congenital obstructions like superior mesenteric artery syndrome, physical exertions like weight lifting, peptic ulcer disease, and pregnancy due to hyperemesis gravidarum are known. Our case, a 52-years-old gentleman presented to gastroenterology OPD with complaints of dysphagia to solids and emaciation. For these complaints, upper GIscopy was advised. Gastroenterologists were unable to pass endoscope so patient was referred for computed tomography of thorax and abdomen, which revealed circumferential irregular thickening retro cardiac segment esophagus and lumen within lumen appearance of esophagus with metastasis to lymph nodes and liver. In adults, intussusceptions of bowel usually have a lead point, for example, mesenteric lipoma or a neoplastic process; in our case, it was carcinoma of esophagus.

**Key words:** Esophago-esophageal intussusception, Esophageal cancer, Dysphagia

## INTRODUCTION

Intussusception predominantly involves pediatric population but approximately 5% of them occur in adult, and it is frequently caused by demonstrable pathologies.<sup>[1,2]</sup> Small and colon are common sites of intussusception leading to obstruction; however, esophageal intussusception is extremely rare.<sup>[3]</sup> Esophageal carcinoma usually presents as asymmetric thickening of wall, <3 mm is considered as normal, and thickness more than 5 mm is considered as abnormal.<sup>[4]</sup> Esophageal carcinoma causing esophago-esophageal intussusception is very rare. Progressive dysphagia and weight loss are usual presentation of patients with esophageal carcinoma. Tobacco, alcohol, environmental carcinogens, and nutritional deficiencies are usual risk factors for developing carcinoma esophagus in which tobacco and alcohol are main culprits.

Cross-sectional imaging like computed tomography (CT) and magnetic resonance imaging (MRI) are being used to stage carcinoma esophagus.

CT and MRI can detect extension of disease process outside lumen of esophagus into mediastinum including trachea, bronchi, aorta, and pericardium.<sup>[4]</sup> It is important to differentiate resectable lesions from non-resectable ones to avoid unnecessary morbidity due to surgical intervention. Endoscopic biopsy usually was done to confirm the diagnosis.

## CASE REPORT

A 52-years-old male patient presented with complaints of progressive dysphagia and emaciation to GI medicine OPD. For these complaints, upper GIscopy was advised. Gastroenterologists were unable to pass the endoscope into thoracic segment of esophagus so patient was referred for computed tomography of thorax and abdomen.

A dual-phase contrast-enhanced CT scan with arterial phase at 30 s and venous phase at 70 s was performed,

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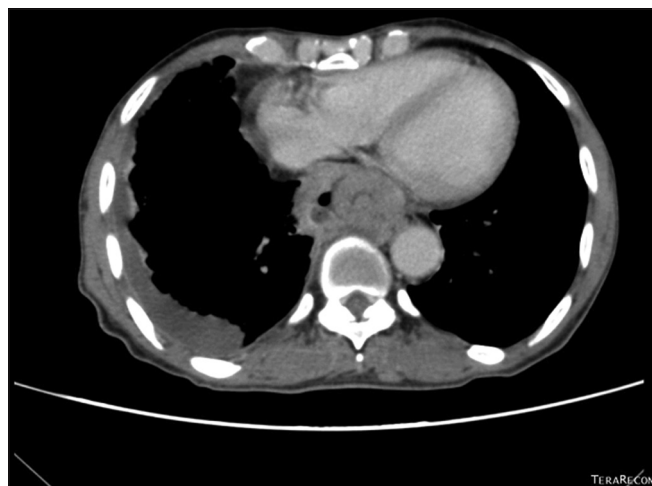


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**Corresponding Author:** Dr. Sagar Sonone, Resident, Department of radiology, Seth G S Medical College and KEM Hospital, Mumbai, Maharashtra, India.

and thorax and abdomen were included in the study. CT scan revealed dilated proximal esophagus with irregular circumferential thickening of retrocardiac segment of esophagus which showed enhancement on contrast study [Figure 1]. Thoracic part of esophagus shows a classic lumen within lumen appearance for the length of 3 cm with the leading point being neoplastic thickening of esophagus [Figures 2 and 3]. The neoplastic growth in the esophagus is abutting the aorta, but fat planes are not compromised [Figure 3]. Fat planes with left atrium are compromised [Figure 4].



**Figure 1:** Axial section of contrast-enhanced computed tomography chest shows lumen within lumen appearance of thoracic esophagus suggestive of intussusception



**Figure 2:** Coronal reformatted section of contrast-enhanced computed tomography chest and abdomen shows lumen within lumen appearance of esophagus with irregular circumferential thickening of esophagus

Additional findings on CT scan were enlarged peripherally enhancing local (mediastinal group) lymph nodes and supra coeliac group of lymph nodes. Mild right-sided pleural effusion was noted with fissural extension into oblique fissure [Figure 5]. Portovenous phase showed hematogenous spread of neoplastic process as multiple ill-defined hypoattenuating lesions involving both right and left lobe of the liver of varying sizes [Figure 6].<sup>[5]</sup>



**Figure 3:** sagittal reformatted section of contrast-enhanced computed tomography chest and abdomen shows lumen within lumen appearance of esophagus suggestive of esophago-esophageal intussusception



**Figure 4:** Axial section of contrast-enhanced computed tomography chest shows circumferential irregular thickening of thoracic esophagus which is suggestive of malignant neoplasm of esophagus





**Figure 5: Axial section of contrast-enhanced computed tomography upper abdomen shows enlarged supraceliac peripherally enhancing lymph nodes suggestive of metastatic lymph node**



**Figure 6: Axial section of contrast-enhanced computed tomography of the upper abdomen shows multiple peripherally enhancing lesions of variable sizes in the right lobe of liver suggestive of metastasis to the liver and also right-sided pleural effusion noted**

## DISCUSSION

To the best of our knowledge, this is the first case as there are no case reports where carcinoma esophagus has been known to cause esophago-esophageal intussusception. The exact incidence of carcinoma esophagus causing intussusception is not known, but the

incidence of partial gastroesophageal intussusception on radiographic examination is around 1.4%.<sup>[6]</sup> Dysphagia and weight loss are the principal complaints of carcinoma esophagus which were present in this case. Various causes of gastroesophageal intussusception have been described as peptic ulcer disease, pregnancy, and small bowel obstruction. Principal symptoms of gastroesophageal intussusception causing acute esophageal obstruction are acute retrosternal chest pain and excessive salivation.

In this case, correction of intussusception and resection of tumor was not possible as esophageal malignancy presented in the advanced stage in the form of lymphatic and hematogenous dissemination disease process. Palliative feeding gastrostomy was done for the patient.

CT scan is useful in the diagnosis of intussusceptions with a leading point. Nowadays, cases of intussusception without leading point are also being diagnosed with the help of CT scan.<sup>[2]</sup> CT scan has a good sensitivity and specificity in cases of carcinoma esophagus, in diagnosing extension to mediastinal structures such as aorta, bronchus, and pericardium. T-staging in the carcinoma esophagus is better with endoscopic ultrasound, but it has some limitations such as stenotic lesions, intussusception, and high-grade strictures in which we cannot pass endoscope further and increase the risk of perforation. In such cases, CT scan is good modality.

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# Dot-in-circle Sign of Mycetoma on Magnetic Resonance Imaging

Deepak Jain<sup>1</sup>, Satya Bhuwan Singh Netam<sup>2</sup>, Sanjay Kumar<sup>3</sup>, Sanjay Agrawal<sup>4</sup>

<sup>1</sup>Assistant Professor, Department of Radiodiagnosis, Pt.J.N.M.Medical College, Raipur, Chhattisgarh, <sup>2</sup>Professor and Head, Department of Radiodiagnosis, Pt.J.N.M.Medical College, Raipur, Chhattisgarh, <sup>3</sup>Associate Professor, Department of Radiodiagnosis, Pt.J.N.M.Medical College, Raipur, Chhattisgarh, <sup>4</sup>Junior Resident, Department of Radiodiagnosis, Pt.J.N.M.Medical College, Raipur, Chhattisgarh, India

## Abstract

Mycetoma is a chronic granulomatous disease prevalent in tropical countries, but it also occurs in Europe and the United States. Early diagnosis is important as it has therapeutic implications. Although biopsy and microbiological culture provide the definitive diagnosis, these are difficult to achieve in many instances. The dot-in-circle sign is a recently proposed magnetic resonance imaging (MRI) sign of mycetoma, which is likely to be highly specific. We present a case of mycetoma of the left calcaneum with characteristic MRI features.

**Key words:** Disease, Mycetoma, MRI

## INTRODUCTION

Mycetoma is a debilitating chronic granulomatous disease prevalent in tropical and subtropical regions, but it also occurs in Europe and the United States. It was first described in Madura, India in 1846; hence, the eponym Madura foot.<sup>[1]</sup> The disease can be caused by two groups of organisms, the Eumyces or true fungi (eumycetoma) and the Actinomyces, which are filamentous bacteria of the order *Actinomycetales* (actinomycetoma).<sup>[1]</sup> The evolution of the disease is slow and mostly painless. Patients present many years after the onset of infection, often with extensive soft tissue and bone involvement.<sup>[2]</sup> The organism first lodges in the soft tissues. Bones are almost always attacked from outside, in contrast to bacterial osteomyelitis which occurs through the hematogenous spread, and periosteal reaction and cortical erosion may then be seen. Early diagnosis, before the appearance of sinuses and grains, is difficult. If left untreated, it may result in severe disability, often necessitating amputation. Although biopsy or microbiological culture of the discharge will yield the definitive diagnosis, both may be difficult to achieve with

fastidious organisms. Imaging can aid in the early diagnosis of the disease.

## CASE REPORT

We present the magnetic resonance imaging (MRI) characteristics of a patient with mycetoma that demonstrated the recently described dot-in-circle sign, suggesting the possible diagnosis before the histological diagnosis. A 25-year-old male came to the emergency department with complain of swelling and pain in the left ankle and foot for 6 months. Progressive in nature, pain increases during walking. No discharging sinus or ulcer is seen. General examination was unremarkable. Blood and serum chemistry were also unremarkable. Plain radiograph of the left ankle with foot showed soft tissue swelling. No calcification or bone destruction was seen.

MRI was performed to characterize and evaluate the extent of the disease. T2-weighted and T2-weighted fat-saturated MRI revealed diffuse hyperintensity involving subcutaneous tissue, muscles with multiple focal fluid collections. In addition, multiple small discrete spherical hyperintense lesions were noted. In the center of some of these lesions, there was a tiny hypointense focus, resulting in the dot-in-circle sign. Small conglomerated low-intensity foci and microabscesses were also seen. The diagnosis of mycetoma was made based on these findings.

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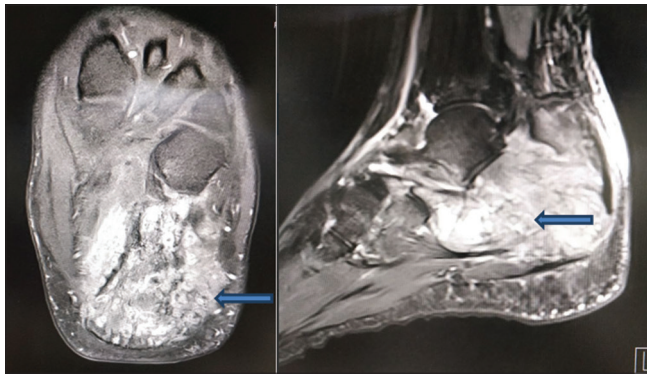
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**Corresponding Author:** Dr. Deepak Jain, Assistant Professor, Department of Radiodiagnosis, Pt.J.N.M.Medical College, Raipur, (I Chhattisgarh, India.

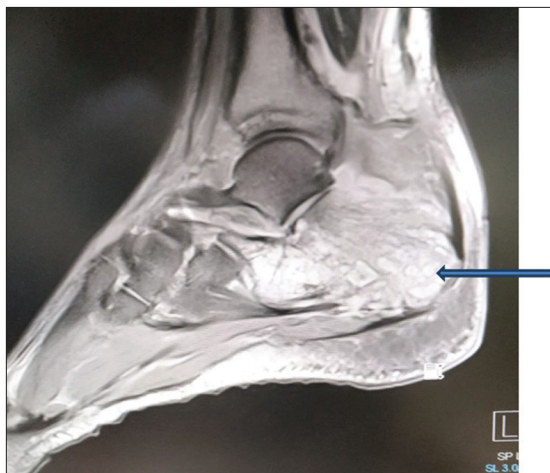
## DISCUSSION

The term mycetoma is a clinical entity, which applies to a chronic inflammatory process of soft tissue, usually of the foot, resulting from the implantation of one or various fungi or actinomycetes. Initially, there is the formation of soft tissue swelling with induration due to the underlying granulation tissue. It usually progresses to the formation of sinuses and extrusion of grains. The lesion may be confined to the soft tissue for years before bone involvement occurs. The diagnosis of mycetoma should not be considered by physicians when presentation is limited to soft tissues, without sinus or bone involvement. Although mainly a disease of the tropics, patients living in temperate regions may also be affected by this entity,<sup>[3,4]</sup> they are often misdiagnosed as soft tissue tumors in the early stage.

Histopathologically, the inflammatory reaction of mycetoma is non-specific and in the absence of isolation of fungal grains, it is difficult to differentiate from other inflammatory soft tissue processes and cold abscesses,



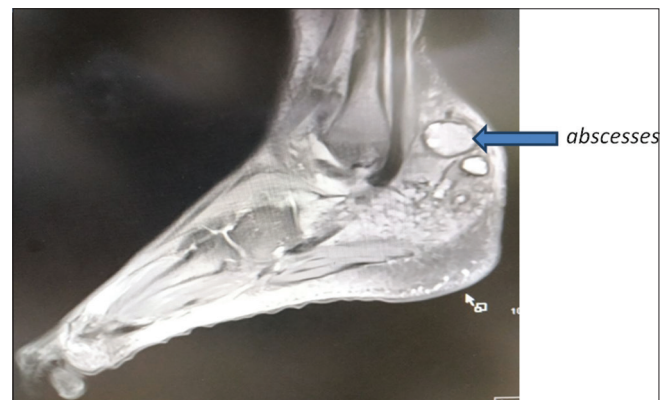
**Figure 1: Magnetic resonance imaging of left ankle with foot. The dot-in-circle sign is a recently proposed magnetic resonance imaging sign of mycetoma, which is likely to be highly specific. Central dot sign (arrow) axial image**



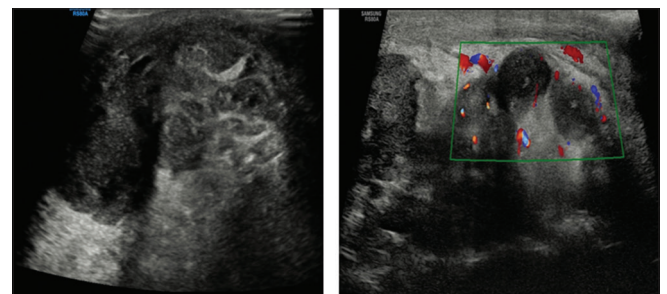
**Figure 2: Sagittal T2-WI shows central dot sign (arrow) in the left calcaneum**

which is not an uncommon occurrence. Although various radiographic bone changes have been described in cases of mycetoma, bone involvement occurs late in the course of the disease, when non-surgical cure is unlikely. Non-invasive imaging with MRI can characterize the soft tissue masses of mycetoma and aid in early diagnosis. Czechowski *et al.*<sup>[5]</sup> described the magnetic resonance (MR) appearance of mycetomas and found small low-signal intensity lesions on T1-weighted and T2-weighted MR images in 16 of 20 patients. They suggested that these appearances were due to susceptibility from the metabolic products within the grains. They observed lesions showing a conglomerate of low-intensity foci, as were seen in the presented case.

The dot-in-circle sign [Figures 1 and 2] is a recently described sign reflecting the unique pathological feature of mycetoma. It is seen as a tiny hypointense focus within high-intensity spherical lesions. This sign was proposed by Sarris *et al.*<sup>[6]</sup> in 2003 on T2-weighted, short inversion time inversion-recovery, and T1-weighted fat-saturated gadolinium-enhanced images. They correlated the MRI and histological findings in 2 cases of mycetoma and concluded



**Figure 3: Magnetic resonance imaging of the Madura foot. A soft tissue ill-defined swelling involved the posterior aspect of the left ankle and foot likely microabscesses with the preserved architecture of calcaneum. In this image: Hyperintense conglomerate areas of nodules which were separated by a low signal intensity rim. In the center of some of these nodules, there is a tiny hypointense focus, resulting in the characteristic dot-in-circle sign, which indicates mycetoma grains**



**Figure 4: Ultrasonography of left ankle showing heterogenous hypoechoic lesion likely abscess formation**



that the small central hypointense foci represented the fungal balls or grains [Figure 3], while the surrounding high-signal intensity foci represented the inflammatory granulomata.<sup>[6]</sup> The low-intensity tissue seen surrounding these lesions represented the fibrous matrix. They proposed that it is likely to be a highly specific sign for mycetoma.<sup>[6]</sup> We were able to demonstrate similar MRI findings in the presented case.

Few radiographic bone changes have been described to distinguish between actinomycetoma and eumycetoma.<sup>[1]</sup> Eumycotic lesions tend to form a few cavities in bone  $\geq 1$  cm in diameter, while actinomycetes often form smaller, but more numerous cavities. In a study by Lewall *et al.*,<sup>[1]</sup> a moth-eaten appearance caused by a combination of irregular periosteal reaction, periosteal erosion, and small cavities within bone was seen in 25% of cases of actinomycetoma, but in none of the patients with eumycetoma. The distinction between the two forms of soft tissue mycetoma was not possible with MRI.

To conclude, we stress the importance of MRI in the early diagnosis of mycetoma, even before the development of sinuses and/or extrusion of grains. Furthermore, as

these fastidious organisms may be difficult to demonstrate either on biopsy or microbiological culture, the clinical picture often necessitates multiple surgical biopsies, thus exacerbating morbidity due to delays in diagnosis and therapeutic intervention. MRI can be useful in such situations. It can strongly suggest the diagnosis of mycetoma when it demonstrates the dot-in-circle sign, conglomerated low signal intensity foci or microabscesses [Figure 4] in the background of a hypointense matrix as described above.

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# Button Battery with Magnet Ingestion in an Infant: Dual Peril – A Case Report

Vivin Sam Daniel<sup>1</sup>, Vishal Michael<sup>2</sup>, Nandini K Bedi<sup>3</sup>

<sup>1</sup>Resident, Department of General Surgery, Christian Medical College, Ludhiana, Punjab, India, <sup>2</sup>Resident, Department of Paediatric Surgery, Christian Medical College, Ludhiana, Punjab, India, <sup>3</sup>Associate Professor and Head, Department of Paediatric Surgery, Christian Medical College, Ludhiana, Punjab, India

## Abstract

Foreign body ingestion is common among children between the ages of 6 months and 3 years. Nearly 80% will pass through uneventfully and 20% will require some intervention, mostly endoscopic removal. Button batteries and magnets are frequent components of children's toys and a potential hazard for the child. We are reporting such a case and the complications which followed, with a view to increasing public awareness.

**Key words:** Button battery ingestion, Foreign body ingestion, Magnet ingestion

## INTRODUCTION

Foreign body ingestion is a common clinical situation encountered in children, usually between the ages of 6 months and 3 years.<sup>[1]</sup> Nearly 80% of these objects pass through the gastrointestinal tract uneventfully and are spontaneously evacuated, thereby not requiring any intervention. The remaining 20% require intervention either in the form of endoscopic retrieval or surgical extraction.<sup>[2]</sup> Magnets and button batteries are a common component in children's toys and gadgets and hence becoming a potential hazard for the child. Ingestion of more than one magnet, or a magnet and a magnetic object, can lead to serious complications in the gastrointestinal tract such as multiple perforations, enteroenteric fistulas, peritonitis, and intestinal obstruction.<sup>[3]</sup> Ingestion of button batteries, usually high-voltage lithium batteries, is in itself a hazard caused by the high voltage which can cause ulceration and perforation.<sup>[4]</sup>

In this report, we are describing the case of a 10-month-old female baby, with intestinal perforations and obstruction

caused by ingestion of a magnetic object and a button cell. This case report aims at creating awareness toward the hazards for children playing with magnetic toys, batteries, and small metallic objects.

## CASE REPORT

A 10-month-old female infant was brought to the emergency department with complaints of abdominal distension, obstipation, and bilious vomiting for 4 days. She was apparently in good health until 4 days before presentation when she developed abdominal distension and vomiting. Abdominal distension was gradually progressive. Vomiting was bilious in nature and occurred after every attempt to feed the child. She was also not able to pass stools or flatus during the time. The child was being managed at a local hospital with a provisional diagnosis of subacute intestinal obstruction but was later referred to our tertiary care center for further management.

There was no history of foreign body ingestion. On physical examination, the child was dehydrated and had tachycardia. On examination, her abdomen was distended with tenderness, guarding, and rigidity. Bowel sounds were absent, and rectum was empty. After resuscitation, abdominal X-ray was taken in both erect and supine posture, which revealed the presence of two small radio-opaque objects adherent to each other in the region of the ileum.

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**Corresponding Author:** Dr. Nandini K Bedi, Residence: A – 273, Rajguru Nagar FF, Ludhiana - 141 012, Punjab, India.

The small bowel loops were grossly dilated with multiple fluid levels. The colon could not be visualized, and there was absence of gas in the pelvis. There was absence of free gas under the domes of the diaphragm [Figure 1].

Once stabilized, the child was taken up for surgery. On exploration, a button battery and a small magnet were found in the distal ileum, approximately 20–25 cm from each other, [Figure 2] but adherent to each other due to the magnetic effect between the two objects. This ultimately resulted in the formation of a loop of bowel with a volvulus like effect, causing acute intestinal obstruction. The magnet as well the button battery had caused perforations in the antimesenteric side of respective bowel loops where they were present, with evidence of corrosion, [Figure 2] most likely due to high-voltage burn from the battery. The proximal bowel was grossly dilated, and the bowel distal to

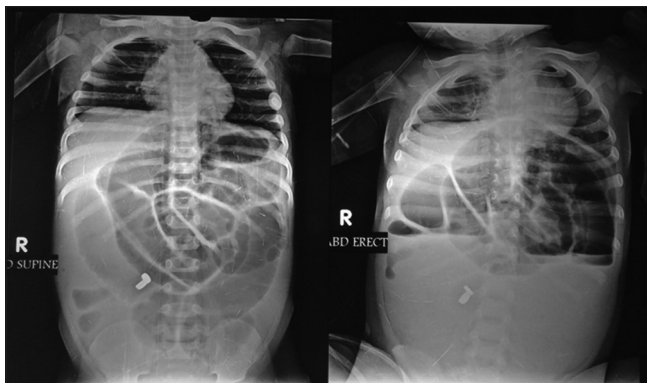
the volvulus caused by twisting of the loop was collapsed. Feculent peritonitis was present. The foreign bodies were removed, and the ileal perforations were debrided and repaired. Peritoneal lavage was done followed by closure.

Post-operatively, in the first 24 h, the baby had hypotension and hypokalemia which were corrected, following which she had an uneventful recovery and was discharged on the 6<sup>th</sup> post-operative day. At present, in more than a year of follow-up, the child has had no related complaints and is thriving well.

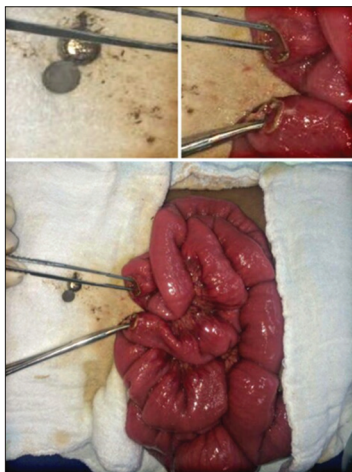
## DISCUSSION

Foreign body ingestion is a common scenario in emergency departments. Infants and children are keen to explore their surroundings, and they do so by putting whatever objects they can find in their mouth. Commonly swallowed objects include small toys, coins, buttons, button-batteries, etc. Ingested foreign bodies usually pass through the gastrointestinal tract without causing any harm. Recently, there has been an increase in the incidence of children presenting with ingestion of magnets. This is likely due to the use of magnetic elements in substandard toys, which have not been scrutinized according to the safety standards.<sup>[3]</sup> Complications caused by magnet ingestion were reported as early as 1989 and 1991, in Japanese literature, as reported by Honzumi *et al.*<sup>[5]</sup> He has also reported the first case study in English literature of a 3-year-old with an intestinal fistula caused by ingestion of magnets.<sup>[5]</sup>

Ingestion of a single magnet may not be harmful since they can pass through the alimentary canal like any other object, but more than one magnet or a magnet along with another magnetic metallic object can pose a serious threat. This is due to magnetic attraction between the two objects which may adhere to one another at two different lengths of intestine, resulting in tissue getting caught in between them. This tissue eventually becomes avascular and necrotic, causing intestinal perforation, enteroenteric fistulas, etc. Involvement of mesenteric vessels may result in extensive devascularization of the bowel or intraperitoneal hemorrhage. Ingestion of button batteries and coin batteries, to some extent, is fairly common. It was earlier thought that alkali which leaks from the battery was the major reason for perforations of the gut. Alkaline batteries have a voltage of approximately 1.5 Volts, whereas lithium batteries, which are longer lasting and are more commonly the button and coin batteries, have a higher voltage of approximately 3.0 Volts. Lee *et al.*<sup>[5]</sup> studied the effects of different types of batteries on the intestine of the child, after ingestion and found that alkaline batteries were most



**Figure 1: Abdominal X-rays showing grossly dilated small bowel loops with very little gas in the large bowel in the supine film and multiple fluid levels in the small bowel in the erect film. In both films, there are two small radio-opaque objects in the same position, right lower quadrant of the abdomen**



**Figure 2: The button battery and magnet are seen with a view of the two perforations in the small bowel, about 20 to 25 cm apart. On closer look, the perforations show a necrotic yellow rim which is likely due to high-voltage burn while pressure necrosis would have also played a part**

commonly passed out without incident whereas high-voltage lithium batteries posed a threat to the child and should be removed within 48 h from the small intestine if not spontaneously passed and immediately from the esophagus and stomach when noticed.

## CONCLUSION

This case report is aimed at increasing awareness of the dangers of substandard toys which contain batteries and magnets, and the threat they pose for children mainly between the ages of 6 months and 3 years. High-voltage lithium batteries are a bigger hazard as compared to alkaline batteries. A single small magnet is not a threat, but when ingested along with another magnet or a metallic object, it can be life threatening.

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