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Original Article

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Neonatal Septicemia: Still a Complicated Problem Due to Extended Spectrum Beta-lactamase Producing Organisms

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Abstract

Introduction: In developing countries, neonatal mortality accounts for 30-50% of the neonatal deaths. Almost 20% of neonates develop sepsis, and 1% die of sepsis-related causes. Neonatal septicemia is characterized by signs and symptoms of infection with or without bacteremia in the 1st month of life. Beta-lactamases are enzymes produced by some bacteria and are responsible for their resistance to beta-lactam antibiotics such as penicillin, cephamycins, and carbapenems.

Materials and Methods: This is a cross-sectional study in which 50 suspected cases were selected on the basis of positive screening for septicemia. Blood samples were collected from the neonatal intensive care unit (NICU). Results were incorporated according to statistical tests. Early or late onset sepsis (LOS) was decided on the basis of clinical features. For each extended-spectrum beta-lactamase (ESBL) producing organism, blood culture is the most important method.

Results: Out of 50 isolates of suspected neonatal sepsis, early onset sepsis was suspected in 38 cases and LOS in 12 cases. 8 out of 50 samples did show positive culture. Out of which 75% were detected as gram-negative organisms and the remaining 25% as gram positive. 25% of the total isolates were found to be ESBL producers.

Conclusion: It was concluded from this study that in the presence of high resistance, it becomes imperative to draw resistance patterns against different antimicrobial agents for the septic neonates in NICU.

Key words: Extended spectrum beta-lactamase, Neonates, Septicemia

INTRODUCTION

In developing countries, neonatal mortality accounts for 30-50% of the neonatal deaths. Almost 20% of neonates develop sepsis, and 1% die of sepsis related causes.[1] *Klebsiella pneumonia* and *Staphylococcus aureus* were frequently isolated pathogens along with pseudomonas and *Escherichia coli* in septicemia.[2] Neonatal septicemia is characterized by signs and symptoms of infection with or without bacteremia in 1st month of life. Sepsis occurring in the first 72 h of life is defined as early onset sepsis (EOS), and that occurring beyond 72 h as late onset sepsis (LOS). The choice of antibiotics is dependent upon the probable source of infection. For infections acquired during the hospital stay, resistant pathogens likely to be present are staphylococcus and organisms of *Enterobacteriaceae* and pseudomonas. It has been known now that these organisms are extended-spectrum beta-lactamase (ESBL) positive organisms. Beta-lactamases are enzymes produced by some bacteria and are responsible for their resistance to beta-lactam antibiotics such as penicillin, cephamycins, and carbapenems. The enzyme is produced by both Gram-positive and Gram-negative bacteria, but usually by Gram-negative bacteria. ESBL are capable of inactivating third generation cephalosporins (ceftazidime, cefotaxime, and cefpodoxime), penicillins, as well as monobactams

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(aztreonam), however, they are susceptible to cephamycins, carbapenems, some beta-lactam-beta-lactamase inhibitor combinations like piperacillin-tazobactum.[3] Most of the ESBL, are assigned to group "2be," molecular class "A," as per functional classification of beta-lactamases, a scheme devised by Bush *et al.*[4] It is also known that organisms producing ESBL, also have the ready capacity to acquire resistance to other antimicrobial classes such as the quinolones, tetracyclines, cotrimoxazole, trimethoprim, and aminoglycosides, which further limits therapeutic options.[5,6] Resistance to carbapenems has also been reported.[7] The mechanism behind this multi-resistance phenomenon is genetic, the gene encoding for resistance for both ESBL and other classes (e.g. quinolones) is often associated on the same mobile DNA element (plasmid).[8] The propagation of this plasmid during conjugation leads to the development of multidrug resistance in previously sensitive organisms. There is no doubt that ESBL producing organisms are of enormous clinical and the microbiological significance. Control of endemic ESBL producers is difficult. Heavy antibiotic use is also a risk factor for acquisition of an ESBL producing organisms. Prolonged intubation of catheters and intravenous cannula can act as a site for growth of opportunistic bacteria and thus can result is increased susceptibility for infection. Furthermore, it can be aided by some reluctant health workers who do not wear gloves or even wash their hands before handling the patients.

Bloodstream infections (BSI) are the most common infection in neonatal units, pneumonia (including ventilator-associated pneumonia), and urinary tract infection, followed by enteric, surgical site, and skin infections.[9] Nosocomial BSI in children are likely to be more frequent and serious in this backward area due to malnourished state of patients and delayed presentation to referral centers. The excessive use of antibiotics has led to widespread resistance of the bacteria toward most of the antibiotics available today. Hence, it becomes imperative to study the ESBL producing organisms in a tertiary care hospital in Eastern India with the service to the rural area of Bihar and Bengal. The people of this area suffer from malnutrition, are financially poor and go to quacks first rather than to doctors. They use higher end antibiotics without any thought of resistance. Intensive care units (ICU) like neonatal ICU (NICUs) are usually the epicenter of ESBL production in hospitals, but may evolve outside the ICUs also, clonal spread has been reported in nursing homes and chronic care facilities.[10] It has been seen that nursing homes may serve as a reservoir for ESBL producing organisms which may get introduced in acute care hospitals. There is usually heavy use of antibiotics, especially 3rd-generation cephalosporins and absence of required aseptic methods for daily procedures in nursing homes, which may cater the present ESBL organisms.[11] Present study was carried out with the main objectives of: (1) Identifying and isolating ESBL producing organisms on the basis of their susceptibility toward specific antibiotics in a neonatal set up-NICUs and, (2) promoting antibiogram policy for NICU.

MATERIALS AND METHODS

It is a cross-sectional study in which 50 suspected cases were selected on the basis of positive screening for septicemia. The study was carried out in the Department of Pediatrics in collaboration with the Department of Microbiology, Katihar Medical College and Hospital, from the period of November-2014 to January-2015 (3 months). Blood samples were collected from the NICU. The attendants of selected neonates were ethically informed, and their consents were taken. Case history of the patient was taken as according to format. Results were interpreted according to the statistical test. All the media used in the study were prepared according to the instruction by the company (Hi-media). Early or LOS was decided on the basis of clinical features. For each ESBL producing organism, blood culture is the most important method. Phenotypic confirmation for ESBL production was done as according to Clinical and Laboratory Standards Institute (CLSI), with ceftazidime + clavulanate and cefotaxime + clavulanate disks.

RESULTS

Out of 50 isolates of suspected neonatal sepsis, EOS was suspected in 38 cases and LOS in 12 cases (Figure 1). 8 out of 50 samples did show positive culture, out of which 75% were detected as Gram-negative organisms and the remaining 25% as Gram-positive (Table 1 and Figure 2). 25% of the total isolates were found to be ESBL

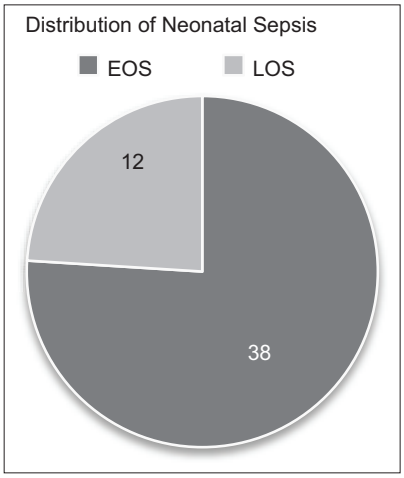

Figure 1: Distribution of neonatal sepsis

producers (Figure 3). Phenotypic confirmation of the ESBL producing isolates was done according to CLSI guidelines with cefotaxime + clavulanate and ceftazidime + clavulanate. 16% of the isolates were culture positive, out of which 25% of the bacterial isolates were found to be ESBL producers (Table 2).

Table 1: Results of blood culture in neonatal septicemia

Case reported	No (*n*=50)	Percentage
Total no of positive growth	08	16
Total no of negative growth	42	84

Table 2: Organisms isolated from cases of neonatal septicemia

Gram-staining reactions	Micro-organisms	Number of isolates	Percentage
Gram-positive	Coagulase negative Staphylococcus (CONS)	02	25
Gram-negative	*Klebsiella* Spp.	04	50
	E. coli	01	12.5
	Others	01	12.5
Total		08	100

E. coli: Escherichia coli

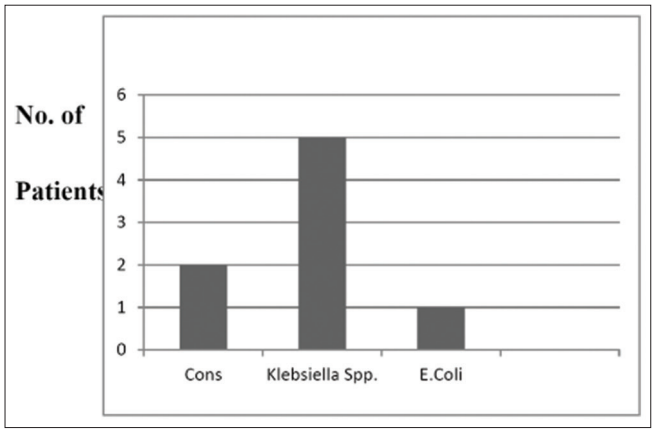

Figure 2: Distribution of bacterial isolates

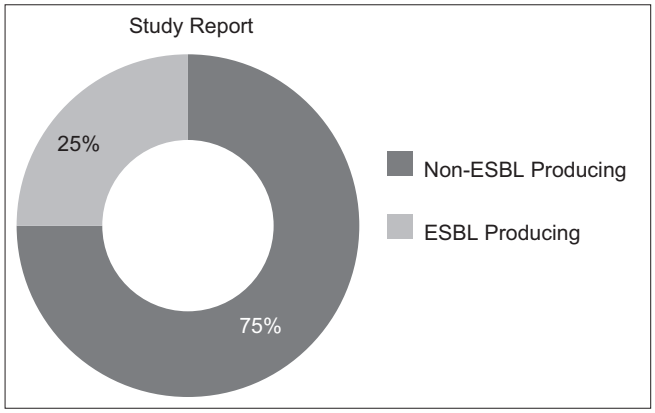

Figure 3: Study report

DISCUSSION

In the present study, the incidence of neonatal sepsis was observed, in which 50 suspected septic cases based on clinical features of EOS and LOS were selected over a period of three months from November-2014 to January-2015. Blood samples were drawn from all the suspected cases. Of total 50 cases, blood culture positivity was observed in 8 (16%) cases, out of which 6 (12%) cases were diagnosed as Gram-negative sepsis. Similar results were found in the studies of Kumhar *et al.* [12] and also in the studies of Roy *et al.*[13]

In this study, *Klebsiella* spp. was isolated predominantly, 4 out of 6 (50%) Gram-negative organisms were of *Klebsiella* spp., followed by *E. coli* in only one case. In the present study, gram-negative organisms constituted the major group of isolates (75%) from the cases of neonatal septicemia, which correlates with the findings (72.3%) of Kumhar *et al.* 12 Among this group, *Klebseilla* species has been found to be the prominent pathogens (50%), which correlates with the findings (47.1%) of Madhu Sharma *et al.*[14] Also, 2 out of total 8 isolates were of coagulase negative Staphylococcus. In this study, 25% of the Gram-negative isolates were found to be ESBL producers with ceftazidime and cefotaxime used as indicator antibiotics, the acquired ESBL producers rate did fall in the wide range, ranging from 6.6% to 91%, as shown by various studies from different regions of India. A total of 25% of Gram-positive organisms has been observed in our study. Similar kind of results were also found by Roy *et al.*[13] It was found that the rate of ESBL production was highest among the *Klebseilla* pneumonia isolates collected in Latin America, followed by Asia/Pacific Rim, Europe, and North America (44%, 22.4%, 13.3%, and 7.5%), respectively.[15]

CONCLUSION

Neonatal septicemia is a life-threatening emergency and rapid treatment with antibiotics is essential for the favorable outcome. Concluding in presence of high resistance, it becomes imperative to draw resistance patterns against different antimicrobial agents for the septic neonates in NICU. With increasing levels of resistance, even to carbapenems now-a-days, a careful and constant monitoring of antibiotic usage at regional and national level is required.

RECOMMENDATIONS

To avoid further development of bacterial resistance, a constant and strict monitoring is required on the antibiotic usage, especially in the rural areas, where patients are

unaware of any of these problems. They readily accept medicinal therapies advised by non-reliable sources such as quacks, inexperienced doctors, and medical non-representatives. An antibiogram policy for the neonatal set up could be prepared. It would hopefully ensure judicial use of antibiotics in the future.

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Original Article

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Hyponatremia in a Tertiary Care Hospital of Rajasthan: An Observational Study

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Abstract

Introduction: Hyponatremia is one of the most common electrolyte disturbances of encountered in medical wards, dialysis unit, and medical intensive care unit (ICU). It is defined as sodium ion concentration <135 mmol. ICU in patients with various comorbid conditions such as congestive heart failure (CHF), chronic kidney disease (CKD), liver cirrhosis, and diarrhea and vomiting. This contributes to substantial morbidity and mortality. However, early recognition and management drastically alters the prognosis.

Objective: This study was conducted to explore the clinical profile of hyponatremia in medically ill patients.

Materials and Methods: Study was conducted on 100 patients admitted in the medical unit from March 2013 to February 2014. All patients underwent clinical examination, routine hemogram, blood urea, sugar, creatinine, serum electrolytes, thyroid function tests, electrocardiogram, ultrasonography, and X-ray chest. Among the 100 patients, there were 65 male and 35 female patients.

Results: Totally, 91 patients had serum sodium 135 meq/l and 9 patients had severe hyponatremia with serum sodium concentration <120 meq/l. In our study, 32 patients were out of CKD, 16 patients of CKD with CHF, 27 of CHF, 7 with liver cirrhosis and 18 patients of diarrhea and vomiting. 7 patients died of which 7 patients were of CKD and CHF, 6 of CKD only, 2 of diarrhea and vomiting.

Conclusion: Hyponatremia is fairly common in patients admitted in medical wards, ICU, dialysis unit as patients with CHF, CKD, Liver cirrhosis, and diarrhea and vomiting hence early recognition and prompt treatment are of supreme importance in such patients.

Key words: Chronic heart failure, Chronic kidney disease, Diarrhea, Hyponatremia, Mortality

INTRODUCTION

Hyponatremia is one of the most common electrolyte abnormalities concentrated in clinical practice.

It is the associated with many different disease states such as congestive heart failure (CHF), liver cirrhosis, chronic kidney disease (CKD), and acquired immune deficiency syndrome.[1,2] Other risk factors of hyponatremia are age factors, advanced age,[3] diabetes, low body weight.[4,5] CKD is known to affect regular water homeostasis. The risk of hyponatremia increases in advance stage of CKD. The clinical presentation has wide spectrum, varying from asymptomatic patients to ones having seizures and coma.[6] Hyponatremia has been associated with various adverse clinical difficulties such as increased mortality,[7,8] length of inpatient stay,[8,9] gait in balance and falls,[10] rhabdomyolysis[11] and bone fractures,[12,13] increase health care costs.[14,15] We conduct an observational, descriptive, hospital-based study in medical intensive care unit (ICU), dialysis unit in tertiary care hospital.

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MATERIALS AND METHODS

This observational study was conducted on 100 patients admitted in the medical unit of SRG Hospital, Jhalawar from March 2013 to February 2014. History and clinical examination were recorded in all patients at the time of admission. History specially indicated compulsive

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water drinking and history of any chronic disease such as diabetes, hypertension, liver disease, and intake of any medicine. Clinical evaluation of the all patients was performed complete hemogram, measurement of fasting blood glucose, blood urea, creatinine, lipid profile, thyroid function tests, liver function test, serum electrolytes, electrocardiogram, ultrasonography, and X-ray chest was done in every patients. Clinical evaluation and serum electrolytes were recorded again at the time of discharge. The normal serum sodium range is 135 meq/l - 145 meq/l, hyponatremia is defined as Na <135 meq/l and severe hyponatremia defined as serum Na <120 meq/l.

RESULT

This study was conducted on 100 patients for a period 1 year admitted in the medical unit of SRG Hospital, Jhalawar from March 2013 to February 2014. Out of them, 65 were male and 35 were female and out of 100 patients 15 patients are of age group 20-40 years, 65 patients from 40 to 60 years and 20 patients from 60 and above (Figure 1).

There were 91 patients having serum sodium <135 meq/l and 9 patients of severe hyponatremia having serum sodium level of <120 meq/l (Table 1).

The most common underline predisposing factor for hyponatremia in our case series was CHF that is 27, CKD with CHF 16, only CKD 32, diarrhea and vomiting 18, and liver cirrhosis 7 patients (Figure 2).

Mortality in this study was 7% and out of which 5 patients were CKD and CHF group, 1 patient from liver cirrhosis and 1 from diarrhea and vomiting (Figure 3).

DISCUSSION

Hyponatremia is associated with substantial morbidity and mortality. The identification of risk factors associated with the development of symptomatic hyponatremia is important in determining preventive strategies. We took up this hospital-based, observational study as an attempt to explore hyponatremia. The incidence of hyponatremia in hospital admitted patients, as quoted in various studies, varies between 12 and 14%, with severe symptomatic hyponatremia being 1-2%.[16-18] In a Hungarian article, the range was quoted as 15-30%.[6] in our study it is 9%. Increased incidence of diarrhea and vomiting in the monsoon season.[19] The commonest type of hyponatremia documented in a risk factor (23.00%) followed by congestive cardiac failure.[20] In our study, the incidence of CHF is 24%.

Table 1: Serum sodium level distribution

Total no of patients	Serum sodium level<135 meq/l	Serum sodium level<120 meq/l
100	91	09

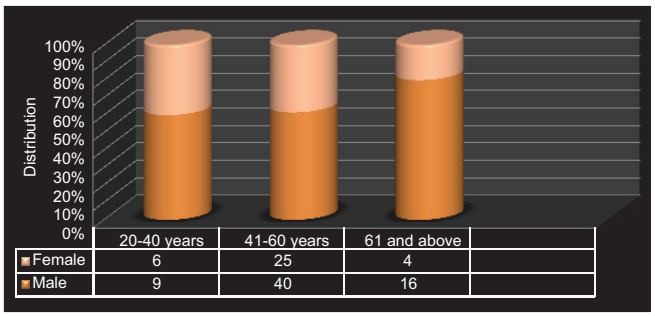

Figure 1: Age and sex distribution

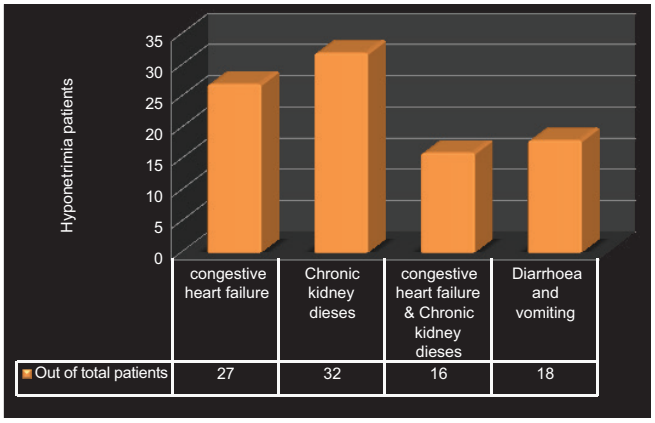

Figure 2: Total patients of hyponatremia

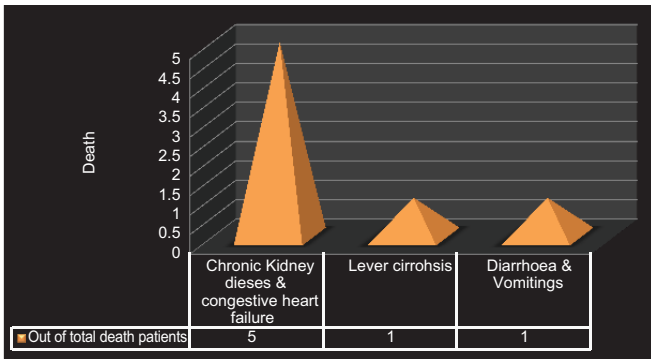

Figure 3: Total death patients

The most common type of hyponatremia is CHF. The severity of kidney disease did not appear to affect the mortality associated with hyponatremia, but patients with advanced chronic kidney dieses displayed relatively more mortality CHF as in this study also mortality in chronic kidney dieses is associated with severe hyponatremia because of underline diseases process. The study has described that association of hyponatremia with a variety of adverse out came including all cause of mortality[7,8]

length of inpatients stay[8,9] gait imbalance and falls, fractures and higher hospitalization cost. A study of maintained hemodialysis patients enrolled in hemodialysis unit also reported significant association of hyponatremia with mortality, even though in anuric dialysis patients, the development of low serum sodium is unrelated to underlying comorbid condition in our study also hyponatremia is present in anuric patients.

Our study population consisted mostly of male patients 65% and 35% female underlying predisposing factor for hyponatremia in our study by gastrointestinal disorder as diarrhea and vomiting is 18% but is higher in study of Chatterjee *et al.* in 2012.[21]

By including laboratory variable reflect abnormal liver function and structure, we had 7% case of cirrhosis liver with hyponatremia as in the study of US.

The diagnosis of probable etiology of hyponatremia is instrumental in formulating the management strategy, which varies widely. Determinants of therapy are extracellular volume status, the neurological signs and symptoms, the severity and duration of hyponatremia, and the rate at which it developed.[22]

CONCLUSION

Hyponatremia is fairly common in patients admitted in medical wards, ICU, dialysis unit as patients with CHF, CKD, liver cirrhosis, and diarrhea vomiting; hence early recognition and prompt treatment are of supreme importance in such patients.

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Original Article

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Demographic Profile of Donors Donating Blood at a District Level Blood Bank in a Teaching Hospital of Southern Karnataka and Reasons for Discard of Blood Units

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Abstract

Introduction: Blood transfusion is a vital component of health care delivery system. Voluntary non-remunerated blood donors are the foundation of a safe, sustainable blood supply. A small proportion of blood units continue to be discarded every year due to various reasons including units found to be infected with transfusion-transmissible infections (TTIs).

The objectives of this study were to determine: (1). The demographic profile of blood donors, who were screened and found eligible by the blood bank at a district level teaching hospital, Mandya. (2) The reasons for discarding of blood units collected by the blood bank.

Materials and Methods: Retrospective, cross-sectional, record-based, descriptive study of one-year duration. Study was conducted in the institutional blood bank of the Government Medical College, Mandya. Statistical analysis: Frequencies and proportions.

Results: A total of 7626 units of blood were collected by the blood bank in the year 2013 of which 7186 (98.2%) were from males and 133 (1.8%) from females. The number of donors aged 25 years and below was 3619 (49.4%), of which 3516 (97.2%) were males and 103 (2.8%) females. Voluntary blood donors contributed to 63.7% (4662 units) of the blood collected through the blood bank. Of the total 234 units of blood discarded, TTIs were the major reasons for discard with Hep B (39.7%) being the leading TTI followed by human immunodeficiency virus (6.4%) and hepatitis C virus (5.1%). The number of blood units discarded due to culture being positive was 30 (12.8%).

Conclusion: Majority of the blood donors are voluntary and males. Both among males and female donors, larger proportion of the blood donors are from younger age groups. A considerably small proportion of the units of blood collected, are discarded due to TTIs majority being due to Hepatitis B.

Key words: Blood donors, Blood safety, Cross-sectional studies, Donor selection

INTRODUCTION

Blood transfusion is a vital component of health care delivery system. Millions of lives are saved each year in routine and emergency situations for medical and surgical indications by availability of safe blood transfusion services. It also dramatically improves the life expectancy and quality-of-life of patients with a variety of acute and chronic conditions.[1]

As per National AIDS Control Programme Phase III findings, there is a serious mismatch between demand and availability of blood in the country: Against 8.5 million units/year requirement, the availability is only 4.4 million units/year of which voluntary blood donation is only 52%.[2]

Voluntary blood donation is the donation of whole blood or plasma voluntarily without inducement or reward.[3]

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Replacement donor is a person who donates blood upon the request of a specific patient or patient's family or acquaintance which, in principle is intended to be used specifically for the treatment of that patient.[4]

Voluntary non-remunerated blood donors are the foundation of a safe, sustainable blood supply. The World Health Organization's goal is for all countries to obtain all blood supplies from voluntary unpaid donors by 2020 in accordance with World Health Assembly resolution 28.72, which was adopted in 1975.[1]

As per the National AIDS Control Organization (NACO) grading of states in performance on blood safety, Karnataka is graded as a moderate performing state. With voluntary blood donation accounting for 53.90% of blood requirement being met by voluntary blood donors.[5]

The supreme court of India ordered a ban on professional blood donation in response to a writ petition filed by common cause against the union of India and others and directed that efforts need to be put into procuring blood through voluntary donors (VD) and replacement donors (RD) family donors. A significant proportion of transfusion-transmissible infections (TTIs) were attributed to professional blood donation which necessitated this legal move. A ban was to be imposed on "professional" blood donations by 1997.[6]

The magnitude of TTIs through unsafe blood transfusions was significantly reduced by the banning of professional blood donation. A small proportion of blood units continue to be discarded every year due to various reasons including units found to be infected with TTIs.[5]

It is important to ensure that the blood collection process does not harm either the donor or the recipient. This is achieved by having donor deferral criteria[7] and stringent screening of collected blood for possible Transfusion transmitted infections.[8]

A study of the demographic profile and other details of the donors who have donated blood help us to analyze and compare trends for a geographic area or community to which the Blood bank caters to.

Objectives

1. To determine the demographic profile of blood donors, who were screened and found eligible by the blood bank at a District level Teaching Hospital, Mandya.
2. To determine the reasons for discarding of blood units collected by the blood bank.

MATERIALS AND METHODS

Type of Study

Cross-sectional, retrospective, record based descriptive study

Tool for Data Collection

Information collected from registers and donor screening questionnaires maintained at the blood bank, district level teaching Hospital Mandya. The donor screening questionnaire is a semi-structured questionnaire common to all blood banks as specified by the NACO.

Inclusion Criteria

All donors who have donated blood to the blood bank of the Institution and all units of blood collected from VD/RD by the blood bank during the year 2013.

Exclusion Criteria

Blood units donated/received by the blood bank from other blood bank were not considered for analysis.

Data entry and Statistical Analysis

Data were entered into Microsoft® Excel™ spreadsheet and analyzed using the same software. Proportions and frequencies were used.

The protocol was approved by the Institutional Ethics Committee. Consent for infectious marker testing was obtained from all donors at the time of pre donation counseling.

Blood grouping and Rh typing was done by forward grouping and reverse grouping method. In the study period, serum specimens were screened for the presence of hepatitis B surface antigen (HBSAg), anti-hepatitis C virus (HCV) antibody and anti-human immunodeficiency virus (HIV) antibody by a commercial microplate enzyme-linked immunosorbent assay method and reagin antibody by a commercial non treponemal rapid plasma reagin card test. A part of the sample was also sent for individual donor nucleic acid testing to a regional lab (recognized by NACO) as a mandate.

Anticoagulated blood sample was also screened for the presence of malaria (Pf/PAN) by a commercial rapid test based on the immune chromatography principle.

RESULTS

A total of 7626 units of blood were collected in the year 2013 of which 307 were received from another blood bank, which were excluded from the analysis. Hence, details of 7319 units of blood were considered for analyses. A total of

7186 (98.2%) males and 133 (1.8%) females donated blood to the Institutional Blood bank. The number of donors aged 25 years and below was 3619 (49.4%) of which 3516 were males and females were 103. In the present study, a majority of the donors were of the age group of 21-25 years (31.6%) followed by those aged 26-30 years (25.8%) (Table 1).

There were no female blood donors (voluntary or replacement) in the age group of 45-60 years. Majority of the female donors were in the age group 18-20 years (Figure 1).

Type of Donors

Voluntary blood donors contributed to 63.7% (4662 units) of the blood collected through the blood bank. Female donors were relatively more among VD than RD (2.7% vs. 0.4%) (Table 2).

O positive followed B positive were the commonly donated blood groups accounting to 39.9% and 26.1% of the total units of blood, respectively. The number of donors with AB negative blood group was the least common accounting to only 21 donors (0.3%) (Table 3).

Reasons for Discard

For the 7319 units of blood procured from donors 234 (3.2%) units were discarded. Of the total 234 units of blood discarded, TTIs were the major reasons for discard with Hep B (39.7%) being the leading TTI followed by HIV (6.4%) and HCV (5.1%). Other reasons such as syphilis and other factors like hemolysis of blood, clotted blood or expiry of the shelf life of blood contributed to minor reasons for discard (0.4%, 1.3% and 3.4%, respectively). For every 100 bags of blood collected, 1 unit of blood was sent for culture to rule out any bacterial contamination/infection as a norm laid down by the Drug Controller General of India Indian Pharmacopeia 2010 and Drugs and Cosmetics Act 1940.[9]

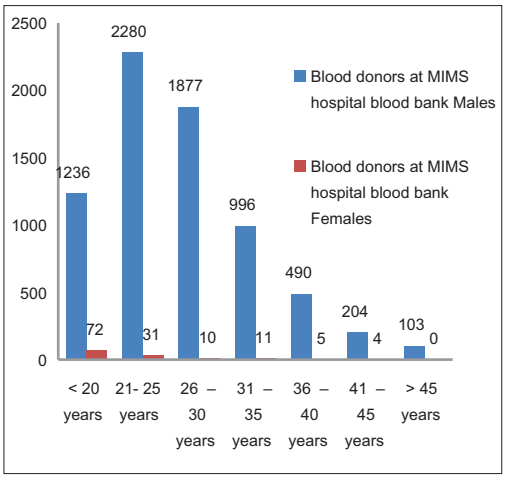

Figure 1: Age group and gender wise distribution of blood donors

The number of blood units discarded due to culture being positive was 30 (12.8%). As VIP protocol, 32 units (13.7%) of the blood were issued, which were returned unused to the blood bank and had to be later discarded (Figure 2).

For the total 7319 units of blood, HIV accounted for 0.2%, HBV for 1.27%, and HCV for 0.16% as reasons for discard when compared to 0.42% for HIV, 1.01% for HBV, and 0.72% for HCV for Karnataka state.[3]

DISCUSSION

As per a study done by Kumar *et al.* in Chattisgarh, India, among the total donors, 97.05% were male and 2.95% were female. Almost 78% were VD and 22% were RD.[10]

In another study by Unnikrishnan *et al.*, the age group of <25 years accounted for 42.9% of donors. Males dominated the donor population (95.13%) with females

Table 1: Age group and gender wise distribution of the blood donors

	Males (%)	Females (%)	Total (%)
<20 years	1236 (94.5)	72 (5.5)	1308 (17.9)
21-25 years	2280 (98.7)	31 (1.3)	2311 (31.6)
26-30 years	1877 (99.5)	10 (0.5)	1887 (25.8)
31-35 years	996 (98.9)	11 (1.1)	1007 (13.8)
36-40 years	490 (98.9)	05 (1.1)	495 (6.8)
41-45 years	204 (98.1)	04 (1.9)	208 (2.8)
>45 years*	103 (100)	00	103 (1.4)
Total	7186 (98.2)	133 (1.8)	7319

*The proportion of donors who were between 45 and 60 years of age constituted only 1.4% of the total donors. So, the class intervals of 45-50, 51-55 and 56-60 years were considered together

Table 2: Distribution of donors based on their sex and the type of donors

	Male (%)	Female (%)	Total (%)
VD	4538 (97.3)	124 (2.7)	4662 (63.7)
RD/FD	1426 (99.6)	6 (0.4)	2657 (36.3)
Total	7186	133	7319

VD: Voluntary donors, RD: Replacement donors, FD: Family donors

Table 3: Distribution of donors based on their sex and blood groups

	Male	Female	Total (%)
O Positive	2871	56	2927 (39.9)
O Negative	157	4	161 (2.2)
A Positive	1724	33	1757 (24.0)
A Negative	83	02	85 (1.2)
B Positive	1878	31	1909 (26.1)
B Negative	78	02	80 (1.1)
AB Positive	374	05	379 (5.2)
AB Negative	21	00	21 (0.3)
Total	7186	133	7319 (100)

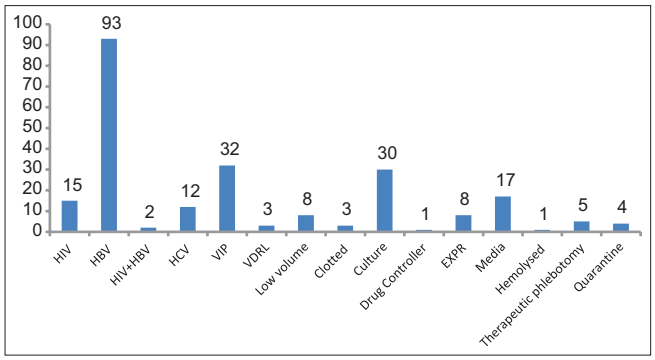

Figure 2: The various reasons for the discard of blood units at the blood bank

making up the numbers with 4.87%. 77.20% were RD and VD formed 22.80% of the study group.[11]

In a study done by Gauravi *et al.* in Saurashtra region of Gujarat, it was found that in 2010, 212 blood bags were discarded against 9441 blood bags collected due to seropositive for TTIs.[12]

In a study done by Thakare *et al.*, it was observed that 3.58% of blood bags were discarded. The main reason for discarding these blood bags was the positivity for different TTIs constituting 68.86% followed by other reasons (31.13%). Among the units discarded, 49.82% were positive for HBSAg, 10% for HIV and 8.97% for HCV while no unit was positive for Venereal Disease Research Laboratory.[13]

CONCLUSION

Majority of the blood donors are voluntary and males. Both among males and female donors, larger proportion of the blood donors are from younger age groups. The number of blood donors considerably reduces toward the older age groups. A considerably small proportion of the units of blood collected are discarded due to TTIs majority being due to hepatitis B.

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Original Article

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Comparison of Conventional Radiography, Radiovisiography and Root Zx Apex Locator in Working Length Determination- An *In Vitro* Study

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ABSTRACT

Introduction: Various techniques are used to determine working length, with no study clearly reporting the superiority of one method over another and each method having its own advantages and constraints.

Aim: The purpose of this study was to compare the working length determination was done using three methods, namely, conventional radiography, radiovisiography (RVG) and a 3rd-generation apex locator (Root ZX).

Materials and Methods: Forty non-carious single rooted human teeth were selected, and each tooth was subjected to all the three methods of working length determination. This was then compared with the actual working length measured histologically after grinding the teeth buccolingually.

Results: Absolute deviations for apex locator was found to be significantly smaller than the corresponding mean of RVG (P = 0.013126) but very significant smaller from the corresponding mean of radiograph (P = 0.001880).

Conclusion: Electronic apex locator was found to be the most accurate in establishing working length. RVG and conventional radiographs are considered to be performed similarly to estimate the working length and can be considered equal in their performance.

Key words: *In vitro* techniques, Digital dental radiovisiography, Radiography

INTRODUCTION

Working length is defined in the endodontic *Glossary* as "the distance from a coronal reference point to the point at which canal preparation and obturation should terminate,"[1] the ideal apical reference point in the canal, the "apical stop," so to speak. A correct working Length is a critical factor within the endodontic "triad of success" - thorough microbial disinfection, ideal canal preparation and hermetic sealing. Failure to determine the proper canal working length can result in short working length with tissues being left in the canal or a long working length, with possible sequelae of damage to the periradicular tissues. This failure can result in increased patient discomfort, possible infection or cyst development and possible of extrusion of irrigating solution beyond the confines of the canal.[2]

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The anatomic or radiographic apex, the apical foramen (major diameter), the apical constriction (minor diameter) are the three important points at the apex of the tooth with which one needs to be familiar if an accurate working length is to be determined.[3]

The quest for this very 'ideal' point has lead to various innovations in methodologies to determine working length.

The radiographic method described by Ingle is one of the oldest and most common and reliable methods in

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determining the working length. However, this method has its own limitations such as the inability to identify the apical constriction; and variables in techniques, angulation and exposure, which distort the image and lead to error due to laterally situated foramina.[4,5] In addition, there is the radiation hazard both to the patients and the dental personnel. The observer's bias in radiographic interpretation may lead to errors.[6]

In recent years, new imaging techniques have been developed to improve the clarity of the image while reducing the radiation dose. Radiovisiography (RVG) is a digital imaging technique that has 60% reduction in radiation dose[7] and has the ability to alter the displayed image so that it may improve the identification of details.[8]

Electronic methods locate the apical constriction without the need to irradiate the patient and get a near accurate working length. However, they too have remained adjuncts to radiography. Kobayashi and Suda developed an apex locator, the Root ZX, which dual frequency and comparative impedance principles and simultaneously measures the 2 impedances at frequencies (8 and 0.4 KHz) inside the canal.[9] It is able to determine the canal length in the presence of an electrolyte or vital pulp tissue and apparently overcomes the limitations encountered by earlier electronic apex locators.[10]

Aim of Study

The aim was to compare the *in vitro* accuracy of determining working length by conventional radiography, RVG and Root ZX apex locator with the actual, i.e., histologically determined working length.

MATERIALS AND METHODS

A total of forty non-carious freshly extracted single-rooted human mandibular first and second premolars were selected for this study. Selection of teeth was done according to following criteria: (a) Teeth with straight root and a single canal with mature apices (as assessed from preoperative radiographs). (b) Absence of root canal calcifications (as assessed from preoperative radiographs). (c) Absence of visible apical resorption. Teeth were resected at the cementoenamel junction (CEJ) using a diamond disc in order to simplify access to the root canal and obtain a wide occlusal landmark and were then mounted on a block made of plaster of Paris (20 cm × 20 cm) mixed with saw dust. Pulp extirpation was done using a barbed broach. Copious irrigation of the root canal was done using 3% hydrogen peroxide, followed by 2.6% sodium hypochlorite. The working length was calculated using the 3 methods.

- Conventional radiograph
- RVG
- Electronic apex locator.

Radiographic Method

A radiographic platform was used to take radiographs to assess the working length of the root canal. It consists of a metallic plate welded to the ring so that it lies parallel to and at the center of the opening of the X-ray tube (Figure 1). The metallic plate was provided with an indentation for stabilization of the mold and the X-ray film.[11] A similar radiographic platform was made to take angulated radiograph to assess the radiographic termination for each canal. In this device, the metallic plate was welded to the ring at the desired mesial horizontal angle and parallel to the opening of the X-ray tube. With the use of both these radiographic platforms, all the samples of the teeth are radiographed at 0° vertical and at 2 different horizontal angles measured form buccolingual plane at 20° to the mesial and 0° for the exposure time of 0.5 s 70 KVP. Following this, Ingle's method for calculating working length was used.

RVG method

For this, a RVG unit from Suni Imaging (Microsystem Inc. USA) was used. A # 15 K-file with the rubber stopper was placed in the root canal with the length 1 mm less than the tooth as noted from the diagnostic radiograph. Disposable plastic sheets were capped to the sensor to protect it from contamination. The sensor was placed between the metallic platform and the mounted tooth (in which the file was placed) and was exposed to X-ray radiation (Figure 2). As the image is stored, it is enhanced for clarity. The file length is observed on the monitor and measured with the RVG measuring grid. The working length was again calculated by Ingle's method as used for radiographic method.

Electronic Method

For this method, working length was determined by Root Zx electronic apex locator (J Morita USA Inc.). The teeth were mounted in an experimental apparatus consisting of a small plastic container filled with 0.9% saline. Both the tooth and the reference electrode (lip clip) were suspended to contact the saline solution. A reference electrode allows for conduction of the electronic apex locator signal (Figure 3). The Root Zx electronic apex locator was then operated according to manufacturer instructions.[11] A #15 K-file with plastic handle and rubber stopper that could reach the apex of the tooth was inserted in the canal until meter reading displayed apex.

Histological Examination

All the 40 specimens are carefully sectioned buccolingually, using a diamond disc at high-speed straight micromotor hand piece to expose the apical constriction (Figure 4). The distance

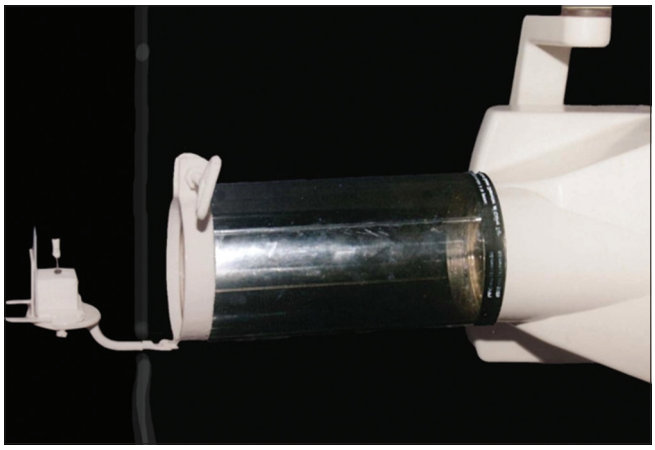


Figure 1: Working length determination by radiographic method

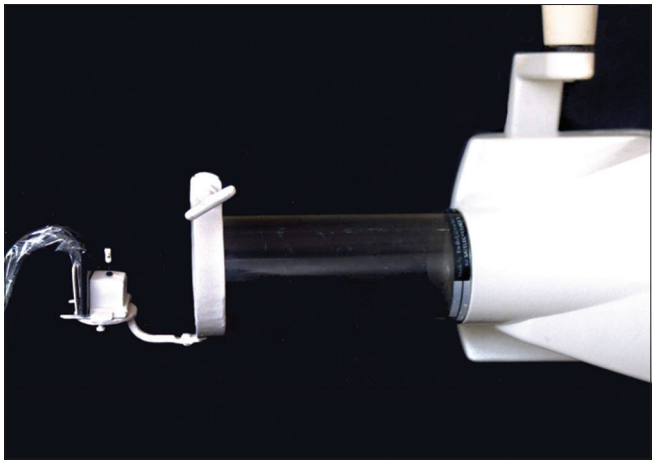


Figure 2: Working length determination by radiovisiography

Figure 3: Working length determination by Root ZX apex locator

Figure 4: Longitudinal Section of a Specimen as viewed under stereomicroscope

between the coronal reference points to the apical constriction was measured for the 40 samples at ×10 magnification using stereomicroscope that had a calibrated eyepiece.

Working length was calculated using the following formula:

$$\text{Micrometer calculation} = \frac{\text{No. of units in eye piece (micrometer)}}{\text{Eye piece magnification} \times \text{Zoom magnifiction}}$$

The data so obtained were tabulated and analyzed by statistical evaluation. Statistical analysis was performed using SPSS® (Statistical Package for Social Sciences, IBM, New York) for Windows®, version 20. Statistical significance was set at $P = 0.05$.

RESULTS

The working length measurements recorded by three different methods i.e., conventional radiograph, RVG and an electronic method compared to histological readings (control) along with the statistical analysis is presented in Table 1 and Graph 1.

Treating the histologic measurements as standard (control), the absolute deviations of the measurement by the other 3 methods are calculated for the sample size of 40 teeth. These deviations were compared with each other using unpair *t*-test to find the significant difference of their mean. The results are presented in Table 2 and Graph 2.

Mean and absolute deviation from the histological readings (control) are given in Graph 3. *t* and *P* values in comparing the mean of absolute deviations for each modality with respect to control is given in Table 3.

From the data thus obtained it is clear that least absolute deviations are for apex locator, which is significantly smaller than the corresponding mean of RVG but very significant smaller from the corresponding mean of radiograph.

Table 1: Mean and standard deviation of working length by the 3 methods and the control

	Mean	Standard deviation
Radiograph	13.8500	1.6220
RVG	13.8400	1.6580
Apex locator	13.9250	1.7267
Histology (control)	13.8825	1.7200

RVG: Radiovisiography

Table 2: Mean and absolute deviation from the histological readings

	Mean	Standard deviation
Radiograph	0.3025	0.1732
RVG	0.2525	0.0816
Apex locator	0.1975	0.1097

RVG: Radiovisiography

Table 3: *t* and *P* values in comparing the mean of absolute deviations with respect to control

Groups compared	*t* value	*P* value	Inference
Radiograph RVG	−1.6517	0.104236	NS
RVG apex locator	−2.5434	0.013126	S
Apex locator radiograph	3.2389	0.001880	VS

NS: Not significant, VS: Very significant, S: Significant, RVG: Radiovisiography

Hence statistically, apex locator can be considered to be most accurate. The readings of conventional radiograph and RVG can be treated at par because there is no significant difference in these 2 readings.

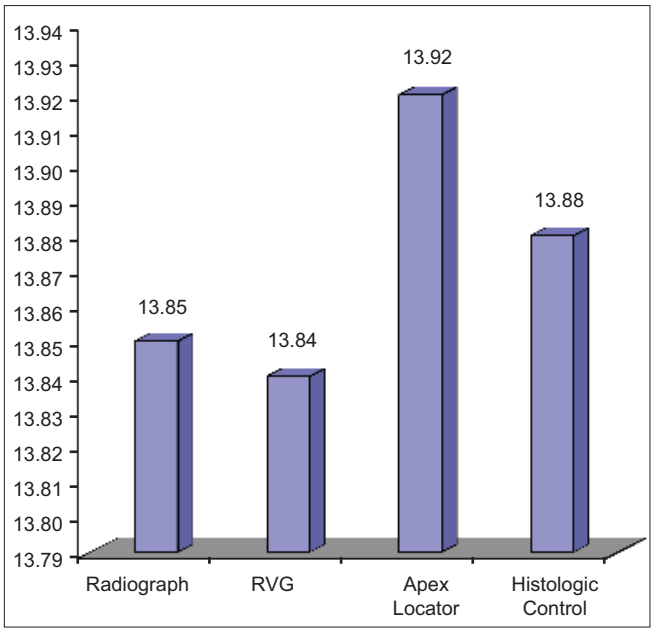
DISCUSSION

The success of an endodontic therapy depends on an ideal access cavity preparation, location of all the canals present, accurate determination of the working length, thorough cleaning and shaping and three dimensional obturation.

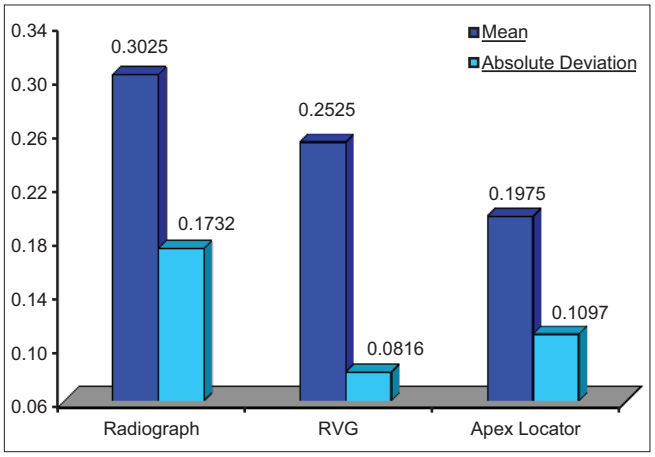
Although of each step constitute a separate procedure, errors in performing any one of these can decrease the overall success rate of the endodontic therapy. Accurate determination of root canal working length is mandatory for a successful endodontic treatment. The significance of these procedures is the following:

1. The calculation determines how far into the canal the instruments are placed and worked.
2. It will limit the depth to which the canal filling may be placed.
3. It will affect the degree of pain and discomfort that the patient will feel following the appointment.[12]

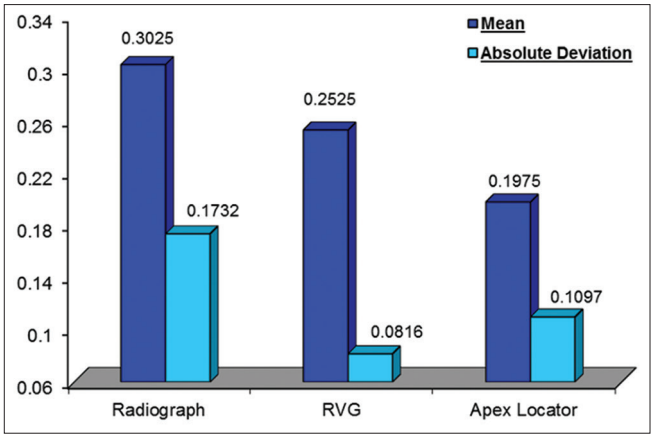
Most experts agree that the canal preparation and thus, the canal filling, should terminate at the cementodentinal junction (CDJ). However, CDJ is a histological landmark



Graph 1: Mean value of the 3 methods and the histologic control



Graph 2: Mean and absolute deviation from the histological readings (control)



Graph 3: Mean and absolute deviation from the histological readings (control)

so "where to end the preparation?" becomes a seemingly dubious point.

Currently, there are several methods employed for the calculation of working length, i.e., radiographic method, RVG method and an electronic method. According to our study amongst the 3 methods used to assess the working length, electronic apex locator was the most accurate in comparison to RVG and radiographic method. The *P* values for apex locator were very significant when compared to radiographic method ($P = 0.001$), respectively, from histological readings (control).

The *P* values for apex locator were significant when compared to RVC method ($P = 0.0131$), respectively, from the histological readings and for both RVG and radiographic method ($P = 0.1042$). *P* values were not significant from the histological readings.

Our results are in agreement with the study done by Pratten and McDonald (1996),[13] where comparison of the radiographic and electronic method was done to determine the reliability of the location of apical constriction. The mean of the absolute value of the deviations from the apical constriction for the apex locator was significantly less ($P < 0.05$) than that of radiographic method.

Schweiz monatsschr Zahnmed, (2001)[14] evaluated the accuracy of an electronic root canal length measuring device and compared the results with those obtained radiographically. In 98.5% of the results of electronic determination of working length, the distance between the file tip and the apical constriction was <0.5 mm, and our results are in agreement with this study.

A number of *in vitro* and *in vivo* studies on the accuracy and reliability of Root Zx have been reported.[15-20] Electronic working length determination made with Root Zx were compared with direct anatomic working length measurements after the extraction of the teeth in the study. Four studies indicated an accuracy for the Root Zx in the range of 82-100% (±0.5 mm from the apical constriction).[17-20]

Several other studies have also been reported on the accuracy and reliability of Root Zx electronic apex locator.[21-23]

Within the constraint of our study, apex locator was also found to be accurate than the RVG.

Martinez-Lozano *et al.* (2001),[24] in their study evaluated the diagnostic accuracy of an electronic system for the determination of working length in comparison with two radiological methods (conventional film and digital radiography). The results showed that the electronic method was satisfactory in 67.8% of cases versus 50.6%, and 61% for the conventional and digital radiological methods, respectively.

However, there is clearly need for more research into the accuracy of RVG and apex locator.

The results of RVG and conventional radiography showed no significant difference between their accuracy from histological readings ($P = 0.104$), respectively.

The results of this study is in agreement with the study done by several authors.[25-29] There was no statistically significant difference reported using two imaging systems.

Different studies that compared digital and conventional radiography[30-33] reported the reliability of the conventional radiograph in measuring working length to be superior to digital images.

On the other hand, Eikenberg LTC Steven and Col Robert Vandra (2000)[34] compared digital dental X-ray systems with self-developing film and manually processed D-speed film, for endodontic file length determination. Results showed that the measurement error was significantly less for digital images than for the film-based images.

At this time, however, the conclusion of studies have not demonstrated that apex locators are clearly superior to radiographic techniques, nor can they replace radiographs in working length determination. It has been determined that they are at least equally accurate.[13]

The future of apex locator is very bright. Future apex locators should be able to determine working length in all electric conditions of root canal without calibration. The meter display should accurately indicate how many millimeters the endodontic instrument tip is from the apical constriction (Kobayashi, 1995).[35]

The use of electronic apex locator in conjunction with radiographs and electronic imaging system provide the clinician with an ability to accurately determine the length of the root canal, thus making apex locators an important component in endodontic therapy.[36-38]

Further *in vivo* evaluation is necessary to determine the clinical utility of these instruments.

CONCLUSION

The following conclusion can be derived from the study:

1. Electronic apex locators are the most accurate in establishing working length.

2. RVG and conventional radiographs are considered to be performed similarly to estimate the working length and can be considered equal in their performance.

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Original Article

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Physiological and Biochemical Responses of Transcendental Meditation in Females

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Abstract

Introduction: As with the advancement of modernization there is increased lack of physical activity resulting in hypokinetic state and higher rate of cardiovascular and respiratory diseases, scientific study of natural methods to maintain good health seems logical. Thus, this study on effects of transcendental meditation (TM) was done.

Purpose: The purpose of this study was to find effects of TM upon physiological and biochemical parameters in females for 12 weeks and thereafter evaluated the therapeutic potential of TM upon subjects with no obvious physical/psychological problems or any previous experience with TM.

Materials and Methods: The case material for this study comprises 30 female medical students of age group 17-22 years. Subjects were divided into two groups, of 15 students each with Group-1 as control and Group-2 as meditating group.

Results: The effect of TM technique was seen on physiological parameters *viz*. heart rate (HR), blood pressure (BP), VO_2 max, body weight and on biochemical parameters of hemoglobin (Hb), serum cholesterol, and blood sugar. Out of various physiological parameters, a significant change was observed in HR and respiratory rate (RR) after 12 weeks of practice. Out of various biochemical parameters, significant change was observed in serum cholesterol after 12 weeks of practice.

Conclusions: Out of various physiological parameters, there was a significant decrease in HR and RR after 12 weeks but no significant change was observed in BP, vital capacity, PEFR, VO_2 max and body weight. Significant lowering of cholesterol was observed, but changes in glucose level, and Hb were insignificant. The available literature although exhibits a significant decrease in all the studied parameters following the practice of the technique for long duration.

Key words: Biochemical markers, Monitoring, Physiological, Transcendental meditation.

INTRODUCTION

In the modem civilization when people are after horizon of artificial environment, dependent on medication for trivial ailments and when the public is becoming scientific minded a scientific study of ways of maintaining their health by natural means with least expenses will be a great service of humanity. One of the hazards of modem industrialization is lack of muscular work which results in hypokinetic state and so most of the individuals do not enjoy robust health.

For the last two decades, we are again looking towards the ancient system of maintaining health through yoga and meditation, and now scientific research are also being done on it. These results showed that these systems have positive effects on health of an individual.

Transcendental meditation (TM) was propagated in 1958 by Maharishi Mahesh Yogi with his idea of natural law as guiding force of life. It is a simple technique that can be learnt easily by any person of any occupation and intellectual levels. During this period, one expected a state of profound rest which dissolves the accumulated stress and fatigue.

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During the investigation of physiology of TM, It was found that it is a simple technique and easy to learn. The study indicated apparent beneficial effects of TM upon various physiological and biochemical parameters.

Cardio-respiratory diseases are one of the major problems affecting large number of population, e.g., diseases like hypertension, hypercholesterolemia causing myocardial infarction and stroke, bronchial asthma, obesity.

Many studies were conducted on the effects of TM on above mentioned parameters. It was found that TM helps in reducing all these risk factors.

However, most of these studies were done on male adults. We undertook a study to find effects of TM upon physiological and biochemical parameters in young females and therefore evaluated the therapeutic potential of TM upon subjects who were neither with any obvious physical and psychological problems nor with previous experience with TM.

The study is done on female medical students for 12 weeks to bridge the gap between existing knowledge and arrive at a definite conclusion.

MATERIALS AND METHODS

The case material for this study comprises 30 female medical students in age group of 17-22 years. The selection of these students was done purely on the voluntary basis, and written consent from each one of them was taken. They were explained about the procedure, time and diet restrictions well in advance. These students were divided into 2 groups, each comprising 15 students.

Group-I: This group was kept as a control group. They were asked not to do anything except sitting quietly for 20 min with eyes closed in the morning and evening. They sat in the same room in which Group II was practicing meditation.

Group-II: This group practiced TM for 20 min - morning and evening.

The TM Technique

TM technique is very simple and easy to learn and is not associated with any specific belief of lifestyle. Its practice requires no mental concentration or physical efforts. A short period of training makes the subject "expert." The subject is made to sit in a comfortable position with eyes closed and asked to recite a suitable "mantra" with instructions not to make any effort to speak aloud the mantra or dispel the stray thoughts, if these happen to cross their minds. Further, after some time of its practice, mind becomes free from worry, thoughts and achieves a sense of bliss and fulfillment.[1]

All subjects sat quietly in a comfortable posture in physical and mentally relaxed state with eyes open for 5 min and then eyes closed for 5-10 min after that they were instructed to practice meditation in way they were taught for 20 min. At the end of 20 min of meditation, the subject sat quietly for another 5 min with eyes closed, another 5 min with eyes open.

Parameters Studies

1. Heart rate (HR)
2. Blood pressure (BP**)** - systolic and diastolic
3. Respiratory rate (RR)
4. Vital capacity
5. Peak expiratory flow rate (PEFR)
6. Hemoglobin (Hb)
7. Serum cholesterol
8. Blood glucose level
9. Body weight
10. Vo_2 max

HR: Subjects were asked to sit and after 5 min of rest the radial pulse of both forearm is recorded by 2 examiners simultaneously for 1 min, 3 successive reading were taken from each forearm and an average of 6 readings were calculated.

RR: Subjects were asked to lie supine and abdominal movements, in 1 min were noted, 3 readings were taken and the average of these readings will give RR.

Body weight: Subjects were asked to stand on weighing machine. Weight was noted in kg.

BP: Was recorded by the auscultatory method.

1. Subjects were prepared first by asking them to lie at ease for 5 min before the measurement, and the cuff of a sphygmomanometer was tied around the upper arm.
2. The stethoscope was placed lightly over the brachial artery in the cubital fossa.
3. The pressure was increased in the cuff to 30 mmHg above the levels at which redial pulsations were no longer felt.
4. The BP was lowered 5 mmHg at the time until the first sound was heard which was the systolic BP (SBP).
5. The pressure in the cuff was continued to decrease until the sounds became faint or inaudible that was recorded as diastolic BP.

Total serum cholesterol was estimated by:

- Wybenga and Pilengi method

Blood Sugar

Glucose oxidase-peroxidase method

Principle: Glucose is oxidized by glucose oxidase to gluconic acid and hydrogen peroxide, in a subsequent peroxidase catalyzed reaction. The oxygen liberated is accepted by the chromogen system to give colored quinone imine compound. The red color so developed is measured at 505 nm and is directly proportional to glucose concentration.

Hb Estimation

Hb estimation was done by Cyan met Hb method

Lung functions

Vital capacity: It is measured by wright's Spirometer. It is a small delicate instrument which measures the volume of air expired at each breath after a forceful inspiration. This metal instrument (63 mm × 15 mm) has a "watch face" type dial with two dials. The larger dial measured volume of each expiration, the smaller dial shows the sum of successive breaths for measurements of minute volume. On the outer aspect of the dial, there is off/on control and a spring loaded button which resets the hands of the dial to zero.

PEFR: It was measured by wright's peak flow meter (mini model). All measurements were taken in sitting position. The peak flow meter was held by the candidate in a horizontal position. Every student was instructed to take as deep a breath as she could, and the mouthpiece was placed in her mouth, which the student gripped lightly with her teeth and sealed it with her lips. Every volunteer was asked to blow out as hard as possible in a short sharp blast, using all the muscular forces of her chest to do so. During the test, student was carefully watched to ensure that no leaks occur between the mouthpiece and her lips. First two blows were not recorded and were taken as practice attempts. The highest of the last three readings were taken as subject's PEFR, and a short interval of rest was allowed for each successive attempts.

Maximum Oxygen Consumption Test

3 min step test:

1. The subjects were asked to perform a four-step cadence up-up-down-down (height of steps 16-1/2 inches).
2. Subjects performed 22 complete steps/min for a duration of 3 min.
3. Pulse rate was noted for 15 s immediately after the exercise. Then it was converted to heart beats/min (15 s PR × 4).
4. Predicted maximum VO_2 is calculated from the equation: Women = max VO_2 = 65.81-(0.184 × hear beats/min) ml/kg/min
5. The predicted max VO_2 of normal healthy individuals should be within + 16% of max VO_2

RESULTS

The TM has effect upon various physiological and biochemical parameters of the body. The HR decreases about 2 beats/min at 6 weeks and 4 beats/min at 12 weeks which is significant (Table 1). The RR decreases about 1 breath/min at 12 weeks, but decrease is not significant at 6 weeks (Table 2).

There is no significant change in SBP and diastolic BP both at 6 weeks and 12 weeks (Tables 3 and 4). No change in vital capacity is seen both at 6 and 12 weeks of TM (Table 5). No change in peak expiratory flow rate was seen both at 6 and 12 weeks of TM (Table 6).

No change is seen in VO_2 max both at 6 and 12 weeks of TM (Table 7). Decline in level of serum cholesterol was seen. 2 mg% at 6 weeks and 3.5 mg% at 12 weeks of TM, which is significant (Table 8). No change is seen in blood glucose level both at 6 and 12 weeks of TM (Table 9). No change is seen in body weight both at 6 and 12 weeks of TM (Table 10). The Hb concentration showed no change both at 6 and 12 weeks (Table 11).

DISCUSSION

Practice of TM produces various physiological and biochemical change in body. The parameters studied are

Table 1: Comparison of HR in Group 2

Parameter	0 week	6 weeks	12 weeks
HR in beats per minute	86.0±7.69	84.10±7.42 *P*<0.05	84.30±7.19 *P*<0.05

HR: Heart rate

Table 2: Comparison of RR in Group 2

Parameter	0 week	6 weeks	12 weeks
RR per minute	16.4±1.30	16.0±1.71 *P*>0.05	16.13±1.50 *P*<0.05

RR: Respiratory rate

Table 3: Comparison of SBP in Group 2

Parameter	0 weeks	6 weeks	12 weeks
SBP in mm of Hg	125±7.8	125.5±6.8 *P*>0.05	120±7.4 *P*>0.05

SBP: Systolic blood pressure

Table 4: Comparison of diastolic BP in Group 2

Parameter	0 weeks	6 weeks	12 weeks
Diastolic BP in mm of Hg	80±3.8	78.5±3.96	77±5.10

BP: Blood pressure

Table 5: Comparison of serum cholesterol mg% in Group 2

Parameter	0 weeks	6 weeks	12 weeks
Serum cholesterol mg%	162.5±10.4	161.2±11.14 $P<0.05$	159±11.11 $P<0.05$

Table 6: Comparison of VO_2 max l/min in Group 2

Parameter	0 weeks	6 weeks	12 weeks
VO_2 max l/min	32.0±2.93	33.8±2.85	35.8±3.81

Table 7: Comparison of vital capacity (l) in Group 2

Parameter	0 weeks	6 weeks	12 weeks
Vital capacity (L)	2.85±0.65	2.88±0.65	3.00±0.492

Table 8: Comparison of PEFR in Group 2

Parameter	0 weeks	6 weeks	12 weeks
PEFR (l/min)	402.4±59.8	412±60.4	418±67.70

PEFR: Peak expiratory flow rate

Table 9: Comparison of serum glucose (mg/dl) in Group 2

Parameter	0 weeks	6 weeks	12 weeks
Serum glucose (mg/dl)	86.90±6.27	87.1±6.42	82.2±67.70

Table 10: Comparison of weight (kg) in Group 2

Parameter	0 weeks	6 weeks	12 weeks
Weight (kg)	53.90±6.15	50.1±5.92	52.90±5.86

Table 11: Comparison of Hb (g/dl) in Group 2

Parameter	0 weeks	6 weeks	12 weeks
Hb (g/dl)	11.82±7.28	11.83±6.86	11.93±6.87

Hb: Hemoglobin

HR, respiration rate, BP, lung functions, Hb concentration, serum cholesterol, blood glucose, and body weight.

Since reports of physiological and biochemical responses of TM in females is very sparse, the present study is concerned with evaluating the effect of TM on physiological and biochemical parameters. In these subjects, the effect on various parameters was noted on different groups of healthy female students after 6 and 12 weeks of doing TM.

In the present study, we found a decrease in HR after 6 weeks and 12 weeks of TM. At 6 weeks, the decrease is about 2 beats/min and it is significant decrease ($P < 0.05$) (Table 1), At 12 weeks the decrease is about 4 beats/min which is also significant $P < 0.05$ (Table 1). But the decrease in HR between 6 and 12 weeks is not significant.

Several studies have been conducted to study the effects of TM on HR. One such study found a significant decrease in HR during practice of TM; he found 5 beats/min decreases in HR.[2]

Another study the cardiovascular system efficiency in 15 subjects practicing TM by using step test. Subjects were stepped with a rate of 30 per min for 3 min after 6 weeks, the mean HR was decreased by 3-14 beats/min in all individuals. The control group improved by 0.5-12 beats per min. The difference in mean improvement was highly significant.[3]

The above findings are similar to our findings, but the decrease in HR is less in our case due to the reason that our study is conducted only for a short period of time (12 weeks).

The cause of decrease in HR is due to reason that since hypothalamus, as Gellhorn has suggested, has unique ability to integrate complex responses via both autonomic and somatic nervous system, it would certainly qualify as one of main neural centers that is actively involved in producing the transcendental state.[4] The hypothalamus directly influences the activity of parasympathetic and sympathetic system which directly or indirectly regulates HR. TM somehow reinforce the hypothalamus which thereby decrease sympathetic activity due to which HR also decrease.

In the present study, there is a significant decrease in RR after 12 week of meditation (one breath/min) (Table 2). But the decrease in not so significant at 6 weeks (Table 2).

Wallace 1970 also found a decrease in RR in individuals meditating for long time for an average period of 29 months. He found decrease in RR about 3 breaths/min doing meditation.[5]

Farrow *et al.* 1982 found 50-60% decrease in RR doing TM.[6] However, in their study they had taken subjects who were practicing TM for long periods about 8 years. Therefore, a decrease in RR is more significant than our study.

The decrease in RR may be due to influence of TM on sympathetic activity which in turn regulates the RR.

In the present study, these is no significant change in mean SBP after practice of TM at 6 weeks and 12 weeks (Table 3) but there was tendency towards decline. Similarly, changes in diastolic BP is seen which were also insignificant (Table 4).

Wallace found a significant decrease in SBP on subjects practicing TM.[7] This difference was independent on diet and exercising pattern but related to the length of time of meditation. The findings suggest the beneficial effect of long-term practice (over 5 years) of TM on SBP.

In our study, no change in SBP occurs because our period of study is short (12 weeks).

Barnes *et al.* (1999) found a decrease in total peripheral resistance significantly during TM.[8]

In his study, he took 32 healthy adults. Subjects were divided into TM and control groups. Hemodynamic functioning was assessed immediately before and during three conditions: 20 min of rest with eyes open (in all subjects), 20 min of TM (TM group) and 20 min of eyes-closed relaxation (control group).

During eye-open rest, TM group had decrease SBP and TPR compared to increase in control group. (SBP; −2.5 vs. +2.4 mm Hg, $P < 0.01$ TPR −0.7 vs. +0.5 mm Hg/lit/min $P < 0.004$).

In the above study, there is a greater decrease in SBP due to concomitantly greater decrease in total peripheral resistance which is due to decrease in vasoconstrictive tone during TM.

No significant changes seen in vital capacity at 6 weeks but there is tendency toward increase is seen at 12 weeks but it is not significant ($P > 0.05$) (Table 7) and no significant change in PEFR (Table 8) and max oxygen consumption (Table 6) is found.

Reddy observed an increase in mean vital capacity by 23 L in fifteen individuals after 6 weeks of meditation.[9] They compared the effects of TM on Hb concentration, vital capacity and exercise tolerance in 30 athletes in Hyderabad. After 6 weeks of TM, they found increased exercise tolerance, a significant increase in vital capacity (Mean 0.23 L) and a mean increase of 3.27% in Hb concentration. They concluded that the increase in vital capacity in meditating athletes is due to their ability to inhale more oxygen and increased Hb in the blood implies that these athletes will in turn be able to absorb more of their inhaled oxygen into their blood. These two factors reinforce each other to produce substantially increased oxygen levels in the blood. As extended physical activity is limited by the ability of the athletes' system to provide oxygen to the muscles and other body tissues, an increased vital capacity and Hb levels resulting from the practice of TM should directly increase the athletic endurance. It was confirmed by stepping tests by the fact that TM group showed an increased exercise tolerance.

Wilson found significant improvement of forced expiratory volume and PEFR after TM.[10] He conducted a 6-month study with crossover at 3 months to evaluate the possible beneficial effects of TM upon bronchial asthma.

Improvement in vital capacity following TM itself may lead to increased PEFR because increase in vital capacity is known to cause an increase in PEFR.

In the present study, no significant change was found due to the fact that the period of study was short as compared to other studies which were conducted for a longer period.

In the present study, no change in Hb concentration was found (Table 11).

One study noted a mean increase of 3.27% in Hb concentration in 6 weeks in TM.[11]

In the present study, there is a decrease in serum cholesterol of about 3.5 mg% at 12 weeks and 2 mg% at 6 weeks (Table 5).

Cooper *et al.* in his study on 22 patients with hypercholesterolemia, after 30 weeks of meditation, found a significant decrease in serum cholesterol.[12] This significant decrease in serum cholesterol was due to longer duration (30 weeks) of practice of TM. Compared to our study which is a short duration (12 weeks).

The causes of this was ascertained to the reduced level of anxiety with decreased sympathetic tone, so that free fatty acids are mobilized from adipose tissue and the deposition on the vessel wall was less because these FFA were mobilized in more efficient manner.[13]

The present study does not find any significant change in blood sugar after TM (Table 9). In our study, we did not find any significant change in weight in the subjects performing TM (Table 10).

Wolkove *et al.* saw the effect of TM on obesity. He took seventy-nine obese and underweight patients and these subjects did the TM for 31 weeks.[14] They were compared to another group of the population who were not doing TM. They found that regular practice of TM seems to have a substantial influence in ameliorating the typical pattern of undesirable weight change with age.

Those subjects who were within the desirable range of weight change gained less weight over the time they were meditating, and overweight individuals enhanced a substantial weight loss.

CONCLUSION

The study revealed that TM has effects on some physiological and biochemical parameters of the body.

In our study, there was a significant change in HR, RR, SBP, and serum cholesterol. Thus, it may be concluded that prolonged practice of TM may be beneficial for overall development of endurance and physical fitness of an individual.

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Original Article

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Rate of Union and Complications, between Muscle Pedicle Bone Grafting and Free Fibular Grafting in Fractures of Neck of Femur: A Comparative study

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Abstract

Background: Fractures of the femoral neck always present a big challenge to surgeons, especially middle age group. In our country, they often present late with variable amount of neck absorption. Various treatment modalities like internal fixation with or without bone graft, various osteotomies, etc. are present.

Objectives: Our objective was to study and compare the rate of union and complications of two procedures, namely vascularized muscle pedicle bone grafting (MPBG) and free fibular grafting in fractures of neck of the femur.

Materials and Methods: This is a comparative retrospective and prospective study comprising 32 patients having fracture neck of femur of more than three weeks duration. One group (Group-A), comprised of 16 patients underwent neck reconstruction by tensor fascia lata or sartorius based muscle pedicle bone graft and iliac grafting when necessary followed by internal fixation through modified Smith Peterson approach. Another group (Group-B) comprises of 16 patients, who underwent internal fixation along with free fibular grafting through separate posterolateral approach to fibula. Internal fixation was done in all cases. This study uses Gupta's classification system for fracture neck of femur and harris hip score for functional outcome.

Results: Of Group-A patients there was an average delay of 5 months from injury to operation; all were of Gupta's 1 b or 2 bc category. Satisfactory union occurred in 14 cases (93%), delayed union in 26% cases and nonunion in one case (6%), with an average Harris hip score (HHS) of 75% at 9 months follow up. Of Group-B patients, average delay was seven weeks and all were 0 or 1b category. Here satisfactory union occurred in 13 cases (86%), delayed union in 14% cases and nonunion in two cases (13%). Average HHS at 9-month follow-up was 80.33%. Post-operative complications were greater in Group-A. Avascular necrosis was seen in one case in Group-B.

Conclusion: Here in our study, union rate is higher in MPBG patients than in fibular grafted ones, may be due to better neck reconstructions and revascularization whereas functional outcomes are better in fibular grafted patients.

Key words: Avascular necrosis, Fracture neck of femur, Free fibular grafting, Muscle pedicle bone grafting, Tensor fascia lata

INTRODUCTION

Fractures of the neck of femur always present a big challenge to surgeons especially in young and middle age group of patients. In our country, patients often present lately with a variable amount of neck absorption, which usually starts three weeks onwards.

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Various treatment modalities are presents for this type of fractures, like osteosynthesis, with or without bone graft, osteotomies, and hemi or total hip arthroplasties for advanced age groups. In young patients, osteosynthesis needs special surgical considerations such as anatomical reduction, secure internal fixation, and supplemented with free or muscle pedicle bone grafting (MPBG) to promote healing. Muscles used for MPBG are Sartorius, tensor fascia lata (TFL) and anterior fibers of gluteus medius anteriorly and quadratus femoris and posterior fibers of gluteus

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medius posteriorly. Free graft includes phemister-type tibial cortical graft, iliac crest, and free fibular graft.

Vascularity and viability of MPBG were shown to be preserved in animal experiments. Moreover, the superiority of vascularized graft over non vascularized ones was proved in animal experiments where almost all osteocytes died in the non vascularized graft while 70% of osteocytes in 88% cases of MPBG were preserved in comparison to the normal side.

Hence, Judet (1962),[1] utilized MPBG in the treatment of femoral neck fractures, but he did not publish the results. Meyers *et al.*[2] in 1974 reported encouraging results with this technique. He noted 1% of nonunion and 8% avascular necrosis (AVN) in cases where MPBG was done as compared to 20-30.8% nonunion and 7.3%-42.8% AVN when treated without MPBG (Parker and Pryor, 1973).[3]

In 1983, Baksi[4] reported encouraging results in post-traumatic avascular necrosis of the femoral head with the use of MPBG. Since un-united femoral neck fractures present special problems, some modifications of this technique, as described by Meyers were made and Baksi applied the evolved technique in a case series in 1986.[5] The technique comprised of freshening of the fracture site, decompression of the avascular femoral head by multiple drilling, reconstruction of absorbed femoral neck with free bone grafts and fixation of MPBG around the internal fixation screws (CHS) with a silk thread. Baksi had a non-union rate of 11%.

Osteotomy has been used to alter biomechanics at the fracturesite to promote healing, both with or without internal fixation, and in some cases with the addition of bone graft to helpstimulate bone healing.

The two main types of osteotomy used in these situations have been the medial displacementosteotomies, such as that employed by Mc-Murray[6] and the angulationosteotomy as employed in studies by Karla and An and.[7] The valgus angulation osteotomy is usually of the subtrochantericor intertrochanteric type. These have been used to convert the shearing forces at the fracturesite into compression forces, thereby improving union chances. In addition, the angulation osteotomy can correct rotationaland limb length discrepancies at the same time.

However, osteotomy has two major problems; shortening, limp, and a decreased range of movement, probablybecause of increased pressures on the femoral head leading todegenerative disease or osteonecrosis[8,9] and potential risks of non-union at the osteotomy site, althoughnot so common in literature.[10] Osteotomies have resulted in ratesof AVN ranging between 6% and 42% and a non-union rate between0% and 45%. Where measured by differing criteria, a "good" functional outcome has been recordedin 35-80% of the subject population*

Henderson[11] treated non-union of the femoral neck fracture by open reduction and free fibular grafting with POP hip Spica for 3 months. Nagi *et al.*[12,13] reviewed young patient treated by ORIF with one cancellous screw with free fibular graft and supplemented it with external immobilization using Thomas knee splint or a foam gutter splint or POP hip Spica and reported encouraging results. Nagi had non-union rate of 5%, and AVN 12%.

In modification of Nagi's technique, Gupta *et al.*[14] have successfully treated 25 cases of neglected fracture neck femur by closed reduction and internal fixation by three peripherally placed cannulated cancellous screws and centrally placed free fibular graft where union occurred in all cases.

In our study, we chose one vascularized i.e. MPBG and another nonvascularized procedure like free fibular grafting and our study is to compare the result of union, rate of avascular changes and complications.

MATERIALS AND METHODS

This comparative retrospective and prospective study was conducted in IPGMER and SSKM hospital, Kolkata from June 2009 to August 2010. We have included in our study patients attending outpatients department, emergency and follow-up clinic, <60 years of age, post traumatic fracture neck of femur more than three weeks duration and no avascular changes of femoral head at plain X-rays at the time of presentation. Patients aged more than 60 years; with comorbid medical condition and fracture neck of femur other than traumatic cause, like pathological fracture etc. or having radiological features of AVN, previous history of any surgery of affected hip and where acetabulum is pathologically affected by any cause, were excluded. This study was conducted on 32 patients after taking proper written informed consent and after obtaining ethical clearance. The cases were divided into two groups, 16 in each group. The first group (denoted as Group A) was treated by reconstruction of the femoral neck by MPBG and internal fixation and the second group (denoted as Group-B) underwent internal fixation and free fibular strut grafting.

Before the procedure, each patient was clinically and radiologically evaluated. We used Gupta's radiological classification system and functionally assessed both pre and post operatively by Harris hip score (HHS).

Technique of MPBG

Modified Smith-Petersen approach was used and we utilized TFL in ten cases and Sartorius based MPBG in five cases. A segment of the iliac crest 2.5 cm long and 2.5 cm broad was then osteotomized and retracted down keeping its attachment to the anterior fibers of the TFL or Sartorius as the case may be, intact. The muscle pedicle bone graft was so prepared that it gets its blood supply from superior gluteal artery and the ascending branch of lateral femoral circumflex artery. Bleeding from the raw surface of muscle pedicle bone graft was observed.

Next, the anterior capsule of the hip joint was opened following section of straight and reflected head of rectus femoris from the capsule. Under imaging, fracture was reduced and temporarily fixed with three guide wires in parallel relation. The bony portion of the MPBG was fixed in a slot, made at the anterosuperior subarticular margin of the femoral head close to the neck, with a 4 mm cancellous screw. We also impacted free iliac graft, when required, to reconstruct the femoral neck. Fracture was finally fixed with, 3 cannulated hip screws through previously placed guide wires. The cut margins of capsule and gluteus minimus muscle are then repaired to secure the graft. The wound is closed after hemostasis in layers over the suction drain. If needed subcutaneous adductor tenotomy was done. Postoperatively after the reduction of pain and discomfort, partial weight bearing with crutches was allowed which was gradually increased to full weight bearing after clinical and radiological evidences of satisfactory union.

Technique Used for Internal Fixation with Free Fibular Strut Grafting

We used standard closed reduction technique in thirteen patients and Lead better technique inflexion in three patients for internal fixation. Fracture was initially fixed with three parallel guide wires under imaging. Appropriately sized cannulated lag screws are then inserted in two of the guidewires. Selection of 3rd guide wire for fibula depends on the space available on anteroposterior and lateral views. In one patient, we had done (case no: 3) closed reduction internal fixation with pediatric sliding hip screw followed by fibular grafting for basicervical fracture of the neck of femur.

Middle third of the fibula, of appropriate length was harvested through separate standard posterolateral approach or by percutaneous method on the same leg. After drilling with a DHS reamer graft was introduced through the 3rd guide wire and impacted. After viewing final construct under imaging, wound was closed in layers. In the post-operative period, wound was inspected after 5 days and sutures removed after 12 days. After 3 weeks, toe-touching weight bearing, with crutches was started. Gradually, full weight bearing was advised after satisfactory maintenance of fixation and radiological evidence of union.

Evaluation of fracture healing was done by clinical, radiological, and functional assessment. All intra and postoperative complications like blood loss, infection, urinary tract infections, hip stiffness were accounted for. Non-union was defined as radiolucent gap existing between sclerosed bony ends after 6 months of surgery.

There is no universally accepted hip score. Different authors have used different hip score. In this study, Harris hip evaluation system (modified) was used to assess the functional outcome of two groups of patients.

Patient satisfaction as graded by the following way:-

- Excellent: Hip score: 90-100, Patient is very satisfied.
- Good: Hip score: 80-90, Patient is satisfied.
- Fair: Hip score: 70-80, Patient is satisfied, but not up to the mark.
- Poor: Hip score is <70, patient is not satisfied.

RESULTS

All the cases were posttraumatic fractures of neck of the femur. In Group-A, nine cases were Type 2 bc and seven cases were Type 1 b and in Group-B ten cases were Type 1 b and six cases were Type 0 according to Gupta's classification system. There were no cases of death and one case in each group was lost to follow-up. The duration of follow-up varied from minimum 6 months to maximum 5 year 6 months, averaging at 15 months. Average time elapsed from injury to operation were 5 months in-Group A and 7 weeks in-Group B. In-Group A an average age of the patients were 38 years with twelve males and four female patients. In-Group B, average age was 40 years with ten males and six female patients. All patients were from lower socioeconomic strata. Majority of Group A patients were healthy, one case had hypertension, and one case had generalized debility. Whereas in-Group B two patients had hypertension and one patient had diabetes. Case no 2 of the same group had contralateral tibial shaft fracture. Preoperative average Harris hip score was 30 in Group A and 18 in-group B, whereas nine months post-operative was 75% in-Group A and 80.33% in Group B.

Satisfactory union was achieved in fourteen cases in-Group A (93%), and thirteen cases in Group B (86%). Average time taken for union was 6 months in group A and 4 months in Group B.

Average operative time was 2 h in group-A patients compared to 1.5 h in group-B patients. Average postoperative stay in hospital was 4 weeks in MPBG patients compared to2 weeks

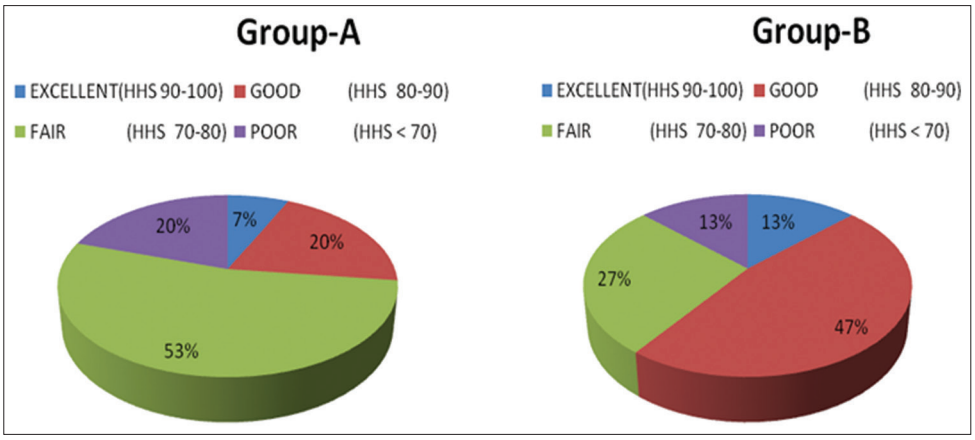

Figure 1: Differential Distribution of outcome of the result of HHS in group A and group B patients

in Group-B. In Group-A, one patient had non-union (6.6%), delayed union occurred in three cases (26%). In-Group B two patients (case no 11,12) had non-union (13%) for which hemiarthroplasty was done later on. Delayed union occurred in two patients (13%). One patient (case no 7 in gr-B) had avascular change in the femoral head, i.e. segmental collapse, sclerosis in plain radiography with painful hip movements. In-group A no patients had AVN change. In group A eight patients had stiffness of hip (case nos. 2, 3, 7, 9, 12, 11, 13, 14) and all patients had limp of which two patients (Case nos. 5, 10) had painful limp. In group B, three patients had hip stiffness (case nos. 9, 10, 13) and eight patients had slight limp (case nos. 3, 5, 7, 9, 11, 12, 13,15) of which two patients had painful limp (case nos. 7, 11). In-group A, four patients (Case no 5, 6, 9, 11) had superficial wound infection all of which subsequently healed with antibiotics and dressing. In-group B, two patients had superficial skin infection (case no 6, 9) of whom one had infection over fibular graft donor site (case no 95). In-group A, two had a deep infection (Case no 2, 10) and recovered after repeated debridement, dressing and prolonged antibiotics. In-group B, no patients had a deep infection.

There were no cases of any neuromuscular complications in any group. In-group A, five patients had increased blood loss per-operatively (case nos. 1, 5,9,14,15). Pre-operative blood investigations were normal in both groups. Two cases in group B and four cases in Group A were given post-operative blood transfusion. There were no cases of thromboembolic episode or heterotopic ossification in any of our study group.

We have found urinary tract infection in two patients in-Group B (Case nos. 6, 9), and three patients in Group A (case nos. 5, 10, 14).

DISCUSSION

Fractures of neck of femur have inherent problem of variable amount of neck absorption resulting in increased shearing stress at fracture gap even after rigid fixation along with microvascular compromise that causes implant loosening, nonunion and avascular changes and thus treatment is always challenging.

We included only posttraumatic fractures of the neck of femur of more than three weeks duration as neck absorption usually starts after that and excluded fractures having radiological AVN changes as this would cause confounding factor. We deliberately excluded patients aged more than 60 years because they have more comorbidities and complications influencing the results. In our series, mean delay from injury to operation was 7 weeks in group-A and five months in Group-B. The various reasons for the delay included late presentation, non-compliance of the patient for surgery, low socio-economic status of the patients, illiteracy, hospital bed unavailability, delay in getting surgical fitness of patients. etc.

HHS was adopted because this is more reproducible and consists of easy day-to-day activities or procedures and with less intra or inter observer variability.

We used modified Smith Petersen approach in our study Group-A. This approach retains the advantages of the anterior iliofemoral approach, but exposes the trochanteric region laterally; this makes aligning a fracture or osteotomy of the femoral neck and inserting screws or nails under direct vision easier. It gives a continuous exposure of the anterior aspect of the hip from the acetabular labrum to the base of the trochanter. We have also used this approach because of choice of muscle pedicle, having patients in the supine position and less damaging effect on medial epiphyseal vessels than in the posterior approach.

We chose free fibular autograft in our study Group B because of low demand, minimal donor site morbidity as

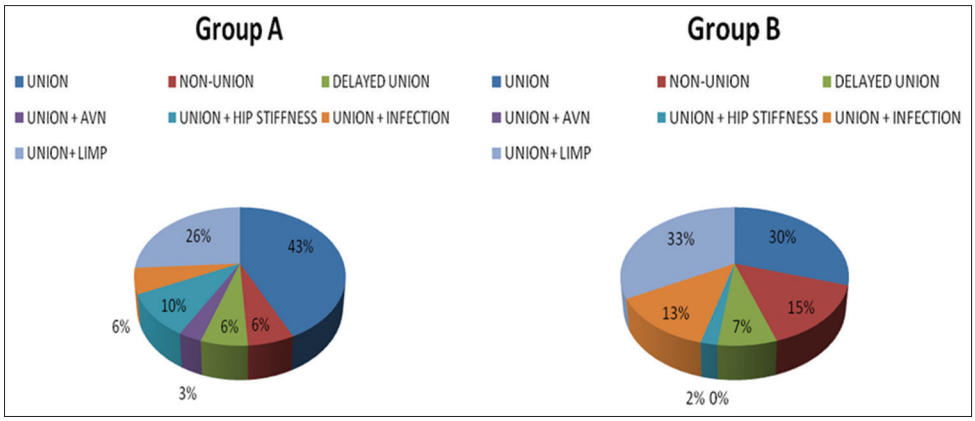

Figure 2: Differential distribution of complications in Group A and Group B patients

percutaneous technique was practiced in the majority of patients. Moreover being cortical, it provides structural support against shearing forces, rotational stability for its trephine shape, and a scaffold for bone healing.

Overall union rate in our study group B was 86%, including delayed union 14%, comparable to that of Nagi *et al.* (90%), Sandhu *et al.* (88.03%),[15] and Lecroy *et al.* (90.90%),[16] but lower than that of Huang[17] and Hou (100%). Varus union occurred in two patients. Decreased union rate in-Group B in respect to Group A was found to be due to inadequate reconstruction of the femoral neck. Varus union may have been due to late collapse as a consequence of instability of internal fixation due to deficient neck. One patient (Case no 7) had avascular change of the femoral head in Group B, with implant migration and persistent painful stiff hip. Avascular changes might be due to initial vascular insult. In this patient implant, migration occurred due to early weight bearing and probably collapse of fracture site. We had to remove the implant after bony union. This again might have been the same reason for screw migration in one patient. Hence, fibular graft is not adequate in those cases where a good amount of neck absorption is present.

Baksi and Meyer popularized muscle pedicle bone grafting. We used three parallel CHS that gives most stable fixation. Meyers' *et al.* and Baksi have preferred fixation with modified Hagie pins in their studies. We have used TFL and Sartorius based MPBG because they are technically less demanding, avoiding prone position, lower morbidity, and also TFL or Sartorius are stronger structures than quadratus graft. Moreover, we faced lower rate of posteromedial comminution in fracture neck of femur. Moreover, posterior approach might lead to damage of medial epiphyseal vessels, which are the only existing blood, supply of fractured femoral neck. We fixed TFL MPBG segment with cancellous screws in most of the cases and used sutures in few cases. Screws were used for better fixation of the graft. Graft dislodgement was not encountered in any patient. It was easy to fix the graft with screw and fixation was better. Meyers' in his series also preferred graft fixation with a screw while Baksi preferred circumferential silk suture for the fixation of the graft. In some cases, cancellous chip graft from ASIS was used for better reconstruction and also for easy exposure. MPBG was used to supplement blood supply to the femoral head to prevent AVN and non-union. No case of avascular necrosis was seen in group A, probably due to successful revascularization procedure.

Table 1: Age and sex wise distribution of patients in Group A

Age	Sex		Side	
	Male	Female	Right	Left
25-36	4	0	3	1
37-48	5	3	5	3
49-60	3	1	3	1

Table 2: Age and sex wise distribution of patients in Group B

Age	Sex		Side	
	Male	Female	Right	Left
25-36	3	1	3	1
37-48	4	3	6	2
49-60	3	2	3	1

Table 3: HHS at nine months follow-up in Group A and in Group B patients

HHS	Group-A	Group-B
0-40	0	0
41-50	0	0
51-60	1	1
61-70	2	1
71-80	8	4
81-90	3	7
91-100	1	2
Average	75	80.33

HHS: Harris hip score

Regarding functional outcome, according to HHS, better results were seen in fibular grafted patients (80%) compared to MPBG group (75%), the cause might have been due to, increased duration of pain, decreased range of motion, longer immobilization, hip stiffness, increased rate of infection in muscle pedicle transferred group.

Restriction in hip movement and hip stiffness was greater in Group A (33%) than in Group B patients (20%). The cause is mainly due to more tissue handling, leading to fibrosis, infection, longer period of immobilization, etc.

Totally, 4 patients had superficial and 2 patients had a deep infection in Group A due to extensive dissection and tissue handling. All of these recovered with repeated debridement, lavage, dressings, and use of antibiotics. In Group B, only 2 patients (13%) had a superficial infection probably due to smaller incision and less tissue handling.

Per-operative amount of blood loss and operating time was more in Group-A than in Group B patients due to more tissue handling and meticulous dissection required in MPBG cases.

Postoperative hospital stay in group A was longer (mean-4 weeks), in comparison to 2 weeks in group B, probably due to increased pain, infection, etc.

Increased rate of urinary tract infection was noted in group A than in group B due to increased use of urinary catheter in Group A patients. Minor morbidities like ankle swelling, leg ache after long walks were observed in Group A patients. Donor site morbidity like tingling or paresthesia on skin over the operative site in Group B due to lateral femoral cutaneous nerve damage during dissection.

In this study, duration of injury and femoral neck absorption were more in group A cases than in fibular grafted patients. In our country, people squat and sit cross legged very often and a large part of the population is manual laborers and patients often present late. In this setup, total hip replacement is not the ideal solution due to poor facilities, poverty, illiteracy, etc. In this scenario, the femoral head salvage is the primary aim of the surgeon, especially in younger patients. From the previous discussion, it is apparent that rigid fixation along with some femoral neck reconstruction is necessary, in old/neglected fractures of the neck of femur.

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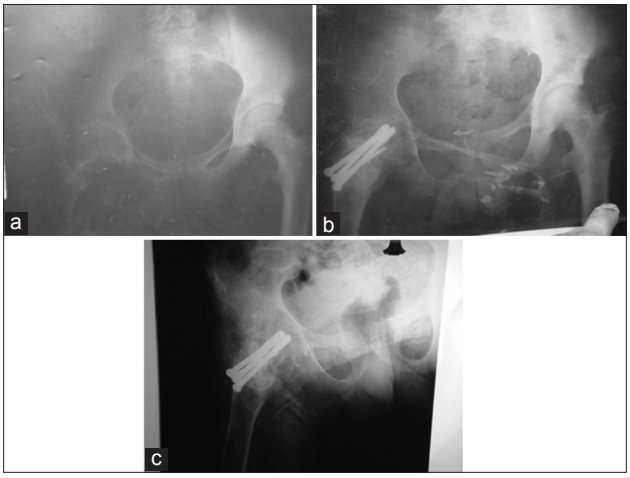
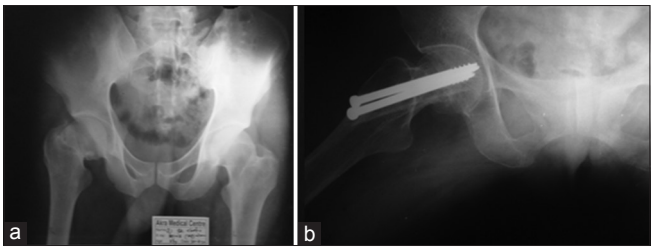
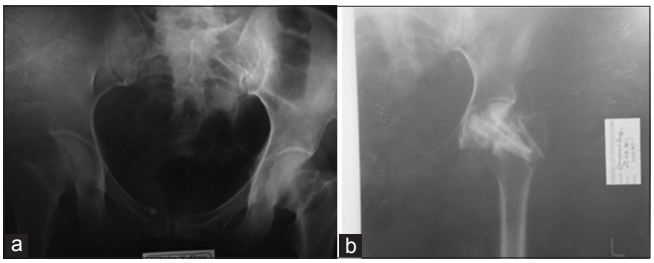
ILLUSTRATION



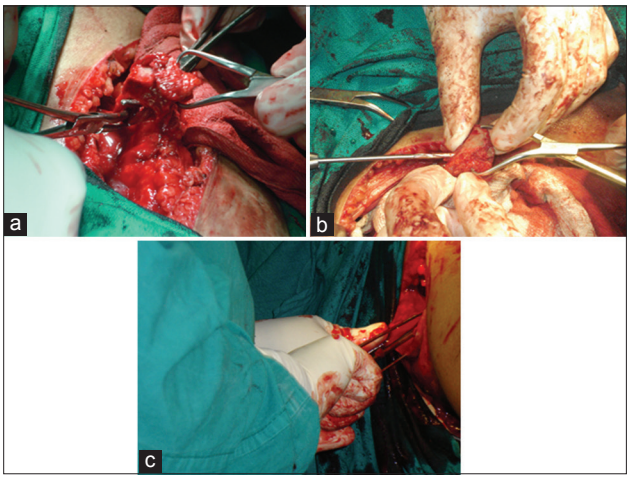
1. Pre and postoperative tomogram of a TFL MPBG patient(Case no 1) of group-A (a) Pre-operative, (b)At 6 months, (b) Union at 9 months



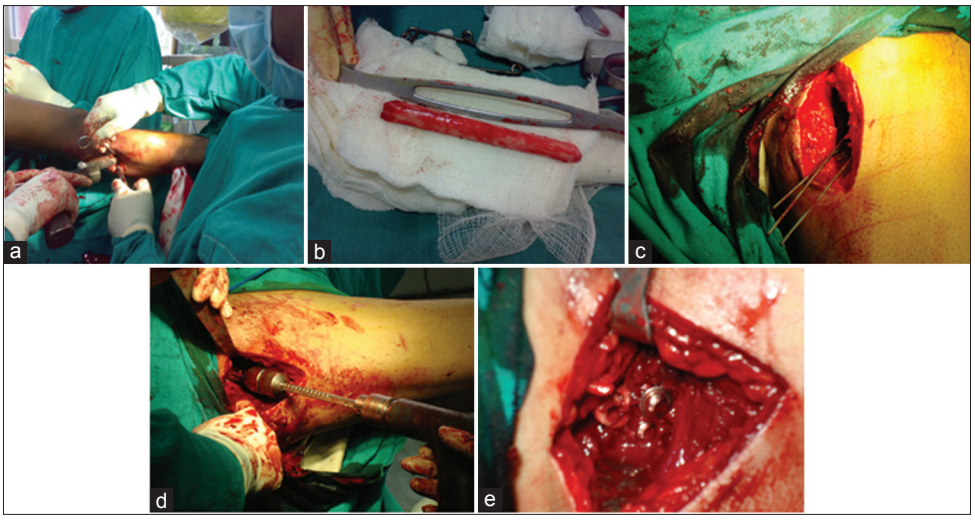
2. Pre and postoperative tomogram of a fibular grafted patient in group B(Case no 8): (a) Pre operation, (b) AVN At 16 months



3. Pre and postoperative tomograms of a fibular grafted patient with AVN (a) Pre operation, (b) AVN At 16 months



4. Photographs of TFL MPBG preparation in case no 1 of group A (a) TFL MPBG secured, (b) Graft placement, (c) Internal fixation



5. Photographs showing percutaneous removal of fibula for graft preparation and internal fixation with CHS and fibular graft in case no 1 of Group B (a)Removal of fibula, (b)Guide wire insertion (c) Reaming (d)Int fixation complete

6. Clinical photographs of fibular grafted patients showing different movements of the hip joint in group B: (a)Sitting cross leg, (b) Squatting, (c)Standing, (d)Hip flexion

7. Clinical photographs of muscle pedicle bone grafted patients, (a)Flexion, (b) Abduction, (c)Sitting cross leg

Original Article

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Comparative Evaluation of Oral Gabapentin versus Oral Pregabalin Premedication for Anxiolysis, Sedation, and Attenuation of Pressor Response to Endotracheal Intubation

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Abstract

Background: Hemodynamic responses of laryngoscopy and tracheal intubation and pre-operative Anxiety due to surgical stress are major problems for patients under General Anesthesia, which should be attenuated by appropriate premedication. The aim of the present study was to compare the effects of Oral Gabapentin versus Oral Pregabalin as premedicants for alleviating anxiety, producing sedation, and Attenuating pressor response to laryngoscopy and tracheal intubation.

Materials and Methods: In this prospective, randomized double-blind study, 60 consented adult patients of ASA Grade I and Grade II, aged between 25 and 55 years of both genders, undergoing elective surgeries requiring intubation, were randomized into 2 groups of 30 patients each as Group G and Group P. Group G received single oral dose of gabapentin 600 mg and Group P received single oral dose of pregabalin 150 mg with sips of water 1 h before surgery. Anxiety and sedation scores were assessed before administration of drugs and 1 h later. Homonymic parameters like heart rate (HR), mean arterial pressure (MAP) were recorded at baseline, after premedication, after induction, during laryngoscopy (0 min) and 1, 3, 5, and 10min after intubation.

Results: In both the groups, there was significant increase in HR and MAP at 0, 1, 3, and 5minutes after intubation, but attenuation of HR and MAP was significantly high in Group P when compared to Group G ($P < 0.001$). The degree of sedation and anxiolysis was significantly high in Group P than Group G ($P < 0.001$).

Conclusion: When compared to Gabapentin 600 mg, Pregabalin 150 mg led to a significant reduction in preoperative anxiety, improved sedation and significantly attenuated hemodynamic response to laryngoscopy and intubation, without significant side effects.

Key words: Anxiety, Gabapentin, Pregabalin, Pressor response, Sedation

INTRODUCTION

Pre-operative anxiety due to surgical stress is a major problem for patients posted for various surgeries under general anaesthesia.[1] Laryngoscopy and tracheal intubation is also associated with abnormal hemodynamic responses which may cause Tachycardia, hypertension, and arrhythmias due to neuroendocrinal stress response.[2] It is very much essential to alleviate anxiety, attenuate these abnormal pressor responses to noxious stimuli during anesthesia and surgery.[3]

Several pharmacological agents like benzodiazepines, opioids, local anesthetics, calcium channel blockers, beta blockers, alpha agonists etc., have been used to reduce anxiety, produce sedation and attenuate pressor responses.[4,5] Each agent has its own merits and demerits.

Recently, gamma-amino butyric acid (GABA) analogs pregabalin and gabapentin have gained prominence in various

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clinical studies, in not only alleviating peri-operative pain but also effective in attenuating pressor response to intubation and in producing peri-operative sedation and anxiolysis.[6]

In this prospective, randomized, double-blinded and comparative study, we aimed to compare the efficacy of oral gabapentin versus oral pregabalin as premedicant drugs for alleviating anxiety, producing sedation, and attenuating hemodynamic response to laryngoscopy and Endotracheal intubation.

MATERIALS AND METHODS

This study was undertaken in orthopedic operation theatre in a tertiary care Government General and Teaching Hospital between May 2014 and January 2015. After obtaining Institutional Ethical Committee approval and written, informed consent, 60 adult patients of ASA Grade I and II, aged between 25 and 55 years were included in the study.

Inclusion Criteria

- Weight between 40 and 70 kg
- Both genders
- Airway: Mallampatti Grade I and Grade II only
- Normotensive patients
- Orotracheal intubation only.

Exclusion Criteria

- H/o allergy to study drugs
- Anticipated difficult intubation
- Laryngoscopy exceeding 20 s with normal airway
- Second attempt for intubation in a normal airway
- Patients on sedatives, hypnotics, and analgesics for chronic pain.

Patients were randomized into 2 groups of 30 each as Group G and Group P. Randomization was done by computer-generated random numbers.

Group G: Patients received Gabapentin 600 mg ($n = 30$).
Group P: Patients received Pregabalin 150 mg ($n = 30$).

Both the drugs are given with sips of water 1 h before surgery. Patients of both the groups are not premedicated with any sedative drugs before surgery. The observer Anesthesiologist who did the peri-operative observations was unaware of the study drugs.

In the pre anesthetic room, all the Baseline parameters like heart rate (HR), blood pressure, Respiratory Rate, and oxygen saturation are recorded. Exactly, 1 h after the study drug premedication, anxiety, and sedation were assessed in all the patients using appropriate scoring systems.

After shifting the patients to operation theater room, standard anesthetic regimen was administered for patients of both the groups, with in. Glycopyrrolate 10 μg/kg intravenous (IV), in. Ondansetron 0.1 mg/kg IV, in. Tramadol 1 mg/kg IV as premedication prior to induction. After preoxygenation for 3 min with 100% oxygen, all patients were induced with in. Thiopentone sodium 5 mg/kg IV, intubated with succinylcholine 1.5 mg/kg IV, maintenance of anesthesia was done with in. Vecuronium 0.1 mg/kg IV, with 60% N20 and 40% O_2 and isoflurane 0.4-0.6%. Laryngoscopy and intubation were performed by an experienced anesthesiologist who was blinded to the study protocol. The following parameters were recorded.

- Duration of laryngoscopy in seconds
- HR and mean arterial pressure (MAP) at baseline (before premedication)
- HR and MAP After premedication and after induction
- HR and MAP at 0 min (during laryngoscopy)
- HR and MAP at 1 min (after intubation)
- HR and MAP at 3 min (after Intubation)
- HR and MAP at 5 min (after Intubation)
- HR and MAP at 10 min (after Intubation).

Thereafter, HR and MAP are monitored every 5 min intervals till the completion of surgery. At the end of the surgery, all the patients were reversed with In. neostigmine 0.05 mg/kg and In. glycopyrrolate 0.01 mg/kg and extubated. All the patients were monitored for any other complications throughout the intraoperative period.

Anxiety and Sedation levels are assessed as per the following clinical scores:

4 - Point anxiety score	4 - Point sedation score
0 - Quiet and comfortable	1 - Wide awake
1 - Uneasy	2 - Sleeping comfortably but responding to verbal commands
2 - Worried or anxious	3 - Deep sleep but arousable
3 - Very worried or very upset	4 - Deep sleep but not arousable

Statistical Analysis

Statistical analysis was done using GraphPad.com software. Data were analyzed and compared using student's *t*-test and chi-square test. Data were represented as mean and standard deviation. $P < 0.05$ was considered statistically significant.

RESULTS

Totally, 60 patients were included in the study. All the patients completed the study successfully.

Demographic characteristics like age, weight, ASA physical status, Mallampatti grading, duration of laryngoscopy were comparable between both the groups $P > 0.05$ (Table 1).

The degree of anxiety, before and after premedication was assessed and compared using 4-point anxiety score. There was alleviation of anxiety in both the groups when compared with baseline values. The reduction in anxiety was highly significant in group P when compared to Group G. ($P = 0.01$ in Group G vs. 0.001 in Group P) (Table 2).

Both the groups were sedated after premedication, but the degree of sedation was significantly higher in Group P when compared to Group G ($P = 0.017$ in group G vs. 0.001 in Group P) (Table 3).

There was no significant difference in baseline HR and MAP values among both the groups ($P = 0.533$). 1 hour, after premedication and immediately after induction also, there was no significant difference in the HR and MAP in both the groups. During Laryngoscopy (0 min) and immediately after 1, 3 and 5 min of laryngoscopy and intubation, there was increase in the HR and MAP in both the groups and the rise was significantly high at 0 min, i.e., during Laryngoscopy in both the groups. But when comparing both the groups, the attenuation of HR and MAP was significantly high in Group P than Group G ($P < 0.001$). After 5 min, the HR and MAP declined in both the groups. And at 10 min after intubation, HR and MAP values almost reached the baseline values and there was no significant difference in the HR and MAP in both the groups ($P = 1.000$) (Tables 4 and 5, Figures 1 and 2).

Complications such as headache and dizziness occurred in few cases of both the groups. In group P, the incidence of headache and dizziness is less when compared to Group G. The incidence of headache is (Group P 3.33% vs. 13.33% Group G) and dizziness is (Group P 3.33% vs. 6.66% Group G). They subsided without any treatment. No other side effects such as somnolence, blurred vision, and peripheral edema were reported in this study (Table 6).

None of the patients had Respiratory depression in the immediate post-operative period and post-operative SpO_2

Table 1: Demographic data

Parameters	Mean±SD (*n*=30)		*P* value
	Group G	Group P	
Age in years (mean±SD)	35.20±6.95	35.83±7.91	0.744
Weight in kgs (mean±SD)	51.46±4.01	51.73±4.31	0.802
Sex (male/female) (*n*)	18:12	21:9	0.588
ASA I/II	26:4	24:6	0.730
Mallampatti (I:II)	23:7	21:9	0.771
Duration of scopy (sec)	16.13±1.65	16.43±1.56	0.472

Data expressed as mean (SD) or ratio or absolute numbers, *Fischer's exact test, SD: Standard deviation

Table 2: Comparison of anxiety score

Groups	Anxiety score (Mean±SD (*n*=30))		*P* value
	Before premedication	1 h after premedication	
Group-G	1.16±0.83	0.63±0.85	0.017*
Group-P	1.26±0.82	0.53±0.81	0.001**

Student-*t*-test, SD: Standard deviation, *Statistically significant, **Statistically highly significant

Table 3: Comparison of sedation score

Groups	Sedation score (Mean±SD (*n*=30))		*P* value
	Before premedication	1 h after premedication	
Group-G	1	1.13±0.34	0.04
Group-P	1	1.33±0.54	0.001**

Student-*t*-test, SD: Standard deviation, **Statistically highly significant *p* value - 0.001

Table 4: Comparison of heart rate (BPM)

Parameters	Mean±SD (*n*=30)		*P* value
	Group G	Group P	
Baseline	79.20±4.52	78.50±3.87	0.522
After premedication	79.93±5.47	78.96±4.52	0.459
After induction	81.53±5.06	80.86±5.07	0.612
During laryngoscopy (0 min)	89.83±6.28	85.13±3.32	0.001**
1 min	88.36±5.79	84.26±3.26	0.001**
3 min	86.93±5.17	82.96±3.51	0.001**
5 min	85.13±4.38	81.96±2.32	0.001**
10 min	78.28±4.52	78.28±2.94	1.000

SD: Standard deviation, **Statistically highly significant

Table 5: Comparison of MAP (mmHg)

Parameters	Mean±SD (*n*=30)		*P* value
	Group G	Group P	
Baseline	89.30±2.74	88.80±3.08	0.509
After premedication	88.72±3.91	87.49±3.89	0.226
After induction	87.41±3.7	86.19±2.84	0.158
During laryngoscopy (0 min)	99.86±2.28	96.28±1.72	0.001**
1 min	97.80±2.52	94.9±2.80	0.001**
3 min	95.20±2.74	92.50±2.10	0.001**
5 min	93.60±2.40	90.17±2.84	0.001**
10 min	88.18±4.30	88.18±2.70	1.000

Student-*t*-test, SD: Standard deviation, **Statistically highly significant, MAP: Mean arterial pressure

Table 6: Comparison of side effects

Side effects	*n*=30 (%)	
	Group G	Group P
Dizziness	2 (6.66)	1 (3.33)
Somnolence	-	-
Blurred vision	-	-
Headache	4 (13.33)	1 (3.33)
Peripheral edema	-	-

Data expressed in absolute numbers

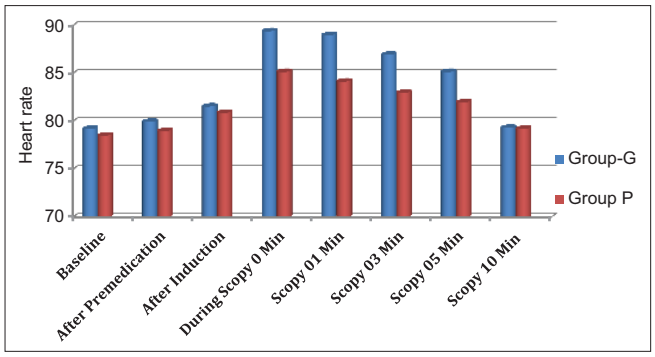

Figure 1: Comparison of heart rate (BPM)

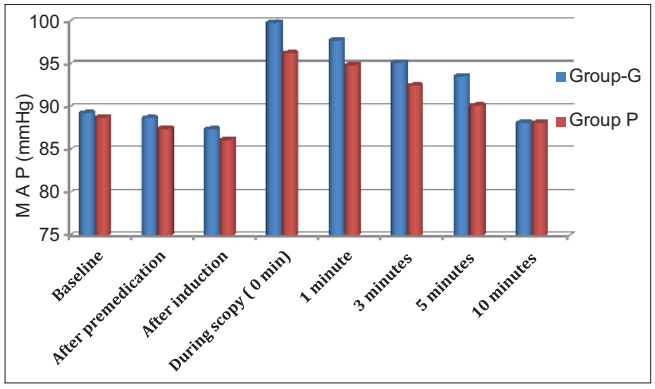

Figure 2: Comparison of mean arterial pressure (mmHg)

values did not fall to <95% in any of the patients in this study. No cases of delayed recovery were reported, and all the patients were extubated successfully on the table immediately after surgery.

DISCUSSION

Attenuation of the hemodynamic response to laryngoscopy and intubation, anxiolysis and peri-operative sedation require different pharmacological agents for each individual action.[7] GABA analogs such as pregabalin and gabapentin are known for their multimodal effects like anxiolysis, sedation peri-operative analgesia, attenuation of hemodynamic responses to laryngoscopy and intubation etc., in various clinical studies.[8,9]

Gabapentin is a structural analogue of neurotransmitter GABA, which acts by selective activation of GABA-B receptors and enhancement of NMDA receptors thus producing the desired pharmacological actions.[10] Pregabalin is also structurally related to GABA but inactivates GABA receptors and acts by decreasing the synthesis of the neurotransmitter glutamate. Thus, it acts as an analgesic, anxiolytic, anticonvulsant, and maintains hemodynamic stability throughout peri-operative period.[11]

Oral bioavailability of Pregabalin (90%) is more than that of gabapentin (60%). As GABA analog performs multiple actions with a single oral dose, we selected these drugs for this study. In both the study groups, there was a significant reduction in anxiety and significant attenuation of pressor response. But the attenuation of pressor response was more significant with pregabalin (150 mg) than gabapentin (600 mg) due to its more sedative effect.[12]

The results of our study correlated with the study of Namratha. S. Urs, Shobha D, who compared oral gabapentin and pregabalin premedication for attenuation of Pressor Response to Endotracheal Intubation. But they did not assess sedation and Anxiety in their study.[13]

De-Paris *et al.* demonstrated that gabapentin attenuated anxiety associated with simulated public speaking in volunteers, which is related to the pre-operative anxiety state.[14] Gabapentin has advantage of decreasing anxiety without causing amnesia.[15]

Anju Ghai *et al.* evaluated the effect of pregabalin 300 mg and gabapentin 900 mg on preoperative anxiety and sedation and concluded that they cause a significant reduction in preoperative anxiety and produce sedation without producing significant side effects.[16] These observations also correlated with our study, but the difference is, they used higher doses when compared to our study.

Kumkum Gupta *et al.* performed a placebo-controlled study with oral pregabalin 150 mg and demonstrated that pregabalin effectively attenuates hemodynamic pressor response to Laryngoscopy and intubation while maintaining hemodynamic stability.[17] In their study, pregabalin was given 60-75 min prior to surgery, as in our study.

Memiş, *et al.* demonstrated that patients receiving 800 mg of oral Gabapentin 1 h prior to surgery had significant reduction in the MAP and HR during the first 10 min after endotracheal intubation compared with 400 mg of oral Gabapentin or placebo.[18] The observations of Memiş, study correlated with our study except that the dose of Gabapentin we used is 600 mg.

Rastogi Bhawan, *et al.* in their study proved that Oral pregabalin 150 mg effectively attenuated the hemodynamic response to orotracheal intubation at the first attempt which is very much useful in patients with cardiovascular diseases.[19,20] The findings of this study were similar to our study.

CONCLUSION

We conclude that oral pregabalin 150 mg and Gabapentin 600 mg given as premedicants 1 h before surgery

decreased preoperative anxiety, improved sedation, and effectively attenuated pressor response to intubation. But when compared to gabapentin 600 mg, pregabalin 150 mg led to a significant reduction in preoperative anxiety, improved sedation and significantly attenuated hemodynamic response to laryngoscopy and intubation, without significant side effects.

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Original Article

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Conduction Blocks in Acute Myocardial Infarction: An Observational Study

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Abstract

Introduction: Conduction defects are one of the immediate complications which occur following acute myocardial infarction (AMI), which results in increased mortality in these patients with AMI. Various types of conduction defects do occur during AMI. Atrioventricular (AV) blocks are more commonly associated with inferior wall infarction and bundle branch blocks are more commonly associated with anterior wall MI. Early recognition and prompt treatment will definitely reduce the mortality in AMI due to conduction blocks.

Aim: To determine the overall frequency and the pattern of conduction disturbances in AMI. To study the relation between site of infarction and the type of block. To study the hospital course and the mortality of patients with conduction disturbances in AMI.

Materials and Methods: Study Involved 50 cases of AMI Admitted to ICCU at Sri Adichunchanagiri Institute of Medical Science Hospital and Research Centre, BG Nagar, during a period of 1 year. Detail history, examination, routine biochemical investigations were carried out. 12 lead electrocardiogram (ECG) was taken at the time of admission and repeated every 12 h for 48 h and followed by one ECG daily. Estimation of cardiac biomarkers and Echo were done in all the patients.

Results: The total frequency of conduction disturbances during AMI is 26%. Complete heart block, 1° AV block, right bundle branch block, are the most common types. AV blocks are mostly associated with inferior wall myocardial infarction. Bundle branch blocks are frequently associated with anterior wall myocardial infarction. Transient blocks are mostly first degree AV block and complete heart block, and 75% of the transient blocks are seen in inferior wall myocardial infarction. The presence of conduction disturbances affects the prognosis in AMI inversely due to extensive myocardial damage in those with conduction disturbances. The overall mortality in AMI is 12% and mortality in AMI having conduction disturbances is 23%.

Conclusion: Conduction defects are common even in this thrombolytic era. Patients with conduction defects are at high risk of developing complications and increased mortality. They need close monitoring and optimum clinical care to reduce mortality and morbidity.

Key words: Acute myocardial infarction, Conduction blocks, Cardiac biomarker, 12 lead electrocardiogram

INTRODUCTION

Conduction disturbance in acute myocardial infarction (AMI) may occur anywhere in the heart and ordinarily expressed as a "block" in general. Impairment of conduction is divided into four major categories according to the location of the block. They are (1) Sinoatrial block (2) Intra-atrial block (3) Atrioventricular (AV) block (4) Interventricular block. Recent electrophysiological studies have demonstrated that a block may also occur within the His bundle.[1] The development of intracardiac electrocardiogram (ECG) recording (His bundle ECG) has brought about renaissance in cardiac electrophysiology and also facilitates the accurate diagnosis of many conduction defects in AMI. The recognition of conduction disturbance is of the value in identifying patient at risk of developing complete heart block.[1,2] AV conduction disturbances occur 2-3 times more frequently in the inferior wall MI in comparison with anterior wall infarction. But the mortality rate with complete AV block in association with anterior wall infarction is almost three times that of patients who

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develop complete AV block with inferior wall MI.[3] This difference is related to the fact that the heart block in inferior wall infarction is usually caused by AV nodal ischemia. In anterior wall infarction, the heart block is usually related to ischemic malfunction of all three fascicles of the conduction system, and this commonly results only from extensive myocardial necrosis.[4-6] The present work is chiefly a clinical study of frequency of conduction defect in relation to age, sex, and evaluation of the ECG.

MATERIALS AND METHODS

The present study included patients with AMI admitted to the ICCU at Sri Adichunchanagiri Institute of Medical Science Hospital and Research centre, BG. Nagar, during a period of 1 year.

Inclusion Criteria

1. Biochemical markers plus one or more of the following:
   a) Typical symptoms of myocardial ischemia.
   b) Q wave in the ECG.
   c) Segment (ST) elevation or ST depression in ECG.
2. Typical symptoms of AMI plus one of the following:
   a) ST elevation in ECG.
   b) Increase cardiac biomarkers.

Biochemical markers of AMI

1. CPK and MB-CPK more than two times upper limit of normal.
2. Troponin T > 0.2 ng/ml.
3. Troponin I >1-1.5 ng/ml.

Exclusion Criteria

1. Presence of AV or intra-ventricular conduction disturbances existing prior to MI.
2. Patients with cardiomyopathy.
3. Patients with congenital heart disease, rheumatic heart disease, and right ventricular hypertrophy.

Patients included in the study were analyzed in detail. A detailed history was taken regarding the predisposing factors like hypertension, diabetes mellitus, smoking habits, alcoholism, hyper-cholestremia, previous infarction, family history of MI, acute breathlessness, pre infarct angina.

During examination features of congestive heart failure, any abnormalities in heart sounds, added sounds and murmurs, features of pericardial involvement, features of papillary muscle dysfunction are specifically looked for. Other systems were also examined in detail to rule out any other associated illness. A 12 lead ECG was taken at the time of admission repeated every 12 h for first 48 h followed by one daily. Routine investigations like random blood sugar, blood urea, serum creatinine were done for all the patients. Lipid profile and serum cardiac-specific enzymes were done for all the patients. Echocardiography was done in all the patients to detect the wall motion abnormalities and to assess the left ventricular function. Written informed consent was taken from patient or guardian. The institutional ethics committee approved the study.

Patients were treated in the usual line with sedation, anti-anginal drugs and thrombolytic treatment. Pacing both temporary and permanent were also planned, but since the facilities were not available pacing could not be done.

RESULTS

During this study period, 140 AMI patients were admitted to ICCU at Sri Adichunchanagiri Institute of Medical Science Hospital and Research centre, BG. Nagar. 50 patients were included in the study after exclusion criteria.

Of the 50 cases in the study group, 41 were males and 9 females. Thus, 82% were constituted by males and 18% by females.

Majority of the patients belonged to the age group 60-69 years that is about 40%. The oldest was 80 years, and the youngest was 27 years (Table 1).

Among the study group, 15 patients had hypertension, and 35 had no hypertension. Of the 15 patients, with hypertension 5 developed conduction disturbances. This constituted 33.33%. Of the 35 with no hypertension, only 8 developed conduction disturbances which was only 22.85% (Table 2).

Table 1: Age distribution of cases

Age in years	Number of cases=50	Percentage %
≤30	01	02
30-49	02	04
50-59	17	34
60-69	20	40
70-79	08	16
80-89	02	04

Table 2: Effect of hypertension on conduction disturbances during MI

	Hypertension present	No hypertension
Number of patients	15	35
Conduction blocks	05	08
Percentage	33.33	22.85

MI: Myocardial infarction

10 patients had diabetes mellitus, of which 4 developed conduction disturbances during MI. This was 40%. Of 40 patients, with no diabetes mellitus, only 9 developed conduction disturbances which was 22.50% (Table 3).

Of the 41 males, 20 were smokers. Hence, 48.78% of the total patients were smokers. All 9 female and 21 male patients were non smokers. Of the 20 smokers, the incidence of conduction disturbances during AMI was seen in 6 patients which accounts for 30%. Among non-smokers, 7 developed conduction disturbances which accounts for 23.33% (Table 4).

Inferior wall MI is the most common type (44%) followed by anterior wall MI (30%), anteroseptal (10%), anteroinferior (8%), inferolateral (6%), and anterolateral (2%) (Table 5).

Among the total 50 patients, 13 developed conduction disturbances during the first 10 days of AMI. Hence, conduction disturbances account for 26%. Of the total 13 blocks, most common were complete heart block (CHB) and 1° AV block (AVB). They constituted 30.76% and 23% respectively. 3 patients out of 13 developed right bundle branch block (RBBB) (23%), 2 patients developed left bundle branch block (LBBB) (15.38%), and 1 patient developed left anterior hemiblock (LAHB) (7.69%) (Table 6).

Table 3: The effect of diabetes mellitus on conduction disturbances during MI

	Diabetes mellitus present	No diabetes mellitus
Number of patients	10	40
Conduction disturbances	04	09
Percentage	40	22.50

MI: Myocardial infarction

Table 4: The effect of smoking on conduction disturbances during AMI

	Smoker	Non-Smoker
Number of patients	20	30
Conduction disturbances	6	7
Percentage	30	23.33

AMI: Acute myocardial infarction

Table 5: Types of AMI

Site of Infarction	Number of cases	Percentage
Inferior wall	22	44
Anterior wall	15	30
Antero septal	05	10
Antero inferior	04	08
Infero lateral	03	06
Anterolateral	01	02

AMI: Acute myocardial infarction

The block present in the immediate post infarction period (on admission) were mostly complete AVB, 1° AVB, RBBB (3 patients each 25%) LBBB and LAHB were the next most common (Table 7).

Among the persistent blocks, RBBB (15.38%), complete heart block (15.38%), LBBB (7.69%) and LAHB (7.69%) were present in respective percentage. They appeared either on admission or appeared later during the course of hospital stay and persisted till the discharge of the patients or death (Table 8).

Transient blocks are blocks appeared at any time during the hospital and disappeared before discharge. Most of the transient blocks were 1° AVHB (Table 9).

Table 6: Frequency of various types of blocks

Type	Number	Percentage	% of total (*n*=50)
CHB	4	30.76	8
1° AVB	3	23.00	6
RBBB	3	23.00	6
LBBB	2	15.38	4
LAHB	1	7.69	2
Type 1 2° AVHB	-	-	-
LPHB	-	-	-
RBBB+LAHB	-	-	-
Type 2 2° AVHB	-	-	-
Total	13		26

AVB: Atrioventricular block, AVHB: AV heart blocks, LAHB: Left anterior hemiblock, RBBB: Right bundle branch block, CHB: Complete heart block, LPHB: Left Posterior Hemiblock

Table 7: AVB present on admission

Type	Number of cases	Percentage %	% of total (*n*=50)
CHB	03	25	6
RBBB	03	25	6
1 AVB	03	25	6
LBBB	02	16.6	4
LAHB	01	8.3	2
2° Type 1	-	-	-
Type 11 2°	-	-	-
LPHB	-	-	-
RBBB+LAHB	-	-	-
RBBB+LPHB	-	-	-
Total	12		24

AVB: Atrioventricular block, AVHB: AV heart blocks, LAHB: Left anterior hemiblock, RBBB: Right bundle branch block, CHB: Complete heart block, LPHB: Left Posterior Hemiblock

Table 8: Blocks persisted till discharge or death

Type of block	Numbers	Percentage
RBBB	2	15.38
CHB	2	15.38
LBBB	1	7.69
LAHB	1	7.69
Total	6	46.14

AVB: Atrioventricular block, AVHB: AV heart blocks, LAHB: Left anterior hemiblock, RBBB: Right bundle branch block, CHB: Complete heart block

Of 13 patients with blocks, 7 had various types of transient blocks (53.84%). Of the 7 patients who had various types of transient blocks, 5 patients had inferior wall MI. Thus, 71.42% of transient blocks were seen in inferior wall MI, and remaining 2 patients (28.5%) were associated with anterior wall MI.

1° AVHB (3 out of 3) and complete heart block (3 out of 4) were most commonly seen in inferior wall MI associated with or without right ventricular infarction and posterior wall MI. At the same time, most common conduction disturbances in the inferior wall MI was 1° AVB and complete heart block (Table 10).

RBBB and LBBB, fascicular blocks are common in anterior, anteroseptal and anterolateral MI. 2 of the 3 RBBB were in those with anterior and anterolateral MI and 1 in inferior anterior wall MI. 1 LAHB and 2 LBBB were present in anterior wall MI.

Total hospital mortality was 12% (6 / 50). Of the 13 patients with conduction disturbances 3 died (23%) but the percentage of mortality among those without conduction disturbances was only 8% (Table 11.1).

About 66.6% of conduction disturbances among those died was CHB, 1 patients had RBBB. Mortality was also more than 50% among those who developed CHB (2 out of 4 with complete heart block Died-50%). Among those developed RBBB death rate was 33.33% (Table 11.2).

Conduction disturbances were significantly higher among those who had developed left ventricular failure (LVF) during AMI. Of the 12 who had LVF, 4 developed conduction disturbances (33.33%), whereas in those who did not have LVF conduction disturbances was only 23.58% (Table 12).

In this study group of 50 patients, 28 patients received thrombolytic therapy following AMI. The development of conduction disturbances found to be low in those who received thrombolytic therapy (6 out of 28) 21%, in contrast to 31.8% of conduction disturbances in those who did not receive the thrombolytic therapy (Table 13).

Table 9: Frequency and the types of transient blocks

	Number	Percentage
1° AVB	3	23.07
CHB	2	15.38
LBBB	1	7.69
RBBB	1	7.69

RBBB: Right bundle branch block, CHB: Complete heart block, LBBB: Left bundle branch block, AVB: Atrioventricular block

DISCUSSION

Age Incidence

In the present study, 40% of patients were in the age group 60-69 years and 34% in 50-59 years. According to the study conducted by Nimetz *et al.* (1975) the mean age was 63 years.[7] In the present study, the mean age was 55 years.

Sex Incidence

In this study group, 82% were males and 18% were females. In the study by Godmen *et al.* (1970), there were 75% males and 25% females.[8]

Predisposing Factor

Gupta *et al.* (1976) have found that the incidence of prior MI, hypertension, and diabetes mellitus were all greater in patients with heart block as compared to controls.[9] In the present study, there was 17.5% increased incidence of conduction disturbances in diabetes and patients who had hypertension showed 10.48% increased incidence of conduction disturbances than those who were not hypertensive. Patients with hypertension and diabetes showed more diffuse coronary artery disease. It was found that conduction disturbances were more in smokers than compared to non-smokers. The percentage of conduction defect was 30% in smokers and 23.33% in non smokers. This can be explained by the fact that smoking will increase incidence and severity of coronary atherosclerosis and so there will be more diffuse coronary artery damage in smokers.[10]

Frequency of Various Blocks

In the present study, the total frequency of conduction defect was 26%. This frequency of 26% is equal to the incidence of 26% and 27% reported by Courler *et al.* and Waugh *et al.,* respectively. Of the total 26%, the most frequent conduction disturbances were complete heart block. They constituted 8% (30.76% of total blocks), 1° AVB, and RBBB were next common 6% (23% of total blocks), LBBB were next common[8-10] comparing these results with other studies.

Table 10: Relationship between site of infarction and type of block

	1° AVB	Type 1 2° AVHB	Types 11 2° AVHB	CHB	RBBB	LBBB	LAHB	LPHB	RBBB+LAHB	RBBB+LPHB	RBBB+AVHB
Inferior wall	3	-	-	3	1	-	-	-	-	-	-
Anterior wall	-	-	-	1	2	2	1	-	-	-	-

AVB: Atrioventricular block, AVHB: AV heart blocks, LAHB: Left anterior hemiblock, RBBB: Right bundle branch block, CHB: Complete heart block, LPHB: Left Posterior Hemiblock, LBBB: Left bundle branch block

Most values are comparable with the results of other studies except for an increased incidence of high degree AVB and complete AVB in the present study. Regarding bundle branch blocks, Gould *et al.* (1972) found that bundle branch block occur in 8-13% of cases of AMI.[11] The same result was observed by Hindman *et al.* In the present study, the incidence of bundle branch block was 38.3% (Table 14).

In most of the studies, RBBB was more common than LBBB. This is probably because the right bundle is a long, slender, discrete structure, and vulnerable to damage by a small area of infarction. Whereas left bundle divides early and, therefore, a large area of damage is necessary to cause LBBB. Of the 2 fascicles of left bundle branch, anterior division is more frequently diseased than posterior division because posterior division is broader fascicle when compared to the anterior division and subject to less injury (Table 15).[12]

Table 11.1: Hospital mortality

Total patients (50)	Mortality	Conduction disturbances present	No conduction disturbances
Number	6	3	3
Percentage	12	23	8

Table 11.2: Types of blocks in the patients who died

Of the 3 died	*N* (%)	% of the total blocks
CHB	2 (66.6)	16.6
RBBB	1 (33.3)	8.3

RBBB: Right bundle branch block, CHB: Complete heart block

Table 12: Relationship between LVF and conduction disturbances

	N	LVF present	No LVF
Total patients	50	12	38
Conduction disturbances	13	4	9
Percentage	26	33.33	23.58

LVF: Left ventricle failure

Table 13: Effect of thrombolytic therapy on the development of conduction disturbances during AMI

	N	Thrombolytic therapy given	No thrombolytic therapy
Total patients	50	28	22
Conduction disturbances present	13	6	7
Percentage	26	21	31.8

AMI: Acute myocardial infarction

Table 14: Comparison with other studies

	1° AVB (%)	Type I 2° AVB (%)	Type II 2° AVB (%)	CAVHB (%)	High degree AVHB
Michael C Hindan	39	4	2	19	25
Scanlan *et al.*	-	-	-	13.7	-
Peter Ciemmensen	-	-	-	13.0	-
Tans *et al.*	-	-	-	-	17
Boris Strasberg *et al.*	-	-	-	-	19
Present study	23	-	-	30.76	38.38

Site of Infarction and Type of Block

In the present study, 75% of complete heart block and 100% of 1° AV block were associated with inferior wall infarction. Complete AVB in anterior wall infarction was 25%.

Norris *et al.* showed only 5% of complete AVB were associated with anterior wall MI (Table 16).[13] Like most previous studies, the present study also showed that all type of AV heart blocks (AVHB) were more common with inferior wall infarction. The increased incidence of AVB in inferior wall infarction are caused by occlusion of dominant artery in more than 70% cases. AV nodal block can also be due to increased vagal tone due to stimulation of afferent nerves adjacent to the AV node by ischemia. Block may also result from the release of the chemical mediator such as potassium and adenosine from the ischemic cells. AV block in posterior wall MI results from damage to the AV node or His bundle, secondary to coronary artery occlusion proximal to the origin of AV nodal artery. The septum and bundle branches are spared.[3,14] Blondeau and associate found that the AV node and His bundle are spared and attribute complete AVB in anteroseptal infarction to direct involvement of the bundle branches by infarction. Goldman *et al.* 1971 found that bilateral

Table 15: Incidence of different type of bundle branch block in various studies

	RBBB (%)	LBBB (%)	LAHB (%)	LPHB (%)	RBBB+ LAHB (%)	RBBB+ LPHB (%)
Schcinman Brenman *et al.*	3.7	6	4	0.2	4.8	1
Imperial *et al.*	7.84	0	-	-	-	-
Norris and Croxan	7	4	-	-	-	
Roos and Dunning *et al.*	-	-	-	-	8.75	-
Present study	6	4	2	-	-	-

AVB: Atrioventricular block, AVHB: AV heart blocks, LAHB: Left anterior hemiblock, RBBB: Right bundle branch block, CHB: Complete heart block, LPHB: Left Posterior hemiblock, LBBB: Left bundle branch block

Table 16: Various studies showing incidence of AVB in inferior wall infarction

	2° AVHB (%)	Complete AVB (%)	High degree AVB (%)
Stock *et al.* 1968	5	8	13
Jewitt *et al.* 1972	16	12	28
Tans *et al.* 1980	6	11	17
Bassan *et al.* 1986	10	8	18
Peter B Rerger *et al.*	-	-	19
Present study	-	6	8

AVB: Atrioventricular block, AVHB: Atrioventricular heart blocks

bundle branch block is usually a complication of anterior rather than inferior wall infarction.[8,15] In the present study, all the bilateral bundle branch block were associated with anterolateral MI.

Several studies have shown that the presence of heart block indicates the concomitant stenosis of left anterior descending artery proximal to the origin of the septal perforators. There was 31% incidence of AVB in those with more than 75% stenosis of the LAD versus 1% incidence among the patients without significant disease of the artery (Table 17).

Hospital Mortality

In the present study, there was a 9.65% increase in mortality during the hospital stay in the patients who had conduction defect during AMI. 66.66% of the patients who died had complete AVB. Of the total 4 patients who had complete AVB, 2 patients died constituting 50% hospital mortality. The increased incidence of 50% of hospital mortality in complete AVB in the present study may be due to the fact that we were not doing prophylactic pacing routinely in our patients.[16-18] Among the bundle branch blocks, mortality was in isolated RBBB in the present study. 1 out of 3 patients died. This is about 33.33%. Various other studies showed the hospital mortality in various bundle branch as follows.

The overall mortality in patients with bundle branch block associated with AMI varies from 32% (Mintz and Katz, 1947) to 62% (Bauer *et al.*, 1965) (Tables 18 and 19). In the present study, the total hospital mortality in patients with bundle branch block was 33.33% as compared with overall mortality of 12% in 50 patients with AMI. Though the mortality in patients with bundle branch block in the present series was less when compared to other studies, bundle branch block is definitely associated with poor prognosis of AMI. The occurrence of bundle branch block in AMI is important because it indicates that the infarction may be extensive and may result in cardiac death. Most authors agree that pump failure, secondary to extensive myocardial damage is the major cause of death.[19] Some studies had demonstrated a lower mortality in patients with LBBB than in patients with isolated RBBB or bi-fascicular block involving right bundle as in the present study. Other few studies have shown an equal or higher mortality with LBBB, often associated with larger area of infarction and severe three-vessel coronary artery disease.[20] In other study, Mullins and Alkins found that mortality rates were similar for the various blocks. Previous studies have shown that the presence of LAHB did not increase the mortality in AMI.[21] In the present study also there were no death in LAHB. Of the blocks which persisted till discharge or death, RBBB, LAHB, 1° AVB, CHB were the most common. Among the 13 patients with conduction defect, 7 patients had various types of transient blocks, of which first-degree AVB and complete AVB were most common. Most of the transient blocks were seen in association with inferior wall MI, 5 of 7 patients which are 71.12%. The increase incidence of transient block in inferior wall MI can be due to increased vagal tone and release of chemical mediator by the ischemic cells around the AV node during inferior wall MI.[22,23] Lie *et al.* found increased mortality in those patients with more persistent RBBB when compared to mortality in patients who had transient RBBB. In the present study one patient who had RBBB died during the hospital stay, one had persistent RBBB, one had transient RBBB. Massive necrosis of AV node has been demonstrated in patients with conduction defect who died of cardiogenic shock.

Table 17: Various studies showing Incidence of RBBB following MI

	Anterior wall MI	Inferior wall MI
Gould *et al.* 1972	83.87	16.13
Killip *et al.* 1972	52.60	47.40
Present study	66.66	36.66

MI: Myocardial infarction, RBBB: Right bundle branch block

Table 18: RBBB and myocardial infarction

	Hunt and Stoman (1969) (%)	Goldman *et al.* (1970) (%)	Norris croxan (1970) (%)	Present study (%)
Episodes of infarction	415	806	565	50
Incidence of RBBB	7	6	7	6
Mortality with RBBB	58	52	61	33.33

MI: Myocardial infarction, RBBB: Right bundle branch block

Table 19: LBBB and MI

	Hunt and Stoman (1969)	Goldman *et al.* (1970)	Norris croxan (1970)	Present study
Incidence %	3	2	4	4
Mortality %	57	65	48	0

LBBB: Left bundle branch block, MI: Myocardial infarction

Left Ventricular Failure and Conduction Defects

Hindman *et al.* 1n 1978 found an incidence of 47% of heart failure in patients with conduction defects, of which 35% were associated with RBBB. In the present study, there was 9.65% increased incidence of LVF in those with conduction defects as compared with those with no conduction defects (33.33% vs. 23.68%). The fact that the patients with conduction disturbances during AMI having high incidence of pump failure and die as a result of progressive and irreversible hemodynamic deterioration due to extensive MI involving the intra-ventricular conduction system.

Effects of Thrombolytic Therapy on Conduction Defects

In the present study, the development of conduction disturbances was low in those who received thrombolytic

therapy. 6 of 28 who received streptokinase developed conduction disturbances that is 21.5%. The incidence of conduction defect was 31.8% in those who did not receive thrombolytic therapy. But according to Clemmensen *et al.* the incidence of complete AVB in patients with AMI treated with thrombolytic therapy was similar to the incidence reported before the thrombolytic era.[8,24-26]

CONCLUSION

Conduction blocks in AMI are not an uncommon problem. The frequency of conduction defect is comparatively high because of continuous monitoring and His bundle recording. The advent of Holter monitoring has helped in recognizing even transient conduction disturbances. The definite diagnosis of conduction blocks can be made by adequate history, clinical examination, electrocardiogram, and continuous monitoring. Complete heart blocks, RBBB with LPHB carry very high mortality particularly in association with anterior wall MI.[27] Early recognition and prompt treatment of conduction blocks will reduce the mortality secondary to infarction. Temporary external pacing and transvenous pacing definitely reduce the mortality in conduction blocks due to AMI. When there is extensive ventricular damage, it is difficult to save the patients in spite of pacing.[28] Conduction defect is an independent prognostic factor and is an indicator of mortality in AMI.[26,29]

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Original Article

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Cranial Index, Circumference, and Shape of Skull in the Central Rajasthan, India: An Autopsy Study

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Abstract

Introduction: Shape of the human skull is different in different ethnic group. It can be divided into dolichocephalic, mesaticephalic, and brachiocephalic depending upon the cranial/cephalic index.

Aims: Autopsy study was done in both gender, above the age of 20 years, i.e., (21-90 years) to study cranial index, circumference, length and breadth and shape of human skull in population of Rajasthan.

Results: Dolichocephalic type of skull is the most common in both sexes followed by mesaticephalic and brachycephalic is least common. Mean cranial index is 74.41 in males and 73.57 in females. All the parameters in males are higher than females.

Conclusion: The present study would be of importance to forensic experts, anthropologist, general practitioners, and geneticists who may find it very useful.

Key words: Anthropometry, Cranial breadth, Cranial circumference, Cranial index, Cranial length, Microcephaly, Shape of skull

INTRODUCTION

The shape of the skull as classified according to the cephalic index as the dolichocephalic, mesaticephalic, and brachycephalic and hyperbrachycephalic. It can also be utilized to find out sexual differences.[1] Cephalic/cranial index is very important to find out racial differences.[2] There have been studies on Gujarati[2] and Nepalese.[3] According to Bharti *et al.* (2001)[4] head form is longer (dolichocephalic) in temperate zone and broad (mesaticephalic or brachycephalic) in the tropical zone.

Kenneth beals determined that there is a relationship between cranial/cephalic index and climate and that the shape of the upper part of the skull is related to heat loss. According to Bharti *et al.* (2001)[4] head form is longer (dolichocephalic) in temperate zone and broad (mesatiocephalic or bracycephalic) in the tropical zone. Narrow heads lose heat more quickly and advantageous in hot climates. Rounded heads lose heat more slowly and are advantageous in cold climates. Hereditary factors primarily affect the shape of the skull, however, environmental factors has a secondary effect on it.[5]

Due to premature closure of sagittal suture skull become elongated (scapho - cephaly) and its incidence is 2.5%.[6] Skull deformities are related to closure of suture involved and effects of increasing growth of brain upon the unfused skull plate. Early closure of anterior fontanels and other sutures causes microcephaly.[7]

Brachiocephalic is due to premature closure of bilateral coronal suture.[6]

Cranial circumference of Indian male is smaller than the American females as reported by Kannapan *et al.*[8] This difference in the cranial circumference of the Indian and American denotes the significant racial variation.[8]

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Cranial circumference in Indian population is smaller than that of the Western population. According to racial origin, Indians are mixed Negroid. Their head is in between dolichocephalic (Caucasian) and brachia - cephalic (negroid).[9]

The cranial circumference among the female in our study was less than male even in all age groups and it suggestive of generalized smallness of all cranium, signifying developmental phenomenon in two sexes i.e., as a rule in all races. In present autopsy study, we have measured circumference of cranium of both male and female on the autopsy table after removing the skin, fascia, temporalis muscle and periosteal.

Cranial dimension of newborn is not stable because cranial length, breath, and height increase as growth progresses.[10] Hence, this study was done above the age of 20 years in both genders.

Aims of Study

To study the cranial index, cranial circumference, and different shapes of adult human skull in population of Rajasthan and compare it with other study in India and abroad.

MATERIAL AND METHODS

A total of 170 cases of both male and female above the age of 20 years i.e., (21-90 years) of age, who were brought for autopsy JLN Medical College Ajmer for period of 6 months were studied. Readings were measured after removal of skin, fascia, temporalis muscles and periosteal layer. Thereafter, antero-posterior length was measured from external occipital protuberance to glabella and transverse diameter were measured between parietal eminences with spreading caliper (Figure 1) and cranial circumference was measured with measuring tape (Figure 2) at the level of external occipital protuberance and supraorbital margin.

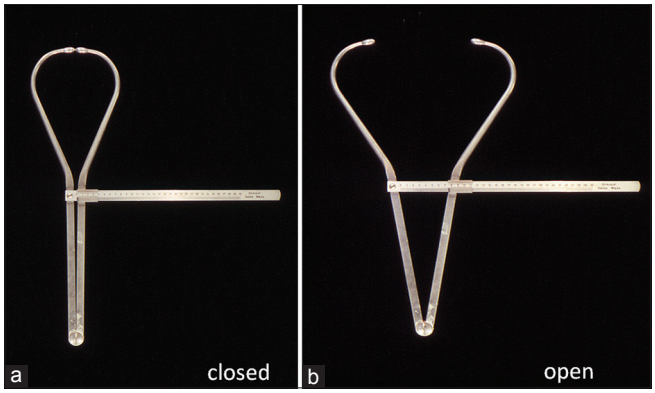

Figure 1: Spreading caliper in both closed and open (a and b)

Cranial index was calculated by = Maximum cranial breadth ×100/Maximum Cranial length

The skull shape is classified according to cranial index as the dolichocephalic (up to 70-74.9), mesaticephalic (75-79.9), and brachycephalic (80-85), and hyper brachycephalic (more than 85).

Above formula was used to calculate the cranial index as per international standard.[1] Mean of all the parameters was calculated and compared between males and females using *t*-test.

RESULTS

Mean cranial circumference in our study was 57.25 cm in male and 56.23 in female. Mean anteroposterior and were 202.66 mms in male and 198.15 mms in female. Mean transverse diameter was 150.61 mms and 145.65 mms in male and female, respectively. Mean cranial index was 74.41 in male and 73.57 in female (Table 1).

The cranial circumference among the female in present study was less than male even in all age groups as shown in Table 2 and it is suggestive of generalized smallness of all cranium, signifying developmental phenomenon in two sexes, i.e., as a rule in all races.

As per Table 3, in present study, 112 (65.9%) male and 22 (13%) female had dolichocephalic skull, 26 (15.3%) male and 9 (5.3%) had mesaticephalic skull. only one female was brachycephalic skull.

Table 1: Gender wise mean parameters

	Male (*n*=138)	Female (*n*=32)
Mean cranial circumference	57.25 cm	56.23 cm
Mean anteroposterior diameter	202.66 mms	198.15 mms
Mean transverse diameter	150.61 mms	145.65 mms
Mean cranial index	74.41	73.57

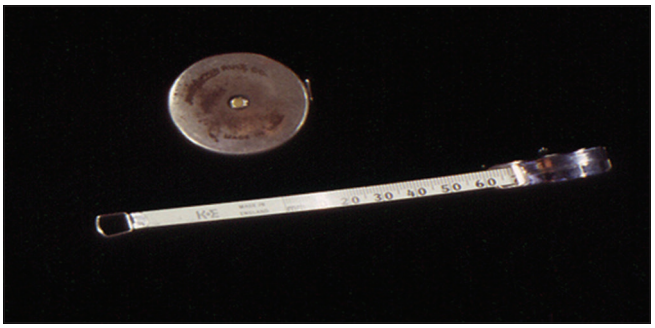

Figure 2: Soft metric tape

DISCUSSION

All the parameters of the males are higher than the female as demonstrated by many studies Maina *et al.* (2011)[11] in Northeastern Nigeria, Deshmukh *et al.* (2006)[12] in India and Ilaypruma *et al.* (2010)[13] in Lanka.

Anthropological study based on racial changes has determined that people from Africa, India, Australia, Central part of Europe, and Northern America are Dolicocephalic, while Middle East-Russia, Central part of Europe, and border of Atlantic ocean are mesaticephalic.[19] According to racial origin, Indians are mixed Negroid[9] as shown in Table 4.

In respect to the variation of head shape in various races and geographical Zones, we believe that hereditary factor primarily affects the head shape.

As per Table 4, in the present study, mean cranial index of males was 74.41 and female was 73.57. This finding was slightly lower than Bhils (76.98),[14] Barelas (79.8).[15] And other groups European (81.19) North of Europe (79.72),[17] Iran (80.4),[19] south of Iran (82.4),[20] Ijaw (80.98) and Igbo (79.04) tribes community,[18] but higher than Baysela state Nigeria (73.68).[21]

As per Table 5, in present study, dominant type of head shape in males was dolichocephalic (78.82) and mesaticephalic (15%). This study was similar to the study of Yagain *et al.* (2012)[5] in Indian students at Manipal (south India) had dominant dolichocephalic 33%, brachycephalic 33%, and 27% mesaticephalic skull. This finding of dolichocephalic was similar to study done on Indian males Bhatia *et al.* (1995)[22] in which 58.5% of the population was dolichocephalic. Whereas the study by Shah *et al.* (2004)[2] in Gujarati mesaticephalic (41%) head shape was common. The dolichocephalic shape was a rare type 7.5% in South Iran,[20] 1.5% in North Iran,[19] and 7% in Indian Gujarati.[2] Turkmanmales in North Iran had dominant brachycephalic head (42.4%).[19] In the present study, least common type of head shape was brachycephalic (1%) in one female but this was dominant type observed in on fars males in North of Iran (52%),[19] South Iran (34.3%).[20]

The cranial circumference among the female in our study was less than male even in all age groups and it suggestive of generalized smallness of all cranium, signifying developmental phenomenon in two sexes i.e., as a rule in all races.

Present study documented sexual dimorphism as suggested by various craniometrical dimensions.

As per Table 1, mean cranial circumference is found to be higher in males (57.25 cm) as compared to females (56.23), and it was found to statistically significant. Mean cranial length and breadth was higher in males as compared to females. Mean cranial index of males was 74.41 and female 73.57. Thus, all the parameters taken were found to be higher in males.

In the present study, mean cranial index of males 74.41 and female 73.57. This finding was slightly lower than Bhils (76.98),[14] Barelas (79.8).[15] And other groups European

Table 2: Gender and age wise cranial circumference/AP diameters/transverse diameter/cranial index

Age group in years	No. of cases		Cranial circumference in cm		Anteroposterior diameter in mms		Transverse diameter in mms		Cranial index	
	Male (*n*=138)	Female (*n*=32)	Male	Female	Male	Female	Male	Female	Male	Female
20-29	35	10	56.92 (2SD±1.68)	55.54 (2SD±2.58)	201.68 (2SD±12.76)	198.5 (2SD±10.76)	146.91 (2SD±30.20)	141.6 (2SD±33.44)	72.81 (2SD±15.38)	71.21 (2SD±13.30)
30-39	39	7	57.14 (2SD±2.70)	56.42 (2SD±1.56)	202.82 (2SD±13.98)	192.71 (2SD±).74	151.69 (2SD±29.86)	153.28 (2SD±29.64)	74.81 (2SD±14.06)	79.61 (2SD±16.80)
40-49	26	6	57.75 (2SD±1.08)	56.85 (2SD±2.32)	203.38 (2SD±12.64)	202.66 (2SD±12.80)	149.88 (2SD±30.40)	146 (2SD±31.78)	73.72 (2SD±14.60)	72.25 (2SD±19.50)
50-59	23	5	57.08 (2SD±2.44)	56.4 (2SD±1.78)	200.82 (2SD±19.80)	197.4 (2SD±4.80)	155.73 (2SD±23.88)	138.4 (2SD±11.36)	77.81 (2SD±15.54)	70.13 (2SD±7.68)
60-69	6	1	57.83 (2SD±1.36)	57	206.66 (2SD±29.24)	200	147 (2SD±36.54)	160	71.52 (2SD±21.52)	80
70-79	6	1	57.48 (2SD±0.88)	56	207 (2SD±1.24)	200	149.33 (2SD±27.90)	138	72.20 (2SD±14.34)	69
80-89	3	2	58 (2SD±0.88)	56.5 (2SD±1.4)	203.33 (2SD±16.64)	202 (2SD±11.30)	156.66 (2SD±36.06)	153 (2SD±4) 2.42	77.10 (2SD±17.56s)	75.92 (2SD±25.24)
Mean of all age group			57.26	56.23	202.67	198.16	150.62	145.66	74.41	73.57

SD: Standard deviation

(81.19), North of Europe (79.72),[17] Iran (80.4),[19] south of Iran (82.4),[20] Ijaw (80.98) and Igbo (79.04) tribes community,[18] but higher than Baysela state Nigeria (73.68)[21] as shown in Table 4.

In present study, dominant type of head shape in males and females was dolichocephalic (78.82%) followed by mesaticephalic (20.6%) and only 0.6% had brachycephalic as per Table 3.

This finding of dolichocephalic was similar to study done on Indian males Bhatia *et al.* (1995)[22] in which majority (58.5%) of the population was dolichocephalic as shown in Table 5. It is also similar to finding by Kumar and Patnaik (2013)[23] in whose study head shape of 85% of males were dolichocephalic, 10.66% mesocephalic, 3.33% brachycephalic, and 1% and female were 69.34% dolichocephalic, 23.34% mesocephalic, 6.33% brachycephalic, and 1% were hyperbrachycephalic. The findings of dolichocephalic were similar to study Anitha *et al.* (2011)[24] done on North Indians in which 40.6% was dolichocephalic. It is in agreement with Singh and Bhasin (2006)[25] in whose study north and central Indian population have dolichocephalic predominance. Previous anthropological studies based on racial changes have determined that people from Africa, India, Australia, Central part of Europe and Northern America are dolichocephalic, while Middle East-Russia, Central part of Europe and border of Atlantic ocean are mesaticephalic Golalipour *et al.* (2007).[19] The dolichocephalic shape was a rare type 7.5% in South Iran, 1.5% in North Iran, and 7% in Indian Gujarati. Turkman males in North Iran had dominant brachycephalic head (42.4%). In the present study least common type of head shape was brachycephalic (1%) in one female whereas this was dominant type in Gujrat Shah *et al.* (2004)[4] and in studies on Iranian population e.g., North of Iran (52%) by Golalipour *et al.* (2006)[19] and South of Iran (34.3%) by Vojdani *et al.* (2009).[20] The cranial circumference among the female in our study was less than male even in all age groups and it suggestive of generalized smallness of all cranium, signifying developmental phenomenon in two sexes i.e., as a rule in all races.

Table 3: Shape of the skull according to cranial indices in the present study

Head shape	Male (*n*=138) (%)	Female (*n*=32) (%)	Total (*n*=170) (%)
Dolichocephalic	112 (65.9)	22 (13)	134 (78.82)
Mesaticephalic	26 (15.3)	9 (5.3)	35 (20.6)
Brachycephalic	Nil	1 (0.6)	1 (0.6)
Hyperbrachycephalic	Nil	Nil	Nil

Table 4: Comparison of cephalic/cranial index with other studies

Author/year	Population	No. of subject studied	Mean cephalic/ cranial index
Bhargava *et al.* (1960)[14]	Bhills	100	76.98
Bhargava *et al.* (1961)[15]	Barelas	100	79.8
Basu *et al.* (1963)[16]	K. Vangaja	100	79.50
Garci and Lips *et al.* (1986)[17]	North Europe	-	79.72
Shah *et al.* (2004)[2]	Gujarat	302	80.42
Oladipo *et al.* (2006)[18]	Ijaw and Igbo tribes community		80.98 and 79.04
Golalipour *et al.* (2007)[19]	Iran	98	80.04
Vojdani *et al.* (2009)[20]	South of Iran	-	82.4
Eroje *et al.* (2010)[21]	Baysela state Nigeria	-	73.68
Yagain *et al.* (2012)[5]	Indian Manipal	100	77.92 (Male), 80.85 (Female)
Present study	Rajasthan	170	74.41 (Male), 73.57 (Female)

CONCLUSION

The mean cranial index in males was 74.41 and in females was 73.57. Hence, Rajasthan population showed predominance of dolichocephalic skull in both sexes, 81.12% (males) and 68.75% (females) and mesocephalic skull was 18.84% in males and 28.12% in females and only one female (3.12%) was encountered having brachycephalic skull. Thus, this study substantiates the findings by other studies that north Indian population have predominantly dolichocephalic skull.

Cranial parameters were found to be higher in males. Mean cranial circumference was higher in males (57.25 cm) than females (56.23 cm).

Table 5: Comparative study of shape of the skull in different population

Form of skull	Dolicocephalic %	Mesaticephalic %	Brachycephalic %	Hyperbrachycephalic %
Present study	78.82	20.6	0.6	-
Yagain *et al.*(2012)[5]	33	27	33	6
Shah *et al.*(2004)[2]	7	41	49.0	-
Golalipour *et al.*(2006)[19]	1.5	-	42.4	53.6
Vojdani *et al.*(2009)[20]	7.5	-	42.2	34.3
Bhatia *et al.*(1955)[22]	58.5	-	-	34.3

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Original Article

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Role of Gender and Menstrual Cycle on Heart Rate Variability, QTc and JT Intervals

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Abstract

Background: Women with long QT interval are predisposed to ventricular arrhythmias. Contrarily, accessory pathway reentry tachycardia and sudden cardiac death are more common in men. Gender and gonadal steroids influence cardiac activities under both physiological and pathological conditions.

Aim: The aim of this study was to assess the role of gender and menstrual cycle on the duration of ventricular repolarization and autonomic control of the heart.

Methods: Electrocardiogram was recorded in 20 healthy, non-obese volunteers (11 women and 9 men). HRV parameters with power spectral analysis, QTc, and JT intervals were noted and analyzed. One-way ANOVA with Tukey Krammer *post-hoc* test, repeated measures ANOVA and Pearson correlation analysis were used.

Results: QTc interval was significantly prolonged in follicular and luteal phases of female subjects compared to males ($P < 0.05$). QT was positively and significantly correlated with JT interval, but only during the menstrual phase ($P < 0.0001$).

Conclusions: HRV measures were not significantly altered during the phases of the menstrual cycle. QTc interval was significantly prolonged in women during their follicular and luteal phases but, without significant correlation to JT interval. JT interval correlated significantly with QTc in the menstrual phase, but larger prospective studies are required to show whether women in their menstrual phase are more likely to develop arrhythmias.

Key words: Gender difference, Heart rate variability, JT intervals, QTc interval, Menstrual cycle

INTRODUCTION

Resting heart rate of women in the reproductive age group is higher than that of men.[1] Although the RR interval shortens with increase in heart rate (as seen in women), there are reports of prolonged QT intervals being noted in women when compared to men.[2,3]

The corrected QT interval for heart rate (QTc) in the electrocardiogram (ECG) represents ventricular depolarization and repolarization.[4,5] Primary repolarization abnormalities can be detected from JT interval (QT duration-QRS duration) which mainly represents ventricular repolarization (Phases 2 and 3 of ventricular muscle action potential).[5] Heart rate is regulated primarily by the autonomic nervous system through vagal and sympathetic fibers.[1] Hence, the RR, QTc, and JT intervals are all influenced by the autonomic nervous system. Heart rate variability (HRV) is one of the best indices to assess the sympathovagal balance.[6]

Prolonged QTc in women is associated with increased propensity to develop torsades de pointes and drug induced arrhythmias. It has been observed that the incidence of atrial fibrillation, accessory pathway reentry tachycardia, and sudden cardiac death are more common in men.[7] Influence of gender on the HRV has been contentious, with studies variously reporting significantly greater,[9] significantly lower[9,10] or similar[11] HRV for females compared to males. Furthermore, there are discrepancies in the reports on

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sympatho - vagal balance during the different phases of menstrual cycle.[12,13]

Hence, in the present study, we have attempted to assess the role of gender and menstrual cycle on HRV and the QTc and JT intervals.

MATERIALS AND METHODS

After obtaining approval from the Research and Ethics Committees of the Indira Gandhi Medical College and Research Institute (IGMC AND RI) Puducherry, the study was conducted in the department of Physiology, IGMC AND RI. The following inclusion and exclusion criteria were applied.

Inclusion Criteria

1. Age 15-55 years
2. Women having regular menstrual cycles (28-32 days) and,
3. Age and body mass index (BMI) matched healthy male subjects.

Exclusion Criteria

1. Patients with ischemic heart disease, hypertension or rhythm disorders
2. Chronic kidney disease
3. Hyperthyroidism, hypothyroidism, and other endocrinological disorders
4. History of menstrual disorders
5. Post-menopausal women and,
6. Women on oral contraceptive pills.

Eleven female subjects with mean (± SD) age of 32.4 (± 2.3) years and nine male subjects with a mean age of 30.2 (± 2.7) years volunteered to participate in the study. Mean BMI in female and male subjects were 22.5 (± 3.2) and 21.6 (± 3.7) kg/m^2, respectively. Informed consent was obtained from individual participants. Detailed cardiac, renal, endocrinological, and menstrual history along with the physical examination was performed in the department of General Medicine, IGMC AND RI. Baseline ECG, serum creatinine, TSH were performed prior to admitting into the study.

Three ECG recordings were taken from each female subject. The dates of first and second recordings were decided as 9th-10th day (follicular phase) and 21st-22nd days (luteal phase), respectively, following menses of the current cycle. The third recording was performed on the 1st or 2nd day of the next menstrual cycle. A single ECG recording was obtained from each male participant.

On the day of recording (between 10.00 am and 11.30 am), electrodes were placed after 15 min of complete rest in the supine position. An ECG recording was taken for 5 min and 30 s, while spontaneously breathing, using INCO data acquisition system, Ambala, at 26°C room temperature. The data were converted into ascii format and saved in the system. Subsequent power spectral analysis of HRV was done with Kubios HRV Version 2.1, Bio-signal analysis, and medical imaging group, Kuopio, Finland. Niviqure software analysis version 52.0, Microsoft Office 2007 were used to estimate QTc (using Bazett formula) and JT intervals. Task force guidelines[7] and AHA/ACCF/HRS[5] recommendations for the standardization and interpretation of the ECG were followed during the analysis.

Data from the participants were divided into four major groups as follows: Group I - males, to represent the effect of male gonadal hormones; Group II - females in the follicular phase (9or 10 days after menses), to represent the effect of increased estrogen: Progesterone ratio; Group III - females in the luteal phase (21or 22 days after menses), to represent the effect of increased progesterone: Estrogen ratio; Group IV - females in the menstrual period (1st or 2nd day of next menses), to represent the state with low female gonadal hormones.

Statistical Tests

GraphPad Instat - Version 3.06 was used for statistical analysis. Data were expressed as mean ± SD and mean ± standard error of mean SEM. One-way ANOVA with Tukey Krammer *post-hoc* was used in analyzing the data within the four groups. Repeated measures ANOVA were used to test the differences in HRV, QTc, and JT interval in female participants during different phases of their menstrual cycle. Correlation between QTc interval and JT interval was assessed by Pearson correlation analysis. A $P < 0.05$ was considered statistically significant.

RESULTS

In the present study, there was no significant difference with regard to age or BMI among male and female subjects. Resting heart rate was significantly greater among female subjects in all the three phases (F-FP, F-LP, F-MP) when compared to males. There was no statistical significance in the mean RR interval and HR within the three phases of the menstrual cycle. QTc interval was significantly prolonged in follicular (0.397 ± 0.02) and luteal (0.395 ± 0.02 s) phases of female subjects and was significant when compared to males (0.344 ± 0.01 s) ($P < 0.05$). There was no statistical difference with regard to QTc within the three different phases of the menstrual cycle. JT interval was greater in male subjects but without statistical significance (Table 1).

QT interval in women, positively and significantly correlated with the JT interval, but only during the menstrual phase (*P*.0001; *r* - 0.8798).

Total power (TP) and low frequency (LF) component (ms^2) in the power spectral analysis were lower in female subjects when compared to males, in all three recordings (follicular, luteal, and menstrual phases). TP and LF in absolute power were higher in the luteal and menstrual phases compared to the follicular phase (Table 2).

High frequency (HF) power (ms^2) in power spectral analysis was greater in female subjects during the menstrual phase (F-MP) when compared to males and also to other phases of menstrual cycles (F-FP, F-LP). But these were not statistically significant.

HF band in the normalized unit (HF nu) was lower in female subjects during the luteal phase (F-LP). HF nu was greater during follicular and menstrual phases. LF in nu was higher in the luteal phase when compared to males, and also to females in the other phases of the menstrual cycle (F-FP. F-MP). The differences in mean ± SEM were not statistically significant.

LF/HF ratio was also greater in the luteal phase when matched with the other phases. LF/HF was also higher in male subjects than in females during all the three phases, but without achieving statistical significance. Time domain analysis: RMSSD, SDNN, pNN 50% were more in males compared to their female counterparts in all three phases.

Table 1: Resting heart rate, RR interval, QTc interval, JT interval

	Male *n*=9	Female - FP; *n*=11	Female - LP; *n*=11	Female - MP; *n*=11
HR [beats/min]	62.9±6.9	82.7±11.1**	80.1±8.9*	79.37±11.7*
RR interval	0.964±0.09	0.740±0.10**	0.759±0.08**	0.772±0.11**
QTc [s]	0.344±0.01	0.397±0.02*	0.395±0.02*	0.360±0.05
JT [s]	0.245±0.01	0.242±0.03	0.245±0.02	0.218±0.05
Correlation between QTc interval and JT interval				
R	0.5188	0.0834	0.302	0.8798
P	0.137	0.3891	0.073	0.001**

Values are mean±SD, F-FP: Female in follicular phase, F-LP: Female in luteal phase, F-MP: Female in menstrual phase, HR: Heart rate, QTc: QT Corrected for heart rate, JT: JT interval=QT duration-QRS duration. Analysis of data was done by one-way ANOVA and post-hoc by Tukey–Krammer test. Repeated measures ANOVA were used to analyze the data within female groups. Pearson correlation was used for the lower half of the table.*P<0.05, **P<0.01

DISCUSSION

In the present study, we had attempted to assess the power spectral analysis of HRV, QTc, and JT intervals in men and in women during the various phases of menstrual cycle (follicular, luteal, and menstrual phases).

Plasma levels of gonadal and gonadotropic hormones are low during menses; conversely estrogen levels (estrogen-progesterone ratio) increases during the follicular phase prior to ovulation.[14] In our study, the TP (ms^2) in HRV was lower during the menstrual phase (F-MP) and higher during the follicular phase when compared to the luteal phase. This supports the association between the level of gonadal hormones and HRV parameters.

LF components, LF power (ms^2) and LF in the normalized unit (LF Band - an index of sympathetic activity) were higher in the luteal phase and lower during menstrual phases. This was similar to the observations made by Sato *et al.*[12] It was also reported with high catecholamine levels in the luteal phase.[15] HF power (ms^2) and HF nu were observed to be relatively high during the menstrual phase, when there was no influence on HRV by gonadal hormones. Nevertheless, no measure of HRV, both in time domain and frequency domain analysis was significantly different with respect to three menstrual cycle phases and also between men and women.

Table 2: Power spectral density - Frequency domain and time domain indices of HRV analysis

	Male *n*=9	Female - FP; *n*=11	Female - LP, *n*=11	Female - MP, *n*=11
TP (ms^2)	2569.5±1240.3	1623.12±728.04	1257.55±277.6	1238±430.3
HF (ms^2)	413.25±164.37	212.38±192.5	285.67±83.53	464.64±192.5
LF (ms^2)	596.75±264.6	241±61.23	387.22±110.81	387.81±183.1
HF (nu)	46.83±12.43	48.43±6.023	42.64±4.501	51.57±5.2
LF (nu)	52.93±12.43	51.337±5.99	56.84±4.47	47.73±5.22
LH/HF	1.67±0.71	1.30±0.30	1.55±0.27	1.19±0.92
RMSSD	41.85±7.06	22.16±3.08	28.13±4.23	30.03±5.31
pNN50%	23.27±9.34	4.81±2.8	7.57±3.9	10.04±4.9
SDNN	46.25±9.4	38.95±8.5	37.86±3.75	34.85±5.36

Values are mean±SEM; F-FP: Female in the follicular phase; F-LP: Female in the luteal phase; F-MP: Female in the menstrual phase; TP: Total power; VLF: Very low frequency; LF: Low frequency; HF: High-frequency bands of power spectrum; RMSSD: Root-mean-square differences of successive R-R intervals; SDNN: Mean of the standard deviations for all R-R intervals. The analysis of data was done by one-way ANOVA and post-hoc by Tukey-Krammer test. Repeated measures ANOVA were used to analyze the data within female groups. No statistical significance was noted in this analysis, SEM: Standard error of the mean

RR interval which represents the duration of single cardiac cycle is significantly longer in men, as their heart rate is lower than women. In our study, there was no significant difference in mean RR interval within female groups in three phases. QTc interval was prolonged in all three phases among female subjects, achieving statistical significance in the follicular and luteal phases, when compared to men. This was akin to the findings of Prasad *et al.*[3] Estrogen may prolong QTc intervals by down-regulating mRNA of potassium channels.[7] Animal studies have shown that both estrogen and progesterone may play a role in regulation of calcium in the sarcoplasmic reticulum.[16] During the menstrual phase, women may have a higher risk of developing arrhythmias[17] and long QT arrhythmias appear to be more common in women[18,19] Various studies have shown that QTc prolongation occurs in different phases of the menstrual cycle. Hence, drugs that prolong QT intervals may induce arrhythmias in women. Testosterone and progesterone may hasten repolarization and provide a protective effect.[16]

In our study, we had also attempted to assess the JT interval, which is considered to be a better index of assessing the repolarization abnormalities in the cardiac muscle.[5] In spite of prolonged QTc in women, JT interval was not significantly prolonged in them (in all three phases) when compared to men. Interestingly, it was also noted that JT interval was longer in men compared to women in all three phases of the menstrual cycle.

Phases 2 and 3 of the ventricular muscle action potential correspond with JT interval.[7] Liu *et al.* had demonstrated smaller density I_{Ks} and I_{Kr} in the ventricular muscle of female rabbits.[20] It is observed that estrogen upregulates $I_{Ca,L}$ density through genomic pathway in ventricular muscle fibers of rats.[18] This increased $I_{Ca,L}$ transmural dispersion results in prolongation of repolarization.[7] Conversely, progesterone rapidly shorten the action potential duration, through enhancement of the slow delayed rectifier K current (I_{Ks}) under basal conditions and inhibition of L-type Ca^{2+} currents ($I_{Ca,L}$) under cAMP-stimulated conditions.[18] Dihydrotestosterone (DHT) has no effect on $I_{Ca,L}$ in male rats.[21] But it limits the effect of K channel blockade.[7]

In our study, JT interval correlated positively to the QTc interval only in the menstrual phase, when levels of gonadal hormones (estrogen and progesterone) are low. QTc and JT intervals did not significantly correlate in the follicular and luteal phases, when the repolarization is influenced by the outcome of an inverse inter-play between estrogen and progesterone. Hence, propensity to develop arrhythmia could be higher in women during menses, when the gonadal hormone levels are lower in the circulation and are unable to modify cardiac repolarization. Hence, it would be more appropriate to analyze the duration of ventricular repolarization with JT interval rather than using QTc interval alone.

Due to the small number of subjects, these findings may not be applicable to a larger population and hence studies with larger number of participants are necessary. Since these subjects were recruited from an outpatient department population, systemic illnesses may have had an effect on resting heart rate. Fever/high temperatures predisposing towards ventricular arrhythmias in Brugada syndrome and fever induced Brugada pattern on ECG have been described.[22,23]

CONCLUSION

Measures of HRV in women are not significantly altered during the various phases of the menstrual cycle and may hence not be able to predict risk of arrhythmia in a particular phase of the cycle. JT interval may be a better predictor of arrhythmias related to prolonged QTc intervals. The JT intervals were higher in men and in women during the menstrual phase, where the effect of estrogen/progesterone is at its nadir. But whether these hormones have a protective effect on rhythm disturbances similar to their effect on ischemic heart disease needs to be studied prospectively in larger population.

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Original Article

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Fingertip Pattern in Schizophrenic Patients: A Dermatoglyphics Study

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Abstract

Introduction: Association of dermatoglyphics with innumerable physical, behavioral, and pathological traits is studied recently. In this study, we have attempted to evaluate fingertip pattern in schizophrenic patients.

Methods: The rolled fingertip prints of 100 schizophrenic patients of both the sexes (50 males and 50 females) clinically diagnosed under DSM-III-R criteria aged between 15 and 65 years were collected for the study from the Department of Psychiatry, Government General Hospital, Guntur, Andhra Pradesh from September 2009 to July 2010. These fingertip patterns were compared with age- and sex-matched 100 controls selected from teaching and non-teaching staff and students of same teaching hospital.

Results: There was a decrease in the percentage of arch patterns in schizophrenics when compared with controls. There was a decrease in the percentage of ulnar loops in schizophrenics when compared with controls. There was no much difference in the percentage of radial loops in schizophrenics when compared with controls. However, whorl patterns are found to be of higher percentage in schizophrenics when compared to controls.

Conclusion: In our study, we have noted that schizophrenic patients have a particular pattern of epidermal ridges with lower frequencies of arches, ulnar loops, and higher frequency of whorls. The clinical use of such data has to be validated in the days to come.

Key words: Dermatoglyphics, Epidermal ridges, Fingertip pattern, Schizophrenia

INTRODUCTION

Association of dermatoglyphics with in numerous physical, behavioral, pathological traits has been reported in past years. As the epidermal ridge pattern is established early in intrauterine life, it is theorized that it can be an effective tool in determining risk of development of a particular trait. In this study, we have evaluated dermatoglyphic pattern in schizophrenic patients. Schizophrenia is a clinical syndrome of variable, but profoundly disrupting, psychopathology that involves cognition, emotion, perception, and other aspects of behavior. Current epidemiological research into possible environmental causes of schizophrenia focuses on three main areas: Pre and perinatal damage, factors affecting early brain development and factors operating at the level of the social and family environment.[1] First two factors also influence establishment of dermatoglyphic pattern, which may give a valuable clue for later risk of development of any psychiatric disorders. Epidermal ridges start to develop during 11th gestational week and during 3rd and 4th month they undergo specific differentiation.[2] This coincides with significant phase of neuronal development.[3]

Many studies have tried to establish the direct link between epidermal ridges and schizophrenia using different features to characterize the configuration of epidermal ridges. In modern day, medicine, significance

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of epidermal ridges association with schizophrenia was noted by Holt.[4] Mellor identified both quantitative and qualitative association of dermatoglyphic pattern with schizophrenia.[5] Even in India, there are many studies under this concept. Of late, the sequential development of such pattern in schizophrenic patients is reported by Ponnudurai.[6] Studies have tried to establish relation of schizophrenia and bipolar affective disorder after noting similar dermatoglyphic pattern.[7] Studies have checked the reliability of a-b ridge count in development of schizophrenia.[8] Bramon *et al.* after meta-analysis of such studies, conclude that there is significant reduction in ABRC in schizophrenics.[9] Chok and Kwapil suggested extralimital triradii as a putative marker of schizotypy.[10] In our present study, we have attempted to study fingertip pattern in schizophrenic patients in urban areas of Andhra Pradesh. This is the first such study in Andhra Pradesh to study epidermal ridge patterns on schizophrenic patients.

METHODS

Study Group

The rolled finger and palmar prints of 100 schizophrenic patients of both the sexes (50 males and 50 females) clinically diagnosed under DSM-III-R criteria aged between 15 and 65 years were collected for the study from the Department of Psychiatry, Government General Hospital, Guntur, Andhra Pradesh from September 2009 to July 2010.

Exclusion Criteria

Patients suffering from schizophreniform disorders, any other psychiatric disorders and those with associated genetic abnormalities were excluded in this study.

Control Group

The rolled finger and palmar prints of 100 normal individuals of both the sexes (50 males and 50 females), aged between 15 and 65 years who were medically and psychologically healthy were taken from the teaching, non-teaching staff and medicos of Guntur Medical College, matched with age group of patients.

Procedure

The modified Pervis Smith method was employed in our study.[11] After taking informed consent from the patient they were asked to wash their hands with soap and water to remove any oil or dirt so that quality of dermatoglyphics print is maintained. A small amount of ink is placed on the inking slab, it was spread with the roller into a thin, even film. The area to be printed is pressed against the slab, taking care that the whole area to be printed is covered with ink. A firm surface is used under the sheet of paper at which the inked finger and palm are pressed. The fingerprints were taken starting from thumb to little finger of the right hand and similarly repeated for left hand. The prints of both hands right and left were taken on separate clean papers and labeled properly. The fingertip analysis was conducted in schizophrenic patients and controls.

Statistical Analysis

The qualitative parameter is expressed as number and percentage, and the quantitative parameters are expressed as the number of cases and controls in a particular range. All statistical calculations are done by using Chi-square test using EpiInfo software. $P = 0.05$ or less was set for statistical significance.

RESULTS

Frequency of fingertip patterns, namely arches, ulnar loops, radial loops, and whorls among patients and controls are tabulated in Table 1. We found a significant reduction in arches in patients than compared to age-related controls (5% vs. 8.8% in males and 2% vs. 6.8% in females). Occurrence of ulnar loops was significantly reduced in patient group than in the control group (56% vs. 60% in males and 46% vs. 52.2% in females). Radial loops were noted in 8 cases. There was no significant difference between male cases and male controls as well as between female cases and female controls Whorl pattern was found in higher frequency both male and female patients (37.6% vs. 30.2% in males and 51.8% vs. 37.8% in females). Statistical significance difference was not found in fingertip pattern in left hands of patients and controls. Cumulative frequency of fingertip pattern in patients and controls is tabulated in Table 2.

DISCUSSION

The scientific value of dermatoglyphics largely derives from the fact that dermal ridges appear in the 3rd-5th month of fetal development, and the patterns once formed never change.[3,12] Dermatoglyphic traits are genetically determined. Dermatoglyphic abnormalities are due to genetic or other factors that express their effect before the end of 5th month of fetal development. The recent evidence from the adoption, twin, and family studies has proved as a basis for genetic contributions in schizophrenia, hence dermatoglyphic variation is an essential investigation in its early diagnosis.[13]

In the present study, we found lesser frequency of ulnar loops in line with previous reports. Frequency of whorl

Table 1: Percentage values of frequency of fingertip patterns in the right hand and left hand and combined right and left hands of 50 male cases and 50 male controls

Fingertip pattern	Right hand (%)		Chi-square	Left hand (%)		Chi-square	Both hand (%)		Chi-square
	Patients	Controls		Patients	Controls		Patients	Controls	
Males			χ^2=11†			χ^2=6.05			χ^2=10.29†
Arches	10 (4)	17 (6.8)		15 (6)	27 (10.8)		25 (5)	44 (8.8)	
Ulnar loops	139 (55.6)	159 (63.6)		141 (56.4)	141 (56.4)		280 (56)	300 (60)	
Radial loops	5 (2)	0		2 (0.8)	5 (2)		7 (1.4)	5 (1)	
Whorls	96 (38.4)	74 (29.6)		92 (36.8)	77 (30.8)		188 (37.6)	151 (30.2)	
Females			χ^2=9.8†			χ^2=21†			χ^2=28.21†
Arches	5 (2)	12 (4.8)		5 (2)	22 (8.8)		10 (2)	34 (6.8)	
Ulnar loops	122 (48.4)	144 (57.6)		108 (43.2)	141 (56.4)		230 (46)	276 (55.2)	
Radial loops	0	1 (0.4)		1 (0.4)	0		1 (0.2)	1 (0.2)	
Whorls	123 (49.2)	93 (37.2)		136 (54.4)	96 (38.4)		259 (51.8)	189 (37.8)	

†*P*<0.05, significant

Table 2: Percentage values of frequency of fingertip patterns in 100 schizophrenia patients (males+females) and 100 controls (males+females)

Fingertip patterns	Schizophrenia patients	Controls	*N*=100
Arches	35	78	χ^2=35.21†
Ulnar loops	510	576	
Radial loops	8	6	
Whorls	447	340	

†*P*<0.05, significant

pattern was increased. Murthy and Wig have reported a similar findings, with lesser ulnar loops and more whorl pattern.[14] Jhingan and Munjal observed fewer arches and whorl patterns and more loops on the fingers of schizophrenic patients.[15] The observations of present study correlate with earlier observations of Maricq,[16] Varma *et al.*[17] and Wolff.[18] In contrast, Dasgupta *et al.* have found a higher frequency of both ulnar loops and whorls.[19] Differential population selection may be the reason for such disparity. Similar confounding factors with regard to the selection of patients and controls might have intervened in our study also. We have taken meticulous care in the selection of controls with regard to age and sex matching. But other factors like developmental neuronal injuries and exposure to nerve detrimental substances in controls can't be ruled out.

Dermatoglyphic data will be of value, only if we can establish the "normal" frequencies in larger population. Till such time, studies like ours will keep adding to the existing literature about occurrence of a particular pattern in specified smaller subset groups.

CONCLUSIONS

In our study, we have noted that schizophrenic patients have a particular pattern of epidermal ridges with lower frequencies of arches, ulnar loops, and higher frequency of whorls. The clinical use of such data has to be validated in the days to come.

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Original Article

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Post-operative Pain Management in Children with Caudal Bupivacaine versus Caudal Bupivacaine with Fentanyl

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Abstract

Background: Caudal anesthesia is one of the most popularly used regional blocks in children for providing post-operative analgesia after infra umbilical operations. A large volume of data are available to support the routine use of various adjuncts including synthetic opioids, alpha 2 agonists, benzodiazepines etc., in pediatric regional anesthesia. There are also concerns about their efficacy and unacceptable side effects. Studies on Indian children assessing the efficacy, safety profile of adjuncts in regional anesthesia are very scarce.

Objectives: The objective was to assess the analgesic efficacy and safety of caudal bupivacaine and fentanyl as compared to plain bupivacaine in children undergoing infra umbilical surgery.

Methods: The study was a prospective randomized double-blind controlled trial undertaken in a tertiary care teaching hospital in India. The children undergoing various infra umbilical surgeries were randomly allocated to either plain bupivacaine or bupivacaine plus fentanyl group, with 25 subjects in each group.

Results: The mean grade of post-operative pain was 1.15 and 1.07 in plain bupivacaine and bupivacaine plus fentanyl groups, respectively, with a mean difference of 0.08 (P = 0.13, 95% CI −0.026-0.18). There was no statistically significant difference in the proportion of subjects, requiring different doses of supplementary analgesia (Chi-square value 1.38, P = 0.70). There was no statistically significant difference observed in any of the hemodynamic parameters even though they were relatively stable in bupivacaine plus fentanyl group. The incidence of adverse effects was slightly higher in bupivacaine plus fentanyl group compared to plain bupivacaine group.

Conclusions: Except for slight stability in hemodynamic parameters, there is no added advantage of adding the fentanyl to caudal bupivacaine for postoperative pain relief in children.

Keywords: Anesthesia, Bupivacaine, Caudal, Fentanyl

INTRODUCTION

The provision of good quality analgesia in the postoperative period is vital, not only for alleviating the patients suffering, but also for the prevention of various cardiovascular and respiratory complications resulting from poor pain control.[1]

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In children, pain associated with various surgical interventions may extend well into the postoperative period. Caudal anesthesia is one of the most popularly used regional blocks in children for providing post-operative analgesia after infra umbilical operations.[2]

The quality and level of the caudal blockade are dependent on the dose, volume, and concentration of the injected drug. One of the major limitations of the single-injection usage in caudal block is the relatively short duration of post-operative analgesia. Even long-acting local anesthetics may not be able to provide effective analgesia in first 24 postoperative hours, which often is the most painful part. The use of adjunct drugs in

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combination with long-acting local anesthetics may be the solution for the problem.[3]

A large volume of data are available to support the routine use of various adjuncts including synthetic opioids, alpha 2 agonists, benzodiazepines etc., in pediatric regional anesthesia.[2,4-10] However, there are also concerns about their lack of efficacy and unacceptable side effects.[8] Many authors recommended the routine use of adjuncts in pediatric regional anesthesia, but with proper care and by respecting the contraindications and potential problems that may be associated with its use.[3]

Studies on Indian children assessing the efficacy, safety profile of adjuncts in regional anesthesia are very scarce. Hence, the current study is undertaken with the following objective.

Objectives

1. To assess the analgesic efficacy and safety of caudal bupivacaine and fentanyl as compared to plain bupivacaine in children undergoing infra umbilical surgery.

METHODS

The study was a prospective randomized double-blind controlled trial undertaken in a tertiary care teaching hospital in India. The study subjects were children between the age group of 2 months to 11 years, weighing between 5 kg and 26 kg undergoing elective infra umbilical surgeries in the study setting. A total of 50 such children were included in the study. The children randomly allocated to either plain bupivacaine or bupivacaine plus fentanyl group, with 25 subjects in each group.

The study was approved by Institutional Human Ethics Committee. After obtaining informed written consent from the parent or guardian, detailed history, and a complete pre-operative examination was undertaken so as to exclude patients with any systemic disease especially, neurological diseases, and bleeding diathesis.

A history of non-steroidal anti-inflammatory drugs intake if any was carefully obtained and excluded such patients from the study. All selected patients belonged to American Society of Anesthesiologist's classification grade-1 (ASA-1). All children were submitted to routine investigations like complete urine analysis and complete blood picture.

Children taken up for the study were not premeditated with analgesic drugs and were fasted for a minimum of 4 h. A resting pre-anesthetic record of blood pressure, pulse rate, respiratory rate was recorded.

All children were anesthetized with standard induction procedure of thiopentone 5 mg/kg preceded by 10 μg/kg of injection atropine intravenously. General anesthesia was maintained by inhalation method, using nitrous oxide (66.66%) oxygen (33.33%) and halothane 0.5-2%, using a Ree's modification of Ayre's T-piece and spontaneous ventilation. Depending on their body weight, fresh gas flow was calculated and set in relation to body weight.

After the induction of anesthesia, all children were turned to left lateral position. Injection bupivacaine 0.8 ml/kg preservative free (0.25% solution) and injection. Bupivacaine with injection. Fentanyl, 1 μg/kg preservative free was injected into the caudal epidural space under strict aseptic conditions, following standard operating procedure.

During the period of surgery blood pressure, pulse rate and respiratory rate were recorded. IV infusion of crystalloid isolate-P was administered at the rate of 10 ml/kg/h. In one instance, the blood volume loss was replaced as the blood loss estimated was more. At the end of surgery, children were allowed to recover completely form general anesthesia and were transferred to the recovery room. After full recovery in the recovery room, children were shifted to post-operative ward. Post-operative assessment for pain and side effects were undertaken at 15 min, 30 min, 1 h, 1½ h, 2 h, 3 h, 6 h, and 12 h following the surgery.

Assessment to the extent of pain was recorded using the following objective pain score.

Grade 1: Pain-free (pain none/insignificant) - happy, contended, playful, calm, or asleep.
Grade 2: Moderate pain (grimacing, restlessness) - can be distracted with toys, Food and parents.
Grade 3: Severe pain (crying, tense, screaming, inconsolable tearful).

Side effects such as motor weakness, vomiting, and retention of urine, pruritus, and, respiratory depression were also recorded, during the 24 h postoperative period.

Statistical analysis was done taking the post-operative pains the primary outcome measure. The baseline parameters and type of surgery were compared between the two study groups by descriptive analysis. The average grade of pain, number, and dose of analgesic supplements required were compared between the two study groups using independent sample *t*-test. Hour by hour pain grade, heart rate, and respiratory rate in the first 24 h postoperative period were compared between the two groups by plotting time trend diagram. IBM SPSS software version 21 and Microsoft excel were used for statistical analysis.

RESULTS

A total of 50 children were included in the study with 25 children each under bupivacaine group and bupivacaine plus fentanyl group.

The baseline characteristics of the study population were compared between the two groups. Mean age of the participants was 4.3 years in both the study groups. The male to female ratio was 3.1 and 4, respectively, in bupivacaine and bupivacaine plus fentanyl group. The mean weight of the children was slightly higher in bupivacaine plus fentanyl group 912.18), compared to bupivacaine group (10.88). However, none of these differences in the baseline variables were statistically significant (Table 1).

Herniotomy, circumcision, and urethroplasty were the most common surgical procedures performed in the study population. The proportion of subjects undergoing each surgical procedure slightly varied between the study groups (Table 2).

Table 1: Comparison of socio-demographic parameters in two study groups

Parameter	Bupivacaine	Bupivacaine plus fentanyl	*P* value
Age in years (mean±SD)	4.33±2.54	4.35±2.67	0.98
Male (frequency [%])	19 (76)	20 (80)	0.73
Female (frequency [%])	6 (24)	5 (20)	
Male: female ratio	3.1	4	0.73
Weight in kg (mean±SD)	10.88±4.54	12.18±4.39	0.30

SD: Standard deviation

Table 2: Descriptive analysis of surgery done in two study groups (*N*=50)

Type of surgery	Treatment category total		
	Bupivacaine (*n*=25) (%)	Bupivacaine+fentanyl (*n*=25) (%)	Total (%)
Herniotomy	10 (40.0)	5 (20.0)	15 (30.0)
Circumcision	3 (12.0)	6 (24.0)	9 (18.0)
Urethroplasty	2 (8.0)	5 (20.0)	7 (14.0)
Appendicectomy	3 (12.0)	3 (12.0)	6 (12.0)
High ligation of sac	2 (8.0)	4 (16.0)	6 (12.0)
Anoplasty	1 (4.0)	1 (4.0)	2 (4.0)
Left orchiopexy	1 (4.0)	0 (0.0)	1 (2.0)
Rectal biopsy	1 (4.0)	0 (0.0)	1 (2.0)
Reduction	1 (4.0)	1 (4.0)	2 (4.0)
Right orchiopexy	1 (4.0)	0 (0.0)	1 (2.0)

Hour by hour comparison of severity of post-operative pain showed that the post-operative pain was similar in both the study groups in the 1st h. The pain in the bupivacaine group was slightly higher in subsequent hours in the bupivacaine group, compared to bupivacaine plus fentanyl group (Figure 1).

The mean grade of post-operative pain was 1.15 in bupivacaine groups and 1.07 in bupivacaine plus fentanyl group, with a mean difference of 0.08. The slight difference in the degree of pain between the two study groups was statistically not significant ($P = 0.13$, 95% CI −0.026 to 0.18) (Table 3).

There was no statistically significant difference in the proportion of subjects, requiring different doses of supplementary analgesia (Chi-square value 1.38, $P = 0.70$) (Table 4).

Even though the hemodynamic parameters (heart rate, blood pressure, and respiratory rate) were relatively stable in bupivacaine plus fentanyl group, the statistically significant difference was observed only for diastolic blood pressure (Table 5).

The incidence of adverse effects was slightly higher in bupivacaine plus fentanyl Group. A total of 4 (16%) subjects in the bupivacaine group reported vomiting, whereas 7 (28%) subjects in the bupivacaine plus fentanyl group reported vomiting. Three (12%) subjects in bupivacaine plus fentanyl group reported retention of

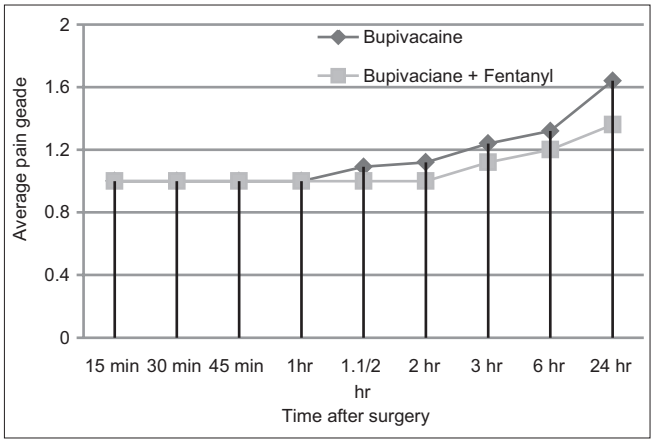

Figure 1: Comparison of hour by hour post-operative pain in two study groups (*n*=50)

Table 3: Comparison of postoperative pain related parameters in both study groups

Parameter	Bupivacaine (*n*=25)	Bupivacaine plus fentanyl (*n*=25)	Mean difference	*P* value	95% CI	
					Lower	Higher
Grade of post-operative pain	1.15	1.07	0.08	0.13	−0.026	0.18

CI: Confidence interval

urine. No other adverse effect was reported both the study groups.

DISCUSSION

The provision of a good quality analgesia in the postoperative period is vital, not only for alleviating the patients suffering, but also for the prevention of various cardiovascular and respiratory complications resulting from poor pain control.[1]

Various opioid derivatives including morphine, tramadol, and fentanyl were tested as adjuncts to local anesthetic to enhance post-operative analgesia.[11-21] However, Grass (1992), in their review on "clinical use of fentanyl, as postoperative analgesia through epidural/intrathecal route" have felt that fentanyl, because of its greater lipophilic, offers a number of advantages over other opioids for epidural analgesia. These include, lower incidence of side effects and reduced risk of delayed - onset respiratory depression.[22]

The current study has compared the analgesic efficacy of bupivacaine versus bupivacaine plus fentanyl in two groups of children, undergoing herniotomy, circumcision, urethroplasty, and other infra umbilical surgeries. Hour by hour comparison of severity of post-operative pain showed that none of the children in both the study groups had post-operative pain in the first hour and children bupivacaine group had slightly higher pain in subsequent hours.

In the current study, the mean grade of post-operative pain was 1.15 and 1.07 in plain bupivacaine and bupivacaine plus fentanyl groups, respectively, with a mean difference of 0.08 ($P = 0.13$, 95% CI −0.026 to 0.18) and there was no statistically significant difference in the proportion of subjects, requiring different doses of supplementary analgesia (Chi-square value 1.38, $P = 0.70$).

In the current study, there was no statistically significant difference observed in any of the hemodynamic parameters (heart rate, blood pressure and respiratory rate) in both the study groups, in the post-operative period. The incidence of adverse effects was slightly higher in bupivacaine plus fentanyl group compared to plain bupivacaine group.

Scott *et al.* (1995). in their study concluded that post-operative epidural fentanyl/bupivacaine infusions are effective and can be managed readily in general post-surgical wards with minimal complications.[1]

Gharsallah *et al.* (1996) in their study have evaluated two dosages of fentanyl (0.5 μg/kg (Group I) and 1 μg/kg (Group II)) in association with bupivacaine 0.25% at a dosage of 1 ml/kg in caudal anesthesia. They have concluded that quality and duration of analgesia were similar in the two groups and suggested caudal block with bupivacaine 0.25% and fentanyl 0.5 μg/kg is a very satisfactory technique.[23]

Ganesh *et al.* (2008), in their study has evaluated the efficacy of addition of fentanyl to epidural bupivacaine on postoperative analgesia after thoracotomy in 32 infants. The authors have concluded that addition of 2 μg/ml epidural fentanyl to 0.1% bupivacaine results in improved post-thoracotomy analgesia without any increase in side effects, compared with 0.1% bupivacaine, in infants up to 6 months of age.[24] Lejus *et al.* (2001). Furthermore, concluded that the combination of bupivacaine-fentanyl provides safe analgesia after major surgery in children.[25]

Karkera *et al.* (2014) in their retrospective cohort study of 849 pediatric patients have concluded that there is no statistically significant difference between concentrations of bupivacaine administered in a caudal block with or without i.v. fentanyl with regard to the outcome.[26] Singh *et al.* (2012) have concluded that clonidine in a dose of 1 μg/kg, added to 0.25% bupivacaine for caudal analgesia and administered as a 0.75 ml/kg mixture in children, for

Table 4: Comparison of number of doses of supplementary analgesics required

Analgesia (number of doses)	Bupivacaine group *n*=25 (%)	Bupivacaine+ Fentanyl *n*=25 (%)	Chi-square value	*P* value
0	17 (68)	18 (72)	1.38	0.70
1	3 (12)	4 (16)		
2	4 (16)	3 (12)		
3	1 (4)	1 (4)		

Table 5: Comparison of hemodynamic parameters in two study groups

Group	Pulse rate (mean±SD)	Blood pressure (mean±SD)		Respiratory rate (bpm) (mean±SD)
		Systolic	Diastolic	
Bupivacaine (*n*=25)	105.60±8.0415	78.56±10.1410	56.2424±5.3015	19.5200±3.0155
Bupivacaine+fentanyl (*n*=25)	104.24±10.3664	80.88±12.2485	61.52±8.6848	20.24±2.7276
P value	0.60	0.46	0.01	0.37
95% CI	−3.91-6.63	−8.71-4.07	−9.36-−1.19	−2.35-0.91

SD: Standard deviation, CI: Confidence interval

umbilical surgery, significantly prolongs the duration of postoperative analgesia when compared to bupivacaine with fentanyl 1 μg/kg or 0.75 ml/kg of 0.25% bupivacaine alone, without any side effects.[27]

Cucchiaro *et al.* (2006) in their study comparing epidural bupivacaine-fentanyl and bupivacaine-clonidine in children observed that the incidence of side effects was significantly less in the bupivacaine + clonidine group (33%) compared with the bupivacaine + fentanyl (92%) and bupivacaine + fentanyl + clonidine (73%) groups ($P = 0.004$). Quality of post-operative analgesia was similar in the three groups. The authors have concluded that clonidine is an effective and safe alternative to epidural opioids.[28]

Constant *et al.* (1998) concluded that, addition of clonidine or fentanyl to local anesthetics prolonged the duration of surgical analgesia of caudal block. Clonidine had some advantages over the fentanyl as it did not produce clinically significant side effects.[29]

Hence, there were many published studies in the literature supporting both the views that addition fentanyl is beneficial and not so beneficial in the literature. However, there were many studies proving other adjuncts like clonidine are much more effective that fentanyl with no risk of any additional adverse effects.

CONCLUSIONS

1. Caudal extradural route has been preferred in children for its higher predictability, as regards to technical aspects of location of space and efficacy of pain relief with drugs administered by this route
2. There is no added advantage of mixing fentanyl to caudal bupivacaine for postoperative pain relief in children
3. The hemodynamic parameters were relatively stable in bupivacaine plus fentanyl group
4. There was minimal incidence of side effects like vomiting and retention of urine which responded to conservative treatment.

Recommendations

1. Fentanyl cannot be recommended as a routine adjunct to bupivacaine in caudal block in children, basing on the study findings and current evidence
2. There is a need to conduct further large-scale randomized controlled trials on the subject, especially in Indian children.

Limitations

1. The role of many confounding factors could not be evaluated due to the relatively smaller sample size of the study
2. Considering the nature of the intervention, effective double blinding was not possible in the study.

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Original Article

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Dropouts of Patients from a Psychiatric Clinic Attending Government Medical College in Surat, Gujarat, India: A Retrospective Study

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Abstract

Introduction: Information on the prevalence and determinants of treatment dropout is essential for designing and targeting interventions and health care policies to increase the proportion of patients who complete adequate courses of care, by having knowledge regarding the vulnerable group for dropout and the predictive variables for dropout therapist can plan measures to decrease the dropout rate.

Materials and Methods: This is a retrospective study of chart review of 700 randomly selected case files of 7000 patients enrolled as outpatients in a period between 2008 and 2013 at Department of Psychiatry, Government Medical College, Surat, Gujarat, India. Case files were evaluated for incidence of dropout. Socio-demographic and clinical profiles of dropouts were compared with that of non-dropouts using statistical tests.

Results: Overall dropout rate was found to be 16%, out of which 30% of dropouts occurring in the 1st month. Patients who were unmarried, more than 40 years of age, illiterate, not working, and poor had significantly high rates of dropout while there was no significant difference as per gender or rural/urban domicile. High dropout rates were seen amongst anxiety disorders, substance-related conditions, and bipolar mood disorder; while schizophrenia and mental retardation had the lowest dropout rates. There was no significant difference in the dropout rate as per the age at onset of illness.

Conclusion: Mental health treatment dropout is a serious problem world over. The identifiable risk population can be identified to tackle the problem of dropout. Psychoeducation, decreasing reasons of dropout, and clear outcome expectations with management plans, agreement regarding total duration of treatment are essential. Further studies in this context are required.

Keywords: Dropouts, Mental health, Psychological disorders, Psychoeducation

INTRODUCTION

Information on the prevalence and determinants of treatment dropout is essential for designing and targeting interventions and health care policies to increase the proportion of patients who complete adequate courses of care, by having knowledge regarding the vulnerable group for dropout and the predictive variables for dropout therapist can plan measures to decrease the dropout rate.

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It is well-recognized that utilization of the meager available psychiatric services in India from mental hospitals, general hospitals, psychiatric units, and private psychiatrists is far from ideal. The ratio of psychiatrists to general population is little over one psychiatrist to every one million people. Hence, it is important to find out if the existing facilities are being utilized to the optimum.

In spite of the availability of effective treatment, dropout from psychiatric care is a common occurrence.[1,2] Multiple factors contribute to dropout such as underestimation

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of severity of emotional problems by patients, failure of treatment,[3-5] patient's economic condition, symptom profile, pessimism regarding treatment effectiveness or sensitivity to treatment side effects[6-9] and finally there can be a difference in what patient perceives as a treatment endpoint as compared to therapist. Identifying the extent and reasons for treatment dropout is important as mental health treatments that are delivered for inadequate durations are ineffective.[10,11]

The most useful definition of last contact/dropout in the field of mental health care, which has been tested using case register data, is a contact, after which there is a gap of 90 days or more without any further contact.[12] As the outpatient clinic in which this study is being carried out supplies free medication for 1-2 months and the patient population is coming for follow-up from considerable far distances, the definition of dropout for this study is taken as a gap of 6 months or more without any further contact. Previous research has shown that socio-demographic factors, such as age, marital status, and living situation, may be important to predict drop-outs[13-15], so they were evaluated in this study. Follow-up studies from around the world including India[16-28] show that 16-60% of patients will not follow-up in spite of the need for further treatment.

Information on the prevalence and determinants of treatment dropout is essential for designing and targeting interventions and health care policies to increase the proportion of patients who complete adequate courses of care and lastly by having a knowledge regarding the vulnerable group for dropout and the predictive variables for dropout therapist can take measures to decrease the dropout rate.

Aim of Study

The aim of our study was to present representative data on the prevalence of mental health treatment dropout in a psychiatric outpatient clinic of a Government Medical College and to evaluate dropout predictors as per socio-demographic and clinical profile. This study also provides a substantial review of other studies on dropouts in psychiatry throughout the world.

MATERIALS AND METHODS

In Psychiatry Department of Government Medical College where study was carried out, records of patients in the form of case files are kept to ease the subsequent follow-up. The record is maintained after initial two follow-ups and expressed an intention of patient and caregiver to be treated in the facility. Patient's socio-demographic data, diagnosis, along with detailed case history are recorded in these files and on subsequent follow ups a note is entered regarding assessment of the patient at follow-up. Out of 7000 such files made from 2008 to 2013, 900 files were selected randomly for evaluation. Out of a list of variables, seven socio-demographic variables and four clinical profile variables were selected for study as they were recorded in almost all files. Those files with incomplete data and those in which consultant had advised to stop treatment further were excluded. Totally 700 files met above criteria and were taken for data analysis. An electronic chart review data sheet (Microsoft Excel Office Worksheet) was prepared based on chosen socio-demographic and clinical variables from case files. The data were analyzed for significance through open Epi version 2.3 (Developed by Centre for Disease Control and Prevention - CDC) using chi-square test. A value of < 0.05 was considered as significant.

Statistical Analysis

For this study, dropping out was defined as the unilateral interruption of treatment by the patient, without a further contact with the service in the following 6 months. Having advised to discontinue treatment by the consultant, having died or having moved to a different health area after informing consultant were not considered as drop-outs. Time for dropout was defined as starting from the date of first consultation till last follow-up. Patients who had interrupted treatment for more than 6 months, but again started consultation afterward were not considered as dropouts.

The dropouts were compared with non-dropouts based on the following parameters:

Socio Demographic Variables:

1. Age divided into following categories in years: 0-10, 10-20, 20-30, 30-40, 40-50, 50-60 and >60 years
2. Sex: Male and female
3. Marital status: Married, unmarried, and widow/widower (at the time of presentation)
4. Occupation: At the time of presentation: Unemployed, unskilled, semi-skilled, and skilled (as per Delhi minimum wages definition)
5. Education level: Illiterate, educated till 7th class, educated till 10th class, educated till 12th class, Graduate, and Postgraduate (at the time of presentation)
6. Domicile: Rural or Urban
7. Monthly per capita income.

Clinical Profile Variables

1. Diagnosis: As per DSM IV TR

2. Age at onset of illness
3. Time since enrolled at clinic
4. Patient indoor admission: Whether the patient was admitted during the course of illness in this hospital.

RESULTS

In this study, total number of case files studied was 700 in number and total dropouts were 112 (16%).

According to result, the dropout rate in this study was found to be 16% with an average time for dropout being 10.7 months. 30% of dropouts occurred in the 1st month (Table 1).

Table 1: Dropout rate

Dropout time	Number of dropouts (*N*=112) (%)
1st month	34 (30.35)
>1 to <=6 months	15 (13.39)
> 6 months to <=12 months	17 (15.17)
>12 months to <=18 months	19 (16.96)
>18 months to <=24 months	12 (10.71)
>24 months	15 (13.39)

As per results, though female gender had higher dropout rate it was not significant. Patients who were married had a statistically significant lower dropout rate than unmarried. Results show that older patient population had a significantly higher dropout rate as compared to younger population although the lowest dropout rate was seen amongst 31-50 years age group (Table 2).

Illiterate patient population was significantly more likely to dropout as compared to literate although graduate and post graduate population had a high dropout rate. There was no significant difference found between the rural and urban patient population. Patients who were not working had significantly higher dropout rates than others. Patients with per capita income <1000 were more likely to dropout as compared with rest of the patients.

As per the diagnosis, highest dropout rates were seen among anxiety disorder patients which was significantly higher as compared to others. Schizophrenia and mental retardation had the lowest dropout rates. There was no significant difference in the dropout rate as per the age at onset of illness. Patients who were first enrolled at the

Table 2: Socio-demographic profile and dropout rate

Factor	Subsets	Sample size (*N*)	Non-dropout *n* (%)	Dropout *n**(%)	Chi-square test (degree of freedom: 1)
Sex	Male	406	348 (85.71)	58 (14.28)	0.14
	Female	294	240 (81.63)	54 (18.36)	
Marital status	Unmarried	310	250 (80.64)	60 (19.35)	0.01 (unmarried vs. married)
	Married	366	320 (87.43)	46 (12.56)	
	Widow/widower/divorced	24	18 (75)	6 (25)	
Age group (years)	<10	65	57 (87.69)	8 (12.30)	0.0001 (≤40 vs. >40)
	11-20	110	95 (86.36)	15 (13.63)	
	21-30	145	124 (85.51)	21 (14.48)	
	31-40	111	103 (92.79)	8 (7.20)	
	41-50	110	96 (87.27)	14 (12.72)	
	51-60	88	63 (71.59)	25 (28.4)	
	>60	71	50 (70.42)	21 (29.57)	
Education status	Illiterate	184	135 (73.36)	49 (26.6)	0.000004 (illiterate vs. literate)
	Upto 7th	237	210 (88.60)	27 (11.39)	
	Upto 10th	93	84 (90.32)	9 (9.67)	
	Upto 12th	53	45 (84.90)	8 (15.09)	
	Graduate	47	34 (72.34)	13 (27.65)	
	Postgraduate	56	46 (82.14)	10 (17.85)	
Domicile	Rural	245	208 (84.89)	37 (15.10)	0.63
	Urban	455	380 (83.51)	75 (16.48)	
Occupation	Not working	114	85 (74.56)	29 (25.43)	0.002 (working vs. non-working)
	Unskilled/house wife	190	158 (83.15)	32 (16.84)	
	Semiskilled	169	150 (88.75)	19 (11.24)	
	Skilled	192	167 (86.97)	25 (13.02)	
	Not known	40	31 (77.5)	9 (22.5)	
Monthly per capita income	≤1000	272	213 (78.30)	59 (21.69)	0.0010 (≤1000 vs. others)
	1001-5000	212	196 (92.45)	16 (7.54)	
	5001-10000	117	105 (89.74)	12 (10.25)	
	10001-25000	74	59 (79.72)	15 (20.27)	
	>25000	25	16 (64)	9 (36)	

clinic 3 years before had a significantly higher dropout rate than newly enrolled patients. Patient with history of indoor admission during the course of consultation from Psychiatry Department had lower dropout rate as compared to those who were never admitted, suggesting more severe illness and taking indoor services as factors important for adherence (Table 3).

DISCUSSION

The dropout rates of 16% in this study is comparable to the dropout rate of 17% recently observed in a study of mental health advocacy group members in 11 countries.[29] This figure is also within the average of previous studies, where the rates varied between 16% and 60%. However, most earlier studies reported much higher rates of treatment dropout.[30,31] In India, Gill *et al.* in 1990 reported 38% dropout and it showed that dropouts were maximum in epilepsy and least in mental retardation and dropouts significantly differed from non-dropouts in terms of income, place of domicile and occupation.[16] The difference can be attributed to increased awareness in Indian society regarding psychiatric illnesses since 1990 and a different criterion for patient selection in that study. The timing of dropout was also consistent with previous studies. Occupation status, education, and income were also associated significantly with dropout in other studies too. Socio-demographic analysis found that patient more than 40 years of age are more vulnerable for dropout, which is in contrast with other western studies[32-34] and in line with recent study done by[35] in 2009. This finding can be attributed to more stigma regarding mental illness among elderly in Indian society as well as a lack of means to avail treatment in elderly.

Being unmarried was found to be a risk factor for drop-out, in line with the majority of previous studies. Our study reports that patients with a diagnosis of schizophrenia were more likely to continue their treatment than patients with neurotic and depressive disorders. A diagnosis of schizophrenia was found to greatly increase the chance of continuing treatment in various studies.

In a study done by Edlund *et al.* in United States and Ontario, it was concluded that mental health treatment dropout is a serious problem, especially among patients who have low income, are young, lack insurance, are offered only single modality treatments, and have negative attitudes about mental health care.[20]

In a study done by Agyapong et al. on factors predicting adherence with psychiatric follow-up appointments results showed that only 56% of the patients were found to have attended their follow-up appointments. Being previously known to psychiatric services was the only statistically significant predictor of adherence with out-patient appointments.[28]

CONCLUSIONS

Mental health treatment dropout is a serious problem, especially among patients who are illiterate, elderly, non-

Table 3: Clinical profile and dropout rate

Factor	Subsets	Sample size (*N*)	Non dropout *n* (%)	Dropout *n** (%)	Chi-square test (degree of freedom: 1)
Diagnosis	Schizophrenia	187	167 (89.30)	20 (10.69)	0.020 (schizophrenia vs. rest),
	Major depressive disorder	119	98 (82.35)	21 (17.64)	0.71(MDD vs. rest),
	Bipolar mood disorder	52	42 (80.76)	10 (19.23)	0.0043 (anxiety vs. rest),
	Substance related	57	46 (80.70)	11 (19.29)	0.50 (Substance related vs. rest),
	Anxiety disorder	63	45 (71.42)	18 (28.37)	0.43 (Bipolar mood disorder vs. rest)
	Mental retardation	21	19 (90.47)	2 (9.5)	
	Epilepsy	45	38 (84.44)	7 (15.55)	
	Adjustment disorder	32	27 (84.37)	5 (15.62)	
	Headache	54	47 (87.03)	7 (12.96)	
	Others	70	59 (84.28)	11 (15.71)	
Age at onset of illness	0-10	78	67 (85.89)	11 (14.10)	0.62 (<=20 vs. rest), 0.36 (<=30 vs. rest)
	11-20	202	167 (82.67)	35 (17.32)	
	21-30	174	152 (87.35)	22 (12.64)	
	31-40	91	78 (85.71)	13 (14.28)	
	41-50	89	74 (83.14)	15 (16.85)	
	51-60	60	47 (78.33)	13 (21.66)	
	>60	21	18 (85.71)	3 (14.28)	
Time since first enrolled at clinic	≤3 years	416	351 (84.37)	65 (15.62)	0.0081
	>3 year	274	207 (75.54)	67 (24.4)	
History of indoor admission	Present	74	67 (90.54)	7 (9.4)	0.1046
	Absent	626	521 (83.23)	105 (16.77)	

working, poor, and unmarried. Diagnosis of anxiety disorders, substance-related conditions, and bipolar mood disorder carry higher risk of dropout. To tackle the problem of dropout, psychoeducation and clear instructions regarding total duration of treatment initially are essential. Various studies throughout the world have shown that use of mobile technology through short message services and phone calls can be used to improve follow-up.[27,36,37]

With the increasing penetration of mobile technology in Indian population, it can be used as an effective way to reduce dropout. Further studies in this context are required.

Limitations of the Study

As this retrospective study was based on a register of cases, it was not possible to determine whether the subjects had genuinely dropped out of psychiatric treatment or had continued their therapy in the private sector or through other healthcare services. This study therefore only applies to non-compliance to the service and not to psychiatric treatment, in general.

The sample included patients who attended at least two appointments, therefore excluding those who dropped out after first appointment. Despite the limitation it entails, this selection criterion was established to guarantee that only patients prescribed treatment in the center were included in the sample, thus ruling out single consultations and cases immediately referred to other medical specialties not pertaining to psychiatry.

Finally, there are minimal charges for case registration. However, free medications are provided in Government Medical College. Thus, these dropout rates may not be representative of other types of psychiatric care facilities. But can be applied across the state with similar services.

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Original Article

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Real Time Polymerase Chain Reaction Assessment of Hepatitis C Infection in a Tertiary Care Centre

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Abstract

Introduction: RNA viruses are very vulnerable for mutations and therefore pose maximum difficulty in diagnosis and treatment. Hepatitis C virus is among one of them. In addition to pose higher mutation rate, its geographic distribution in different countries and even in different states in India is quite remarkable. This study is being undertaken to study its prevalence by real time polymerase chain reaction (RT-PCR) method, which is a gold standard for diagnostic assessment for such type of viral infections.

Materials and Methods: This study was conducted in the blood bank on 820 units of blood at Teerthanker Mahaveer Medical College and Research Centre (TMMCRC) and associated hospital with prior consent of medical superintendent of the hospital. Along with other screening test RT-PCR was applied as gold standard. All conditions for this type of diagnostic tests were maintained and results were obtained and appropriate statistical test applied.

Results: Of the 820 units, 0.51% showed the seropositivity. On statistical analysis, there was statistically significant ($P < 0.05\%$) seropositivity and higher response rate ($P < 0.005$) was observed. The seropositivity was found to be maximum in old age (55-65 years males), while it was found to be least in young 18-25 years males.

Conclusion: As we go through the literature available on the topic we found that there is a major difference in the seropositivity in different continents of the world and even the different states in India. Hence, we conducted the study using RT-PCR method and found the prevalence rate of 0.51% in our hospital, which addresses to us for being more vigilant at the time of receiving blood.

Keywords: Hepatitis, RNA virus, Real time polymerase chain reaction, Seropositivity.

INTRODUCTION

Hepatitis C is a RNA virus that belongs to the Flaviviridae family and genus *Hepacivirus* (Choo *et al.* 1989) saw first it in infected animals.[1] Worldwide prevalence of hepatitis C virus (HCV) is approximately 1.8%.[2] The HCV is single-stranded RNA virus. Being RNA virus it has got maximum genetic variability in terms of mutations. The high mutation rate is associated with high morbidity and mortality. Unsafe blood transfusion and neglect of prescribed guidelines to prevent such type of infections are the leading cause of the emergence of HCV in India. HCV genome differs in different geographical regions.[3] Antiviral therapy is affected by the genome of the virus.

While in India seropositivity rate varies from 0.11% to 3.8%, but globally it varies from 0.36% to 18.6%.[4]

In addition to various tests available for detecting HCV antibodies, polymerase chain reaction (PCR) real time PCR (RT-PCR) for HCV is the test of choice because it easily detects antibodies in serum in 7-12 days after infection.[5] Real-time PCR method has got added advantage of lower detection limits.

MATERIALS AND METHODS

This study was conducted in the blood bank (pathology department) TMMCRC, Moradabad, India. A total of

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820 units of blood were screened. Persons found reactive for anti-HCV were informed. After information persons who gave the consent to be included in the study were accessed for further detailed history, examination and other blood tests, other blood tests which were performed included liver function test, prothrombin time, activated partial thromboplastin time, and HCV RNA detection and detection of HCV RNA by real-time PCR HCV RNA by RT-PCR.

To guarantee ideal conditions, serum samples were stored at temperature −80°C. The study was approved by the Ethics Committee of Medical Research Division of TMMCRC, Moradabad, India.

RT-PCR technique involved following steps in sequential manner

1. Denaturation at 92°C for 1 min,
2. Annealing at 52°C for 1 min,
3. Extension at 72°C for 1 min, for 30 cycles.

The amplified products were analyzed under ultraviolet illumination.

Statistical Analysis

The data were statistically evaluated using Student's - *t*-test.

RESULTS

Of the 820 units, 4 were found positive for anti-HCV antibodies, showing seropositivity of approximately of 0.51%. When checked for concomitant infections no one found to be positive. Of the four, three responded back to the department (making it to 75%). A significantly lower HCV seropositivity ($P < 0.05$) and a higher response rate ($P < 0.005$) pattern were observed.

The seropositivity was found to be maximum in old age (55-65 years males), while it was found to be least in young 18-25 years males (Table 1, Figure 1).

Samples that were positive showed the band size of 270 base pairs. Following molecular genomic sequencing of different regions were obtained (Table 2, Figure 2).

Table 1: Age wise distribution of seropositivity

Age in years	Rate of seropositivity (%)
16-25	0.26
26-35	0.32
36-45	0.41
46-55	0.42
56-65	0.51

DISCUSSION

HCV RNA is one of the most important parameters for diagnostic and prognostic significance of hepatitis C.

Real-time PCR technology has now become the technique of choice for highly sensitive assessment of RNA targets.[6-8]

Chances of transmission of HCV through contaminated transfusion are approximately 88-90%. Safe transfusion does not only involve only screening of blood, but other factors like age, area of study, incidence and prevalence, and proper history taking. In the present study, anti-HCV seropositivity was 0.51% among healthy donors. Studies from Northern India found HCV seroprevalence ranging from 0.53% to 5.1% in their blood donors.[9-11] This well correlates with our study.

A study conducted in other part of western India showed seropositivity between 0.33% and 2.6%.[12,13] This difference from our study may be due to different

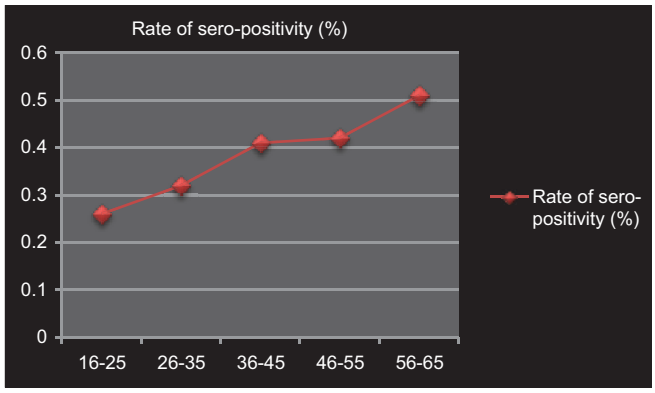

Figure 1: Graphic representation of age wise distribution of seropositivity

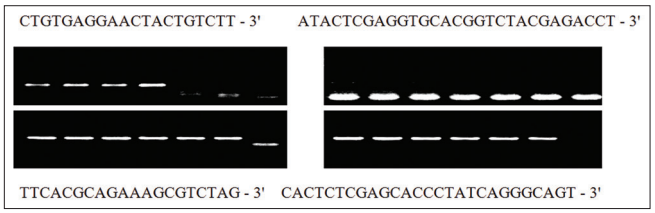

Figure 2: Base pairing sequence of hepatitis C virus - RNA by real time polymerase chain reaction

Table 2: Sowing base pairing sequence of HCV - RNA

Region	Base pairing sequence
Outer sense: 5'	CTGTGAGGAACTACTGTCTT – 3'
Outer antisense: 5'	ATACTCGAGGTGCACGGTCTACGAGACCT – 3'
Inner sense: 5'	TTCACGCAGAAAGCGTCTAG – 3'
Inner antisense: 5'	CACTCTCGAGCACCCTATCAGGGCAGT – 3'

HCV: Hepatitis C virus

methods of testing, strict regulations whether followed or not like in our study and high-risk donors did not return back for confirmation.

In our hospital, we take blood of those only who well know about safe sexual practices, relatives of patients, and who full fill our criteria of safe blood donation. Even after that 0.51% seropositivity reflects very strict testing of blood.

When we compared and analyzed the seropositivity between relative donors and voluntary donors, we found seropositivity was less in blood units of relative to some extent, but not statistically significant ($P > 0.5$) from voluntary donors.

Our study is well in accordance with the study conducted by Schreiber *et al.* 2001,[14] who also did not find statistically significant difference ($P > 0.05$) between donors of different socio-economic class, and other concurrent factors like safe sexual practices, and relatives of patients.

When we track the record, we found that seropositivity was maximum in age group between 55 and 65 years of age group individuals, which is similar in results shown by Okayama *et al.*[15,16]

CONCLUSION

Spread of HCV, through blood and blood products is an important mode of transmission because even the very meager amount of blood transfers a large amount of the infective agent into potential recipient. There have been various methods used to combat such type of blood borne infections, which effectively reduced the prevalence of such type of infections in developing countries. In India, various studies showed varied results, so taking their reference is not adequate to implement in our hospital and to avoid spread of hepatitis C we employed the ultimate test RT-PCR for confirming the susceptibility of hepatitis C infection and we were successful in achieving the results. Still we feel that a large sample than this should be taken to validate the study.

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Original Article

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Comparison of Insertion Characteristics and Hemodynamic Changes of Halothane + Propofol versus Sevoflurane + Propofol using I-Gel in Children Undergoing Short Surgical Procedures

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Abstract

Background: Goals of pediatric anesthesia for short surgical procedures are fast emergence and smooth recovery. Aim was to compare halothane + propofol and sevoflurane + propofol in pediatric patients undergoing short surgical procedures using I-Gel.

Materials and Methods: In a double-blind study, 80 patients of 3-10 years were premedicated with injection. Atropine and midazolam spray and were randomly divided into two groups of forty each. In Group A, induction was done with 50% oxygen + 50% nitrous oxide + 0.5% halothane followed by stepwise increase by 0.5% till loss of eyelash reflex. At centralization of pupil, intravenous cannulation was done, injection. Propofol was given and I-Gel was inserted. Maintenance was done with 1-2% halothane + nitrous oxide + oxygen and propofol infusion. Similar technique was used in Group B except for induction was done with 1% sevoflurane followed by stepwise increase by 1% and maintenance with 1-2%. Both groups were compared for induction, insertion conditions for I-Gel, hemodynamics, and emergence.

Results: Induction was more rapid in Group B as time for loss of eyelash reflex and centralization of pupil was significantly less in Group B (73.90 ± 6.830 and 170.33 ± 4.751 s) as compared to Group A (112.13 ± 5.661 and 249.33 ± 6.472 s). Insertion conditions for I-Gel were excellent. Induction time was significantly less in Group B as compared to Group A. Heart rate and blood pressure was on lower side in Group A as compared to Group B. Emergence was significantly more rapid in Group B. No side effect or complication was noted in both groups. Parametric data was analyzed using unpaired *t*-test and non-parametric data with "Chi-square" test. *P* value was determined to evaluate the levels of significance.

Conclusion: Sevoflurane + propofol have rapid onset and emergence of anesthesia as compared to halothane + propofol with more stable hemodynamic parameters.

Keywords: Halothane, Pediatric anesthesia, Propofol, Sevoflurane

INTRODUCTION

Airway management during general anesthesia in pediatric patients is always challenging for an anesthesiologist as it requires an understanding of the characteristics unique to a child's airway.[1] So far, endotracheal tube was the gold standard for securing airway, which has its own disadvantages like soft tissue trauma, hemodynamic instability, sore throat, and increased chances of laryngospasm and bronchospasm, as it requires manipulation of vocal cords for its placement.[2] With the advent of a novel supraglottic airway device "I-Gel," the incidence of complications associated with endotracheal intubation has decreased.[3] Goals of pediatric anesthesia for short surgical procedures are fast emergence and early recovery with low incidence of post-operative side effects.[4] Newer techniques are continually being explored to fulfill these criteria. Inhalation induction is the preferred technique for anesthesia in

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children. Among these, halothane with its sweet odor and minimal effects on airway reactivity makes it a suitable induction agent, despite its propensity to cause bradycardia, hypotension, and arrhythmias.[5,6] Sevoflurane has non-pungent odor, provides rapid onset and emergence from anesthesia and has less cardiovascular side effects, which makes it an attractive alternative for pediatric anesthesia.[6,7] Various authors had already compared the induction and emergence characteristics and hemodynamic changes associated with halothane and sevoflurane anesthesia in pediatric patients.[5-11] In the present study, we have used propofol in addition to halothane and sevoflurane with an aim of improving the insertion conditions for I-Gel and to decrease the incidence of emergence complications associated with inhalational agents.

Aim and objectives of the present study was to compare halothane + propofol and sevoflurane + propofol in terms of:

- Induction and insertion parameters
- Hemodynamic changes
- Emergence parameters
- Side effect and complications of study drugs and I-Gel in pediatric patients undergoing short surgical procedures.

MATERIALS AND METHODS

After approval from the Institutional Ethics Committee, this double-blind, randomized study was conducted on eighty patients of American Society of Anesthesiologist Grade I and II in the age group of 3-10 years undergoing short surgical procedures using I-Gel. Patients with history of acute upper respiratory infection, hematocrit <25%, bleeding disorders, hepatic or renal dysfunction, congenital anomaly, exposure to general anesthetic agents in previous 7 days, contraindication for using study drugs or personal or family history of malignant hyperthermia were excluded from the study. A well-informed consent was taken from the parents or guardians of the children included in this study. Pre-anesthetic checkup of the patients was done a day before surgery. General physical examination and systemic examination was carried. Airway was assessed using Mallampati grading. Routine investigations were reviewed. Weight of each patient was recorded and were randomly divided into two groups of forty each, Group A (halothane + propofol), Group B (sevoflurane + propofol), using a computer-generated randomization technique.

On the day of surgery, patients were reassessed preoperatively and after confirming overnight fasting, they were pre-medicated with injection atropine sulfate 0.02 mg/kg body weight intramuscularly and midazolam nasal spray 0.2 mg/kg body weight 45 min before surgery. Patients were shifted to operating room and multipara monitor was attached to monitor baseline heart rate (HR), respiratory rate (RR), systolic blood pressure (SBP), diastolic BP (DBP), SPO_2, electrocardiograph (ECG), and end-tidal carbon dioxide concentration ($ETCO_2$). Continuous monitoring of vitals was then started.

Face mask of appropriate size was kept on the face of spontaneously breathing patient for induction of anesthesia. In Group A (halothane + propofol), induction was done with 50% oxygen + 50% nitrous oxide + 0.5% halothane followed by stepwise increase by 0.5% every 3-5 breaths. In Group B (sevoflurane +propofol), induction was done with 50% oxygen + 50% nitrous oxide +1% sevoflurane followed by stepwise increase by 1% every 3-5 breaths till loss of eyelash reflex was achieved. Time taken to loss of eyelash reflex as a sign of loss of consciousness and time taken to complete induction (centralization of pupil, no gross bodily movements) was recorded. Induction was done by an anesthesiologist with the vaporizers concealed by a screen and dial settings were adjusted by an anesthesia assistant. All the induction and recovery parameters were assessed by a senior anesthesiologist who was unaware of the agent used. After centralization of pupil, intravenous cannulation was done and infusion of Isolyte P was started. Any bodily movements occurring at the time of cannulation were noted. The concentration of inhalational agents was reduced to half after giving injection propofol 3 mg/kg body weight intravenously in both the groups. Bag and mask ventilation was done and after obtaining adequate jaw relaxation, I-Gel of appropriate size was inserted without using any muscle relaxant. Number of attempts and time taken for I-Gel insertion was noted. Maximum three attempts were made for insertion using maneuvers like chin lift, jaw thrust, head extension and neck flexion for easy insertion. I-Gel was connected to breathing circuit and after confirming the correct placement, patients were ventilated manually. A lubricated gastric tube was passed through gastric channel of the I-Gel. Quality of insertion conditions like jaw relaxation, coughing on insertion and any limb movement on insertion were noted.[12] For all variables, score of 1-4 was taken and score of 1 was taken as ideal conditions, therefore total score of three was taken as best possible score. Ease of insertion of I-Gel was assessed as: E - easy, A - acceptable, D - difficult, F - failure.[13] Any episode of laryngospasm, struggling, oxygen desaturation and hemodynamic changes occurring during induction and insertion were also recorded. Immediately after I-Gel insertion, paracetamol suppository (20 mg/kg body weight) per rectum was given for analgesia. Maintenance of anesthesia was done with either 50% oxygen: 50% nitrous oxide + 1-2% halothane in Group A or 50% oxygen: 50% nitrous oxide + 2-4% sevoflurane in Group B.

Continuous intravenous infusion of propofol at the rate of 5-7 mg/kg/h was given during maintenance of anesthesia in both groups.

Continuous monitoring of RR, systolic and DBP, HR, SPO_2, $ETCO_2$, and ECG was done at 1 min interval for first 10 min, then every 5 min for initial 30 min and thereafter every 10 min till the completion of study. Bradycardia defined as HR <20% of the baseline value and was treated with an injection atropine. Hypotension defined as fall in SBP more than 20% was treated by decreasing the concentration of inhalational agents or by giving additional fluids. At the completion of surgery, inhalational agents and propofol infusion was stopped and 100% oxygen was given. I-Gel was removed when spontaneous respiration was considered adequate and oxygen was continued till the patient was shifted to the recovery room. During recovery, emergence time (time taken from stoppage of anesthetic agent to that when patient responds to verbal commands) was noted. Any coughing, laryngospasm, and struggling on emergence were noted. Patients were monitored for nausea and vomiting in the postoperative period and syrup ondansetron was given for managing nausea and vomiting. Rescue analgesia was given as syrup ibuprofen + paracetamol. All the patients were observed for any side effect or complication of the procedure for 24 h like sore throat, hoarse cry, pain on swallowing, pain in jaw/mouth/neck, tongue swelling or dental or lip trauma, ear pain, and vomiting. At the end of the study, Anesthesiologist ratings for I-Gel performance were done by using following parameters:[14]

- Airway quality - excellent, good, fair, poor, inadequate
- Ease of hands-free anesthesia - excellent, good, fair, poor, inadequate
- Overall usefulness of device - excellent, good, fair, poor, inadequate.

Statistical Analysis

The data from the present study was systematically collected, compiled and analyzed using statistical package for social science (SPSS 17.0 evaluation version) to draw relevant conclusions. The data were expressed as means and standard deviations and percentages. The patient's characteristics (non-parametric data) were analyzed using the "Chi-square" tests while the inter group comparison of the parametric data was done using unpaired *t*-test. The *P* value was determined finally to evaluate the levels of significance. The $P > 0.05$ was considered not significant; $P < 0.05$ was considered significant and $P < 0.001$ was considered highly significant. The results were then analyzed and compared with the previous studies. Power analysis of the study was done to calculate the power of the study by taking α error at 0.05. Effect size was calculated by taking parameters (mean time for loss of eyelash reflex, centralization of pupil and emergence time) and it was found that the power of the present study was above 90%.

RESULTS

In the present study, both groups were comparable with respect to age, sex ratio, weight and duration of surgery (Table 1). During induction, time taken for loss of the eyelash reflex and centralization of pupil was significantly less in Group B as compared to Group A ($P = 0.00$). Mean time taken from the application of the facemask to insertion of I-Gel (induction time) was also significantly less in Group B as compared to Group A (Table 2). However, insertion conditions were excellent and comparable in both the groups. Jaw relaxation was complete with no coughing, laryngospasm, limb movement or struggling during induction, and insertion in both the groups. None of the patients had oxygen desaturation or cyanosis (Table 2) I-Gel was easily inserted in first attempt in most of the patients of both groups. It was inserted in second attempt in three patients in Group A and two patients in Group B. However, mean time taken for insertion was comparable in both groups (11.07 ± 2.03 s in Group A and 10.87 ± 1.77 s in Group B). During the maintenance of anesthesia, none of the patient required non-depolarizing muscle relaxant in both the groups. Total amount of propofol required in Group A (82.067 ± 17.50 mg) and Group B (75.767 ± 14.68 mg) was also comparable ($P = 0.136$).

Mean HR in Group A remained significantly on lower side as compared to Group B from 2nd min onward till the end of the study as shown in Figure 1. The maximum percentage fall in HR was observed at 5th min in Group A (−16.73 ± 3.10) and at 4th min in Group B (−12.83 ± 1.36). In Group B, after 5th min HR remained on higher side from baseline values till the end of the study as shown in Figure 2. Mean SBP remained stable and comparable

Table 1: Demographic profile of patients in Group A and Group B

Parameters	Group A (Halothane+ propofol)	Group B (Sevoflurane+ propofol)	*P* value	Significance
Number of patients	40	40	-	-
Age in years	6.40±2.175	6.57±2.161	0.767	NS
Weight in kg	17.97±4.476	17.47±4.305	0.661	NS
Sex ratio				
Male (%)	31 (76.7)	32 (80)	0.754	NS
Female (%)	9 (23.3)	8 (20)		
Duration of surgery (min)	30.77±2.849	31.33±3.133	0.467	NS

Values are expressed as mean and standard deviation or number and percentage. *P*>0.05 is non-significant. Number of patient in both groups was comparable. Mean age, mean weight, sex ratio, and duration of surgery in minutes was comparable in both groups (*P*>0.05). NS: Non-significant

Table 2: Induction, insertion and emergence parameters in Group A and Group B

Parameters	Group A (Halothane+propofol) *n*=40	Group B (Sevoflurane+propofol) *n*=40	*P* value	Significance
Loss of eyelash reflex in seconds	112.13±5.661	73.90±6.830	0.000	HS
Centralization of pupil in seconds	249.33±6.472	170.33±4.751	0.000	HS
Mean Induction time in seconds	324.33±6.472	245.50±5.138	0.000	HS
Quality of induction	No cyanosis	No cyanosis	-	-
	No pain on I/V access	No pain on I/V access		
	No laryngospasm	No laryngospasm		
	No body movement	No body movement		
Insertion parameters	Jaw relaxation complete	Jaw relaxation complete	-	-
	No cough	No Cough		
	No limb movement	No limb movement		
	No laryngospasm	No laryngospasm		
	No regurgitation	No regurgitation		
Emergence time in minutes	25.63±1.564	15.50±1.656	0.000	HS

HS: Highly significant, Values are expressed as mean and standard deviation. *P*>0.05 is non-significant, *P*<0.01 is significant (S), *P*<0.001 is highly significant. In Group B (sevoflurane+propofol) loss of eyelash reflex, centralisation of pupil and induction time was significantly less as compared to Group A (halothane+propofol) *P*<0.001. However, quality of induction and insertion conditions were comparable in both groups. Emergence was also earlier in Group B as compared to Group A *P*<0.001

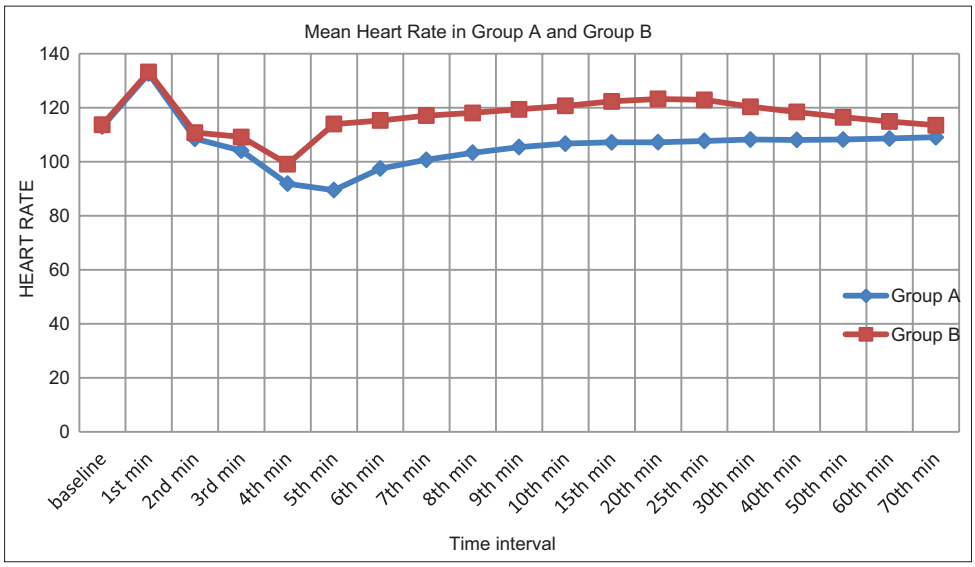

Figure 1: The mean heart rate (HR) at various time intervals in both groups. HR remained stable for first 2 min and then there was decrease in HR in both groups with maximum fall in HR at 4th min in Group B and at 5th min in Group A. Later on HR remained on higher side in Group B. Group A: Halothane + propofol. Group B: Sevoflurane + propofol.

for first 2 min in both groups ($P > 0.05$), after 3rd min SBP remained significantly on lower side in Group A as compared to Group B for first 10 min. After that SBP remained stable and comparable in both groups till the end of the study as shown in Figure 3. Maximum percentage fall in SBP was at 5th min (−15.06 ± 1.93) in Group A and at 4th min in Group B (−10.89 ± 2.03) and at both intervals fall was more in Group A as compared to Group B $P = 0.00$. Mean DBP also remained on lower side in Group A as compared to Group B from third to 5th min ($P = 0.00$) after that DBP remained stable and comparable ($P > 0.05$) as shown in Figure 3. Maximum percentage fall in DBP was at 5th min in Group A (−10.12 ± 2.83) and at 4th min in Group B (−8.22 ± 2.75) and that too was significantly more in Group A than Group B. RR, SPO_2 and $ETCO_2$ remained stable and comparable in both the groups at all measured intervals till the end of surgery. None of the patients had any ECG changes from induction to recovery in both groups.

After completion of surgery, emergence from anesthesia was significantly faster in Group B (15.50±1.656 min) as compared to Group A (25.63±1.564 min) ($P = 0.001$) (Table 2). None of the patients had cough, laryngospasm, oxygen desaturation or struggling during emergence in both the groups. During extubation, I-Gel was blood stained in only three patients in Group A and two patients in Group B. $P = 0.644$. None of the patients developed nausea and vomiting, sore throat, hoarse cry, dental and lip trauma or pain in both the groups during postoperative period. Rating of the performance of I-Gel was done by the anesthesiologist regarding quality of airway maintenance, ease of hands-free anesthesia and overall usefulness. All parameters were rated as excellent in both groups.

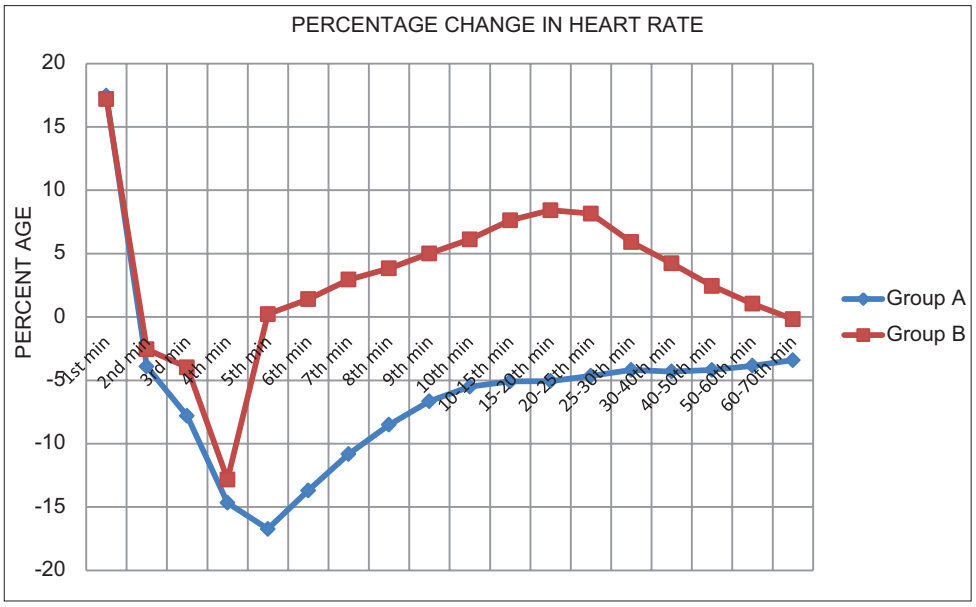

Figure 2: The percentage change of heart rate (HR) from baseline in Group A and Group B at various time intervals. 6th min onward Group B maintained HR on higher side as compared to Group A. Group A: Halothane + propofol. Group B: Sevoflurane + propofol.

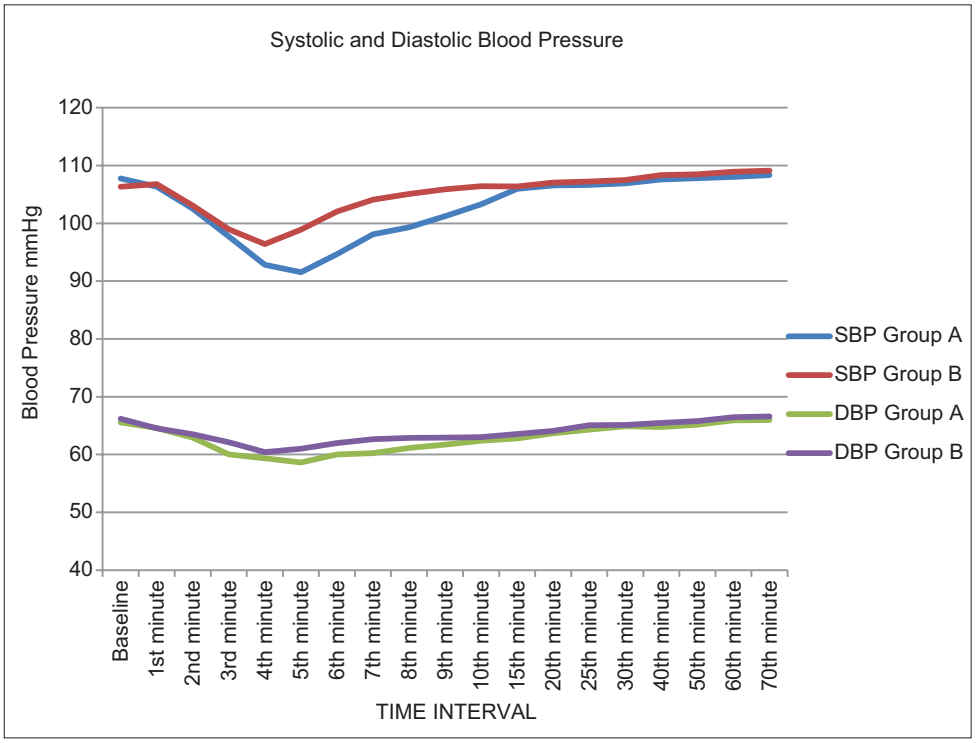

Figure 3: Systolic and diastolic blood pressure at various time intervals in Group A and Group B. There was maximum fall in BP at fifth minute in Group A (15.06 ± 1.93%) and at fourth minute in Group B (10.89 ± 2.03%). Later on BP remained on lower side in Group A as compared to Group B. Group A: Halothane + propofol. Group B: Sevoflurane + propofol

DISCUSSION

Advent of supraglottic devices made a significant impact in the management of the airway in pediatric patients for short surgical procedures.[3] I-Gel is the latest innovation which is easy to insert and requires lesser depth of anesthesia for insertion, with minimal hemodynamic changes and has very few post-operative complications.[13] Smooth emergence and fewer post-operative complications are the prerequisites for safe and rapid discharge of patients after short surgical procedures.[1] Sevoflurane fulfills these criteria as it provides rapid induction and emergence due to its low blood gas solubility.[8] Propofol also has very short elimination half-life, leading to smooth emergence, and rapid recovery.[15]

It provides better jaw relaxation and attenuates laryngeal and pharyngeal reflexes thus making insertion of I-Gel easy and also decreases the incidence of extubation related complications.[16,17] In the present study, insertion conditions were excellent in both groups. I-Gel was inserted easily in first attempt in 92.5% patients in Group A and 95% patients in Group B. Only 7.5% patients in Group A and 5% patients in Group B required manipulation for I-Gel insertion during the second attempt. Time taken for insertion was comparable in both groups with no stress response observed and none of the patient had any cough, laryngospasm or struggling during I-Gel insertion.

Induction of anesthesia was more rapid in sevoflurane group, as the time taken to loss of eyelash reflex, centralization of pupil and induction time just before I-Gel insertion was significantly less in Group B as compared to Group A ($P < 0.01$). Rapid induction with sevoflurane as compared to halothane was reported by previous studies.[5-8,10,11] Quality of induction was good and comparable in both groups as no struggling, bodily movement, laryngospasm or cyanosis was observed during induction. Use of atropine as premedication might have decreased the airway complications during induction.[18] Addition of nitrous oxide to sevoflurane and halothane during induction decreases the incidence of struggling associated with the use of high concentrations of inhalational agents.[6]

Halothane causes slowing of the sinoatrial node and blunts the baroreceptor reflex, whereas sevoflurane maintains the HR. Myocardial conduction system is also less prone to develop reentry phenomenon, hence arrhythmias are less common with the use of sevoflurane.[9] In halothane + propofol group, mean HR remained on lower side as compared to sevoflurane + propofol group. Sevoflurane + propofol group maintained higher HR after 5 min of induction and during maintenance of anesthesia. Similar results were reported by Paris *et al.*,[11] Sarner *et al.*,[6] Dedhia and Kudalkar ,[7] Piat *et al.*[19] and Ibraheem *et al.*[9]

BP remained on lower side and maximum fall in BP was also more in Group A as compared to Group B. Both sevoflurane and halothane decrease myocardial contractility, but decrease in cardiac output is observed more with halothane.[9] Previous studies also documented that BP was better maintained with sevoflurane as compared to halothane in stable conditions.[6,7,9,11,19]

Emergence from anesthesia was more rapid in Group B as compared to Group A. None of the patients had coughing, laryngospasm, emergence agitation, and post-operative nausea and vomiting during emergence in both the groups. Sevoflurane due to its less blood gas solubility leads to rapid emergence from anesthesia which was observed by the previous studies also.[5,7,8,11,19] However, emergence agitation after sevoflurane anesthesia was reported by previous studies.[5,8,11] Use of propofol during maintenance might have decreased the incidence of emergence agitation as well as nausea and vomiting in the present study. Moore *et al.*[20] observed that emergence agitation was more frequently observed when sevoflurane alone was used for maintenance and use of propofol decreases the incidence of emergence agitation. Picard *et al.*[4] also concluded that emergence agitation and post-operative nausea and vomiting was most commonly observed after maintenance with sevoflurane as compared to the use of propofol for maintenance.

CONCLUSION

Hence, it was concluded that halothane + propofol and sevoflurane + propofol provided excellent conditions for I-Gel insertion with no stress response. However, sevoflurane + propofol were better as it provided faster induction and rapid recovery from anesthesia with more stable hemodynamics as compared to halothane + propofol group. This technique will be helpful in the patients scheduled for short surgical procedure where muscle relaxants are contraindicated.

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Original Article

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Impact of Obsessive Compulsive Symptoms in Schizophrenia: A Clinical Study

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Abstract

Introduction: In schizophrenia patients, usually less attention is given to additional non-schizophrenic psychopathologies such as obsessive-compulsive disorder. Recent studies provide support for the validity of a putative schizo-obsessive diagnostic entity. Compared to schizophrenia, schizo-obsessive patients have distinct clinical features and more psychotic symptoms.

Aims and Objectives: To compare the symptom profile of schizophrenic patients with and without significant obsessive-compulsive symptoms (OCS).

Methods: A total of 100 consecutive schizophrenia patients were recruited in the study from psychiatry outpatient department and were assessed using positive and negative syndrome scale. We then categorized patients into three groups depending on total Yale-Brown obsessive-compulsive scale (Y-BOCS) score. Those scoring ≥16 were put in the first group, 8-15 in the second group and <8 in the third group. The correlations among symptom profile of patients were analyzed using SPSS 17.

Results: There was a significant correlation between positive symptoms score with the score on Y-BOCS compulsive scale in Group 1 (P = 0.037) and Group 2 (P = 0.026) and Y-BOCS total score (P = 0.008 and 0.005). There was no significant correlation between positive symptoms with Y-BOCS obsessive score in all three groups (P = 0.834, 0.234 and 0.242).

Conclusion: Finding of our study suggests that schizophrenia patients may have more compulsive symptoms as a result of hypervigilance, worry, rumination, internal distress, and suspiciousness. And compared with schizophrenia patients, Schizo-obsessive patients have distinct clinical profile.

Keywords: Obsessive compulsive disorder, Positive and negative syndrome scale, Schizophrenia, Yale-Brown obsessive-compulsive scale

INTRODUCTION

It is generally believed that schizophrenia is heterogeneous in its clinical presentation still there is a widespread tendency to treat it as a single, unitary disorder. In schizophrenia patients, usually less attention is given to additional non-schizophrenic psychopathologies such as depression, obsessive-compulsive disorder (OCD) and anxiety disorder. In contrast to positive, negative and cognitive symptoms, obsessive-compulsive symptoms (OCS) are not considered primary features of schizophrenia.[1] Nonetheless, it is being realized nowadays that comorbidity in schizophrenia is very common, and it might substantially contribute to the patient's morbidity, course, and outcome.[2] Differences between patients and changes within patients are substantial, the question then remains whether obsessive-compulsive (OC) symptoms are manifestations of comorbid OCD or whether they are characteristics of a distinct subtype of schizophrenia. There are some points which provide basis for a relationship between schizophrenia and OCD like, frequent comorbidity of these two conditions,[3] Initiation or exacerbation of OCS in patients with schizophrenia treated with atypical antipsychotics,[4] and subsequent development of schizophrenia or psychotic symptoms in patients with a prior primary diagnosis of OCD.[5]

Available studies in those patients with schizophrenia and comorbid OC symptoms compared to patients

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with schizophrenia alone have yielded interesting and contradictory results, the pattern of findings was highly variable; correlations between OCS and various schizophrenic symptom dimensions have often been found, but rarely replicated. Some reported less severe positive and negative symptoms, other reported no differences, and still others reported more severe positive and negative symptoms.

We set out to study to compare the clinical characteristics of stable schizophrenia outpatients with OC symptoms, by standardized diagnostic interview schedules and valid psychometric instruments, with groups having schizophrenia alone. Thus, we were interested in examining the cross-sectional relationships between OC symptoms and schizophrenia.

Aims and Objectives

The main aim of this study was to evaluate the impact of OCS on clinical features, in schizophrenia. To compare the clinical feature, symptom profile, dimensions, severity, overall level of functioning in schizophrenic patients with significant OC symptom and schizophrenia patients without significant OCS.

METHODS

Source of Data for the Current Study

The proposed aims were accomplished through analysis of data from the study conducted at Psychiatry Centre, Department of Psychiatry, SMS Medical College, Jaipur. It is tertiary referral center. The department has an outpatient department of average 150 patients/day which includes patients from the state of Rajasthan and adjoining areas of Haryana, Punjab, UP, MP, and Delhi. The study design was approved by the institutional review board.

Study Design and Procedure

Data for the current study aims are derived after administering Yale-Brown obsessive-compulsive scale (Y-BOCS) and positive and negative syndrome scale (PANSS) to individuals with schizophrenia. A cross-sectional study was carried out. Samples were drawn from participants with schizophrenia recruited between month of June and September 2011 at Psychiatry Centre, Jaipur (Psychiatry Department of SMS Medical College). Consecutive 100 patients with schizophrenia (The diagnosis of all patients was reviewed and confirmed by two psychiatrists independently based on DSM-IV criteria) fulfilling inclusion criteria for the study on were included.

An informed consent was obtained from the subject prior to participation in the study. To include in the study, the subject were screened with a specially designed screening pro forma. That encompassed all the exclusion criteria. Those subjects who satisfied the screening process were recruited in the study.

The patient's socio-demographic data were recorded. After that, each participant in the study was subjected to clinical instruments (Y-BOCS, PANSS). Patients were divided into three groups on the basis of the score achieved on Y-BOCS. We categorized patients into three groups according to severity of OC symptoms score of 0-7 were in group first 8-15 in group second and those achieved 16 or more than 16 were included in group third group were compared, results were drawn and discussed in light of existing literature. Y-BOCS total score severity measured as; 0-7 subclinical, 8-15: Mild, 16-23: Moderate, 24-31: Severe, 32-40: Extreme. We required a minimum score of 8 corresponding to mild severity of the OC symptoms on the Y-BOCS. Hence, our first group comprising schizophrenia patient without OCS or only subclinical OCS, the second group mild OCS, and the third group had at least moderate OCS.

RESULTS

In our study, all the three groups were comparable in age, sex, marital status, and religion. No significant difference was found between the groups in occupation, education, economic status, family type, and locality. These results are compatible with other studies that reported no differences between schizophrenia patients with and without OC symptoms in terms of age,[6] occupational status,[7] marital status, and level of education. There was a preponderance of men in the all the three groups, which is similar to some earlier studies.[8]

Prevalence of Co-morbidity

In our study, 38 patients were found to have clinically significant OC symptoms, defined as a minimum score of 8 on the Y-BOCS, while 14 patients scored even more than 16, OCS s of moderate severity. Compare to this a previous studies,[9] found a co-morbidity rate of 17% in a sample of 63 patients with schizophrenia, using the Y-BOCS score of at least 16 to define clinically significant OC symptoms.

Distributions of OC Symptoms in All Three Groups

In our study, (Table 1) distributions of OC symptoms in group first 23.14 (Standard deviation [SD] = 6.38), in second 11.08 (SD = 2.38) and in group third were 1.89 (SD = 2.19).

DISCUSSION

Impact of OCS on Clinical Features, Symptom Dimensions, Severity in Schizophrenia

We found higher levels of positive symptomatology in patients with significant OCS compared with those without or subclinical OCS (Table 2). There was a significant correlation of positive symptoms with the Y-BOCS compulsive scale ($P = 0.037$and 0.026) and Y-BOCS total score ($P = 0.008$ and 0.005) in Group 1 and 2, but not in Group 3.There may are several explanations of this positive correlation that schizophrenia patients may have more compulsive symptoms as a result of hypervigilance, worry, rumination, internal distress, and suspiciousness.

Earlier studies have found an association between OC symptoms and the clinical characteristics of schizophrenia; however the findings were highly variable.

Consistent with Findings from Other Research Studies

In a study, Lysaker,[10] reported that OCS intimately linked with higher level of positive symptoms on the PANSS in schizophrenia. In an another study, Ongür and Goff (2005),[11] studied 118 patients, found a positive correlation was found between the Y-BOCS score and the PANSS positive score. Kayahan *et al.* (2005),[12] in a study of 100 patients with schizophrenia, found a positive correlation between the Y-BOCS score and the PANSS positive score, and PANSS total score. Rajkumar *et al.* (2008),[13] reported study between two groups of 50 schizophrenic outpatients (with and without OCD co-morbidity) found that co-morbid OCD was associated with more severe paranoid and first-rank symptoms.

In a review and meta-analysis of 23 studies,[14] comparing schizophrenia with and without OC symptoms, found that presence of OC symptoms was associated with more severe global, positive and negative symptoms compared to the group without OC symptoms. In contrast, Poyurovsky *et al.* (2001),[15] reported that drug-naive and first-episode schizophrenia patients with OCD scored significantly lower on the formal thought disorder (scale for the assessment of positive symptoms) and flattened affect (schedule for the assessment of negative symptoms) subscales.

There was no significant correlation of negative symptoms with Y-BOCS compulsive and total score in Group 1 and 2, in our study. However, a positive correlation was found between the Y-BOCS score and the PANSS negative Score in a study done by Lysaker *et al.* (2002).[9]

Opposite to it, Tibbo *et al.* (2000),[8] reported that patients with schizophrenia and OCD appeared to have fewer PANSS-negative symptoms.

Like our study, comparing three groups of schizophrenic patients, distinguishing patients fulfilling the DSM-IV criteria for OCD from those with OCS but not fulfilling the diagnostic criteria for OCD, de Haan *et al.* (2005),[16] found that group of patients with OCD had not differ significantly than the other two groups in terms of positive and negative symptoms (measured by PANSS) and the group with OCS not fulfilling the criteria for OCD had less severe negative symptoms than the other two groups.

Some studies that observed the relationship between OCS and severity of schizophrenia symptoms could not find any correlation between OCS and positive and/or negative symptoms.[17,18]

The discrepancies in the results of these studies might be due to differences in diagnostic criteria, method of evaluation, duration of disease. In most of these studies when only two categories was used, no differences were found between OCD schizophrenia and non-OCD schizophrenia, while when a dimensional was used, OCS schizophrenia showed a greater severity of psychotic symptoms than non-OCS schizophrenia. Our explanation for it that a markedly higher weighted mean of total Y-BOCS scores was found in the

Table 1: Distribution of OC symptoms in all three groups

Symptoms	Mean (SD)		
	Group 1	Group 2	Group 3
Obsessions	11.50 (3.48)	5.46 (2.28)	0.79 (1.18)
Compulsions	11.79 (5.28)	5.63 (2.68)	1.10 (1.49)
Total	23.14 (6.38)	11.08 (2.38)	1.89 (2.19)

SD: Standard deviation, OC: Obsessive-compulsive

Table 2: Correlation of OC symptoms and psychopathology in all three groups

Instrument	Group	*r* (*P*)		
		YBOCS obsessions	YBOCS compulsions	YBOCS total
PANSS positive	1	0.351 (0.219)	0.562 (0.037)	0.673 (0.008)
	2	0.045 (0.834)	0.453 (0.026)	0.555 (0.005)
	3	−0.026 (0.842)	0.174 (0.177)	0.104 (0.420)
PANSS negative	1	−0.272 (0.347)	−0.003 (0.991)	−0.162 (0.580)
	2	0.282 (0.182)	−0.027 (0.889)	0.190 (0.373)
	3	0.128 (0.321)	0.253 (0.048)	0.241 (0.059)
PANSS general psychopathology score	1	0.238 (0.413)	0.099 (0.737)	0.179 (0.541)
	2	0.269 (0.202)	0.079 (0.712)	0.303 (0.150)
	3	0.258 (0.043)	0.361 (0.004)	0.384 (0.002)
PANSS total score	1	−0.336 (0.241)	0.218 (0.445)	−0.016 (0.995)
	2	0.017 (0.937)	0.075 (0.729)	0.099 (0.645)
	3	0.239 (0.061)	0.426 (0.001)	0.419 (0.001)

r: Pearson correlation, PANSS: Positive and negative syndrome scale, Y-BOCS: Yale-Brown obsessive-compulsive scale

non-OCD group compared with the non-OCS group. Because when the OCD definition was used, the control groups most likely included some subjects with varying degrees of OCS resulting in a dilution of the effect of obsessive and compulsion on the severity of psychotic symptoms.

Differences between patient samples, for example, clinical severity, stage (early or chronic), course (continuous deteriorating or episodic) and type of medication taken could also affect the prevalence and clinical features.

Limitations of Our Study

The small sample size in this study may have limited the ability to detect effects of OCS, and there may be difficulty in generalization of results. The cross-sectional design of the study firstly does not allow us to comment more comprehensively on the impact of OCD or OCS on schizophrenia. Lack of information about other comorbidities, most of them can bias results and except for substance abuse other comorbidities were not excluded. Furthermore, most of the patients were taking psychotropic which was taken into account while interpreting results.

SUMMARY AND CONCLUSION

Non-schizophrenic psychopathologies in schizophrenia patients like OCS are often ignored. This study provides support for the validity of schizo-obsessive diagnostic entity. Compared with schizophrenia patients, schizo-obsessive patients have distinct clinical profile.

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Original Article

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Implementation of Students' Quality Circle in Medical Microbiology Course

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Abstract

Introduction: Trends in higher education show that student-faculty partnerships enhance the quality of teaching and learning experiences. The use of students' quality circle (SQC) is gaining importance in higher education, as a pedagogical tool to motivate and involve the students in their learning process. Self-managing SQC's are led by students and ably supported by responsive faculty and administrators.

Objective: This study investigated the implementation of SQC in a medical microbiology course and the perception of students about SQC.

Methods: The study involved students in a microbiology course of a medical school during the academic year 2013-2014. Students formed a SQC team which consisted of a team leader and 17 members. The team collected students' feedback about academic and non-academic issues, held meetings where they analyzed the issues, identified problems, and suggested possible solutions under the supervision of a microbiology faculty as facilitator. At the end of the project, a questionnaire was administered to all students in the course to evaluate their perception about SQC.

Results: Over the duration of the project, almost three-quarters of the class students participated and provided feedback to the SQC team about issues of concern for the microbiology course. Most of these issues were related to laboratory experiments, lectures, or examinations. Possible solutions were suggested by SQC. Appropriate measures were then taken by the faculty to address the issues. The overall perception of the students about SQC was favorable. Moreover, faculty observed several benefits of SQC in terms of improvements in student behavior.

Conclusion: Overall, the SQC provided a platform for the students and faculty to work together as partners to enhance the educational experience in a medical microbiology course.

Keywords: Education, Learning, Medical, Management quality circles, Quality improvement

INTRODUCTION

The amount of student learning and personal development associated with any educational program is influenced by the quality and quantity of student involvement in that program. In conventional pedagogical teaching, the teacher provides information to students, who are usually assigned a passive role in the learning process.[1] However, in higher education, there is growing interest in student engagement, in the student voice, and in staff working in partnership with students to deliver the education program, and to facilitate changes in the educational process. The perceived benefits of student engagement in education include, for students, improved student experience, and achievement, and for institutions, an indicator of educational quality assurance and teaching success.[2] Students' quality circle (SQC), an innovation that is gaining importance in higher education, provides a platform for active involvement of students in influencing the experiences and outcomes of their education.[3]

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SQC was developed from the original quality circle (QC) concept; a practice devised in the early 1960's for use in Japan's manufacturing industry. The concept of SQC was implemented later in primary and secondary schools in an attempt to raise the quality of the teaching and learning experience. The application of SQC to education, particularly to higher education is a relatively new development. The philosophy of QC originates from the assumption that those who are involved in the work are best qualified to identify defects and suggest improvements. The same philosophy applied to the SQC may serve as a quality improvement instrument to ensure quality in higher education. In general, SQC in the classroom setting is composed of a small group of student volunteers, who meet regularly to identify, analyze, and solve problems related to a course, and implement solutions.[3-5] Several authors have reported on the usefulness of SQC as a pedagogical tool for quality improvement in higher education, including general chemistry,[6] engineering,[7] business management,[8,9] law,[10] food science and human nutrition,[11] surgical and medical nursing,[12] and medical undergraduate[5] courses. SQC allows students and teachers to become co-learners, motivates, and empowers the students to take ownership of the course, imbue students with a greater sense of purpose in the classroom, provides an enhanced sense of self-worth, increases student satisfaction with both the course and mastery of the course content, allows for a positive perception of faculty concern on their learning, and improves the interpersonal relationship. Participation in SQC strengthens the skill of giving and receiving feedback, improves time management, attendance, and other factors that are central to a student's reliance. SQC helps in improving employee attitudes, the quality of instructional and support services and the work environment, student participation in co-curricular activities and to resolve non-academic environmental issues.[3-12]

Although, QC activities have evolved as an important method of quality improvement in primary care medicine,[13] its application in medical academic settings is limited. Like in any higher educational program, the student-centered learning is gaining focus in medical education and it is considered imperative that medical students take an active role and are consulted, involved and participate in shaping their teaching and learning experience.[2] In this context, we planned a study with an aim to implement SQC in the medical microbiology course in our medical school and to evaluate the students' perception about the SQC. We aspired that the SQC forum helps to break the traditional student-faculty barrier and improve the teaching and learning experience of our students.

METHODS

This study involved preclinical medical students enrolled in a microbiology course at Oman Medical College during the academic year 2013-2014. Approval of Institutional Research Review Board was obtained before the conduct of this study. Students' anonymity was respected while answering the questionnaire. The SQC team was composed of a microbiology faculty member as facilitator, a student as team leader, and 17 student members. At the beginning of SQC project, the facilitator described the history, concept, objectives, and plan for execution of SQC to the entire class. On request, 18 students volunteered to become SQC members and the members elected the team leader. The team leader and members then were oriented about their role in SQC and the code of conduct, and were trained on the procedure of conducting SQC meetings, problem-solving and research methods. The SQC team held a total of nine meetings between November 2013 and May 2014, initially twice monthly for the first 2 months and once monthly thereafter. Each meeting lasted for 45 min and included the team leader and, at least, seven members. Two chosen members attended all the meetings to ensure continuity of the process and the others took part on a rotation basis.

The SQC members collected student issues and concerns related to the course and educational environment on a continual basis, through pen and paper method, discussions, random student interviews, and e-mail. During each meeting, the team took up the issues on a priority basis, analyzed them by brainstorming and cause and effect analysis techniques and generated possible solutions. When feasible, the SQC solutions were implemented. When not feasible, the class students were provided a suitable explanation. Each meeting of the SQC team also considered the execution and success of previous team decisions. The facilitator supervised these meetings and acted as a link between the SQC and teaching faculty and policy makers.

At the end of the course (June 2014), a self-designed, structured questionnaire was administered online for access to all class students. This questionnaire consisted of 12 closed-end questions that evaluated the perception of the students about the SQC, scored on a five-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = undecided, 4 = agree, 5 = strongly agree). The questionnaire also allowed open comments from the students. The data were then entered in a Microsoft Excel sheet; the mean scores, and the frequency of scores of each item of the questionnaire were calculated.

RESULTS

Of the total 92-class students, 68 (74%) identified issues related to the course and educational environment. A total of 81 students (88%) completed the questionnaire. Table 1 depicts the mean scores of the questionnaire items. Figure 1 presents the frequency of scores to the individual items of the questionnaire.

DISCUSSION

This pilot study witnessed a successful execution of SQC in medical microbiology course with an overall positive impact on enhancing the educational experience of the course. Identifying issues and giving a continuous feedback to the SQC team is an essential component of SQC which empowers the SQC team to take further action in view of improving the content, structure, and delivery of the course.

Table 1: Mean scores of students' perception about SQC

Questionnaire items	Mean	SD
SQC is effective in generating new ideas to improve the course delivery	3.78	0.85
SQC improved the teaching and learning experience	3.77	0.77
SQC improved the students' preparedness to take exams	4.02	0.79
SQC helped to solve course-related problems	3.76	0.74
SQC helped to solve non-academic problems	3.53	0.73
SQC improved the student-teacher interaction	3.83	0.85
SQC instilled a sense of belonging and ownership of the course	3.53	0.73
SQC increased motivation in learning this course	3.46	0.86
SQC team conducted the operation of SQC efficiently	3.54	0.86
Overall satisfied with the implementation of the SQC	3.70	0.86
Motivated to act as a member of SQC team	3.46	0.83
Recommend SQC for other courses also	3.80	0.74

SQC: Students' quality circle, SD: Standard deviation

Identification of Issues and Measures Taken to Solve Them

A total of 108 issues were identified, related to the course either directly or indirectly. The most common concern of students was the dearth of hands-on experience in the microbiology laboratory and inadequate exposure to hospital-based teaching of infectious diseases. Oman Medical College is a private organization attached to a government regional hospital for clinical training. Year 5 curriculum provides year-long horizontal integration in pathology, pharmacology, epidemiology, and public health courses in addition to microbiology course which carries 12 credit hours. Microbiology teaching includes conventional lectures using PowerPoint and demonstration of microscopic slides and specimens in the practical laboratory. Secured online learning environment (SOLE) intranet platform is used for teaching and learning activity. The clinical teaching is restricted to physical examination, and clinical interpretation and the students generally do not get the opportunity to examine infectious disease cases. This grievance was partly addressed by coordinating hospital visits of the students under microbiology course. Students were demonstrated microbiological techniques in the hospital laboratory and hospital waste management techniques in the sterilization and incineration unit. Students were given hospital-based graded assignments that included hospital visits to observe microbiology laboratory techniques and documentation of the students' observations as a case write-up. Another issue raised by the students was about the monotonous nature of the didactic lectures. Several measures were taken to tackle this issue. Lecture slides were enriched by adding animations and

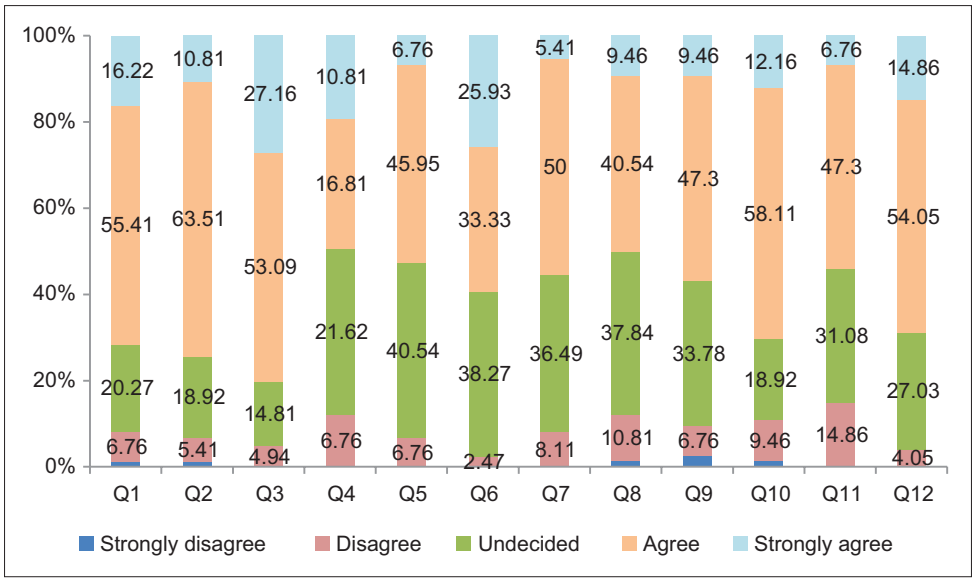

Figure 1: Analysis of individual items of the questionnaire

video clips. Further, lectures were made more interesting by incorporating clinical case scenarios, problem-solving, story-telling, and real life examples about infectious diseases and current news about worldwide infection outbreak. Guest lectures by the clinical faculty in relevant fields were also arranged.

Students also identified examinations as a source of concern. Multiple choice questions (MCQs) form the major component of students' assessment in our curriculum, whereas a small percentage is devoted to short-answer questions and objective structured practical examination. Students have to write a total of eight block examinations during the 10 months course period in addition to a final comprehensive examination. Students identified frequent examinations as a source of mental stress. College policy precludes us from regularly conducting post-examination review and discussing practice questions before each examination. Students expressed their discontent about these lacunae. Exam-related issues were handled to some extent by asking students to prepare MCQs before each block examination and post the questions on SOLE. These student-generated MCQs were available to all students and were reviewed subsequently in class. A demand-based care was given in the form of academic mentoring and extra coaching to academically weak students. Few students felt that the integration between the pre-clinical courses is not up to expectations, and necessary steps were taken after discussing this matter with other course coordinators.

There were also grievances about non-academic matters, including the available time for recreation and social activities, seating arrangements in the lecture halls, availability of library books, and internet connection problems in the college premises. These issues were brought to the notice of the respective departments and policy makers by way of representations of the possible solutions.

Students' Perception of SQC

More than half of the responding students expressed their favorable opinion about the SQC (overall mean score was more than 3.5). More than 70% agreed that SQC helped to generate new ideas to improve the course delivery, improve the teaching and learning experience, increase their preparedness to take exams and to solve course-related problems. In their open comments, 38 students expressed their appreciation for applying SQC in their course. Most responders felt that faculty cared for their suggestions and that lead to an improved student-faculty relationship. Students felt honored to be actively participating in the development of the course. This also created a feeling of self-worth, instilled a feeling of belonging and ownership of the course which motivated them to take more interest in learning the course. All the open comments, except five, unanimously upheld the notion that the SQC helped to improve the overall teaching and learning experience in the microbiology course. However, the five students who expressed their reservations about the SQC did not mention any reason for their opinion.

Faculty Perception (Subjective) of SQC

Continuous students' feedback kept the faculty alert and motivated. Faculty was driven to view course related issues more from the students' perspective that led to a better understanding between the duos, and felt a greater sense of fulfillment in the job. Engagement of students in the course improvement accelerated the course dynamics and created a positive environment in the process of teaching and learning. Students felt more confident to face the examinations. Enhanced were student's decision-making, problem-solving, and independent thinking skills. SQC helped to inculcate qualities of a doctor, including a willingness to assume responsibility and obligations toward their profession. SQC provided a stage for the faculty and the students to play their role as academic partners.

Study Limitations

Initially students were reluctant to come out with problems as reported by earlier studies. Students were perhaps skeptical about the novel concept that is introduced for the first time in an educational environment that is not well-adapted to the quality culture. Students could not devote undivided time and attention as they had to study other courses in the academic year. Similarly, there could be some lacunae from the faculty side in terms of time devotion, execution of SQC, and evaluation of students' satisfaction.

CONCLUSION

Overall, SQC was found to be a promising tool to enhance the teaching and learning experience of students in medical microbiology course. This is a humble beginning in an attempt to improve the quality of education in our medical school. The favorable outcome of this pilot study encouraged us to invite the other courses, as well as the new cohort of students on the platform of SQC.

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Original Article

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Comparative Assessment of Caries Removal Time and Patient Acceptance of Papacarie Gel in Healthy and Children with Special Health Care Needs: An *In-Vivo* Study

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Abstract

Introduction: Recent advances in dentistry concentrated its effort on conserving tooth structure with chemomechanical caries removal agents like Papacarie gel especially in treating disabled children.

Objectives: The objective was to assess the caries removal time and patient acceptance of Papacarie gel in healthy and children with special health care needs (SHCN).

Materials and Methods: A total of 60 children aged 5-15 years were divided into three groups and each group consisted of 20 children. Group I (healthy children), Group II (children with hearing impairment), and Group III (children with motor impairment of upper or lower limb). Carious molar fulfilling the selection criteria was included. Proper isolation is achieved through the rubber dam and cotton rolls followed by Papacarie gel application. Teeth in all groups were restored with conventional glass ionomer cement. Patient acceptance by visual analogy scale of faces was recorded in all three phases and treatment duration was also measured.

Results: Average time taken for complete caries removal in Groups I, II, III were found to be 5.1 min, 7.01 min, and 7.02 min, respectively. Average time taken per tooth was 6.3 min. Groups II and III showed more degree of discomfort when compared to Group I which was statistically significant whereas between Groups II and III was not statistically significant.

Conclusion: Papacarie gel showed mild discomfort for SHCN children its usage proved to be a promising alternative for treating SHCN children although more studies are necessary to claim it as a new and alternative in treating caries.

Key words: Caries, Disabled children, Papacarie

INTRODUCTION

Dental caries is ubiquitous in all population throughout the world and is the key factor responsible for dental pain and tooth loss throughout the world unless carefully controlled, it will continue to develop and progress throughout life.[1,2]

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The concept of conserving healthy tooth structures during cavity preparation is minimal invasive dentistry giving comfort, solace, and instilling a positive attitude toward dental treatment, which justifies the specialty of pediatric dentistry.[2]

The first study on chemomechanical caries removal (CMCR) was carried out by Kronmann *et al.*, in 1975 using 5% sodium hypochlorite solution on carious tooth resulted in the removal of carious dentin. However, sodium hypochlorite alone was aggressive to sound tissue, which encouraged the addition of buffer solution (sodium hydroxide, sodium chloride, and glycerin) generating a new formula (GK 101), in which glycine was later replaced by amino butyric acid to improve the reaction speed. First,

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commercially available agent from this formula emerged under the name of Caridex.[3,4]

Carisolv (1998) for caries removal was introduced in the market. Carisolv differs from Caridex was with the use of three amino acids - glutamic acid, leucine, and lysine to neutralize the aggressive effect of sodium hypochlorite on sound oral tissues.[5]

In 2003, a Brazilian gel was developed based on papain, chloramines, and toluidine blue called Papacarie, was launched which is less costly than Carisolv. The union of these three components confers antibiotic, bacteriostatic, and anti-inflammatory properties to this agent.[5,6]

Young special health care needs (SHCN) patients will have little voice in demanding care for themselves if their parents or guardians do not seek it for them. Dental care is low on the list of priorities in parents of SHCN children. Hence, it would be rare for a dentist to treat such patient except as an emergency.[7]

Treatment acceptance depends on the type of disability, degree of disability, and age of onset. For this reason, disabled children require special attention and approach towards oral care. Therefore, the CMCR technique is an efficient option when approaching and supplying oral care for disabled children.[7]

Aims and Objectives

The present *in-vivo* study was conducted to compare and evaluate complete caries removal time and patient acceptance in healthy children and children with SHCNs. Hence, objective of this study was to assess the caries removal time and patient acceptance of Papacarie gel in healthy and children with SHCNs.

MATERIALS AND METHODS

Source of Data

The study included 60 children aged 5-15 years in which 20 children with sensory impairment from Dr. Chandrasekhar Institute of Speech and Hearing, Bengaluru, 20 children with motor impairment from Vidyaranya Home for Disabled, Bengaluru and 20 healthy children reporting to Department of Pediatric and Preventive dentistry, V.S. Dental College and Hospital, Bengaluru for routine dental checkup. Institutional ethical clearance was obtained before conducting the study. Signed written informed consent was obtained from parents/caretakers.

Selection Criteria

Inclusion criteria

i. Disabled children with hearing impairment and motor disability of upper or lower limbs
ii. Teeth with open carious lesions with the dentin involvement but not involving pulp
iii. The access of the carious lesion has to be large enough to allow the penetration of the excavator
iv. Teeth with no proximal caries as evident by bitewing/intraoral periapical radiography
v. Asymptomatic vital teeth, without clinical or radiographical evidence of pulp, furcation or periapical pathology.

Exclusion criteria

i. Children with systemic diseases.

Armamentarium

- Mouth mirror
- Explorer
- Spoon excavators
- Rubber dam kit
- Papacarie gel (formula and Acao, Sao Paulo, Brazil) (Figure 1)
- Visual analogy of faces (VAF) scale
- Radiographs.

Clinical Procedure

Children are divided into three groups according to the systemic condition. Each group consisted of 20 children.

Group I: 20 healthy children who showed normal development for age and having no defects in tooth formation or tooth development.
Group II: 20 children with hearing impairment who can respond to simple verbal commands.
Group III: 20 children with motor impairment of upper or lower limb who can respond to simple verbal command.

The cases were selected through simple clinical examination (Figure 2) completed by periapical radiography. Pulpal involvement of carious lesions with the help of periapical radiograph was evaluated prior to the study. In each child,

Figure 1: Papacarie gel

one carious molar fulfilling the selection criteria was included.

Visual analogy scale of faces was presented at this phase (Phase A) of treatment with the following question: "If you compare yourself to this face right now, which face would represent you the most?" The child would then point to the corresponding face that best represented their degree of pain or discomfort. The scale given by Whaley and Wong (1987) is composed of 6 facial expression scores: 0 = no hurt, 1 = hurts little bit, 2 = hurts little more, 3 = hurts even more, 4 = hurts whole lot, 5 = hurts worst.[8] Proper isolation is achieved through the rubber dam and cotton rolls followed by Papacarie gel application (Figure 3). The digital chronometer was turned on at this stage to measure the duration of treatment in all groups. Papacarie is supplied as a single component in a syringe. According to the manufacturer's instructions, the gel was applied to the carious dentin and allowed to work for 60 s. The softened decayed dentin was scraped away with an excavator in a pendulum movement (Figure 4). The procedure was repeated until the gel appeared clear and reached an unchanged light color. After complete removal of caries, visual analogy scale was presented to the patient at this phase (Phase B) and score was recorded. Teeth in all groups were restored with conventional glass ionomer cement. The digital chronometer was stopped and duration of treatment was measured and recorded after restoring the teeth with glass ionomer cement (Figure 5). The VAF scale was presented to the patient after the restoring the teeth with glass ionomer cement (Phase C) and score was recorded (Figure 6). Scores of visual analogy scale of faces were recorded in all these three phases and were subjected to statistical analysis for assessment of patient acceptance.

Statistical Analysis

Scores were recorded in all these three phases among all three groups according to the methodology and were subjected to statistical analysis. Analysis of obtained results was done with:

A. Kruskal–Wallis test

Figure 2: Intra oral assessment of carious lesion

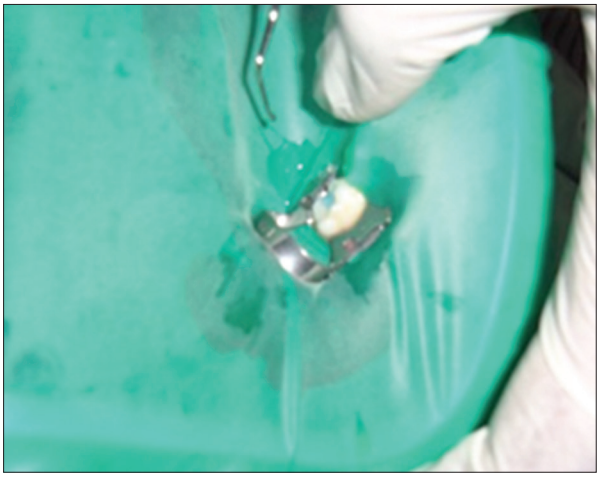


Figure 4: Excavation of carious lesion

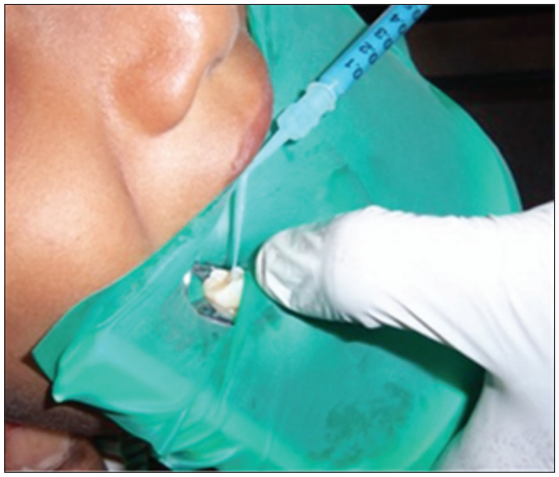


Figure 3: Application of Papacarie gel

Figure 5: Restored tooth

B. Arithmetic mean
C. ANOVA.

RESULTS

Patient Acceptance of Papacarie among all Three Groups

Patient acceptances between all three groups were measured using VAF and scores were compared. Patient acceptance scores in Phase A (after the radiography of the child before beginning of treatment) in Groups I, II, and III was 2.00 (Table 1).

There was no statistically significant difference found in the scores between the groups $P = 0.731$ (Table 2) ($P > 0.05$). Children in all three groups showed less degree of discomfort with scores 0, 1 and 2 of VAF scale.

Patient acceptance in Phase B (during the treatment after removal of carious lesion of the teeth) and Phase C (after the restoration and treatment were finished) in all three groups were compared. Scores of children in Group I, Groups II, and III was found to be 1.00, 4.00 and 3.00, respectively (Table 1).

Children in Group I showed less degree of discomfort when compared to Group II and level of significance was found to be statistically significant ($P < 0.05$) (Table 2).

Children in Group I showed less degree of discomfort when compared to Group III and level of significance was found to be statistically significant ($P < 0.05$) (Table 2).

Complete Caries Removal Time among all Three Groups

Average time taken for complete caries removal in Group I was found to be 5.1 min (Table 3 and Graph 1) whereas in Group II and Group III it was found to be 7.01 min and 7.02 min, respectively (Table 3 and Graph 1). Average time taken in all three groups was 6.3 min (Table 3).

Comparison of time taken between Group I and Group II was statistically significant ($P < 0.05$) (Table 4).

Comparison of time taken between Group I and Group III was statistically significant ($P < 0.05$) (Table 4).

Table 1: Patient acceptance of Papacarie duo between the groups

Percentilesa								
Weighted average (definition 1)	Group	Percentiles						
		5	10	25	50	75	90	95
Phase_A	Group I	1.00	1.00	1.00	1.50	2.00	2.00	2.00
	Group II	1.00	1.00	1.00	2.00	2.00	2.00	2.00
	Group III	1.00	1.00	1.00	2.00	2.00	2.00	2.95
Phase_B	Group I	1.00	1.00	1.00	1.00	1.00	1.90	2.00
	Group II	2.00	2.00	2.00	3.00	4.00	4.90	5.00
	Group III	2.00	2.00	2.00	2.00	3.00	3.00	3.00
Phase_C	Group II	2.00	2.00	3.00	3.00	4.75	5.00	5.00
	Group III	2.00	2.00	2.00	2.00	3.00	3.00	3.95

Table 2: Test statistics

	Phase_A	Phase_B	Phase_C
Chi-square	0.627	41.633	47.277
df	2	2	2
Asymptotic significant	0.731	<0.001*	<0.001*

*: Statistically significant

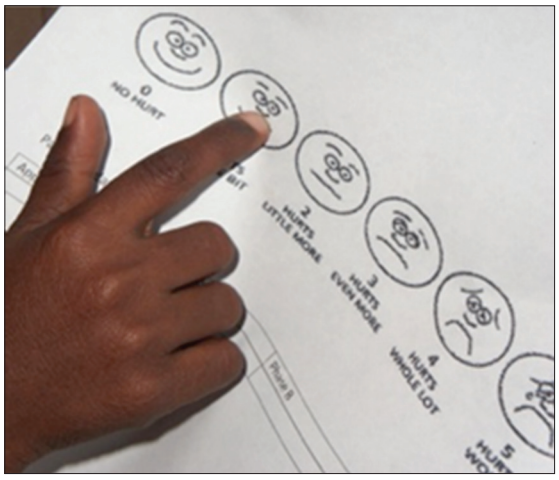
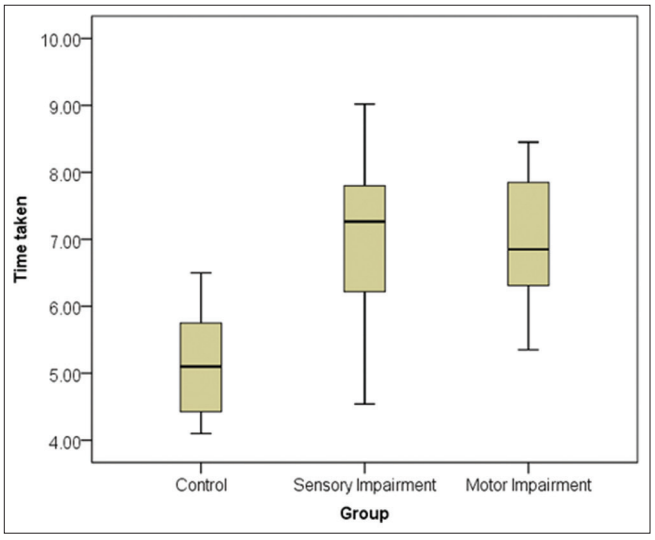


Figure 6: On visual analogy faces scale child showing face corresponding to a degree of discomfort

DISCUSSION

Research in dentistry has concentrated its efforts on the quality of treatment given to SHCN children, those who



Graph 1: Complete caries removal time of Papacarie duo between the groups

Table 3: Complete caries removal time of Papacarie duo between the groups

Descriptive								
Time_taken								
Groups	*N*	Mean	Standard deviation	Standard error	95% confidence interval for mean		Minimum	Maximum
					Lower bound	Upper bound		
Group I (healthy children)	20	5.1545	0.75478	0.16877	4.8013	5.5077	4.10	6.50
Group II (sensory impairment)	20	7.0160	1.16828	0.26124	6.4692	7.5628	4.54	9.02
Group III (motor impairment)	20	7.0205	0.98354	0.21993	6.5602	7.4808	5.35	8.45
Total	60	6.3970	1.31130	0.16929	6.0583	6.7357	4.10	9.02

Table 4: Complete caries removal time of Papacarie duo between the groups

Multiple comparisons						
Dependent variable: Time_taken LSD						
(I) Group	(J) Group	Mean difference (I-J)	Standard error	Significant	95% confidence interval	
					Lower bound	Upper bound
Control	Sensory impairment	−1.86150*	0.31102	0.000	−2.4843	−1.2387
	Motor impairment	−1.86600*	0.31102	0.000	−2.4888	−1.2432
Sensory impairment	Healthy children	1.86150*	0.31102	0.000	1.2387	2.4843
	Motor impairment	−0.00450	0.31102	0.989	−0.6273	0.6183
Motor impairment	Healthy children	1.86600*	0.31102	0.000	1.2432	2.4888
	Sensory impairment	0.00450	0.31102	0.989	−0.6183	0.6273

*The mean difference is significant at the 0.05 level, LSD: Least significance difference

require special attention and approach. Therefore, the CMCR agent is an efficient option when approaching and giving oral health for SHCN children.[8]

Since Papacarie was developed recently, there are not many studies in the literature comparing efficacy of this gel in healthy and children with SHCNs.

This is the first study of its kind as per the published literature till date.

Carrillo *et al.* evaluated in children with SHCNs reported 8 min as caries removal time and evaluated patient acceptance with Papacarie gel in children with SHCNs using visual analogy faces scale. They stated that Papacarie gel presented good acceptance in children with SHCNs.[8]

In the above-mentioned study, special health care children were included, and they were not segregated based on their disability, rather they were segregated based on their ability to respond to simple verbal commands. It gives very less information regarding the relation between patient acceptance and the type of disability.

Kotb *et al.* compared the efficacy of Papacarie gel to conventional rotary instrument and calculated complete caries removal time and found it to be 6.05 min.[9] Singh *et al.* estimated time was 5.4 min and compared pain perception with Papacarie gel and conventional method of caries removal using Wong-Bakers facial scale. Pain scores were found to be less when children were treated with Papacarie gel.[10] Matsumoto *et al.* estimated time was 2.45 min and pointed out that patients experienced pain in both chemomechanical and conventional caries removal methods used in their study.[11] Kochhar *et al.* conducted a study to calculate caries removal time in primary and permanent teeth, it was found to be 4.17 min and 4.2 min, respectively.[12]

Longer caries removal time when compared to the present study were reported by Konde *et al.* which was 11.2 min and evaluated the perception of pain when children were treated with Papacarie gel and conventional method of caries removal using visual analogy pain scale and stated that patient acceptability with Papacarie gel was significantly higher when compared to conventional method of caries removal.[13] Kumar *et al.* estimated caries removal time with Papacarie gel was 10.48 min.[14] Anegundi *et al.* estimated caries removal time was 17.96 min and determined the effectiveness of Papacarie gel to conventional rotary method of caries removal in terms of pain perception. Majority of the children (86%) experienced no pain with Papacarie gel.[15] Kaur *et al.* evaluated pain threshold experienced by children during various caries removal methods such as hand instruments, airotor, Carisolv, and Papacarie gel using Ericson *et al.* scale and visual analogy scale. It was concluded that pain threshold experienced by children was very less when treated with Papacarie and Carisolv. Motta *et al.* assessed pain and need for anesthesia during CMCR agent Papacarie and conventional method using a face scale. Use of Papacarie resulted in a lesser

degree of pain when compared to the conventional method of caries removal.[16] Inglehart *et al.*, found that subject's fear of dentists increased in CMCR method while it is slightly decreased in a conventional method. Attributing factor was longer treatment time required for CMCR method.[17]

In this study, time taken for complete caries removal in healthy children was 5.1 min, which is in unison with above-mentioned studies. In the present study, time taken for complete caries removal time with Papacarie gel in sensory impaired and motor impaired children was 7.01 and 7.02 min, respectively. This shows that complete caries removal for special health care children was more than the healthy children, which was statistically significant. The time difference between sensory and motor disability was not statistically significant. This demonstrated that time taken for SHCN children is not affected by the type of disability, whether it is sensory or motor impairment.

In the present study, patient acceptance in healthy children with Papacarie gel before the treatment, during, and after the treatment was evaluated using visual analogy faces scale. Children showed a lesser degree of discomfort with the use of Papacarie gel.

In the present study, patient acceptance with Papacarie gel was measured for sensory and motor impairment children before the treatment, during, and after the treatment. Results showed that sensory and motor impairment children showed more degree of discomfort, which is in contrast to the study done by Carrillo *et al.*

In the present study, the attributing factor was found to be that application of Papacarie gel on tooth surface, which simulated the situation of giving local anesthesia in the oral cavity. Papacarie gel dispensed in a tube which resembled local anesthetic syringe in India.

Children who were administered local anesthesia during dental treatment demonstrated more fear than those who were not subjected to anesthesia. Bedi *et al.* and Locker *et al.*, reported that the patient's strongest fears are caused by injection followed by drill.[18,19] In studies involving Papacarie, did not cause any pain yet in some cases there was a small degree of pain involved which require local anesthesia.

Fear and anxiety are mentioned as barriers to oral care among children. Children who are submitted to prolonged hospitalization are more fearful regarding dental treatment. Hence, CMCR is an efficient therapeutic alternative to prevent fear and anxiety.

The material of choice for this study was the conventional glass ionomer, since it presents advantages such as gradual fluoride release in the oral cavity, good adhesiveness, possibility of repair, and ease of use. Piva *et al.*, (2011) concluded that Papacarie negatively affected the microtensile bond strength of self-etching adhesive system. This study limits the usage of self-etching adhesives and promotes the usage of glass ionomer cements.[20]

Glass ionomer has low resistance to wear and presents low durability. Thus, periodical control is necessary to assess and follow up the restorations performed. These periodic visits are advantageous when dealing with SHCN children since they present a high incidence of oral diseases especially caries and periodontal diseases.[20]

In this study, even though Papacarie gel gave mild discomfort for SHCN children its usage proved to be a promising alternative for treating SHCN children although more studies are necessary to claim it as a new and alternative in treating caries.

CONCLUSION

Present *in-vivo* study concludes that the average time taken for complete caries removal in healthy children was found to be 5.1 min, whereas in sensory impairment and motor impairment were found to be 7.01 min and 7.02 min, respectively. Average time taken for complete caries removal per tooth was 6.3 min. Time taken for complete caries removal in SHCN children was more than the healthy children, which was statistically significant.

No statistically significant difference was found in time taken for complete caries removal between sensory and motor impairment children. This shows that time taken for SHCN children were not affected by the type of disability whether it is sensory or motor impairment.

Healthy children showed a lesser degree of discomfort with the use of Papacarie gel. Sensory and motor impairment children showed more degree of discomfort when compared to healthy children, which was statistically significant. Degree of discomfort between the children with sensory and motor impairment was not statistically significant.

CMCR is an efficient therapeutic alternative to children with fear and anxiety. Papacarie gel proved to be a promising alternative for treating SHCN children.

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Original Article

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Clinicopathological Analysis of Urinary Bladder Tumors at a Tertiary Care Institute in North India

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Abstract

Introduction: Urinary bladder tumors constitute 4th and 12th most common cancer among men and women worldwide. In India, they constitute 6th most common cancer in males. Urothelial carcinoma is most common type (90%), followed by squamous cell carcinoma (SCC) (3-5%). There are limited studies on bladder tumors in India and no available study from Rajasthan. The main objective of the study was to analyze clinical and pathological features of bladder tumor in biopsies and cystectomy specimen at a tertiary care institute.

Materials and Methods: We retrieved all bladder tumor cases reported in Department of Pathology over a period of 2 years from October 2011 to November 2013, and the results were assessed using frequency.

Results: During this period, we received 158 bladder tumors, comprising 93.6% urothelial neoplasms, SCC (2.53%), mesenchymal tumor (2.53%), and pheochromocytoma (1.26%). The male to female (M:F) ratio was 14.8. Mean age was 59 years (range 26-86 years). The commonest age group was seen in the 61-70 years (32.2%). Out of 148 cases of urothelial neoplasm, 92 (62.2%) were low grade, 42 (28.4%) were high grade, 12 (8.1%) were papillary urothelial neoplasm of low malignant potential and 2 (1.3%) were papilloma. 70.9% cases of urothelial neoplasm were superficial while 29.1% showed muscle invasion.

Conclusion: Age of presentation of bladder tumors was lower and M:F ratio higher in our study than in the west. As expected, urothelial carcinoma was the most common bladder tumor. The prevalence of SCC was similar to western literature, but mesenchymal tumors were more frequent. Most of the urothelial neoplasms were low grade and more than half of high grade were muscle invasive.

Key words: High grade, Low grade, Muscle invasion, Urothelial tumor

INTRODUCTION

Urinary bladder tumor is one of the most common urological malignancies with the highest incidence in developed countries. It accounts for about 3.2% of all cancers worldwide. It is 4th and 12th month. most common malignancy in men and women, respectively.[1] In India, it is the ninth most common malignancy accounting for 3.9% of all cancer cases.[2]

Bladder tumors are more common in males than in females, with a sex ratio of 3:1. The highest incidence is in the sixth and seventh decades of life. The major risk factors are smoking, industrial exposure to arylamines, prolonged therapy of cyclophosphamide, schistosomiasis. The most common symptom is painless gross hematuria which occurs almost in 85% of patients. Urothelial (transitional cell) carcinoma is the most common bladder tumor comprising >90% of all cases.[3] Squamous cell carcinoma (SCC) is second most common which accounts for approximately 3-5% cases, followed by adenocarcinoma (0.5-2.0%), sarcomas and paraganglioma were exceedingly rare (<0.1).[4]

Pathological staging and grading are the two most important determinants of prognosis and treatment. According to WHO (2004)/ISUP, papillary urothelial tumors are classified as papilloma (Figure 1), urothelial neoplasm of low malignant potential, low grade and high grade papillary urothelial carcinoma (Figure 2).[5] Superficial bladder tumors

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(which confined to the mucosa and lamina propria, stages Ta, T1 and carcinoma *in situ*) accounts for approximately 75-80% of all newly diagnosed cases, while approximately 20-25% have muscle invasion at first presentation.[6]

There are limited studies on bladder tumors in India, and no data are available from Rajasthan. The aim of this study was to analyze clinicopathological features of bladder tumor and to determine the stage and grade of urothelial tumors in biopsies and cystectomy specimen at a tertiary care institute.

MATERIALS AND METHODS

This was a retrospective study conducted in Department of Pathology, SMS Medical College, Jaipur. We retrieved all urinary bladder tumor cases reported in our department over a period of 2 years from October 2011 to November 2013. During the study period, we received a total of 158 of bladder tumor cases (150 transurethral resection biopsies and 8 cystectomy specimen) in the histopathology department, and the results were assesses using frequency. The medical records of these patients (age, sex, symptoms and history of smoking) were reviewed and included in the present study. Ethical clearance had been obtained from Institutional Ethics Committee.

The histopathological diagnoses of all cases were recorded. All cases of urothelial carcinoma were graded histologically, according to WHO (2004)/ISUP classification. Pathological staging of the urothelial tumor was done according to the TNM system, and data recorded as pTa: Tumor limited to the mucosa, pT1: Invasion of lamina propria and pT2: Invasion of muscle.[7]

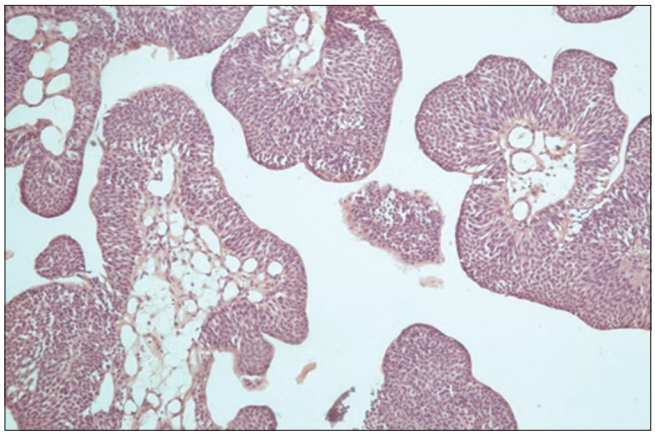

Figure 1: Microphotograph of papilloma

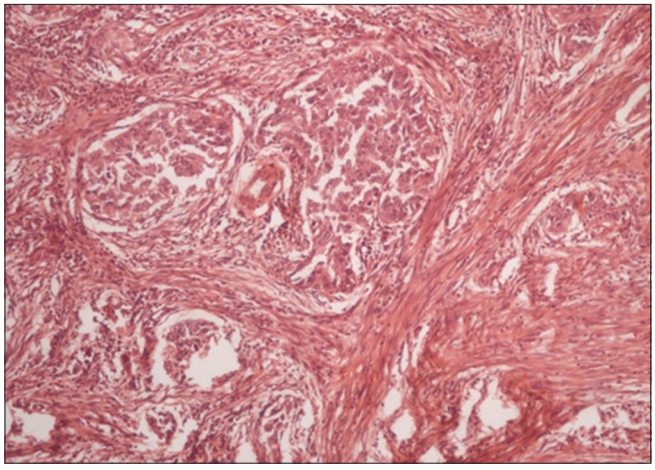

Figure 2: Microphotograph showing high-grade papillary tumor with muscle invasion

RESULTS

During this period, we received 158 cases of bladder tumors (150 transurethral resection biopsies and 8 cystectomy specimen) [Table 1].

The most common age group was seen in the 61-70 years (32.2%), followed by 51-60 years (22%). The mean age of the patient was 59 years (range 26-86 years) [Table 2].

Staging of urothelial tumor showed 70.9% cases were superficial (pTa and pT1), and 29.1% cases were muscle invasive (pT2) [Table 3]. For low-grade carcinoma, 20 (21.7%) out of 92 cases showed muscle invasion whereas 23 (54.7%) out of 42 cases of high-grade were muscle invasive [Table 4].

Table 1: Clinicopathological features of the bladder tumor cases

Features	Number of cases (%)
Gender	
Male	148 (93.6)
Female	10 (6.3)
Male-to-female ratio	14.8:1
Histological type	
Urothelial carcinoma	148 (93.6)
SCC	4 (2.53)
Mesenchymal tumor	4 (2.53)
Pheochromocytoma	2 (1.26)

SCC: Squamous cell carcinoma

Table 2: Age and sex distribution of bladder tumor cases

Age group	Male (%)	Female (%)	Total (%)
≤40	8 (5.0)	1 (0.6)	9 (5.6)
41-50	16 (10.1)	1 (0.6)	17 (10.7)
51-60	33 (20.8)	2 (1.2)	35 (22)
61-70	48 (30.4)	3 (1.8)	51 (32.2)
71-80	29 (18.3)	2 (1.2)	31 (19.5)
81-90	14 (8.8)	1 (0.6)	15 (9.4)
Total (%)	148 (93.6)	10 (6.4)	158 (100)

Table 3: Histological grading of urothelial carcinoma in 148 cases

Histological grade	Number of cases (%)
Papilloma	2 (1.3)
PUNLMP	12 (8.1)
Low grade	92 (62.2)
High grade	42 (28.4)

PUNLMP: Papillary urothelial tumor of low malignant potential

Table 4: Staging of urothelial carcinoma according to the grade

Histological grade	Stage			Number of cases (%)
	PTa	PT1	PT2	
Papilloma	2	0	0	2 (1.3)
PUNLMP	12	0	0	12 (8.1)
Low grade	8	64	20	92 (62.2)
High grade	2	17	23	42 (28.4)
Total (%)	24 (16.2)	81 (54.7)	43 (29)	148 (100)

PUNLMP: Papillary urothelial tumor of low malignant potential

DISCUSSION

The bladder tumor accounted for 2.07% of total cancer cases with formed 3.06% and 0.65% of all cancer cases in males and females, respectively, in Jaipur region.[8] The present study was conducted to analyze clinicopathological features of bladder tumor in biopsies and cystectomy specimen at a tertiary care institute in Rajasthan over a 2 years period.

In this study, urothelial neoplasm was the most common bladder tumor (93.6%), which is similar to report in western literature.[9] The prevalence of SCC varies in different parts of the world, accounts for 3-7% in the United States but as much as 75% in Egypt where schistosomiasis is endemic.[10] In our study, SCC constituted 2.53% of total, which was similar to the results from Western countries.[3] Mesenchymal tumors accounted for 2.53% cases which were higher than western literature (<0.1%).[4] In our study, bladder cancer was more common in males as compared to females. Our study showed a ratio of 14.8:1 which is comparable to studies from other part of Asia,[11,12] but was much higher than finding in United States, where it ranges from 3:1 to 4:1.[3] However, these results are in contrast to study from East India, where the ratio was 1.5:1.[13] The incidence of bladder tumors in females compared to males could be due to decreased exposure to the industrial carcinogens as there are less women working outside the home and few women who smoke as compared to men, which is a major risk factor.[10] The possible explanation for much higher M:F ratio from North India compared to the east could be that smoking trend, and outdoor activities are less common in North Indian females. The mean age of presentation was 59 years (range 26-85 years) which is comparable to other studies from India[10,13] and similar to that reported in western countries.[11] Almost 83.7% patient were older than 50 years, similar data were noted by Al-Bazzaz *et al.* which showed that 80.6% were older than 50 years.[14] These results indicate that bladder tumors are more prevalent in old age groups.

Tumor grading and staging are the two major determinants for recurrence, progression and treatment option for patients. There are significant survival differences between patients with superficial tumors and muscle invasive tumors.[15]

In this study, according to WHO (2004)/ISUP grading of urothelial tumors, low-grade carcinoma was most common with 62.2% cases, followed by high grade with 28.4% cases. Higher incidence of low-grade carcinoma was also revealed in studies by Laishram *et al.*[13] and Ahmed *et al.*[16] (53.85% and 44%, respectively) compared to high grade (26.41% and 29.5%, respectively), whereas contrast results were also noted in some studies with higher incidence of high-grade tumors.[17,18]

Pathological staging of urothelial tumor s in our study showed 70.9% cases were superficial (PTa, PT1 and 29.1% cases were muscle invasive PT2), similar to studies from other part of India revealing muscle invasion in 26% cases.[10] Husain *et al.*[19] reported a high percentage of muscle invasion in higher grade tumors, similarly 54.7% cases of high-grade were muscle invasive in our study. The importance of including muscle in the biopsy needs for proper staging and preventing recurrence.

CONCLUSION

In our study, age of presentation of bladder tumors was lower, and sex ratio was higher in our study than in the west. As expected, urothelial tumor was the most common bladder tumor. The prevalence of SCC is similar to western literature, but mesenchymal tumors were more frequent. Most of the urothelial tumors were low grade and non-invasive. More than half of the high grades were muscle invasive.

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Original Article

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Epidemiological Profile of Cholera Outbreaks in Parts of Rural West Bengal in Last 2 Years

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Abstract

Background: Diarrheal outbreaks are major public health emergencies in rural West Bengal. This study was done in our hospital on diarrheal samples collected from various blocks of Bankura and Purulia district of West Bengal where on an average 10 diarrheal deaths occur annually.

Objectives: The main objective of the study was: Isolation, biotyping, and serotyping of vibrio isolates, determining the antibiotic sensitivity pattern of the isolates, mapping of confirmed cholera cases for finding incidence and geographical location of cholera among diarrheal outbreaks in Bankura and Purulia district of West Bengal.

Materials and Methods: Stool samples collected from 170 diarrheal patients in Cary Blair media along with their proper address from July 2012 to April 2014. Microbiological processing was done by conventional methods; antibiotic sensitivity test of all samples was done by Kirby Bauer disc diffusion method.

Results: 170 diarrheal cases and 55 outbreaks were reported in the study period. Out of which 43 cases (25%) and 25 outbreaks (45.45%) were caused by *Vibrio cholerae* O1, with increased incidence in the rainy season. Among 43 cholera cases, 28 (65%) and 15 (35%) cases occurred in Bankura and Purulia, respectively, with significant clustering of cases in two blocks of Bankura. Among these strains 70% were classical, 30% were El tor biotype and all were of Ogawa serotype. Antibiotic sensitivity testing showed all isolates were sensitive to ofloxacin, norfloxacin, tetracycline, amikacin, azithromycin; 70% isolates were resistant to amoxicillin; 50% were resistant to chloramphenicol. No significant age and sex variation were noticed.

Conclusion: The study reveals that in this part of West Bengal classical biotype is predominant contrary to other parts with El Tor biotype predominance. This is a significant finding for formulating future health strategy for combating diarrheal outbreaks in these areas of rural Bengal.

Key words: Cholera, Classical biotype, Diarrheal outbreaks, *Vibrio cholerae*

INTRODUCTION

Cholera, a disease which was once considered a menace to the mankind, caused by *Vibrio cholerae* has been responsible for seven global pandemics over the past two centuries. It is an acute intestinal infection caused by ingestion of food or water contaminated with the bacterium *V. cholerae*. It has a short incubation period (1-5 days) and produces an enterotoxin that causes copious, painless, watery diarrhea along with vomiting in some patients leading to severe dehydration and death if prompt treatment is not ensured.

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Epidemic cholera remains a significant public health concern in the developing world even today. Since 1817, seven global pandemics have occurred. Among these first six pandemic were caused by classical strain and the seventh pandemic was caused by El Tor, which began in Indonesia in 1961 and spread throughout Asia. Cholera represents an estimated burden of almost 5 million cases and 28,000-142,000 deaths per year worldwide. Though underreported, burden of cholera in India approximately 3-5 million cases and 100,000-130,000 deaths per year. This

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was mainly caused by *V. cholerae* O1 and O139. At present, among the two biotypes, the El Tor biotype is the more common in India.[1-3]

Diarrheal outbreaks are major public health emergencies in many parts of India including rural West Bengal. *V. cholerae* El Tor biotype being one of the major causes of such outbreaks. In 2008, 2010 and 2012 cholera outbreak were reported from different districts of West Bengal caused by *V. cholerae* El Tor biotype. Year 2013 showed a different picture when north 24 Parganas reported outbreak caused by classical biotype.[4] The present study was done in our hospital on diarrheal samples collected from various blocks of Bankura and Purulia districts of West Bengal where on an average 10 diarrheal deaths occur annually.

Aims and Objective

- Isolation, biotyping, serotyping of vibrio isolates
- Determining the antibiotic sensitivity pattern of the isolates
- Mapping of confirmed cholera cases for finding incidence and geographical location of cholera among diarrheal outbreaks in Bankura and Purulia district of West Bengal.

MATERIALS AND METHODS

Stool samples were collected from 170 diarrheal patients in Cary Blair media along with their proper addresses from July 2012 to April 2014. Further enrichment was done in alkaline peptone water followed by inoculation in MacConkey's agar, (xylose lysine deoxycholate agar) and thiosulfate-citrate-bile salts sucrose agar media for overnight incubation at 37°C.

The following day, discrete colonies were further studied by Gram-staining, tests for motility and a battery of conventional biochemical tests which phenotypically implied the organism to be *V. cholera*.

Voges–Proskauer test reactivity, polymyxin-B susceptibility (50 U disk) and hemolytic properties were used to differentiate between classical and El Tor biotype.

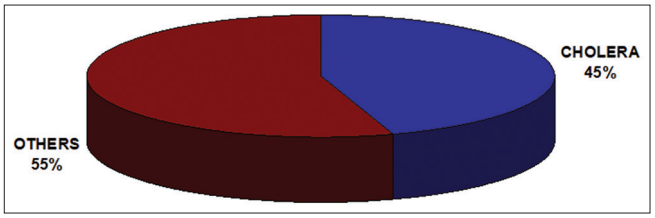
Serogrouping of isolates was done by polyvalent O1 antisera, and serotyping was done by Inaba and Ogawa antisera (Supplied by BD Difco™ Cat. No. 224321, 224301 and 224311 respectively).

Antibiotic sensitivity test of all isolates were done with amoxicillin, chloramphenicol, ofloxacin, norfloxacin, tetracycline, amikacin, azithromycin discs by Kirby-Bauer disc diffusion method,[4-6] following CLSI guidelines.[7] Ethical clearance for this study was obtained from Ethics Committee, Bankura Sammilani Medical College, Bankura.

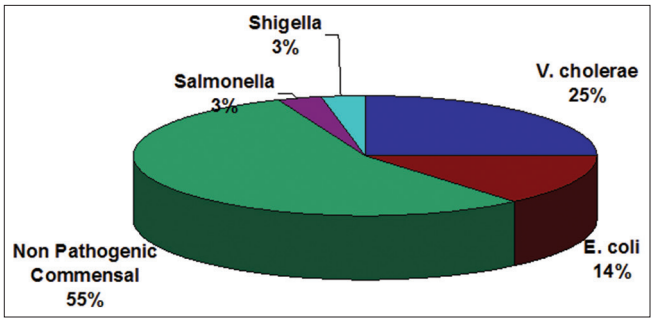
RESULTS

In the study period, 170 diarrheal cases and 55 outbreaks were reported. Among them, 43 cases (25%) and 25 outbreaks (45.45%) were caused by *V. cholerae* O1. Rest were caused by *Escherichia coli* (14%), *Salmonella typhi* (3%), *Shigella* (3%) (Graphs 1 and 2) increased incidence in the rainy season.

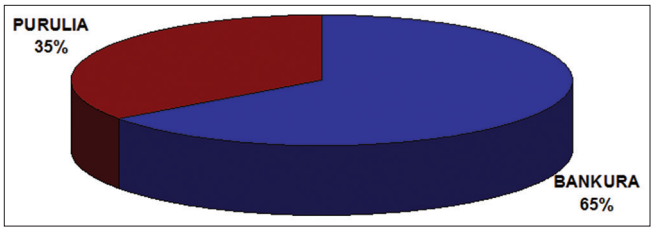
Among 43 cholera cases, 28 (65%) and 15 (35%) cases occurred in Bankura and Purulia respectively (Graph 3). Significant clustering of cases in Onda (30%) and Bankura-1 (23%) blocks of Bankura were observed (Graph 4). Among 43 cases, 30 cases (70%) occurred by classical biotype and 13 cases (30%) occurred by El Tor



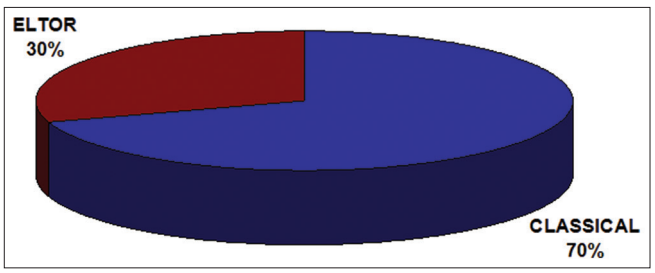
Graph 1: Distribution of out-breaks



Graph 2: Percentage of pathogens



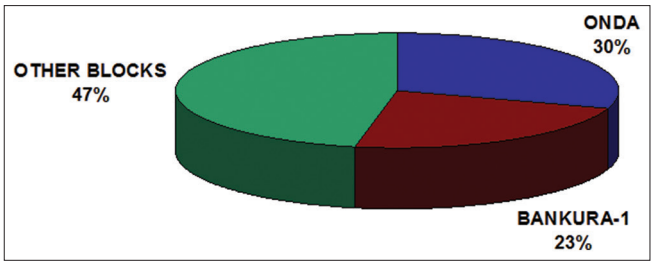
Graph 3: Distribution of cases in Bankura and Purulia



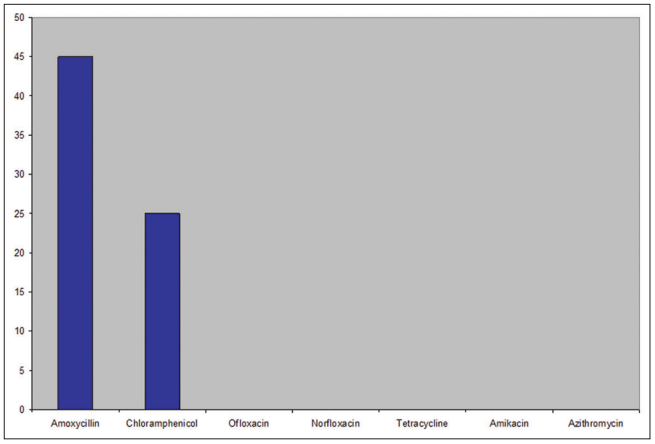
Graph 4: Distribution of biotypes

biotype (Graph 5). All the isolates were of Ogawa serotype. No significant age and sex variation were noticed.

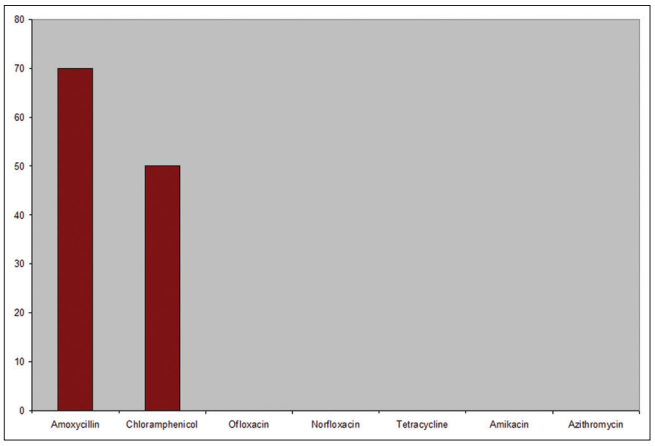
Antibiotic sensitivity testing of the isolates showed all isolates were sensitive to ofloxacin, norfloxacin, tetracycline, amikacin, azithromycin; 70% isolates of El Tor biotype were resistant to amoxicillin and 50% were resistant to chloramphenicol compared to classical biotype having lower resistance to the same drugs (Graphs 6 and 7).



Graph 5: Distribution of cases in different blocks



Graph 6: Antibiotic resistance pattern of isolates (classical biotype)



Graph 7: Antibiotic resistance pattern of isolates (El Tor biotype)

DISCUSSION

There is a constant tug of war between the serotype Inaba and Ogawa in West Bengal since 1999.[4] In this part of West Bengal main causative organism of the cholera outbreak is *V. cholerae* O1 serotype Ogawa. According to De and Mathur 83 *V. cholerae* O1 isolates were sent to the National Institute of Cholera and Enteric Diseases in Kolkata for serotyping and phage typing. All the *V. cholerae* O1 isolates were of El Tor biotype.[7,8] Our study reveals that in this region classical biotype is predominant in contrast to other parts where El Tor is predominant. Significant clustering of cases occurred in two blocks of Bankura district with seasonal predominance. *V. cholerae* classical causes more severe disease than El Tor, its reemergence is no doubt an upcoming threat; especially in its multidrug-resistant pattern leaving behind scanty therapeutic portal specially for pregnant women.

In the year 2012, multi-drug-resistant *V. cholerae* O1 El Tor was isolated by Roy *et al.* in Belgaum, south India.[9] Contrary to this study, in the year 2013, Bhattacharyya *et al.* reported classical *V. cholerae* outbreak with multidrug resistance in North 24 Pargana district of West Bengal.[4] With a discordance to the classical belief that El Tor biotype,[10] is more drug resistant, classical biotype was resistant to almost all drugs except fluoroquinolones, azithromycin and polymyxin-B in the study by Bhattacharyya *et al.*[4] Our study revealed the *V. cholerae* strains isolated in this part of rural West Bengal showing better antibiotic sensitivity pattern. Since classical biotype causes more severe disease than El Tor, its reemergence is no doubt an upcoming threat; specially in its multidrug-resistant pattern. So is it a warning signal for re-emergence of the classical biotype in this part of the country?

CONCLUSION

Resistance of *V. cholerae* to commonly used antimicrobial drugs is becoming a major public health concern because it complicates treatment and may result in longer hospital stays for patients.[11] However, we are not yet stranded because strains in this region are still sensitive to a varied plater of antimicrobials. Nonetheless, the expanding spectrum of drug resistance among the *V. cholerae* isolates is a cause for serious concern and is it a warning signal for re-emergence of the classical biotype in this part of the country?

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Original Article

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Prenatal Factors Influencing the Interpretation of Cord Blood Thyroid Stimulating Hormone Levels

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Abstract

Introduction: In past few years, congenital hypothyroidism has rapidly increased, and screening of congenital hypothyroidism forms the major tool for diagnosis and early initiation of therapy to treat this preventable cause of mental retardation.

Objectives: The objective was to study the effect of various perinatal stress factors and mode of delivery on the cord blood (CB) thyroid stimulating hormone (TSH) levels.

Materials and Methods: CB TSH levels were measured in 100 live-born infants in the hospital from April 2014 to June 2014 using electrochemiluminescence immunoassay. The effect of perinatal factors on the CB TSH levels was analyzed statistically. statistical variables of certain perinatal factors were analyzed for their influence on the TSH levels like parity, duration of labor, obstructed labor/cephalopelvic disproportion, fetal distress (including meconium stained amniotic fluid), mode of delivery (normal vaginal/caesarean section/assisted vaginal/forceps), presence of asphyxia, apgar at 1 and 5 min, resuscitation beyond initial steps.

Result: Median CB TSH value was found to be 9.243 μIU/ml. It was found that mode of delivery, resuscitation beyond the initial steps and apgar scores were statistically significant with a $P < 0.05$. Neonates who had fetal distress or non-progress of labor had significantly higher CB TSH than those who were delivered by elective caesarean section. Requirement of resuscitation beyond the initial steps and low apgar scores at 1 min resulted in significantly raised CB TSH (both $P < 0.05$).

Conclusion: On multiple regression analysis of various perinatal factors, the need for resuscitation beyond initial steps, apgar scores, mode of delivery and fetal distress as indication for lower segment caesarean section were significant factors affecting CB TSH values. Hence, these values need to be interpreted in light of these perinatal factors while using CB TSH as a screening tool for congenital hypothyroidism.

Key words: Cord blood, Newborn screening, Perinatal factors, Thyroid stimulating hormone

INTRODUCTION

Newborn screening has been recognized as the most effective method and a cornerstone for diagnosis of congenital hypothyroidism at birth. Most infants with congenital hypothyroidism appear unaffected at birth because of placental transfer of thyroid hormones. Only 5-10% of children can be diagnosed clinically which points out the role of instituting screening program for diagnosis and early initiation of therapy to prevent congenital hypothyroidism.[1]

Congenital hypothyroidism can cause mental retardation and developmental delay unless thyroid therapy is initiated within 2 weeks of birth.

Since past few years knowledge about congenital hypothyroidism has rapidly increased, and screening of congenital hypothyroidism forms the major tool for diagnosis and early initiation of therapy to treat this preventable cause of mental retardation.

Screening and treatment including regimes that more aggressively target early correction of thyroid stimulating

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hormone (TSH) levels have led to improved levels of intellectual and neurological progress.

Neonatal screening method measures TSH in either cord blood (CB) sample or that obtained from heel prick sample on 3rd or 4th day of life. Although the AAP recommends a heel prick sample after 48 h of life, umbilical cord sampling is a practical and effective way to diagnose congenital hypothyroidism and has been recommended by IAP as an alternative.[2,3] When CB TSH is measured for congenital hypothyroidism screening, it has a high sensitivity but with a high false positive rates.

Various maternal and perinatal factors are known to affect CB TSH levels. This study analyses various perinatal factors that influence the interpretation of CB TSH levels while considering it as a means of newborn screening for congenital hypothyroidism.

MATERIALS AND METHODS

It is a cross-sectional study conducted on newborns delivered in the obstetrics and gynecology unit of Cheluvamba hospital attached to MMC and RI from April 2014 to July 2014.

Sample size was calculated using 20% error and 5% significance and was found to be 100 for the period of April 2014-July, 2014.

Statistical Variables

The following perinatal factors were analyzed for their influence on TSH levels:

1. Parity
2. Duration of labor
3. Obstructed labor/cephalopelvic disproportion (CPD)
4. Fetal distress (including meconium stained amniotic fluid)
5. Mode of delivery (normal vaginal/caesarean section/elective/emergency and indication)
6. Presence of asphyxia
7. Apgar at 1 and 5 min
8. Resuscitation beyond initial steps.

Statistical Tests

Following statistical tests were applied to study the various perinatal factors:

1. Descriptive statistics
2. Multiple regressive analysis.

Inclusion Criteria

The study includes 100 live-born neonates delivered at our hospital from April 2014 onwards to account for a maximum of 20% drop out/consent withdrawal or sample processing issue.

Exclusion Criteria

Neonates with major life-threatening malformations, those with antenatally detected central nervous system malformations, neonates whose mothers are on anti-thyroid drugs. Also neonates whose mothers have pregnancy-induced hypertension and gestational diabetes were excluded from the study.

Methodology

The protocol of the study was approved by the Ethical Committee of Mysore, Karnataka. Informed consent was obtained from either of the parents. Antenatal and intra-partum information was noted from mother's medical records. Blood was obtained for TSH assay from the maternal end of umbilical cord immediately after clamping. The sample was preserved at room temperature and transported to the laboratory within 1 h. The samples were analyzed within 3 h using the ultra-sensitive sandwich chemiluminescence immunoassay. Neonates whose blood samples could not be studied due to technical reasons (inadequate sample or hemolyzed sample) were excluded from the study. All neonates who had CB TSH levels more than 20 were advised to repeat the TSH levels within 14 days of life.

Method of Data Analysis

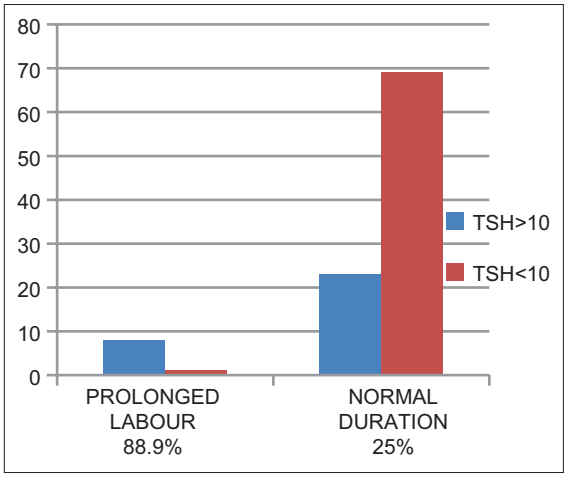
The data will be entered in excel sheets and percentage of various parameters will be analyzed using statistical package for the social sciences software version 16. The relationship between various parameters was first analyzed by univariate analysis and then analyzed by multivariate analysis. $P < 0.05$ was taken as significant.

RESULTS

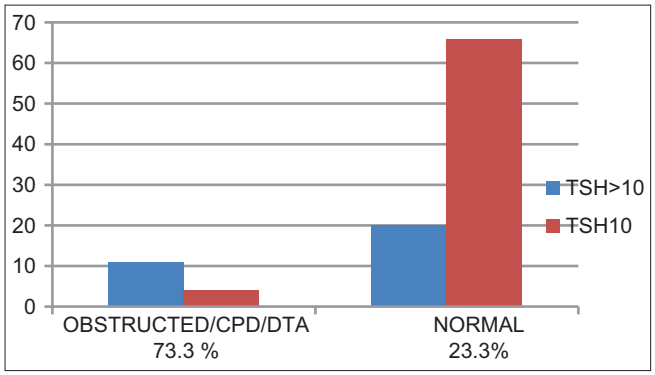
CB TSH levels were studied in 100 live born infants and were inferred in light of various prenatal factors. The CB TSH values ranged between 2.27 and 33.8 μIU/L with a median of 9.243. 31 out of 100 neonates (31%) had values more than 10 μIU/L, 14% had values more than 15 μIU/L and 7% had values more than 20 μIU/L.

1. CB TSH values were found to be significantly raised in neonates delivered as 1st order compared to multiparous mothers ($P = 0.03$)
2. CB TSH values were elevated significantly with prolonged duration of the second stage of labor ($P = 0.01$). Also in cases of obstructed labor/CPD/deep transverse arrest of labor, CB TSH values were significantly elevated with $P = 0.01$) (Graphs 1 and 2)

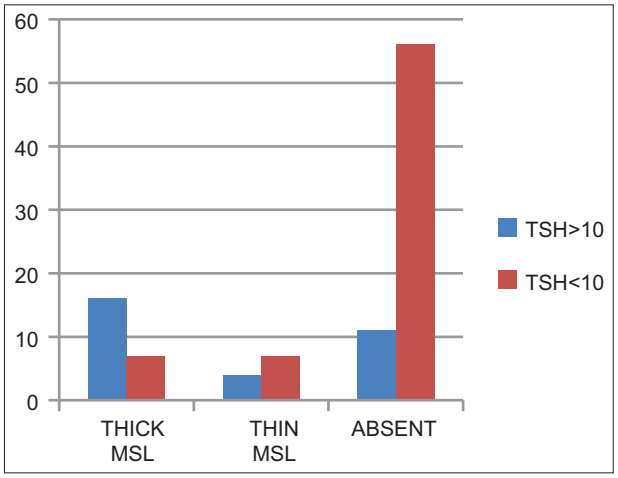
3. In deliveries with history of fetal distress and meconium-stained amniotic fluid (thick meconium-stained liquor), the CB TSH values were significantly elevated ($P = 0.01$) (Graphs 3 and 4)
4. CB values were high in normal vaginal deliveries compared to caesarean; emergency caesarean section had higher TSH values than elective
5. Presence of birth asphyxia, requirement of resuscitation beyond the initial steps and low apgar scores of <6 at 1 min also resulted in significant elevation of CB TSH valued ($P = 0.01$) (Graphs 5-7).



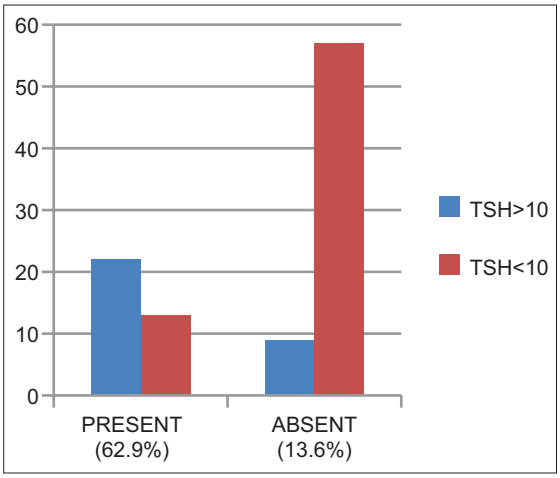
Graph 1: During of labor



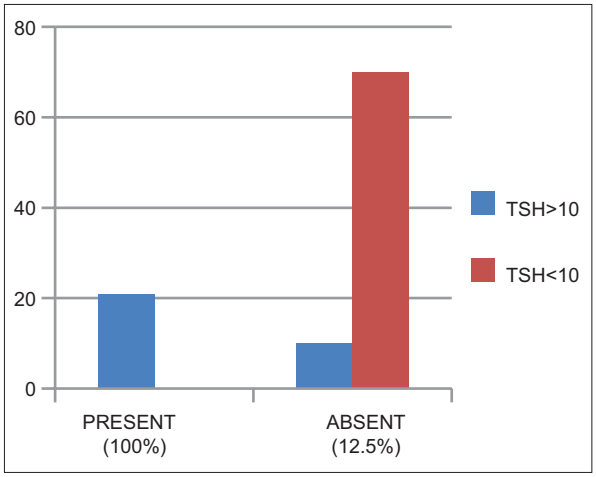
Graph 2: Obstructed labor/deep transverse arrest/cephalopelvic disproportion



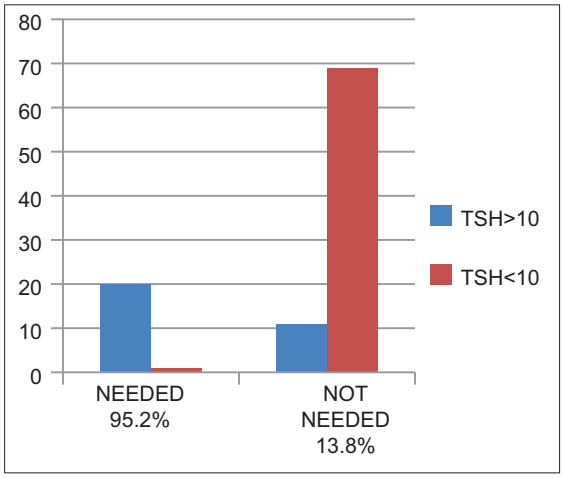
Graph 3: Presence of meconium stained amniotic fluid



Graph 4: Fetal distress



Graph 5: Birth asphyxia

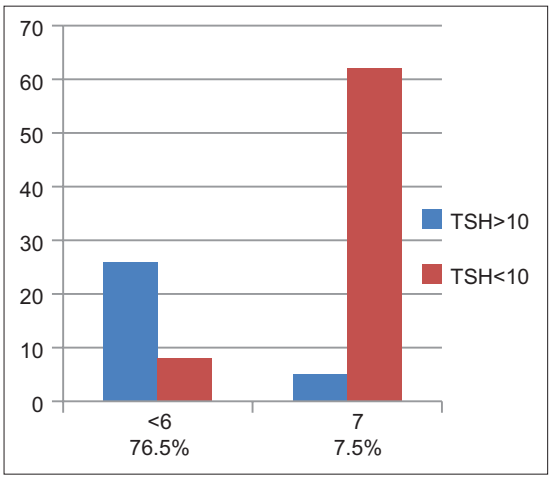


Graph 6: Resuscitation beyond initial steps

Table 1 showing the significance of various parameters with corresponding *P* values and number of neonates with significantly elevates TSH values.

DISCUSSION

Screening of congenital hypothyroidism decreases the burden of mental retardation by early initiation of thyroid supplementation.[4] There are different strategies for screening; few countries employ measurement of TSH levels, others prefer T4 levels and some countries do a simultaneous assay of both T4 and TSH.[5,6]



Graph 7: Apgar score <6 at 1 min

Collection of CB for TSH is a convenient method when compared to heel prick sampling on 3rd day, as its more practical for mothers with a shorter duration of hospital stay following delivery, also loss of follow-up is minimized.[7,8]

Various studies state that there is correlation of TSH with factors like birth asphyxia and difficult delivery, prenatal stress events, birth weight, male infant and instrumental delivery and negative correlation with cesarean section as mode of delivery but the mechanisms involved are poorly understood.[9-12]

According to a study conducted by Rashmi *et al.* where they analyzed 1590 students and found that CB TSH values decline with increasing birth weight and presence of birth asphyxia. Highest values were found in forceps extraction and lowest in infants born by elective cesarean section. There was no significant elevation with factors like infant

Table 1: Significance of various parameters with corresponding P values and number of neonates with significantly elevated TSH values

Parity	Number	TSH<10	TSH>10	Contingency coefficient	Significance (*P*) value
Primi	45	22	23	0.372	0.003
G2	43	37	6		
G3	11	9	2		
G4	1	1	0		
G5	1	1	0		
Duration of labor				0.367	0.001
Prolonged	9	1	8		
Normal	92	69	23		
Obstructed labor/CPD/DTA				0.360	0.001
Present	15	4	11		
Absent	86	66	20		
Fetal distress				0.453	0.001
Present	35	13	22		
Absent	66	57	9		
Meconium					
Absent	67	56	11		
Thin MSL	11	7	4		
Thick MSL	23	7	16		
Mode of delivery				0.343	0.002
Normal vaginal	35	20	15		
Emergency CS	43	27	16		
Elective CS	23	23	0		
Birth asphyxia				0.610	0.001
Present	21	0	21		
Absent	80	70	10		
Apgar at 5 min				0.577	0.000
<6	8	0	8		
7+	93	70	23		
Resuscitation beyond initial steps				0.583	0.001
Present	21	1	20		
Absent	80	69	11		

TSH: Thyroid stimulating hormone, CPD: Cephalopelvic disproportion, MSL: Meconium-stained liquor, CS: Caesarean section

sex, appropriate for gestation or Small for gestational age babies.[9]

In another study done by Kim *et al*., in 2005 CB TSH, T3 and T4 levels were measured using radio immunoassay method in 130 newborns. Factors like gestation age, sex, birth weight, delivery method, prenatal asphyxia, gestational diabetes, pregnancy-induced hypertension were assessed by ANOVA test, Student's *t*-test and multiple regression analysis and it was found that birth weight and sex did not affect the CB TSH levels. TSH levels in neonates born vaginally was higher than those born by cesarean section. CB TSH levels increased with gestation age and were higher in asphyxiated infants and infants of mothers with gestational diabetes and pregnancy induced hypertension.[10]

Another study done by Chan *et al*. published in 2006, the amount of prenatal stress undergone by neonate like asphyxia was analyzed by estimating the CB acid-base status and was correlated with elevation of CB TSH levels. The study population consisted of 2366 neonates. It was found that there was a significant negative correlation between CB TSH levels and cord arterial and venous pH, i.e., there was a significant elevation of CB TSH levels with a decline in CB pH. Negative correlation was particularly significant in neonates delivered vaginally as compared to emergency lower segment caesarean section (LSCS) and not in elective LSCS. Overall incidence of CB acidosis is significantly higher in neonates with elevated TSH levels. Thus, the study showed that stress-induced elevation of CB TSH levels may be mediated through intrapartal fetal asphyxia.[11]

In another study done by Chan *et al*. published in 2001, where the study group consisted of 20,086 newborns delivered over a period of 3 years wherein the effects of - Mode of delivery, infant sex, gestation at birth, birth weight and duration of labor on the incidence of false elevation of CB TSH was assessed by univariate analysis and logistic regression. It was found that CB TSH levels were falsely elevated for instrumental deliveries, male sex and birth weight and no elevation for elective or emergency LSCS. False elevations were seen for fetal distress and failed instrumental deliveries than in cases of failure in progress of labour.[12]

In our present study detailed analysis was done for stressful factors of prenatal period, the parameter of fetal distress was studied along with contributing factors like meconium-stained amniotic fluid (thick/thin), apgar scores, the need for resuscitation beyond the initial steps, so as to indicate the presence of significant birth asphyxia. The mode of delivery like normal vaginal or cesarean section were studied with due consideration for factors like prolonged second stage of labor, presence of cephalopelvic disproportion, deep transverse arrest, etc., were analyzed for effects on CB TSH profile. Premature babies were eliminated from the study as we give antenatal steroids for preterm deliveries which blunts the catecholamine surge hence can affect the estimation of TSH values.[13,14]

In a cross-sectional study done by Raj *et al*. in a rural center in southern India in 2014, 3 out of 430 newborns screened were found to be congenital hypothyroidism on the basis of CB TSH values with respect to the maternal, paternal and perinatal parameters. Re-estimation of TSH values were done on 3rd postnatal day for abnormal values. It was found in the study that CB TSH levels showed no gender variability but increased with increase in gestation age of the baby, with an increase in maternal age and babies born to the mothers with a history of hypothyroidism.[15]

Though the mechanism behind this upsurge of TSH levels was not clearly understood in these studies but in an animal study it was demonstrated that perinatal stress factors cause an increase in the levels of catecholamine. Catecholamine, especially noradrenalin may regulate the secretion of TSH from the pituitary gland and is believed to have a stimulatory effect. CB TSH level was significantly elevated in various adverse antepartum conditions. This may be related to the placental insufficiency and fetal hypoxia commonly found in these high-risk pregnancies.[16]

CONCLUSION

On multivariate analysis, presence of birth asphyxia, fetal distress (meconium stained amniotic fluid), resuscitation beyond initial steps, low apgar values, prolonged second stage of labor, and obstructed labor contributed to significant elevation of CB TSH values. Primigravida and delivery through normal vaginal mode had a comparatively higher CB TSH values. Hence, these values need to be interpreted in light of prenatal factors.

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Original Article

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Comparison of Merocel with Medicated Gauge Packing as a Packing Material after Nasal Surgery: A Prospective, Randomized, Double-Blinded Controlled Trial

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Abstract

Background: In the present study, we have evaluated Merocel (Medtronic Xomed surgical products, Jacksonville, FL) as a packing material after nasal surgery compared with medicated gauze packing (MGP), in terms of clinical efficacy and mucosal wound healing.

Materials and Methods: A prospective, randomized, double-blinded controlled trial was performed in 50 patients who underwent nasal surgery. The patients were randomized to receive Merocel or MGP after nasal surgery. Assessment of clinical efficacy on bleeding at the time of pack removal, pain with pack *in-situ* and effects over mucosal wound healing was made.

Results: Pain with pack *in-situ* and bleeding at the time of pack removal was considerably less in patients in Merocel group, than seen in the MGP group. Furthermore, the mucosal wound healing was much better in the Merocel group. The difference observed between the two groups was statistically significant.

Conclusion: Merocel is a suitable packing material to be used after nasal surgery with beneficial effects on pain, bleeding, and mucosal wound healing.

Key Words: Granulation, Merocel, Nasal surgery, Synechia

INTRODUCTION

An important aspect of any surgery is the post-operative period, wherein the patient is happy if he/she has to undergo minimum suffering. Keeping this in mind, otorhinolaryngologist has been practicing nasal packing following nasal surgery, as an attempt to reduce post-operative complications such as bleeding, septal hematoma, and adhesions, thereby limiting morbidity at the lowest level possible. Various problems related with nasal packing have also been cited, mainly the pain during nasal packing and pack removal and the associated bleeding.[1-5]

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Many surgeons believe that postoperative nasal packing is not needed if the correct technique has been followed and should be avoided to prevent the related morbidity.[6,7] Some others argue that packing should be reserved for cases where there is a concern about persistent hemorrhage.[8] In spite of all these arguments, postoperative nasal packing is carried as a routine, almost globally.

Currently, at our institution, we pack the nasal cavities post-operatively with medicated gauze packing (MGP - 1 m long ribbon gauge, moistened with antibiotic ointment). However, we were forced to seek alternatives, because of problems caused by MGP, mainly being pain, mucosal irritation, secondary bleeding, and adhesion formations. Merocel (Medtronic Xomed, Jacksonville, FL, USA) is a non-absorbable material, used for postoperative nasal

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packing. It is an expandable polyvinyl acetate compound that can control bleeding in cases of epistaxis in about 91.5% cases.[9] It has hemostatic potential and can reduce synechia formation. It is a readily available and easy to use the product and provides adequate support.[10] Therefore, with a quest for betterment we planned to compare the effects of Merocel and MGP on the post-operative complications in patients who underwent nasal surgery.

Aims and Objectives

Comparing Merocel and MGP as packing material in terms of:

1. Pain with pack *in-situ* and bleeding at the time of pack removal
2. Mucosal wound healing.

MATERIALS AND METHODS

After approval from the Institutional Ethics Committee a prospective, randomized, double-blinded controlled clinical trial was undertaken at Hi-Tech Medical College and Hospital, Bhubaneswar, with a total of 50 patients, who underwent either one or more of the following types of nasal surgery at a single sitting, from June 2012 to May 2014.

1. Bilateral endoscopic intranasal ethmoidectomy
2. Submucosal resection of the nasal septum, septoplasty, endoscopic septoplasty
3. Surgery for granulomatous diseases of the nose
4. Bilateral turbinate reduction
5. Reduction of nasal bone fracture.

Each one of these patients were fully examined clinically and appropriately investigated. They were subjected to the following criteria for being eligible for consideration as a study case.

Inclusion Criteria

1. Patients undergoing any of the fore mentioned nasal surgery
2. Patients of both sexes were included in the study.

Exclusion Criteria

1. Patients age <18 years and >60 years
2. Patients with revision surgery
3. Patients with bleeding or coagulation disorders, active menstruation
4. Patients with systemic disorders like collagen diseases, diabetes mellitus where poor healing is expected
5. Patients lost to follow-up.

Patients were randomly divided into two groups (Group A and Group B). All cases were operated by a single surgeon, under general or local anesthesia, as deemed necessary for the case. After the required procedure, post-operative packing was done with 8 cm long Merocel in both nasal cavities in Group A, while MGP was used in Group B. Packing was removed after 48 h, and the patients were discharged after an observation period of 6 h. Packing and pack removal was performed by one researcher while the complications and mucosal effects were graded by another researcher. Bleeding associated with pack removal was graded and managed as summarized in Table 1.

Postoperatively, all patients were reviewed using 0° nasal endoscope at 1st and 4th post-operative weeks. Mucosal effects of packing material used were observed and graded as per grades depicted in Table 2.

Study Variables

Pain, bleeding, crusting, synechia, granulations.

RESULTS

Of 50 patients who underwent the nasal surgeries with subsequent nasal packing, 28 were males and 22 were females. The age range of patients was 19-57 years. All patients were reviewed at 1st and 4th post-operative weeks following discharge, without any follow-up loss. Bleeding at the bleeding at the time of pack removal was managed as per grade. Grade 1 controlled with observation alone. Grade 2 was controlled with suction and xylometazoline nasal drops.

Observations regarding the bleeding at the time of pack removal and mucosal findings at the end of 4th post-operative week have been tabulated in Tables 3 and 4, respectively. By applying Chi-square test there is a statistical

Table 1: Grading scale for bleeding during pack removal

Grade	Bleeding
0	No bleeding
1	Minimal (controlled with xylometazoline drops)
2	Moderate (bleeding outside nasal cavity)
3	Severe (requires repacking)

Table 2: Grading scale of mucosal findings at the end of 4 weeks

Grade	Granulation	Synechia	Crusting
0	No granulations	No adhesion	No crusting
1	Minimal	Mild (easy separation)	Minimal
2	Moderate	Moderate (difficult separation)	Moderate (crusts removed with saline)
3	Severe	Severe (needs division)	Severe (bleeding upon crusts removal)

evidence of significant association of complications (bleeding, granulation, synechia, crusting) with MGP ($P < 0.01$) than with Merocel. Furthermore, by applying *Z*-test of difference between two proportions there is highly significant difference between proportions of bleeding, granulation, synechia, and crusting when MGP compared with Merocel group as per grading scale 0, 1, 2, and 3, respectively ($P < 0.01$).

For pain management, all patients were put on twice daily doses of 50 mg diclofenac sodium tablets on the first 2 days and then on SOS basis thereafter. Pain assessment was done by calculating the number of tablets consumed in the first post-operative week. For both the groups, the number of tablets consumed was averaged from the actual data for the ease of study. Results depicted in Table 5, suggest that postoperative pain was reduced to almost 50% with the use of Merocel.

DISCUSSION

MGP is a promising option because of its low cost, feasibility, and its ability to completely fill the nasal cavity. In spite of all these merits, MGP is not well-tolerated because of the severe pain that the patient has to undergo during pack removal and also due to the bleeding caused by the oozing from the mucosal injury produced by the rough texture of MGP.

Therefore, a prospective, randomized, controlled study using merocel as a packing material after nasal surgery was designed. Till date, various studies have been conducted to study the effect of packing material on wound healing utilizing various parameters. Serial mucosal biopsies for light and electron microscopic evaluations were done in a sheep model of sinusitis by McIntosh *et al.*[11] They studied wound healing process in terms of the degree of mucosal re-epithelialization, percentage of the area covered by cilia, height of the epithelium and the maturity of the cilia. However, since a human trial utilizing several biopsies was not feasible, they selected synechia formation, mucosal edema, and infection as the parameters for analyses.[12] Formation of granulation tissue and synechiae in the middle meatus has been described as the parameters to assess healing by various researchers.[13-15] We gave emphasis to both the mucosal findings (objective) like bleeding, synechia, granulation, and crusting as well as the subjective complaint of pain. Various authors have advocated that synechia are most frequently seen in 2nd post-operative week.[10] It has also been reported that by 4th week most of the crust formation ceases with rare postoperative bleeding consequently.[4] Therefore, we chose to have a strict follow-up of all patients till 4th post-operative week and took it as an end point for the study.

Our results show that 16% patients in MGP group required repacking at the time of pack removal due to nasal bleeding, while only 4% in Merocel group. During pack removal, 32% patients of MGP group showed grade 1 bleeding and 44% patients showed Grade 2 bleeding respectively, while 72% patients of Merocel group showed Grade 0 bleeding. In a retrospective analysis of Merocel usage conducted by Pomerantz and Dutton, none of the patients showed post-operative bleeding that required packing.[16]

Prevention of septal hematoma is another aim with nasal packing. In our study, no septal hematoma was seen in either of the study groups. This implies that the pressure exerted by the Merocel pack is adequate enough to prevent septal hematoma and its sequel. Mucosal status assessed with endoscope in follow-up visits showed much less incidence of crusting, granulations and synechia in the Merocel group, thus proving its superiority. It was also

Table 3: Incidence and grading of bleeding during pack removal

Grade	Bleeding (%)	
	MGP	Merocel
0	2 (8)	18 (72)
2	11 (44)	2 (8)
3	4 (16)	1 (4)
	Value of χ^2=22.164, P<0.001, highly significant	

MGP: Medicated gauge packing

Table 4: Incidence and grading of mucosal findings at the end of 4 weeks

Grade	Granulation (%)		Synechia (%)		Crusting (%)	
	MGP	Merocel	MGP	Merocel	MGP	Merocel
0	5 (20)	22 (88)	4 (16)	19 (76)	6 (24)	15 (60)
1	5 (20)	2 (8)	10 (40)	3 (12)	9 (36)	6 (24)
2	8 (32)	1 (4)	8 (32)	2 (8)	6 (24)	3 (12)
3	7 (28)	0	3 (12)	1 (4)	4 (16)	1 (4)
	Value of χ^2=24.434, P<0.001, highly significant		Value of χ^2=18.152, P<0.001, highly significant		Value of χ^2=7.929, P<0.001, highly significant	

MGP: Medicated gauge packing

Table 5: Diclofenac sodium tablets (50 mg) consumed for pain management

Group A (MGP)	Group B (Merocel)
11 tablets	6 tablets

MGP: Medicated gauge packing

realized that Merocel prevents synechia formation and provides relief from occurrence of secondary hemorrhage and pain that occurs in association with division of synechia.[17]

The nasal packing associated post-operative pain is of much lower severity and duration with Merocel use than with MGP.[18] Merocel group reported significantly less pain during both pack *in-situ* and pack removal. Analgesic requirement was almost reduced to 50% in case of Merocel. This can be attributed to the smooth texture of Merocel and the much less time needed to remove the pack with minimal interference with the nasal mucosa. In contrast, during MGP removal, the possibility of bleeding from the mucosa is much higher as the rough ribbon gauge strikes against the raw epithelium and also disturbs the bloody crusts or clots, lying over the epithelium which leads to increased amounts of bleeding and pain.

CONCLUSION

Removal of nasal packing is painful and fearful to the patients. Merocel is easy to insert, handle, available in sterile packing and provides a superior outcome in terms of pain and satisfaction to both patients and surgeons by preventing the trauma of revision procedures. Thus, taking into consideration the hemostatic effects, ability to prevent post-operative synechia, better wound healing and markedly reduced post-operative pain, we recommend the routine use of Merocel as a nasal packing material following nasal surgery.

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Original Article

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Open and Laparoscopic Non-gynecological Abdominal Surgery during Pregnancy

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Abstract

Introduction: Non-obstetrics abdominal surgery during pregnancy is rarely indicated. During pregnancy, incidence of non-obstetric surgery varies from 1.5% to 2%. Laparoscopic or open surgery during pregnancy is controversial because data regarding procedure safety is limited.

Aim and Objective: The aim of our study was to demonstrate that during pregnancy a large variety of non-gynecological abdominal pathologies can be safely managed with surgery and in an emergency, open, and laparoscopic surgery can be performed safely during surgery.

Materials and Methods: The study was conducted at Department of Surgery, Major S.D. Singh Medical College and Hospital, Farrukhabad from January 10th, 2013 to January 10th, 2015. Eight patients medical records were reviewed who were pregnant, admitted and went under open and laparoscopic surgery.

Results: Seven out of Eight pregnant females have given birth at term. All babies were healthy with normal weights. Each laparoscopic surgery was performed safely without intra-operative or post-operative complications.

Conclusion: Laparoscopic abdominal surgery during pregnancy shows no risk to mother or child if done during an emergency.

Key words: Laparoscopy, Laparotomy, Pregnancy

INTRODUCTION

Abdominal surgery during pregnancy is rarely indicated. However, the infrequent occurrence of conditions requiring laparotomy in no way detracts from their importance. In pregnancy, diagnosis of acute abdomen and the surgical procedure required for the same provide a challenge to the surgeon and obstetricians. The diagnosis of an acute abdomen during pregnancy usually masked by the nausea, vomiting, abdominal distention, and hypertension that are also characteristic clinical symptoms of pregnancy.[1] Pregnancy-associated hyper-leukocytosis, modified abdominal landmarks and a diminished peritoneal response further complicates the diagnosis.

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In practice, surgery during pregnancy can be classified as[2,3]

1. Elective surgery: Can be postponed until 6 weeks after delivery
2. Urgent surgery: The cases that without risking the mother can be deferred until the second trimester
3. Emergent surgery: Those that cannot be delayed because they increase maternal morbidity and mortality, and should be performed during any trimester of pregnancy.

Basic medical training suggests that surgery under general anesthesia if performed during pregnancy increases the risk of abortions and pre-term labor. The incidence of non-obstetric surgery during pregnancy is between 1.5% and 2%[4,5] of which 42% of the cases occurred during the first trimester, 35% in the second trimester and 23% in the third trimester.[6] In general practice, surgery is postponed until after delivery, if possible; if not, then at least until after the first trimester. However, postponement is not always possible, especially when confronted with an acute abdomen, whether medical or traumatic. Risk of surgery

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during pregnancy is related to[4-6] - physiological changes during pregnancy, the possible adverse effects of anesthetic medication, gestational age, type, duration and location of the surgery, anesthetic technique and general condition of the patient. Anesthetic procedure independently of the method chosen must meet these objectives[2,4,5] - guarantee maternal and fetal safety, control teratogenicity, avoid intrauterine fetal asphyxia, and avoid preterm labor. Current American College of Obstetricians and Gynecologists recommendation suggests that each case requires a team approach (anesthesiologist, obstetricians, and surgeons) to guarantee optimum safety for the woman and her baby.[7-9]

The aim of our study was to demonstrate that in an emergency non-gynecological abdominal pathology, open and laparoscopic surgery can be performed safely during pregnancy.

MATERIALS AND METHODS

This study, open and laparoscopic non-gynecological abdominal surgery during pregnancy was conducted in the Department of Surgery and Obstetrics and Gynecology in Major S. D. Singh medical college and hospital in Farrukhabad, from January 10th, 2013 to January 10th, 2015. During this period, non-elective abdominal surgery was performed on eight patients who were pregnant. Eight surgical procedures were carried out for non-gynecological abdominal pathologies. Two abdominal surgeries were performed during the first trimester. Five abdominal surgeries were performed during the second trimester and one abdominal surgery was performed during the third trimester of pregnancy, respectively (Figures 1 and 2).

RESULTS

Table 1 gives details concerning age of the patient, gestational age, surgical indications, and outcomes. Five out of eight surgical procedures were performed laparoscopically without complications. The post-operative course of the remaining three laparotomies was uneventful. Seven out of the eight patients under the study delivered at term. A week later surgical procedure one patient had spontaneous termination of pregnancy. Reports in other literature documents two patients experienced premature contractions that were successfully treated with tocolytic medications. Five out of seven patients had unremarkable vaginal deliveries. Two patients underwent caesarean sections including one woman who had two previous cesarean deliveries. All the deliveries were successful and newborn babies were healthy with regular weights, sizes, and APGAR scores.

DISCUSSION

The Society of American Gastrointestinal and Endoscopic Surgeon (SAGES) has recently published guidelines for the diagnosis, treatment and the use of laparoscopy for surgical problems during pregnancy.[10] Laparoscopy has demonstrated to be safe surgical technique regarding maternal hemodynamics and fetal well-being as long as the necessary anesthetic modification are consider.[11-14] The fetal prognosis seems to be equally safe in laparoscopic surgery compared to the cases in which the open techniques are used. The same incidence of low birth weight and intrauterine growth retardation occurs.[14] Visser *et al.* concluded in the study, surgery during the first or second trimester was not associated with a significant increase in premature delivery rate, fetal loss, or teratogenicity. Visser *et al.*, also found that surgery during the third trimester increased the risk of preterm labour.[15] The most common indications for laparoscopy during pregnancy were appendicitis and cholecystitis. Conron *et al.* compared open

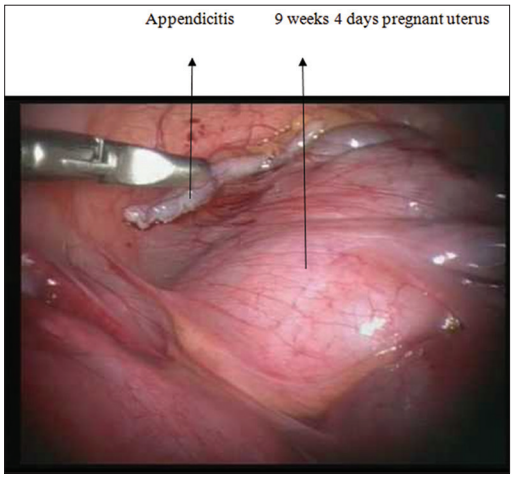

Figure 1: Laparoscopic appendicectomy in first trimester

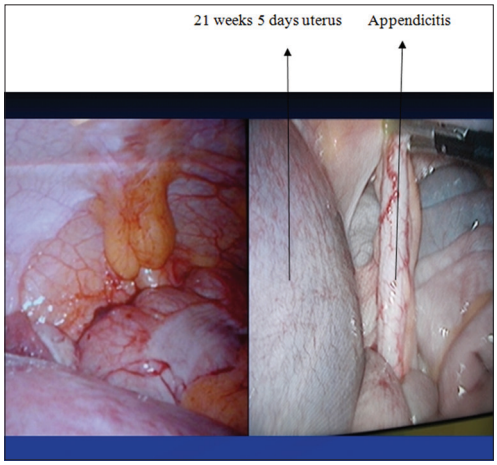

Figure 2: Laparoscopic appendicectomy in second trimester

Table 1: Surgical indications and results

Age (years)	Gestational age	Pathology	Treatment	Delivery	W/S/A
33	23 weeks 1 day	Acute cholecystitis	Laparoscopic cholecystectomy	LSCS at term	Normal
23	11 weeks 4 days	Strangulated umbilical hernia	Hernioplasty	NVD	Normal
24	31 weeks 2 days	Rupture liver abscess	Laparoscopic abdominal drainage	LSCS at term	Normal
32	21 weeks 5 days	Acute appendicitis	Laparoscopic appendicectomy	NVD	Normal
29	18 weeks 2 days	Small bowel intestinal obstruction	Open exploration and adhesiolysis	NVD	Normal
25	20 weeks 1 day	Acute cholecystitis	Laparoscopic cholecystectomy	NVD	Normal
34	17 weeks 5 days	Perforated appendicitis	Open appendicectomy	NVD	Normal
19	9 weeks 4 days	Acute appendicitis	Laparoscopic appendicectomy	Spontaneous abortion after 1 week of surgery	-

LSCS: Lower segment caesarean section, NVD: Normal vaginal delivery, W: Weight, S: Size, A: Apgar score

and laparoscopic in these cases and showed that laparoscopy resulted in a short hospital stay and a reduction in the use of parenteral analgesics.[16] Affleck *et al.* reported a retrospective study that compared open surgery with laparoscopic procedures for appendicectomy and cholecystectomy: They concluded no significant differences in term of rate of premature deliveries, infant birth weights or APGAR scores.[17] Compare to open surgery, laparoscopy requires less handling of the uterus and thus induces premature labor less frequently.[17] Acute appendicitis occurs with equal frequency in pregnant women and in the general population. The rate of appendicectomy during pregnancy is 1 out of 500-2000 pregnancies.[15] When appendicectomy is performed before any signs of the appendicular perforation, it poses a risk to the further evolution of pregnancy. In surgically treated, uncomplicated appendicitis, the rate of fetal loss is 1.5% that, however, reaches 35% in cases of ruptured appendicitis.[16] Therefore, appendicectomy should be performed, either by laparotomy or laparoscopy whenever acute appendicitis is diagnosed. Other common pathology during pregnancy is symptomatic cholelithiasis, which may be induced by pregnancy itself. 2-4% of the women that are pregnant were found to have asymptomatic gallstones.[17] In 1-8 out of 10,000 pregnancies, a laparoscopic cholecystectomy is required, with an associated 5% risk of fetal loss that may increase to 60% with concomitant pancreatitis.[16] Muench *et al.* recommended laparoscopic cholecystectomy in women who are pregnant and also have symptomatic biliary disease.[18] They reported that 70% of the patients developed recurrent symptoms and 30-40% need a cholecystectomy before delivery. Muench *et al.* concluded that the average operating time, the technical aspects of the procedure, and the intra-operative difficulties are the same in patients that are pregnant and those that are not pregnant. These findings were also confirmed by other authors.[19]

CONCLUSION

Surgical treatment is delayed, as diagnosis of non-obstetrical abdominal pathologies is low in pregnancy, which leads to increased fetal and maternal morbidity and mortality. Abdominal surgery during pregnancy is a relatively safe procedure, provided that we follow long established and proven principals of good surgery. These include early diagnosis and treatment, a multidisciplinary assessment and approach, avoidance of unnecessary trauma, strict asepsis, and hemostasis. If we adhere to these principles, we shall note a gratifying decrease in both maternal and fetal mortality and morbidity.

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Original Article

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Comparative Assessment of Reduction in Discomfort by Topical Anesthetic Gels before Local Anesthetic Injections in Children: An *in-vivo* Study

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Abstract

Background: Pediatric dentists always feel the need of topical anesthetics that would make the local anesthetics administration painless for children. At present number of agents are being marketed each claiming better results. Supporting literature regarding their efficacy is lacking.

Aim: The aim was to compare efficacy of 20% benzocaine and combination of 8% lidocaine + 0.8% dibucaine as flavored topical anesthetic agents in reducing discomfort by intraoral local anesthetic injections and extraction of deciduous teeth with pre shedding mobility.

Methodology: Study included 30 children who were grouped under three treatment categories - Palatal injection, inferior alveolar nerve block, and extraction of pre-shedding mobile deciduous teeth. Both the products were tested for each treatment category using split-mouth design in two appointments. Pain assessment was done under visual analog scale and sound eye motor pain scale. Statistical analysis of data obtained was done using Mann–Whitney *U*-test.

Results: 8% lidocaine + 0.8% dibucaine provides significantly better anesthesia ($P < 0.5$) before palatal injection and inferior alveolar nerve block. No significant difference ($P > 0.5$) was found in anesthesia while extracting mobile primary teeth. No significant difference ($P > 0.5$) on gender wise comparison or appointment wise comparison was seen.

Conclusion: 8% lidocaine + 0.8% dibucaine can be used when anesthesia is required for deeper tissue, when better penetration is required as in inferior alveolar nerve block and palatal injection.

Key words: Benzocaine, Dibucaine, Lidocaine, Sound eye motor, Topical anesthetic, Visual analog scale

INTRODUCTION

Children's most common fear to dentistry is associated with thought of local anesthetic injection. It is well recognized that avoidance of routine dental care by some patients specially children occurs because of the negative thoughts associated with local anesthetic injections given during treatment.[1] Pediatric dentists try to minimize this discomfort by the application of topical anesthesia.[2] On prior application of topical anesthesia, pain associated with needle insertion can be minimized, however, it cannot be completely eliminated.[3] These anesthetic agents are also known to provide a placebo effect along with their pharmacological action.

A number of agents with different formulations have been tried to gain anesthetic effects.[4] Factors that influence the efficacy of topical anesthetics depend on the composition as well as concentration of the each component.[5] Time of onset of action and its penetrability will also determine its effectiveness. Benzocaine 20% gel is one of the commonly used topical anesthetic preparations. Its onset of action is 30 s; taste is acceptable to patient and is not absorbed systemically.[6] Another less frequently used agent is lidocaine

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5% ointment. It has a slower onset of action (2-5 min), disagreeable taste, and its systemic absorption due to its water solubility may result in greater complications. To mask the less acceptable taste of topical anesthetics, many flavored formulations have been introduced. One such preparation is precaine which contains lidocaine and dibucaine in combination. There is vast literature on use of dibucaine in medical field to relieve pain and irritation caused by cuts, minor burns, scratches, insect bites, stings and hemorrhoids, sunburn, or other minor skin irritation problems.[7] Dibucaine has also been tried in dental field to obtain relief from pain of oral ulcers.

A topical anesthetic agent that fulfills the requirement of both faster onset of action, as well as prolonged action needed to eliminate post-operative pain has to be introduced. Thus, the purpose of this study is to compare two flavored topical anesthetic agents, 20% of benzocaine available under trade name, precaine B with combination topical anesthetic agent, 8% lidocaine + 0.8% dibucaine available under trade name, precaine in reducing discomfort of intraoral procedures like palatal injections, inferior alveolar nerve block and extraction of primary teeth with pre-shedding mobility in two different appointments.

METHODOLOGY

The study enrolled 30 patients with the gender distribution, males 14 (47%) and females 16 (53%). Children enrolled were between 4 and 12 years of age, visiting outpatient Department of Pediatric and Preventive Dentistry. Institutional ethical clearance was obtained. Signed written informed consent from parents or guardians of all children was obtained.

Inclusion Criteria

1. Cooperative behavior
2. Mental capability of completing visual analog scale (VAS)
3. Non-contributory medical history
4. Requirement of bilateral palatal injections, bilateral inferior alveolar nerve block or bilateral extraction of deciduous teeth with pre-shedding mobility.

Exclusion Criteria

Any systemic or mental illness.

Selected children were included under one of the three treatment categories:

Treatment category 1: Children requiring palatal injections.

Treatment category 2: Children requiring inferior alveolar nerve block.

Treatment category 3: Children requiring extraction of primary teeth with pre-shedding mobility.

The child, operator, and assistant, all were blinded of the type of topical anesthetic product being used. A single operator performed all the procedures throughout the study. A well-trained assistant recorded pain response through sound eye motor scale (SEM scale – Table 1). Details of the procedure were explained to children before their inclusion in the study according to their age and understanding capacity, and they were explained about the (VAS - Figure 1). The children in each of the treatment category were tested for both the strawberry flavored topical anesthetic products, product A, (precaine - combination of 8% of lidocaine and 0.8% of dibucaine), and product B (precaine B - 20% of benzocaine). Split mouth design was used to test the products. For split-mouth design children requiring bilateral treatment were selected. In the first appointment, in half of selected children product A was applied and the other half product B was applied in the subsequent appointment, children who received product A in the first appointment received product B before treatment on contra-lateral side and vice versa.

Procedure comprised of drying of mucosa, after which 0.5 ml of strawberry flavored topical anesthetic gel was applied with the help of cotton applicator tip on the requisite site. For ½ min, gel was rubbed using moderate pressure for its better penetration. Excess of agent was cleaned with gauze. Local anesthetic was administered 1 min after anesthetic gel application in the first two treatment categories. In treatment category three, 1 min after topical anesthetic gel application extraction was carried out without administration of local anesthetic injection.

Pain assessment was done both by a subjective scale (VAS) and an objective scale (SEM). Child was asked to mark his pain experience on VAS scale as explained before. For the first two treatment categories, child's response was documented just after the injection prick while for treatment category three, documentation was done soon after tooth extraction. To measure pain response through SEM scale, an assistant was trained for recording of values of responses as observed. The operator oversaw values that were entered by assistant. VAS is a five-point scale where

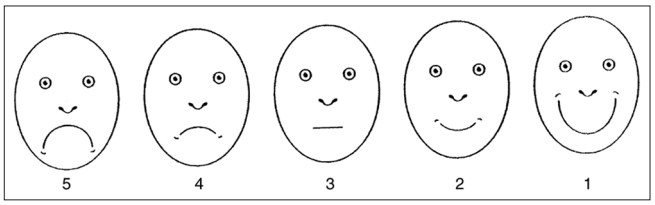


Figure 1: Visual analog scale

responses range from 1 to 5 (Figure 1). For SEM scale, values range from 1 to 4 (Table 1). Higher values signify greater pain response for both the scales.

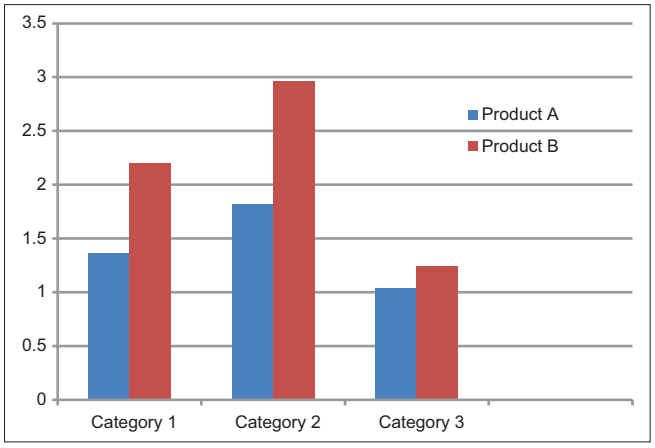
RESULTS

The obtained scores from both the pain scales, VAS and SEM of all thirty children were recorded in an Excel spreadsheet and statistical analysis was carried out using SPSS version 13.0. Mann–Whitney test was used to compare products, visit wise comparison between products, as well as gender wise comparison of pain responses.

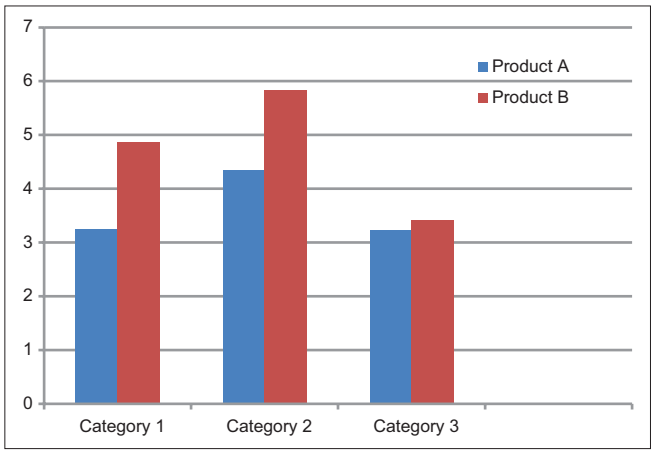
Table 2 depicts product comparison under VAS (Graph 1) and SEM (Graph 2) pain scales in three techniques. Significantly lower mean scores ($P < 0.05$) were obtained for 8% lidocaine + 0.8% dibucaine (product A) under both VAS (1.36 ± 0.2) and SEM scales (3.24 ± 0.9) for palatal injections. For inferior alveolar nerve block significantly lower mean scores ($P < 0.05$) were recorded for precaine (product A) under VAS scale (1.82 ± 0.6) and SEM scale 4.34 ± 0.9). Mean scores recorded for extraction procedure were lower under VAS pain scale (1.04 ± 0.2) as well as SEM pain scale (3.22 ± 0.3), but the difference obtained was not statistically significant ($P > 0.05$).

Table 3 shows scores of gender wise comparison between two test products under VAS and SEM pain scales. For 8% lidocaine + 0.8% dibucaine (product A) boys showed lower mean scores as compared to 20% benzocaine (product B) under VAS as well as SEM pain scale. However, difference was statistically insignificant. Both males and females showed lower mean scores for 8% lidocaine + 0.8% dibucaine (product A) as compared to 20% benzocaine; however, the difference was not statistically significant.

Table 4 shows appointment wise comparison of both test products under three treatment categories using VAS pain scale and SEM pain scale. In the second appointment



Graph 1: Comparison of two products under three techniques using visual analog scale



Graph 2: Comparison of two products under three techniques using sound eye motor scale

Table 1: Sounds, eyes, motor scale

Parameter	Comfort	Mild discomfort	Moderate discomfort	Severe discomfort
Grade	1	2	3	4
Sounds	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint shouting, crying
Eyes	No sign	Dilated eye without tear (anxiety sign)	Tears, sudden eye movements	Crying, tears all over the face
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defense, turning the head to the opposite side

Table 2: Comparison of two products under three treatment categories using VAS and SEM pain scale scores

Treatment category	Number of children	Mean±SD			
		VAS		SEM	
		Product A	Product B	Product A	Product B
1	10	1.36±0.2	2.2±0.6	3.24±0.9	4.86±0.9
2	10	1.82±0.6	2.96±0.7	4.34±0.9	5.84±0.7
3	10	1.04±0.2	1.24±0.2	3.22±0.3	3.42±0.3

VAS: Visual analog scale, SEM: Sound eye motor, SD: Standard deviation

precaine, as well as precaine, B showed lower values for all the three treatment categories. This was seen for both the subjective (VAS) as well as objective (SEM) pain scales. However, for any of the techniques, difference was not statistically significant ($P > 0.05$).

DISCUSSION

Topical anesthetics are commonly being used in pediatric dentistry to decrease pain associated with anesthetic injections and to allow completion of dental procedure without pain. For better acceptance of these topical anesthetics, flavored preparations are available. Recently released newer flavored topical anesthetic gels claim superior efficacy in providing anesthesia and faster onset of action. Local anesthetics can broadly be classified into esters and amides. Benzocaine is an ester anesthetic. Esters are more likely to produce allergic reactions. Lidocaine and dibucaine contain an amide linkage. Precaine anesthetic gel aims to combine beneficial properties of lidocaine and dibucaine. Lidocaine gives it the property of quicker onset while dibucaine prolongs its duration of action. Yamamura *et al.* used mucosal adhesive film containing dibucaine to decrease pain of oral ulcer. They reported pain relief lasting for 2-5 h after its application.[8] In contrast; benzocaine absorption is slow due to its poor solubility in an aqueous medium. Therefore, the objective of this study was to test the efficiency of a combination of topical anesthetic gel containing 8% lidocaine and 0.8% dibucaine compared to commonly used anesthetic gel i.e., 20% benzocaine.

Apart from their pharmacological actions, the psychological benefit of topical anesthetics has been reported. Keller found no differences between topical anesthetics and placebo in reducing injection pain.[9] Furthermore, the pre-procedural information given about action of topical anesthetics have been reported to decrease the pain response.[10] Benefits of topical anesthetics were explained to children according to their level of understanding before gel application.

In the present study, gel application was done after drying of site of application with rubbing the motion for ½ min. For better penetration, it was left over the mucosa for another ½ min after which it was swiped off. To gain benefits of topical anesthetics in relieving anesthetic injection pain at least 1 min application time has generally been recommended.[11]

Reported and observed pain was measured using a subjective scale VAS pain scale and objective scale SEM pain scale. VAS pain scale is most commonly used scale for the subjective measurement of pain and has been shown to give reliable and valid results among children. Assistant was trained to record SEM pain scale according to the observation, which was also crosschecked by the operator for correct recording.

Deepika *et al.* compared 20% benzocaine and 8% lidocaine + 0.8% dibucaine combination. She reported lower mean scores for lidocaine - dibucaine combination but the difference was not found to be significant for palatal as well as inferior alveolar block injections.[7] The result of present study was in contrast with this finding, where significantly lower pain scores were seen after application of lidocaine and dibucaine combination gel. No difference between 20% benzocaine, 5% lidocaine and placebo has been reported during palatal injections by Giddon *et al.*[12] Better results shown by lidocaine and dibucaine combination could be related to the dibucaine component of the gel which has better penetration ability and longer duration of action. No significant difference between both the products was seen in the present study during extraction of deciduous teeth with pre-shedding mobility. Similar results were reported by Deepika *et al.*, who reported better results by lidocaine and dibucaine gel

Table 3: Gender wise comparisons between two test products using VAS and SEM scores

Variable	Gender	Mean±SD	
		Product A	Product B
VAS	Males	1.96±0.6	2.18±0.8
	Females	2.09±0.5	2.12±0.6
SEM	Males	4.38±0.9	4.48±0.8
	Females	4.5±0.9	4.74±0.8

VAS: Visual analog scale, SEM: Sound eye motor, SD: Standard deviation

Table 4: Visit wise comparison of two test products under three techniques using VAS and SEM pain scale scores

Treatment category	Product	VAS		SEM	
		Appointment 1	Appointment 2	Appointment 1	Appointment 2
1	Product A	1.36±0.3	1.13±0.4	3.8±0.5	3.6±0.5
	Product B	2.04±0.4	1.96±0.5	5.04±0.9	4.86±0.9
2	Product A	1.68±0.5	1.36±0.6	4.4±0.6	4.18±0.5
	Product B	2.39±0.7	2.02±0.4	5.6±0.7	5.34±0.9
3	Product A	1.04±0.6	0.92±0.7	3.43±0.9	3.33±0.7
	Product B	1.28±0.6	1.26±0.5	3.60±0.9	3.49±0.8

VAS: Visual analog scale, SEM: Sound eye motor

for extraction of Grade III mobile primary teeth but the difference was not statistically significant.[7] Hence, both products were supposed to give similar results when limited penetration was needed.

Girls are generally seen to be more anxious as compared to boys in dental practice. The reason given for this is their inherent timidity. Boys are more encouraged not to express their feelings by society. However, in our study no statistically significant gender wise difference was seen for both the products. This was in accordance to a study conducted by Ram and Peretz, who reported no significant difference in children's reaction to pain during intraoral injection according to their gender.[11] In contrary, Peretz and Efrat have reported significantly lower pain scores in boys than in girls as seen in dental practice.[13] The possible explanation can be that the pre-procedural information and behavior medication technique for anxiety reduction carried out during the procedure could have reduced the anxiety difference between boys and girls.

Martin *et al.* found that the order of injection could influence patient's pain. He reported the second injection given on contralateral side in the same appointment immediately after first was perceived as more painful.[14] However, according to Bågesund and Tabrizi good pain control in the first appointment could decrease patient's anxiety in the second appointment.[15] In our study, no significant difference was seen in pain reduction between the two appointments. In contrast, Deepika *et al.* reported significant lower mean scores of pain in visit 2 under SEM pain scale in inferior alveolar nerve block, and extraction of mobile teeth when 20% benzocaine was used as topical anesthetic.[7] The difference could be attributed to the different levels of pain threshold among the participants.

Our study indicates that the combination of 8% lidocaine + 0.8% dibucaine topical anesthetic gel can be used effectively to reduce pain of injection. This combination has the advantage of better penetration, longer duration of action, and lower allergic reactions.

CONCLUSION

About 8% lidocaine and 0.8% dibucaine in combination can be suggested as better pain reducing anesthetic gels compared to 20% benzocaine gel when deeper anesthetic actions and longer duration of anesthesia to reduce post-operative pain are required as in inferior alveolar nerve block or palatal injections. For the extraction of mobile deciduous teeth, both the anesthetic gels are effective in pain reduction. However, due to few documented cases of allergic reactions to an ester group of anesthetic, amide group of anesthetics such as lidocaine and dibucaine are more preferable.

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Original Article

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Human Development Index of Indian States and Related Dentition Status among 5-year-old Children

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Abstract

Introduction: For a holistic approach to health oral health status is the key determinant. Any observation on health status of community or nation thus needs to include the oral health status as one of the parameters.

Aim: The present study aimed to point through reflections the miss of oral health from national indicators on health.

Materials and Methods: The paper has put forth studies from the local areas and from the national level on oral health of 5 years and compared with human development index (HDI) score/rank.

Results: HDI ranking of states and oral health status of children do not commensurate. The medium HDI states report higher dental caries prevalence (with the exception of Punjab) as compared to states with low and high HDI score. A similar pattern is noted for the decayed, missing, filled, teeth scores among children from different state studies, as well as the report from National Oral Survey.

Conclusion: Children are a priority because improvements in child oral health and prevention will reduce the overall burden of disease. It is central to include oral health index along with other health parameters when measuring national health and development index.

Key words: Dentition, DMF Index, Holistic health, Human development index, Prevalence

INTRODUCTION

Well-recognized predisposing factors to oral health status are the socio-economic status, education, and nutrition. A good oral health foundation in childhood is a key determinant of oral health throughout life. Children are a priority because improvements in child oral health and prevention will reduce the overall burden of disease and improve long–term oral health across the population.[1-4] Oral health has a significant functional impact on many other aspects of health, and can have long-term consequences for a person's appearance and hence their self-esteem - which is particularly important for children. Dental decay in early childhood is a significant predictor of long-term dental health problems.[5-7]

The critical parameter for an Indian state to be recognized as relatively more developed is through the score in the human development index (HDI). The HDI is a statistical tool used to measure a country's overall achievement in its social and economic dimensions. The social and economic dimensions of a country are based on the health of people, their level of education attainment and their standard of living.[7,8]

As oral health is fundamental to general health; consequently, the HDI of the Indian state should signify the oral health status of children.

Aim of the Study

1. To evaluate the oral health and primary dentition status of children (5-7) years of Indian states with high medium and low HDI

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2. To locate the present study on oral health status of 5 years in Jaipur city within the context of selected states (as above).

MATERIALS AND METHODS

Indian states with high medium and low HDI states were selected from the list given by GOI 2007-2008 (Appendix 1 and 2).[8,9]

Studies on oral health status among 5-7 years children of the selected states were reviewed.

Exclusion

Studies on oral health of children (5-7) years with special needs or belonging to special locales like orphanage, tribal belt, and rural areas were not included in the review as the special needs are not recognized well before this age.

Inclusion

Studies on oral health of children (5-7) years of HDI states were included.

HDI of a state in India is an aggregate numerical value, representing the overall education, health, and income levels of a state.

States were selected from the list of HDI (2011) with differing HDI numerical value each representing a numerical group. Though the available state studies on oral health of children are conducted on a small homogenous sample it is a representative of the area.

Given the above understanding, evaluating the oral health status of 5-7 years old children from different HDI level states of India was seen meaningful to evolve a landscape of the childhood oral health status.

A study was conducted in the walled city of Jaipur on 5 years old a sample of 230 with WHO Oral Health Survey form 2013 to assess the oral health status.

RESULTS

The medium HDI states report higher dental caries prevalence (with the exception of Punjab) as compared to states with low and high HDI score. The range of dental caries prevalence is from 65% to +81% for medium ranked HDI states while for high and low HDI states the range varies of dental caries prevalence is between 29.4% and 57%. The national prevalence is at 50% for the age group of 5 years old (Table 1).

The same pattern is noted for the decayed, missing, filled, teeth (DMFT) scores. Children (5 years) from states ranked with medium HDI have low to high DMFT scores range:

Appendix 1

State	HDI 1999-2000	HDI 2007-2008	Rank 1999-2000	Rank 2007-2008
Kerala	0.677	0.790	2	1
Delhi	0.783	0.750	1	2
Himachal Pradesh	0.581	0.652	4	3
Goa	0.595	0.617	3	4
Punjab	0.543	0.605	5	5
NE (excluding Assam)	0.473	0.573	9	6
Maharashtra	0.501	0.572	6	7
Tamil Nadu	0.480	0.570	8	8
Haryana	0.501	0.552	7	9
Jammu and Kashmir	0.465	0.529	11	10
Gujarat	0.466	0.527	10	11
Karnataka	0.432	0.519	12	12
West Bengal	0.422	0.492	13	13
Uttarakhand	0.339	0.490	16	14
Andhra Pradesh	0.368	0.473	15	15
Assam	0.336	0.444	17	16
Rajasthan	0.387	0.434	14	17
Uttar Pradesh	0.316	0.380	18	18
Jharkhand	0.268	0.376	23	19
Madhya Pradesh	0.285	0.375	20	20
Bihar	0.292	0.367	22	22
Orissa	0.275	0.362	22	22
Chhattisgarh	0.278	0.358	21	23
All India	0.387	0.467		

Appendix 2

Rank	State/Union territory	Consumption based HDI (2007-08)
High HDI		
1	Kerala	0.940
2	Delhi	0.750
Medium HDI		
3	Himachal Pradesh	0.652
4	Goa	0.617
5	Punjab	0.605
6	North eastern India (excluding Assam)	0.573
7	Maharashtra	0.572
8	Tamil Nadu	0.736
9	Haryana	0.552
10	Jammu and Kashmir	0.529
11	Gujarat	0.527
12	Karnataka	0.519
Low HDI		
13	West Bengal	0.492
14	Uttarakhand	0.490
15	Andhra Pradesh	0.473
16	Assam	0.444
17	Rajasthan	0.434
18	Uttar Pradesh	0.380
19	Jharkhand	0.376
20	Madhya Pradesh	0.375
21	Bihar	0.367
22	Odisha	0.362
23	Chhattisgarh	0.358

HDI: Human development index

Table 1: Dental caries prevalence across states with high, medium and low HDI

State	HDI score/ rank	Dental caries %	Study: DMFT or DEFT score/interpretation	State: DMFT or deft score/interpretation
Kerala	0.940/High		2.16/Low	3.3/Moderate
Varkala[10]		67.5		
Kannur[11]		40.06		
Tamil Nadu	0.736/Medium			2.4/Low
Chidambaram (Rural)[12]		71.7	3.00/Moderate	
Chidambaram (Urban)[13]		65.73	2.56/Low	
Vellore (Rural)[2]		64.5	2.38/Low	
Chennai[3]		83	3.51±2.96/Moderate	
Punjab[14]	0.605/medium	48.30		2.4/Low
Maharashtra[15]	0.572/medium	78.50		1.9/Low
Karnataka	0.519/medium			2.4/Moderate
Puttur[16]		81.25,	4.8/High,	
Bangalore[4]		40.5	1.81±0.1/Low	
Andhra Pradesh	0.473/Low			
Guntur (urban/rural)[17]		32.25, 34	0.71/0.95/Very low	1.5/Low
Rajasthan	0.434/low			0.7/Very low
Udaipur (Rural) 2009[18]		51.53	2.60±2.05/Low	
Udaipur (Urban)[19]		56.8	1.60±2.05/Low	
Walled city of Jaipur[20]		73	1.04/Very low	
Odisha	0.362/Low	57.9	2.59/Low	2.6/Low
Cuttackurban[21]				
All India[22]	0.554	50	Low to moderate	

HDI score and related rank (2007-2008): Very high/high: 0.8-0.89, medium: 0.5-0.79, <0.2-0.49 DMFT score and related status of oral health: Very low: <1.2, low: 1.2-2.6, moderate: 2.7-4.4, high: 4.5-6.6, very high: >6.5. HDI: Human development index, DMFT: Decayed, missing, filled, teeth

2.38-4.86, while states ranked low in HDI have very low to low DMFT score, range: 0.71-2.60 (Table 1).

The pattern is noted to be same when the state wise DMFT scores are observed in different levels of states HDI. Rajasthan and Odisha with low HDI rank have better oral health status as compared to Kerala with high HDI score. Rajasthan and Odisha present similar or better oral health status among 5 years olds than states with medium HDI score. The states with a medium score of HDI present low to moderate oral health status of children (Table 1).

The survey of children of Jaipur walled city noted 71.3% children with decayed, missing teeth with mean DMFT score of 1.43.

DISCUSSION

Dental caries prevalence is relatively high in medium HDI states as compared to states with low and high HDI. The dental caries prevalence in low and high HDI states is about comparable to the all India average prevalence of dental caries.

These are rather disarray as well as disarming results which forces to hold certain conjectures, as stated below:

1. HDI score is an aggregate of education (literacy levels and primary school enrolments), general health (longevity and/or infant mortality rate [IMR]) and income for a district, state, or country as a whole. It is a comparative measure; compared with the best and worst performers on a scale of 0 to 1. In contrast, the studies are generally conducted on low-income groups of individual patients and not aggregates, and mostly in cities. There is no a priori reason for the dental health status of individuals in these samples should match with the aggregate numbers that the HDI throws up. However, noting the similar results at the state level this observation is a pointer towards the need to develop a health index that is more sensitive to other health parameters that just the longevity or IMR[6,7]
2. The dental health status of individuals much also depends upon the food habits, oral and other hygiene habits and the environmental conditions, each of which need not be related to the aggregate indicators that the HDI is composed of[10,13,17]
3. The HDI aggregates all individuals: rich and poor, rural and urban, all ages, both sexes, and so on. The individual studies in contrast are specific to each of these in most cases. Thus, if a much larger number of small studies spanning different socioeconomic groups would show a better association with the HDI. A limited pointer is seen from the fact that Punjab, a medium HDI state, has lower dental caries prevalence when compared to its other counterpart low HDI states. It is a small state with homogenous community. Thus, HDI and oral health scores complement each other. While states like Maharashtra, Karnataka, Andhra Pradesh, are large and heterogeneous the

HDI and oral health status of a small sample are not in harmony.[23-26]

The study of Jaipur shows a low DMFT score with a high component of decayed/carious teeth. The low socio-economic profile of the surveyed community was the probable reason for high decayed score which is noted in a study in the city of Chidambaram[13] and Chennai[3] study. The DMFT score of 5 years old is similar to national average.[22]

Given similar pattern at the state levels it leaves a thought, to address HDI with additional health parameters like oral health status which largely influences overall health.

CONCLUSION

The paper reflects on the disparities in the dentition status among 5-year-old children across states of India with varying HDI ranking. A need to include the oral health status in the health component of HDI is important to give an overall health status of the individual. Its major arguments are that: One, aggregate measures like HDI should not be compared with micro level specific observations unless the contrast is really stark; and two, there is need to develop indices sensitive to other health parameters and not just longevity.

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Original Article

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Assessment of Perceptions about Sedation in Dentistry among General Dental Practitioners, Dental Students and General Public - A Descriptive Cross-Sectional Study

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Abstract

Introduction: The use of sedation in dentistry is a controversial topic with varying views about it among the people who are potentially related to it. Among the various other unanswered questions, it is clearly necessary to find out what dental practitioners, dental students, and the general public think about the use of sedation in routine dental practice.

Aim: The aim was to assess the perceptions of dentists, dental students, and the general public concerning sedation in the dental office.

Methodology: Three categories of participants were selected to participate in the study. Questionnaires regarding sedation in dentistry were distributed amongst 30 dental practitioners, 30 dental students, and 30 lay people. The questions were broadly classified into three categories: Knowledge about sedation, in favor of the use of sedation by dentists, and sedation risks. The data were then tabulated, and response frequencies were converted to percentages to obtain the results.

Results: A total of 27 dentists and dental students claimed to have knowledge about sedation. Among 30 general public interviewers, 11 said they knew about sedation, whereas 19 claimed they didn't have any knowledge. Among 30 dental practitioners, 21 (70%) favored the use of sedatives by dentist, and 23 (77%) students favored the use of sedatives by dentists. When asked if sedation presents risk, 7 (23%) of the dental practitioners thought it did, while 13 (43%) of the students, and 23 (90%) of the general public said it did.

Conclusion: The study showed that level of knowledge about sedation was high for dentists and the dental students when compared to the general public. For the dentists, however, this knowledge was mostly theoretical. Dental practitioners and dental students both agreed about the limited coverage of this subject in their dental colleges and asserted on including this topic in their curriculum.

Key words: Dentists, Dental students, General public, Sedation

INTRODUCTION

In children, the existence of dental fear and anxiety are very well known. Many basic behavior guidance techniques have been employed for managing dental fear and anxiety. Children can be given a sense of control over proceedings by making them hold a mouth mirror or a toy. The dentist's first meeting can be a casual one and a little "social" time with the fearful child before treatment can be of a lot of help.[1] American Academy of Pediatric Dentistry has given a list of behavior guidance techniques, which include distraction, physical restraint etc.[2] However, when basic behavior guidance techniques fail, advanced techniques have to be employed, for example, nitrous oxide/oxygen inhalation sedation.[3-5]

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Sedation in dental patients has always been a controversial topic because it involves the intersection of dentistry and medicine.[6] There also is a debate regarding the type of the pharmacological approach used to modify patient behavior. Leaving aside nitrous oxide and some oral benzodiazepines, other forms of sedation are rarely used.

Among the various other unanswered questions, it is clearly necessary to find out what dental practitioners, dental students, and the general public think about the use of sedation in routine dental practice. This is important based on the fact that in a culture like ours there is a certain mystique regarding human anesthesiology. There are only a few studies published regarding this aspect worldwide. In India, there are no studies reported regarding this subject.

Therefore, the aim of this study was to assess the perceptions of dentists, dental students, and the general public concerning sedation in the dental office.

METHODOLOGY

After getting approval from Institutional Ethical Committee Board, the following participants were invited to participate in the study (convenience sampling): 30 dental surgeons in general practice from clinics in South Bengaluru, 30 dental students, aged above 18, from among undergraduate students from V S Dental College and Hospital, Bengaluru, and 30 people from general public, aged above 18, literate, contacted in waiting areas of out-patient department in Kempegowda Institute of Medical Sciences.

Signed written informed consent was obtained from each participant and the study was explained to all of them. Following this, each participant received a questionnaire depending on his/her category: Dentist, dental student, or the general public (Table 1). The questionnaire was filled out by the subject in the presence of the researcher. The researcher was available to answer any queries. For certain questions, more than one response was acceptable. After completion of the questionnaire, the researcher looked it over briefly and explained any question that had remained unanswered. The data were then tabulated and analyzed using quantitative-descriptive techniques and response frequencies were converted to percentages to obtain the results.

RESULTS

Profile of the 90 Subjects

The dentists' ages varied from 24 to 52 years. The majority (n = 23) had graduated from various institutions in Karnataka, India. The others had graduated from institutions in other regions of India. The dental students, ranged in age from 18 to 23, were all from V S Dental College and Hospital, Bengaluru. General public ranged in age from 19 to 50 years. 14 of them had finished elementary school, 11 had finished graduation, and 5 were pursuing post-graduation. 15 of them had a previous dental treatment experience.

The questions were broadly classified into three categories:

1. Knowledge about sedation
2. In favor of the use of sedation by dentists
3. Sedation risks.

Knowledge about Sedation

Among the dental practitioners, 27 (90%) claimed to have knowledge about sedation whereas 3 (10%) dentists claimed they did not have any knowledge. Of the 27 dentists who claimed having knowledge about sedation, 18 said the source of information was from undergraduate and post-graduate training, 5 said they acquired it from continuing education programs and 4 said the source was complimentary reading.

Among the students, although 27 (90%) had knowledge about sedation in dentistry which they claimed to have acquired from various teaching classes regarding pharmacology and pediatric dentistry, none of the interviewed students had practiced or observed such a procedure in dental college (100%).

When general public was considered, only 11 (37%) said they had knowledge about sedation in dentistry. 19 (63%) said they did not have any knowledge about the same. Most of the people (n = 7) who claimed to have knowledge, said the source was media and complementary reading (Table 2).

The questions were based on inhalation sedation, general anesthesia, oral sedation, sleep, and unconsciousness.

In Favor of the Use of Sedation by Dentists

This particular category was for the dental practitioners and the dental students.

Among 30 dental practitioners, 21 (70%) favored the use of sedatives by dentist. Of them, 11 were in favor of inhalation sedation, 7 favored oral sedation, and only 3 favored intravenous sedation. All of them (n = 21) favored general anesthesia as a good treatment alternative.

Among 30 dental students, 23 (77%) students favored the use of sedatives by dentists. All of them agreed that sedation should be used as a common practice in dentistry (Table 2).

Table 1: Model Questionnaire

Dentists	Dental students	General public
Do you know about sedation in dental practice? Yes No	Do you know about sedation? Yes. Please comment No	When did you last visit the dentist? Why?
What is the source of your knowledge?	Was this topic taught at dental school? Yes. Please comment No	Do you feel any pain or fear when you go to the dentist? Yes. Please comment No
Have you done/doing this type of procedure? Yes. (Go to Part A) No. (Go to Part B)	Have you done or seen this procedure at dental school? Yes. Please comment No	Do you think you would visit the dentist more often if there was less discomfort?
Part A - Which technique do you use? - Have you ever observed an adverse event? Please comment (continue to Part C)	In your dental school is there any use of sedation in dentistry (research, teaching, extension)? Yes. Please comment No I don't know	Do you know what sedation is? Yes. Please comment No. In this case, the researcher gave a summary of the definition of sedation according to the AAPD
Part B - If you do not do this type of procedure, do you feel a need to use sedatives? How did you solve this problem? (continue to Part C)	Do you like the subject? Yes. Please comment No	Were you ever sedated? Yes No
Part C - Have you ever referred a patient to a specialist for this kind of procedure? Yes (Explain) No	What is your opinion about the use of sedatives by dentists? Do you think there are risks with use of sedatives? Yes No	Do you know anyone who has been sedated? What for?
What is your opinion about the use of sedatives by dentists?	Do you know how to handle a medical emergency? What is the source of your knowledge? Yes No	How would you feel if you or your child would be sedated for dental treatment? Yes. Please comment No
Do you think there are risks with use of sedatives? Yes No	Would you like to make any other comments about the topic?	Do you think there are risks with use of sedatives? Yes No
Do you know how to handle a medical emergency? What is the source of your knowledge? Would you like to make any other comments about the topic? No		Would you like to make any other comments about the subject?

Table 2: Responses to questions about dentistry

Subtopics	*n* (%)	
	Yes	No
Knowledge about sedation		
Dentists	27 (90)	3 (10)
Dental students	27 (90)	3 (10)
General public	11 (37)	19 (63)
In favor of the use of sedation		
Dentists	21 (71)	9 (30)
Dental students	23 (77)	7 (23)
Does sedation present risks		
Dentists	7 (23)	23 (77)
Dental students	13 (43)	17 (57)
General public	23 (90)	7 (23)

Sedation Risks

When asked if sedation presents risk, 7 (23%) of the dental practitioners replied in "yes," while 13 (43%) of the students, and 23 (90%) of the general public said it did. Since emergency management was an important aspect in sedation, dentists and dental students were asked about their knowledge to act in these situations. 22 dentists said they knew how to react in the event of a medical emergency and that they had acquired this knowledge in continuing education and hospital training programs. However, the interviewees seemed insecure in their answers due to the lack of clinical experience in dealing with such situations (Table 2).

DISCUSSION

Knowledge of the perceptions of the people potentially involved in sedation in dentistry is useful in assessing awareness and misapprehensions regarding the same. This can be useful as a guide for future research and understanding the barriers for using sedation in dentistry.

There are very few studies reported worldwide regarding this aspect. In India, there are no studies reported till date.

The results of the present study showed that the level of knowledge about sedation was high among dental practitioners and the dental students as compared to the general public. This was also found to be in sync with their being in favor of its use, and to the notion of associated risks. For example, the general public had the least knowledge about the subject, and, therefore, were not great supporters of the technique, and judged sedation to be a risky procedure. This was found to be in accordance with a study conducted in Brazil.[7]

The results of the present study also showed that the knowledge of the dentists and the students was mostly theoretical. It was not backed up with practical experience or hands on experience.

When practicing sedation in the dental clinic was considered, the need for professional training in carrying out sedation was cited by all the three categories of participants. However, the results showed that only the dental practitioners mentioned the need for adequate equipment, and the importance of teamwork.

With regards to this finding, we agree with Ranali, who included the following points to be discussed with respect to this topic: Adequate training of the staff, and the risks of using inappropriate equipment.[8]

At present, only a few institutions offer training in nitrous oxide-oxygen inhalation sedation in its undergraduate course in line with the recommendations of the American Dental Association.[9]

Physical restraint was found to be widely accepted by the dental practitioners as an alternative to sedation in dentistry. However, it is considered as an advanced child-behavior control method according to the Dental Clinics of North America.[10] This might be due to the ethical/legal issues associated with it. Therefore, the importance of sedation in dentistry and awareness about it has to stressed upon.

Sedation should however be considered in the light of its contraindications, which may be summarized as certain medical conditions, such as pregnancy, certain syndromes, obstructive respiratory diseases, cooperative patients with a minimal need for treatment, etc.[11]

CONCLUSION

The study showed that level of knowledge about sedation was high for dentists and the dental students when compared to the general public. For the dentists, however, this knowledge was mostly theoretical.

Dental practitioners and dental students both agreed about the limited coverage of this subject in their dental colleges and asserted on including this topic in their curriculum. The need for professional training in carrying out sedation for dental procedure was cited by the dentists, dental students, and the general public. There is a need to carry out more such studies worldwide on larger scale to know the "true" awareness about this subject among the people who are potentially involved with it.

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Original Article

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Personality Change in Intractable Epilepsy: A Clinical Study

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Abstract

Background: A specific kind of personality has been described in patients with temporal lobe epilepsy (TLE). However, this has not been studied in intractable epilepsy.

Aims: The aim was to study the personality in medically intractable complex partial epilepsy and its association with electroencephalograph (EEG) magnetic resonance imaging (MRI) variables.

Materials and Methods: A total of 40 random samples of patients with medically intractable epilepsy were assessed for personality on the neurobehavioral inventory (NBI). The relationship between EEG, MRI variables, and personality were computed.

Results: More than 50% of people scored significantly on domains of viscosity (orderliness, interest in details, and persistence), spirituality (increased religious convictions and cosmic interests), and conscientiousness (sense of law and order and guilt). No association of NBI scores with any of the demographic characteristics, seizure variables, EEG, and MRI changes was found, except for a trend towards association with bilateral mesial temporal sclerosis.

Conclusion: A specific TLE personality seems to exist. However, it is not clear if this is different from other organic personality changes. Its association with seizure variables, EEG, and MRI findings need to be further elucidated.

Keywords: Electroencephalograph, Intractable epilepsy, Medial temporal sclerosis, Personality changes

INTRODUCTION

Personality is the unique way in which a person thinks, perceives and behaves in different situations. Patients with epilepsy have been found to have personality difficulties in addition to other psychological problems like psychiatric disorders, aggression, cognitive and psychosocial difficulties, more than that seen in general population[1,2] and in other neurological disorders.[3] Personality disturbances in addition to other psychiatric disorders cause a significant burden to both patients and carers, especially in intractable epilepsy.

Significant personality problems have been reported patients with epilepsy by some,[4] especially in temporal lobe epilepsy (TLE),[5,6] however, others have not found any personality change.[7] Most studies have been cross-sectional in nature, therefore cannot differentiate premorbid personality disturbances from those occurring after the onset of seizures.

A specific personality pattern has been described for patients with epilepsy, with mixed evidence. Accentuations of normal personality traits have been found in both directions, either becoming irritable and aggressive or timid and apathetic. A triad of intensified emotionality, viscosity, and hyposexuality in patients with TLE has been described, which is akin to a temporal hyperconnection syndrome and opposite in manifestation of the Kluver-Bucy syndrome. This is due to the irritative lesion present in TLE as opposed to a state of depression after ablation in Kluver-Bucy syndrome.[8,9]

Bear and Fedio[10] developed an inventory (BFI) to specifically detect these personality traits. They found that patients with right temporal lobe focus were found to have intensified emotionality and exaggerated socially acceptable traits. In contrast, patients with left temporal focus had intensified

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ideational traits with ruminative nature, increased religious preoccupation, philosophical interests, increased sense of personal destiny, and they exaggerated unacceptable traits. Though scores on BFI differentiates well between patients with TLE and non-psychiatric disorders, patients with psychiatric disorders also scored high on the scale. Therefore, a revised version developed by Blumer[11] in collaboration with David Bear called the neurobehavioral inventory (NBI) is being used more recently.

However, studies related to personality change in epilepsy are limited by, not using proper standardized assessment instruments, proper tools for localizing seizure foci, missed structural lesions, no clear differentiation of postictal from interictal periods, transient from sustained behavioral changes, scope of behavioral changes studied (e.g. classic psychiatric syndromes versus other pathologic and non-pathologic behaviors such as increased emotionality or religiosity), different criteria used to define epilepsy populations, disparate epilepsy and comparison group populations and comparisons between different types of epilepsy (TLE, generalized epilepsy, frontal lobe epilepsy, juvenile myoclonic epilepsy, etc.).

Aims

To study the personality syndrome in medically intractable complex partial epilepsy, in the interictal period and to study the association of personality syndrome with electroencephalograph (EEG) findings and with magnetic resonance imaging (MRI) findings of medial temporal sclerosis.

METHODS

A random sample of 40 patients was selected from refractory epilepsy clinic, a mutli-speciality integrated outpatient clinic held once in a fortnight, exclusively for patients diagnosed to have medically intractable epilepsy. Informed consent was taken for all patients.

Inclusion Criteria

Patients in the age group 16-55 years, belonging to either gender, clinically diagnosed as having medically intractable complex partial seizures (CPS) with or without secondary generalization. Medically intractable being defined as those individuals, continuing to have seizures with an average frequency of at least twice every month, for a period of at least 2 years, in spite of therapy with at least two standard anticonvulsants in maximum tolerated doses.[12]

Exclusion Criteria

1. Presence of a psychiatric disorder prior to the onset of seizure disorder
2. Presence of other types of seizures, which are associated with intractability
3. Presence of mental retardation.

Tools Used

1. Pre-designed proforma to collect data, which included the socio-demographic, seizure related, and antiepileptic drug-related history
2. Scalp EEG as per standard international 10-20 - electrode placement technique was done and assessed for background and paroxysmal activity and for site and laterality of the lesion. EEG was done for all patients around the time of psychiatric evaluation. All EEGs were assessed with the help of a consultant neurologist. Sphenoidal EEG was done as part of work-up of refractory epilepsy in those patients where the scalp EEG did not yield good results
3. MRI images were obtained in T_1 and T_2 weighted, and flair modes to demonstrate the medial temporal lobe structures and to exclude other structural lesions. An MRI done as part of the workup for refractive epilepsy was considered. All MRIs were assessed with the help of the radiologist and the consultant neurologist
4. Clinical assessment – was done using relevant scales as follows:
   a. MMSE[13] patients with a cut-off score of >24 were included in the study
   b. NBI.[11]

Consists of a self-report patient and a carer version with 100 items in each version. NBI has been translated and back translated into the local language, Kannada, which was also used in the study. Two kinds of traits have been described: Stable and episodic as shown in Table 1. These are thought to be characteristic of chronic medial TLE.

This scale is still under experimental use and the test-retest reliability, correlation of scores obtained by patient and next of kin and internal consistency of the scales is yet to be established. Both inventories have been found to aid in clinical assessment of patients with epilepsy, but may not be useful for comparison studies with controls.[14]

Analysis

Data obtained were coded using a SPSS statistical package; it was analyzed using descriptive statistics, parametric statistics, and non-parametric statistics. The data were analyzed for frequencies and severity of personality change. The relationship between EEG, MRI variables, and personality was computed.

RESULTS

The details of socio-demographic distribution are shown in Table 2. Mean age of the subjects was 30.18 (SD 8.37).

Table 1: NBI

Stable traits	Patient version	Kin version	Correlation
Emotionality			
Emotionality	16 (40)	19 (47.5)	0.001*
Seriousness	13 (32.5)	14 (35)	0.00*
Writing tendency	13 (32.5)	11 (27.5)	0.000*
Sense of personal destiny	10 (25)	06 (15)	0.001*
Conscience			
Guilt	18 (45)	16 (40)	0.002*
Sense of law and order	17 (42.5)	21 (52.5)	0.000*
Spirituality			
Religious convictions	21 (50)	17 (42.5)	0.000*
Cosmic interests	10 (25)	07 (17.5)	0.007*
Viscosity			
Interests in details	22 (55)	21 (52.5)	0.007*
Order	21 (52.5)	21 (52.5)	0.000*
Persistence and repetitiveness	20 (50)	20 (50)	0.000*
Hyposexuality			
Hyposexuality	15 (37.5)	13 (32.5)	0.052
Dependency			
Dependency	17 (42.5)	15 (37.5)	0.008*
Episodic traits			
Mood			
Sadness	24 (60)	20 (50)	0.000*
Physical well-being	19 (47.5)	17 (42.5)	0.095
Happiness	9 (22.5)	09 (22.5)	0.007*
Irritability			
Temper	19 (47.5)	21 (52.5)	0.000*
Hatred and revenge	8 (20)	06 (15)	0.000*
Anxiety			
Fearfulness	15 (37.5)	17 (42.5)	0.000*
Paranoia			
Suspiciousness	9 (22.5)	11 (27.5)	0.038*

*Significant, NBI: Neurobehavioral inventory

Table 2: Socio-demographic details

Socio-demographic details	Frequency (*n*=40)	Percentage
Age		
Min:16	Mean: 30.18	SD:8.37
Max:51		
Sex		
Male	26	65
Female	14	35
Occupation		
Student	03	7.5
Manual laborer	11	27.5
Professional	09	22.5
Business	01	2.5
Others	10	25
Unemployed	6	15
Marital status		
Never married	27	67.5
Married	11	27.5
Separated	2	5
Education		
<10 years	21	52.5
10-15 years	14	35
>15 years	5	12.5
Residence		
Urban	32	80
Rural	8	20

SD: Standard deviation

Table 3: Seizure-related variables

Variables	Frequency (*n*=40)	Percentage
Age at onset		
<10 years	15	37.5
10-20	19	47.5
20-30	5	12.5
>30	1	2.5
Duration of seizures		
<10	9	22.5
10-20	21	52.5
20-30	10	25.0
Frequency (per month) of seizures		
1-4	29	72.5
4-8	5	12.5
9-12	3	7.5
>12	3	7.5
Duration before treatment (months)		
1-6	31	77.5
7-12	3	7.5
13-36	5	12.5
>36	1	2.5
Type of seizure		
CPS	7	17.5
CPS -Generalization	17	42.5
SPS-CPS	6	15
SPS-CPS-Gen	10	25

CPS: Complex partial seizure, SPS: Simple partial seizure

Males comprised 65% of the sample and females 35%. Majority of the patients were from the urban background and never married. Equal number of people educated below and above 10 years. A total of 85% were employed.

As shown in Table 3, majority (85%) of patients had age at onset of seizures below 20 years and 37.5% of them below 10 years. The frequency of seizures in a majority of them was 1-4 per month. Most people had sought treatment within 6 months of the onset of seizures indicating that patients in this sample had developed intractability in spite of seeking early treatment. Duration in a majority was more than 10 years, 52.5% had a duration of 10-20 years, 25% had a duration of >20 years, 22.5% had a duration of <10 years. CPS with secondary generalization was the most common type.

Past history of febrile seizures was present in 25% and head injury in 5.4%. Family history of seizures in a first-degree relative was present in 32.5% of patients. Head injury was present in 5% patients. Five of our patients (12.5%) had undergone surgery. EEG was abnormal in 80% ($n = 32$) of patients. Background was normal in 92.5% of patients. The abnormalities were in the form of diffuse or hemispheric or focal slow waves. A temporal focus on EEG was present in 75% of patients, of whom 12 had right, 7 had a left, and 11 had bilateral temporal focus. Generalized seizure discharge was present in 12.5%.

MRI could not be done in 8 (20%) patients. Among the 32 (80%) people who had MRI, it was normal in 9 patients

(28%) and abnormal in 23 (72%). Presence of hippocampal atrophy and hyperintensity on T2 was considered as medial temporal sclerosis. Mesial temporal sclerosis (MTS) was absent in 19 patients (57%), and present in 13 patients (39%) of whom 6 had right unilateral, 6 had left unilateral and 1 bilateral MTS. 10 patients had an abnormality other than MTS, which included focal gliosis or infarct in a different area, cerebellar atrophy and temporal atrophy due to past infarct.

Scores on NBI are shown in Table 1. Endorsement of two or more items on each trait is considered significant for that trait or a total score of 20 on each version is considered as significant.

Both the patient and Kin versions showed good correlation ($P < 0.05$), except on 2 traits, physical ($P = 0.095$), and on sex ($P = 0.052$). Traits on which significance was found were temper, sadness, sex, religiosity, persistence, orderliness, moral, importance to detail, guilt, dependence, and physical symptoms. Overall significance, that is, a score of more than 20 was found in 21 (52.5%) on both patient and kin versions.

Scores on different traits were grouped into different domains as described by Blumer (1995).[11] Emotionality: Emotions, seriousness, sense of personal destiny and writing tendency, conscience: Sense of law and order and guilt, spirituality: Religious conviction and cosmic interests, viscosity: Orderliness, interests in details and persistence and repetitiveness. Scores were significant for emotionality in 52.5% in the patient version and 65% in the Kin version, on spirituality in 52.5% and 50%, on conscience in 52.5% and 65% and viscosity 57.5% and 65% and in mood in 35% and 55%, respectively.

Association between NBI scores on patient version and any of the EEG variables is shown in Table 4 and with MRI in Table 5.

NBI scores were not found to be significantly associated with any of the socio-demographic variables, any of the seizure variables, use of any AED, EEG variables, presence of temporal focus and presence of MTS. There was a significant association between NBI (patient version) scores and presence of bilateral MTS.

Table 4: NBI patient version and EEG variables

Variables	Mean±SD	*t* value	*P* value
Temporal focus			
Present	26.63±16.88	0.248	0.806
Absent	28.20±18.71		
Temporal focus			
Unilateral	36.6±15.71	1.623	0.136
Bilateral	23.50±18.32		
Temporal focus			
Right	30.92±20.84	1.339	0.198
Left	19.71±8.99		
EEG generalized discharge			
Absent	24.62±21.5	0.613	0.544
Present	28.19±14.9		

EEG: Electroencephalograph, NBI: Neurobehavioral inventory, SD: Standard deviation

Table 5: NBI patient version and MRI variables

Variables	Mean±SD	*t* value	*P* value
MTS			
Present	27.46±16.71	0.154	0.879
Absent	28.42±17.72		
MTS			
Unilateral	24.83±14.38	2.283	0.043*
Bilateral	59.0±0.00		

*Significant, NBI: Neurobehavioral inventory, MTS: Mesial temporal sclerosis, MRI: Magnetic resonance imaging, SD: Standard deviation

DISCUSSION

Personality change is a significant problem in epilepsy, more so in intractable epilepsy. On the NBI, earlier studies have found that patients with chronic TLE commonly endorse items reflecting deepened emotionality (emotions, seriousness, sense of personal destiny, and writing tendency), strong conscience (sense of law and order and guilt), spirituality (religious conviction and cosmic interest), viscosity (orderliness, interest in details, persistence and repetitiveness), hyposexuality, and dependency, while endorsement of other items reflecting generally episodic symptoms of sadness, irritability, anxiety, suspicion might be indicative of intermittent dysphoric disorder an episodic mood syndrome described in epilepsy.[14]

In the current study, more than 50% of people scored significantly on domains of viscosity (orderliness, interest in details, and persistence), spirituality (increased religious convictions and cosmic interests), and conscientiousness (sense of law and order and guilt), and some on mood and irritability.

The traits that were endorsed by the lowest number of people were personal destiny, cosmic interests, and fear. Thus, except for these three traits all the other traits of NBI were present in a significant number of subjects. This is in keeping with the earlier studies.[11]

Since the present study did not use a control sample, it is not clear if the presence of these traits in our sample indicates the presence of a temporal lobe personality or if these traits also occur in other non-TLE epilepsy patients and other non-epileptic neurological illness. Similar high score on the traits of BFI have been observed earlier in generalized epilepsy and other psychiatric patients.[15,16]

Patients with epilepsy are at a greater disadvantage in terms of psychosocial circumstances, due to chronic invalidation,

stigma, and frequent overprotection, which lays increased stress on the temperament probably leading to personality change. The current study did not find any significant association between education, occupation, place of residence or marital status and personality scores. We also did not find any association with age or gender. This could be because of small sample size and also because we did not study psychosocial factors which are of significance e.g. stigma.

Behavioral disorders can also be due to multiple factors that often coexist, including those related to biologic, medication, and psychosocial variables. Because of problems in the definition of these disorders, identifying their mechanism has been problematic. Thus, none of the seizure-related mechanisms have been studied systematically in specific relation to personality change.[17] The present study did not find any association between personality scores on either patient or kin version of NBI and any of the seizure-related variables including age at onset of seizures, duration of seizures, frequency of seizures per month, history of febrile seizures or family history of seizures or use of any antiepileptic medication. However, there was a trend towards an association of personality scores on kin version of NBI with age at onset. It is possible that the significance was not found because of small sample size.

Many authors have noted a specific relation between personality changes and TLE compared to generalized epilepsy,[5] others have found higher scores of personality in left-sided TLE patients compared to right sided TLE patients.[15] However, these results have not been conclusive as other studies did not support this finding.[16] The current study did not find any association between either presence or laterality of temporal focus and personality scores, however, an association of personality scores on kin version of NBI and presence of generalized seizures discharges on EEG was found. But only five patients (12.5%) had generalized discharges compared to 35 (87.5%) who did not have, thus no meaningful interpretation can be made of the above finding.

Behavioral change associated with localization-related epilepsy suggests that specific structures are involved in their pathogenesis. However, an association between structural lesions such as MTS or dysplasia and behavioral change has not been studied.[17] Our study did not find any association of personality scores with presence or absence of MTS. However, a significant association with the presence of bilateral MTS was seen. However, as only one patient had bilateral MTS it precludes any meaningful interpretation, and further studies are necessary to look at this association.

CONCLUSION

A specific TLE personality seems to exist. It needs to be further differentiated from other organic personality types and characterized in terms of its association with seizure variables, EEG, and MRI changes in larger systematic studies.

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Original Article

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Study of Drug Interactions and Associated Factors in Prescriptions of General Practitioners in Ardabil City, 2013-2014

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Abstract

Background: Drug interactions are made very serious problems for thousands of people every year. In most cases, doctors and pharmacists have not spent enough time for careful monitoring of patients in terms of drug interactions harmful effects.

Aim: The aim of this study was to investigate the frequency of drug interactions and associated factors in prescriptions of general practitioners in Ardabil city.

Materials and Methods: This descriptive cross-sectional study has been done on 1000 prescriptions in Ardabil city which randomly selected from all prescriptions. Necessary information such as sex, the number of prescription items, the degree of doctor, and place of practice completed by a checklist. For obtain drug interactions, we used drug interaction facts and for analysis data we used SPSS 19.

Results: Overall incidence of drug interaction was 19.7% from that 9.13% was severe, 37.1% was moderate and the rest had minor interactions. Drug interactions in specialties were more than general doctors. Prescriptions of male physicians had a significant increase in drug interactions. Increase in mean number of drugs in each prescription caused to a significant increase in the incidence of drug interactions.

Conclusions: Knowledge of drug interactions and replace them with other drugs and decreasing the number of drugs we can reduce significantly these interactions.

Keywords: Drug interactions, Incidence, Prescriptions

INTRODUCTION

One of the biggest issues facing healthcare organizations today is how to maintain patient safety. Several studies show that each year more people die due to medical errors that medical errors and accidents caused by drug side effects are in the first place. These errors are usually expensive and clinically important topics.[1]

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The process of pharmacotherapy consists of five steps prescribed medication, duplication, drug distribution, drug use management, and monitoring of treatment. Medical errors can occur at each of these stages, but drug interactions may occur only in the prescribed step.[2]

Drug interactions are one of the most important drug mistakes which are only predictable and preventable by revision of previous documentations, reports, and clinical studies. However, most physicians are unaware of major and clinically important drug interactions.[3]

Drug interactions defined as a pharmacological or clinical response induced by administration of two or more drugs.[1]

Using two or more prescribed drugs may lead to drug interactions. Some drug interactions are very harmful and

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may have potential threats to the patient's health that is called antagonism.[4]

Drug interactions are not limited to the co-administration of two or more drugs, and can be occur in the forms drug interactions with drug, drug with food, drug with disease, and drug with environmental factors.[5]

Furthermore, drug interactions each year due to the increased length of hospitalization impose an enormous cost to the society economy and even in some cases this drug interactions may lead to patient's death.

In Iran, 8% of hospital treatment will leading to side effects, which is more than the American country (2.4-5.6%).[2] Study in Nepal at 2010 showed that from 2985 prescribed drugs, the error occurred in the 1233 drug (41.3%).[6]

In Gurvitz *et al.* study, the incidence rate of unwanted side effects in patients up 65 years, was about 50 per 1000 patients.[7]

Due to the lack of similar studies in this area in Ardabil province, this study aimed to investigate drug Interactions and associated factors in prescriptions of general practitioners in Ardabil city.

MATERIALS AND METHODS

In this cross-sectional study, 1000 prescriptions selected randomly from all prescribed prescriptions by general practitioner from April 2013 to December 2014. Available data on prescriptions included physician identification, name, sex of the patient, and quantity of the medications dispensed. Information such as the number and intensity of interactions and drug interactions causing interference was calculated by the software drug interaction facts.

This software, in terms of severity of drug interactions are divided into five categories

Interference with life-threatening or may cause permanent damage (severe).

Interference with the patient's clinical condition worsened and we find the need for additional treatment or the patient may be admitted to our hospital for a long time (medium).

Interference effects are usually mild, but they cannot affect the outcome, so there is usually no need for additional treatment (mild).

Interference that may cause moderate to severe side effects, but there is not enough information in this case (unknown).

Interference effects may be severe, but it is highly unlikely, or there is no evidence of clinical effects (inconsistent).

Collected data were analyzed by statistical methods in SPSS 19.

RESULTS

From all 1000 prescriptions, 611 prescriptions (61.1%) were for male patients (Table 1).

In summary, 197 (19.7%) interactions were seen in all prescriptions.

543 (54.3%) of all prescriptions has been scribed by general practitioners (Figure 1).

Totally, 197 interactions were seen in 132 prescriptions, which from them 92 (69.7%) prescriptions have one interaction (Figure 2).

Aspirin with 38 (19.3%) of all interactions has the most common drug interactions with other drugs. The most common drug interactions were seen between atorvastatin and gemfibrozil with a severe degree of interference, and the frequency was four. Of all 197 drug interactions, 73 interference (37.1%) was Type 2 (moderate) (Figure 3).

Most of drug interactions with 58.4% related to specialists and rest of them for general practitioners.

With increasing the number of prescribed drugs, the number of drug interactions had been increased significantly ($P = 0.001$). Male physicians have significantly more drug interactions than female physicians ($P = 0.004$).

There was not significant relationship between drug interactions and place of practice. Specialists with mean drug interactions 0.29 ± 0.8 have more interferences than others.

Table 1: Characterized variables in study prescriptions

Variables	*N* (%)
Sex of patients	
Male	611 (61.1)
Female	389 (38.9)
Drug interactions	
+	197 (19.7)
–	803 (80.3)
Place of practice	
General clinic	103 (52.3)
Private clinic	94 (47.7)
Sex of prescribers	
Male	612 (61.2)
Female	388 (38.8)

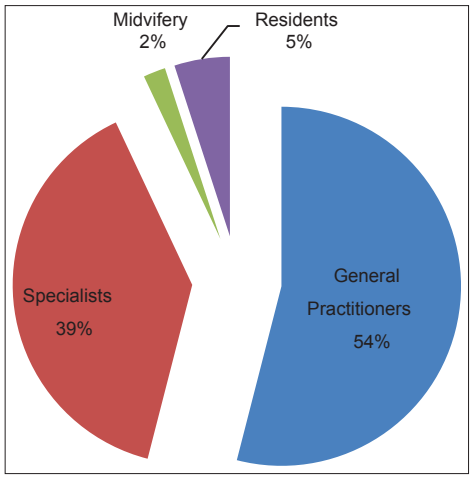

Figure 1: Prescriptions by doctor specialty

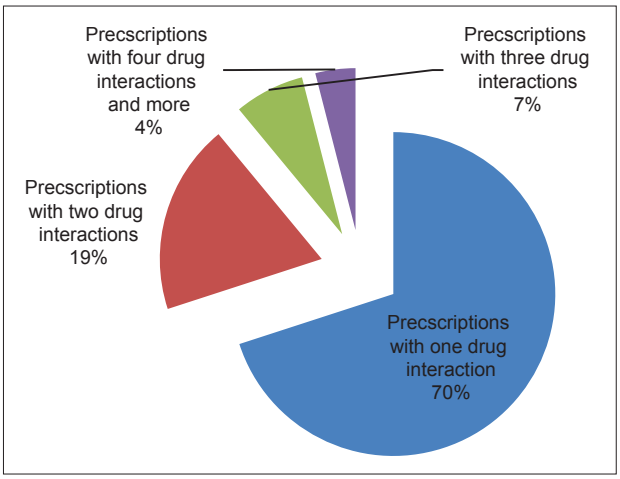

Figure 2: Prescriptions with number of drug prescriptions

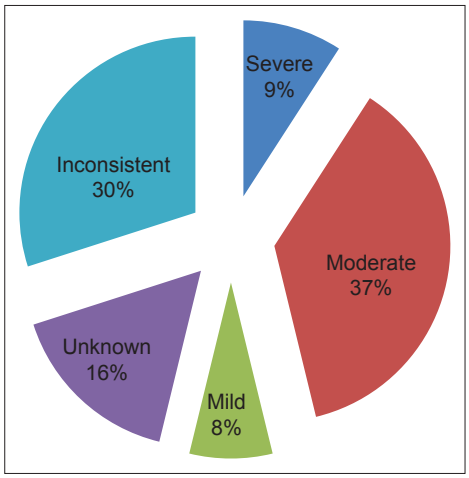

Figure 3: Type of interference in prescriptions

DISCUSSION

Drug interactions have been introduced as one of the major errors in prescribing medication and several factors can cause to drug interactions which it can be noted the important role of human factors.[8]

Results showed that the rate of drug interactions in these prescriptions was 197 (19.7%) which from them 9.1% have severe drug interactions.

Khouri *et al.* in study resulted that 8.2% of all studied prescriptions have drug interactions which 8.7% of them have severe interference.[8]

When compared our study results with other places, we could result that more than half of prescriptions in Ardabil province have interference Types 3 and 4 that no have effective on treatment result and no need for additional treatment, but in Gorgan study, more interferences have Type 2 (moderate) which can worsen the patient's clinical status.[8]

In Pudasaini *et al.* study, 16% of prescriptions have interference and the rate of drug interactions in specialists with 58.4% was significantly more than general practitioner.[9]

In Khouri *et al.* study, the rate of drug interactions in general practitioner was significantly more than specialists which this difference can be due to aspirin interaction with more drugs in specialists prescriptions and in our study, 19.3% of interactions related to aspirin interaction with other drugs.[8] With increasing the number of prescribed drugs, the number of drug interactions had been increased significantly ($P = 0.001$). This finding is similar to Rafeian *et al.* study. One reason for the large number of drugs prescribed, resulting in high rates of drug interactions can result in urging patients to prescribe more drugs and with an increasing number of drugs in a particular situation, find drug interactions will be difficult.[10-12]

In our study similar to Khouri *et al.* study, the study revealed that there was not relationship between place of practice and patients' sex and drug interaction prevalence. 84.8% of drug interactions have ben occurred by male and 15.2% by female physicians and there was significant relation between sex of physician and number of interferences ($P = 0.001$) which was similar to other study results and this can be probably noted to the greater sensitivity of female doctors in prescribing which further studies are needed to prove this.[8]

CONCLUSION

The prevalence of drug interactions (Type 1-5) in Ardabil city prescriptions with 19.7% was more than other studies. However, regardless of Types 4 and 5 interactions that are of clinically not importance, the rate of interactions

with 10.6% has not difference with other studies. 46.2% of drug interaction was clinically important and so, risk of incidence complications from these drug interactions in patients is high and follow-up of patients and some tips to avoid such complications is essential. In this study, the prevalence of drug interactions had a significant relationship with various factors such as gender, doctor specialty (specialist or general), and the mean number of drugs prescribed per prescription which need to exact and wide study in future. Furthermore, by the appropriate dosage adjustments or modifications and or correction method and time-consuming, we can prevent many of the negative effects from drug interactions.

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Original Article

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Assessment of Stress Level among Dental Undergraduate Students: A Questionnaire Survey

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Abstract

Introduction: Stress is a state of mental or emotional strain resulting from adverse or demanding circumstances. Student's life imposes inevitable stress, which involves physiological and practical challenges. Dentistry is a stressful profession resulting in anxiety, depression, burnout, etc.

Aims: The aim was to assess the various sources of stress, any particular stressor related to the year of study and gender and to determine the role of parents in inducing stress in students.

Materials and Methods: A total of 96 undergraduates students were included in our study and stress was measured using modified dental environment stress questionnaire and Likert scale with response options as: (1) Not stressful, (2) slightly stressful, (3) moderately stressful, and (4) severely stressful.

Results: The primary top stressors were fear of failing, need to find own patients. Students whose secondary choice of joining dentistry due to parental pressure showed high-stress factor than those who joined of their self-interest. Male students experienced greater stress than females.

Conclusion: Appropriate environment needs to be created to relieve the stress in undergraduate students and also parents should not force their children in their career decision.

Keywords: Dental students, Dentistry, Stress, Stressors, Stressful

INTRODUCTION

Stress affects one's personal body and mind. Various stressors cause hindrance in student's behavior and poor academic performances.[1] High levels of stress are associated with dental practice, it appears to begin during dental school and is manifested differently during different years of study.[2-4] Dentists suffer from extraordinarily high degrees of stress even when compared with other health professions.[5] Stressors vary by individual attitude, beliefs, and cultural background.[6] Different stressors in field of dentistry included convincing and managing uncooperative patients, accurate pre-clinical works, time management, etc.,[2,6,7] tends students to undergo depression, lack of confidence, anxiety etc., resulting in lower level of academic performances.[3,4,8]

The study intends to investigate various sources of stress among dental undergraduate students, any particular stressor related to the year of study or gender and role of parents in student's career decision.

Aims

1. To assess various sources of stress among dental undergraduate students
2. To determine whether any particular stressor was related to the year of study or gender and
3. Evaluating role of parents in contribution to stress level among students.

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MATERIALS AND METHODS

The study was conducted in the middle academic year 2013-2014. Ethical approval was obtained from the ethical committee. All actively participated students were

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included in the study and those who remained absent were considered under the exclusion criteria. Prior to the procedure, all the students were explained in detail regarding the aims and the purpose of the study. A list of 25 questions was distributed to all the participants and time allocated was 15 min.

Stress was measured using modified dental environment stress (DES) questionnaire,[6] which included 25 questions. The response for each question was based on a Likert scale with response options as: (1) Not stressful, (2) slightly stressful, (3) moderately stressful, and (4) severely stressful.

Study Population

A total of 96 individuals were invited to participate in the study and all the students reported for the study with a response rate of 100%.

Statistical Analysis

Data analysis was done using SPSS software version 10.0. Student's *t*-test was used for males and females comparison. Evaluation of different reasons for joining dentistry with respect to stress was done by one-way ANOVA. Mean value and standard deviations were evaluated for individual stress scores and were used to compare the classes, genders, and choices. $P = 0.05$ was considered for statistical significance.

RESULTS

A total of 96 undergraduate enrolled students participated in the study at the rate of 100%. Among the total 96 respondents, 21 (21.88%) were males and the remaining were females 75 (78.12%) with the age range between 19 and 25 years. Among 21 males, 8 (23.6%) were from 1st year, 4 (17.4%) were from 2nd year, 5 (20.8%) were from 3rd year, 4 (26.7%) were from final year. Out of 75 females, 26 (76.4%) were from 1st year, 19 (82.6%) were from 2nd year, 19 (79.2%) were from 3rd year and 11 (73.3%) were from final year respectively (Table 1 and Figure 1). Mean value scores for each questions were compared for different academic years. Male students had high mean DES scores than female students, which was statistically significant.

Among the primary top stressors for all the years fear of failing (3.42 ± 0.71) was the topmost stress factor, followed by need to find own patients (3.03 ± 0.0.56), lack of time for relaxation (2.82 ± 0.84), financial sources (2.71 ± 0.83), rules and regulations (2.53 ± 0.87), atmosphere created by clinical staff (2.53 ± 0.91) and lack of home atmosphere (2.03 ± 0.73) which were statistically highly significant (Table 2). For most of these questions, third and final year students reported more stress than 1st and 2nd year, but the final year students showed maximum stress among all academic years.

Secondary top stressors were compulsion of internal marks (2.98 ± 0.72), shortage of allocated clinical (2.98 ± 0.63), fear of not having possibility to pursue a PG program (2.94 ± 0.87), difficulty in learning clinical procedures (2.58 ± 0.86), responsibilities for comprehensive patient care (2.35 ± 0.86), competition with peers for grades (2.32 ± 0.91), joined dentistry by (2.23 ± 0.83), health problems (1.84 ± 0.78) which were statistically significant (Table 3).

The least stress factors were making new friends, dependences (smoking/alcohol), compulsion of attendance, language barrier, availability of assistance of lab technician during clinical procedure, fear of being unable to catch up if left behind, working on patients with poor oral hygiene, fear of facing parents after failure, expectation versus reality of dental college, fear of unemployment, which were not statistically significant (Table 4).

DISCUSSION

Stress is defined as "pressure or worry caused by problems in somebody's life." Earlier studies,[2,8,9] reported that dental education causes varying degrees of stress on students. Dental field includes the professional artwork with sound knowledge in patient's treatment and care. Hence, the students have to develop the practical skill along with theoretical knowledge to become a good dentist.[10]

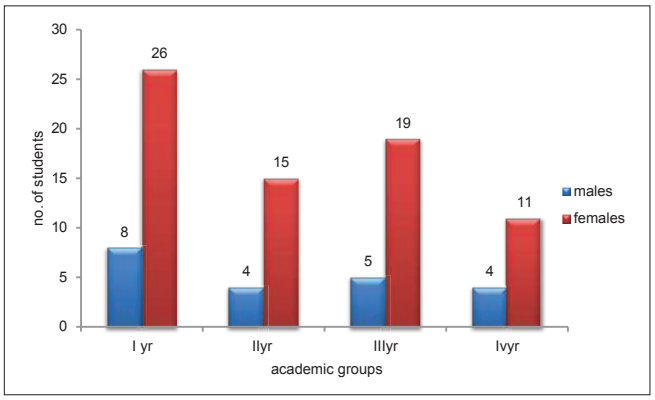

Figure 1: Distribution of study subjects according to academic year and gender

Table 1: Distribution of study subjects according to academic year and gender

Class	*N* (%)		
	Males	Females	Total
I year	8 (23.6)	26 (76.4)	34 (35.4)
II year	4 (17.4)	19 (82.6)	23 (23.9)
III year	5 (20.8)	19 (79.2)	24 (25.0)
IV year	4 (26.7)	11 (73.3)	15 (15.7)
Total	21 (21.88)	75 (78.12)	96 (100.00)

Table 2: Primary top sources of stress and differences in the mean stress scores according to the classes

Items	Mean±SD					*P* value	Significant
	I year	II year	III year	IV year	Total		
Fear of failing	2.943±0.83	3.56±0.67	3.66±0.54	3.52±0.65	3.42±0.71	0.024	HS
Need to find own patients	1.16±0.22	3.54±0.81	3.62±0.48	4.0±0.0	3.03±0.56	0.0016	HS
Lack of time for relaxation	2.16±0.79	3.32±0.67	2.96±0.62	2.61±0.76	2.82±0.84	0.007	HS
Financial resources	2.46±1.21	2.38±0.73	1.92±0.84	1.31±0.51	2.03±1.17	0.0018	HS
Rules and regulations	2.21±0.98	2.43±0.97	2.38±0.81	2.84±0.71	2.53±0.87	0.001	HS
Atmosphere created by clinical staff	2.18±0.84	2.31±0.82	3.38±0.73	2.81±0.93	2.53±0.91	0.003	HS
Lack of home atmosphere	1.90±0.78	1.86±0.84	2.21±0.78	2.31±0.71	2.03±0.73	0.004	HS

SD: Standard deviation, HS: Highly significant

Table 3: Secondary top sources of stress and differences in the mean stress scores according to the classes

Items	Mean±SD					*P* value	Signifcant
	I year	II year	III year	IV year	Total		
Compulsion of internal marks	2.82±1.03	3.48±0.53	2.58±0.89	3.26±0.62	2.98±0.72	0.013	S
Shortage of allocated clinical work	2.59±0.96	2.96±0.91	3.13±0.62	3.26±0.62	2.98±0.63	0.047	S
Fear of not having possibility to persue a PG program	2.21±0.86	2.68±0.87	3.26±0.84	3.21±1.02	2.94±0.87	0.024	S
Difficulty in learning clinical procedures	2.62±0.94	2.44±0.68	2.81±0.86	2.41±0.52	2.58±0.86	0.028	S
Responsibilities for comprehensive patient care	1.52±0.52	2.76±0.72	2.4±0.62	2.73±0.92	2.35±0.86	0.0123	S
Competition with peers for grades	2.86±1.06	2.72±0.86	2.75±0.88	1.81±0.71	2.32±0.91	0.032	S
Joined dentistry by	2.34±0.84	2.37±0.96	2.1±0.98	1.67±0.67	2.23±0.83	0.042	S
Health problems	1.82±0.97	2.37±0.96	2.21±0.84	1.61±0.72	1.84±0.78	0.040	S

SD: Standard deviation, S: Significant

Table 4: Least sources of stress and differences in the mean stress scores according to the classes

Items	Mean±SD					*P* value	Significant
	I year	II year	III year	IV year	Total		
Making new friends	1.76±0.87	1.68±0.94	1.62±0.84	1.32±0.47	1.59±0.78	0.086	NS
Dependences (smoking/alcohol)	1.0±0.0	1.0±0.0	1.0±0.0	1.1±0.18	1.01±0.11	0.316	NS
Compulsion of attendance	2.78±0.83	2.48±0.89	2.54±0.64	2.64±0.64	2.58±0.87	0.076	NS
Language barrier	1.21±0.56	1.43±0.58	1.82±0.88	1.80±0.72	1.53±0.89	0.087	NS
Availability of assistance of lab technician during clinical procedure	2.03±0.63	2.32±0.91	2.41±0.81	2.36±0.81	2.28±0.84	0.073	NS
Fear of being unable to catch up if left behind	3.16±0.91	2.98±0.80	2.97±0.91	2.89±0.73	3.01±0.96	0.346	NS
Working on patients with poor oral hygiene	3.72±0.52	2.87±0.96	3.16±0.73	3.14±0.58	3.21±0.68	0.086	NS
Fear of facing parents after failure	4.0±0.0	3.91±0.28	3.01±1.05	3.91±0.51	3.9±0.71	0.261	NS
Expectation versus reality of dental college	2.56±0.92	2.97±0.81	2.04±0.10	2.81±0.72	2.62±0.78	0.176	NS
Fear of unemployment	2.36±0.82	2.97±0.93	2.64±0.78	2.36±0.84	2.42±0.81	0.201	NS

SD: Standard deviation, NS: Not significant

The objective of this study was to identify various sources of stress among dental undergraduate students, any particular stressor related to a year of study or gender and role of parents in students career decision.

In our study the primary stressor was "fear of failing" as topmost stress factor, which was highly significant followed by need to find own patients, lack of time for relaxation, financial sources, rules and regulations, atmosphere created by clinical staff and lack of home atmosphere, and our results were similar to the study reported by Acharya.[6]

Previous studies done by few authors,[2,6,11] reported "rules and regulations," "atmosphere created by clinical faculty" were stressful factors which coincide with our study as primary top stressors. Even the financial resources was also a primary top stressor due to the fact that dental college needs immense fee, instruments and books charges during the academic year, which was also reported by Acharya.[6]

To search ideal patient for exams or to complete clinical quota, 3rd and final year students showed "need to find own patients" as high stressful factor, which was highly significant, which was in agreement with studies reported by Tangade *et al.*,[2] Acharya,[6] Paudel *et al.*,[12] Ahmad *et al.*[13] When comparison was made between day scholars and hostellers, more stress was found to be in hostellers due lack of "home atmosphere" and emotional support during exams, which was in accordance with Tangade *et al.*,[2] Acharya.[6]

As the era in work pattern changes from preclinical work to clinical work, this tends to induce more responsible towards patient's treatment and care, in our study 3rd year and final year students showed "difficulty in learning clinical procedure" as stressful factor, which was in correspondence with the studies reported by Tangade *et al.*,[2] Naidu *et al.*,[14] Heath *et al.*,[15] Sanders and Lushington.[16]

"Shortage of clinical allotted work" for students to fulfill quota before examinations also found to be stressful factor which was also reported by Ahmad *et al.*,[13] whereas Westerman *et al.*,[1] Naidu *et al.*,[14] Kumar *et al.*,[5] Al-Sowgyh *et al.*[11] studies reported that "competition with peers for grades" was high in 1st and 2nd year students, which is in agreement with our study.

Meanwhile the students who were forced by their parents for joining dentistry showed greater stressful factor due to lack of interest in the course, resulting in poor outcome in student's life, which was statistically significant and similar with study of Acharya.[6]

The overall results of the present study showed that male students (3.85%) perceived more stress than female students (2.50%), which was in agreement with Acharya[6] and Kumar *et al.*[5] Men are considered as primary earning source of most of the families depending upon their social and economical status, which tends to increase stress amongst men because of the desire to complete the dental course with a good outcome.

CONCLUSION

Dental students experience stress arising from both academic and socio-cultural environment. Dental educators should counsel the students in decreasing the amount of stress and increasing the ability to cope with stress and also a favorable environment and motivation need to be provided to the students, and parents should not force their children in career decision.

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Original Article

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Comparative Evaluation of Composite Bonding to Primary Stainless Steel Crowns Using Different Bonding Agents: An *In-vitro* Study

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Abstract

Introduction: Stainless steel crowns (SSCs) have been used in multi surface carious teeth and those which have undergone pulp therapy. Despite the favorable qualities of strength, durability, and low cost, they have a major drawback, their poor esthetic appearance. Therefore, composites are bonded to them to increase their esthetic appearance.

Aim: The aim of this study was to evaluate the shear bond strength of nanocomposites to SSCs using three different bonding agents.

Materials and Methods: Total 120 pre-trimmed, pre-contoured primary SSCs were sandblasted. Crowns were divided into four groups containing 30 crowns in each group. Group 1 (control group) consisted of nanocomposite bonded with SSCs without use of bonding agent. In Group 2, nanocomposite was bonded to SSCs using a bonding agent Adper Single bond 2. In Group 3, SSCs were bonded to nanocomposites using Prime and Bond NT whereas in Group 4, Bond Plus was used as a bonding agent. All crowns were embedded in a uniform acrylic mold. Shear bond strength was tested for all specimens using universal testing machine. The type of failure of the bond was also determined. Statistical analysis was done using ANOVA and Chi-square tests.

Results: Highest mean shear strength was recorded in Group 4. Most of the samples in all the groups had undergone adhesive failure. Cohesive failure was seen 17%, 13% and 23% samples of Groups 2, 3 and 4 respectively.

Conclusion: New adhesive agent, Bond Plus had higher shear bond strength and demonstrated less adhesive failure. So it can be used as better material for those who need esthetically modified crowns. Further studies are needed to validate the results of the current study.

Keywords: Adhesive agent, Shear bond strength, Stainless steel crowns

INTRODUCTION

Dental caries is the single most common disease of childhood and the most prevalent oral disease. Also, it is not amenable to short-term pharmacological management. More than 80% of the pediatric population is affected by dental caries by the age of 17.[1] There is practically no geographic area in the world where dental caries is not evident. It affects both the sexes, all races, all socioeconomic status groups and all age groups.[2] It not only causes pain and discomfort, but also in addition, places a financial burden on the parent.[3]

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Since the introduction of stainless steel crown (SSC) by Humphrey in 1950's, they have been extensively used to treat multi-surface carious teeth and those which have undergone pulp therapy.

The popularity of SSCs is due to advantages such as their easy placement, good durability and relatively low cost.

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However, SSCs have a metallic gray appearance that causes considerable patient dissatisfaction.[4]

SSCs have been the restoration of choice in the following clinical situations: Multi surface carious lesions on primary molars, following endodontic procedures, restoration of primary molars affected by developmental defects, restoration of fractured primary molars, in patients with a high caries susceptibility, as an abutment for certain appliances such as space maintainers, in patients where routine oral hygiene measures are impaired e.g. patients with special care needs, in patients undergoing restorative care under general anesthesia if two or more surfaces are involved, and in patients with infra-occluded primary molars to maintain mesiodistal space.[5]

Pediatric SSCs can be untrimmed, pre-trimmed or pre-contoured. According to the composition, these crowns are austenitic and nickel-chromium crowns. Austenitic SSCs are composed of iron (67%), chromium (17-19%), nickel (10-13%), and minor elements (4%), whereas nickel chromium crown contains nickel (76%), chromium (15%), iron (8%), carbon (0.08%), manganese (0.35%), and silicon (0.2%).[6] Despite various favorable qualities, SSCs have a major drawback, their poor esthetic appearance. A growing demand for esthetic restorations has led to an increased use of resin-based composites and glass ionomer cements.[7] Esthetic modifications of SSCs have been done by placement of composite resin on the labial face of the crown. Furthermore, prefabricated SSCs with tooth colored buccal and occlusal facings are available.[5]

Composite or porcelain coatings are chemically or mechanically bonded to the SSCs preferably onto their buccal or occlusal surfaces.

This has been made possible by various advances in the fields of restorative materials and metal bonding procedures. These procedures combine the advantages of SSCs with esthetics of composite restorative materials.[4]

The aim of the present study, therefore, was to evaluate the shear bond strength of nanocomposites to SSCs using three different bonding agents.

MATERIALS AND METHODS

The present study was a randomized comparative study conducted in the Department of Pediatric and Preventive Dentistry, V.S. Dental College and Hospital, Bengaluru, India and Laboratory of Civil Aid Pvt. Ltd; Bengaluru, India and Bhatt Laboratory, Bengaluru, India. Ethical clearance for the study was not required as it was an *in-vitro* study conducted on SSCs and resin molds.

120 pre-trimmed, pre-contoured lower left primary second molar pediatric SSCs of E5 size (KIDS Crown) were selected for the study (Figure 1).

The crowns were divided into four equal groups. Each group contained 30 crowns.

Sandblasting of the Crowns

Each crown was subjected for sandblasting in sandblasting unit used for dental purpose. The buccal surface of each crown was sandblasted for 20 s with aluminum oxide (Al_2O_3) particles having diameter of 50 μm.

Acrylic Base

After sandblasting all crowns were embedded in uniform acrylic mold with DPI-RR cold-cure acrylic resin. The sandblasted buccal surface of each crown was exposed and embedded perpendicular to the acrylic base (Figure 2).

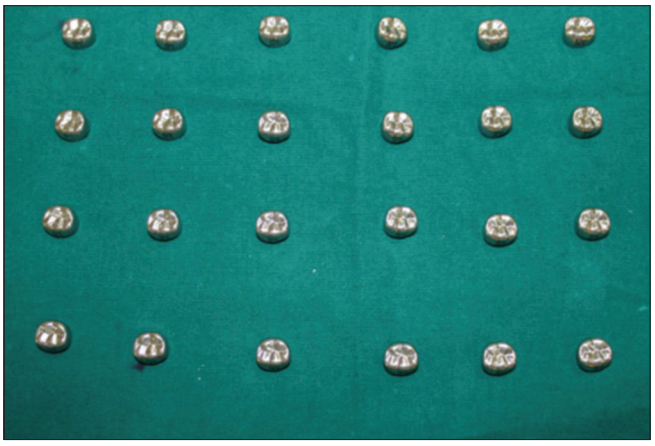


Figure 1: Stainless steel crowns (KIDS Crown)

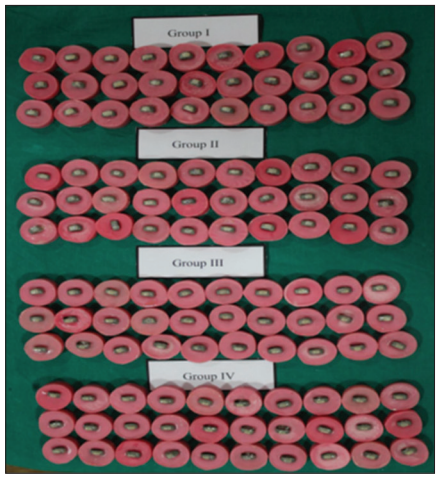


Figure 2: Stainless steel crowns embedded in acrylic molds and divided into four groups

Acid Etching of Crowns

The sandblasted buccal surface of each crown was then acid etched with 37% phosphoric acid (Fine Etch 37, Spident Co. Ltd) for 15 s and washed with water air spray.

Bonding of Composite

The sandblasted and acid etched buccal surface of each crown was bonded to different composite materials using three types of bonding agents.

Group 1 (control group): In this group the buccal surface of crowns were bonded to nanocomposite (Z100 TM Restorative, 3M ESPE) without the use of a bonding agent.

Group 2: In this group the buccal surfaces of crowns were bonded to nanocomposite (Z100 TM Restorative, 3M-ESPE) using Adper Single Bond 2 (3MESPE).

Group 3: In this group the buccal surface of crowns were bonded to nanocomposites (ceram-X mono + dentsply) using a bonding agent Prime and Bond NT (dentsply).

Group 4: In this group the buccal surface of crowns were bonded to nanocomposites (cream X mono + dentsply) using a bonding agent Bond Plus (Medicept-UK Ltd.) (Figure 2).

Thermocycling of Specimens

Thermocycling was carried out for all the specimens (500 cycles of thermocycling between 5°C and 55°C) to simulate thermal changes in the oral cavity.

Shear Bond Strength Testing for Specimens

After thermocycling, all specimens were sent to the laboratory for testing of shear bond strength. The shear bond strength of the composite attached to the buccal surface of SSCs was measured using a universal testing machine (UTM). A load cell of capacity 1.0 kN was applied with a force of 10 N at an acceleration of 0.5 mm/min on the crown-composite interface in a direction parallel to the long axis of the crown (Figure 3). All strength readings were calculated in megapascals (MPa), and the force at which the bond fractured was recorded as the shear bond strength of the adhesive. After the fracture of the bond between the composite and the SSCs, the crown samples were examined under a magnifying loupe and using a dark background, and type of failure was determined. The data were collected and sent for statistical analysis. SPSS software version 13 was used for analysis which was done using ANOVA and Chi-square tests.

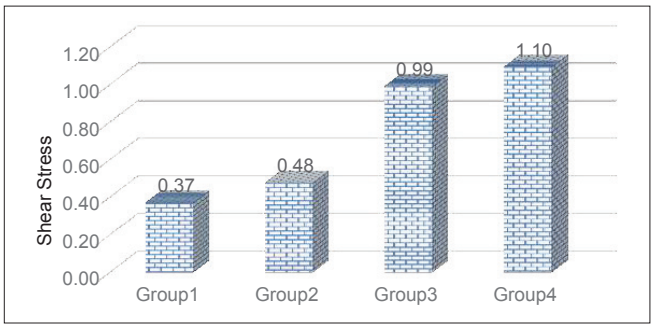
RESULTS

The results of the present study showed that the highest mean shear strength was recorded in Group 4 (Bond Plus) i.e., 1.10 MPa followed by Group 3 (Prime and Bond NT) i.e., 0.99 MPa, Group 2 (Adper Single Bond) i.e., 0.48 MPa and 1 (control group) i.e. 0.37 MPa (Table 1 and Graph 1).

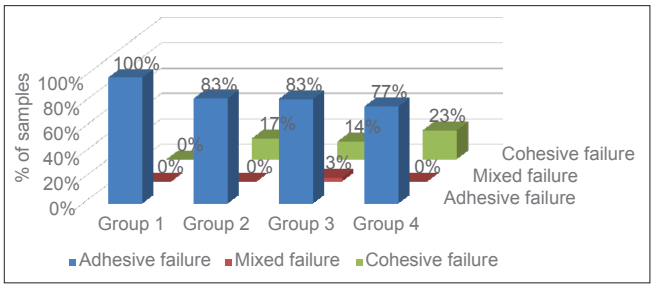
The difference in mean shear stress was found to be statistically significant between Group 1 and Group 3 ($P < 0.001$), Group 1 and Group 4 ($P < 0.001$), Group 2 and Group3 ($P < 0.01$) as well as between Group 2 Group 4 ($P < 0.001$) (Table 2). No significant difference was observed between the other pair of groups ($P > 0.05$).

Table 3 and Graph 2 show the association between the type of failure and the groups examined. All the samples in Group 1 (100%) had undergone an adhesive failure while

Figure 3: Shear bond stress testing



Graph 1: Mean shear stress recorded in groups



Graph 2: Type of failure in different groups

Table 1: Mean shear stress recorded in the groups (in MPa)

Group	Mean	SD	SE of mean	95% CI for mean		Min	Max
				Lower bound	Upper bound		
Group 1	0.37	0.44	0.08	0.21	0.54	0.12	2.22
Group 2	0.48	0.43	0.08	0.32	0.64	0.12	2.16
Group 3	0.99	0.65	0.12	0.75	1.24	0.12	2.4
Group 4	1.10	0.83	0.15	0.79	1.40	0.12	3.3

SD: Standard deviation, SE: Standard error, CI: Confidence interval

Table 2: Difference in mean shear stress among the groups

Group (I)	Group (J)	Mean difference (I-J)	*P* value
Group 1	Group 2	−0.106	1.000
	Group 3	−0.620	<0.001*
	Group 4	−0.724	<0.001*
Group 2	Group 1	0.106	1.000
	Group 3	−0.514	0.009*
	Group 4	−0.618	<0.001*
Group 3	Group 1	0.620	<0.001*
	Group 2	0.514	0.009*
	Group 4	−0.104	1.000
Group 4	Group 1	0.724	<0.001*
	Group 2	0.618	<0.001*
	Group 3	0.104	1.000

*Significant difference

Table 3: Type of failure in different groups

Type of failure	*n* (%)				χ^2	*P* value
	Group 1	Group 2	Group 3	Group 4		
Adhesive failure	30 (100)	25 (83)	25 (83)	23 (77)	10.539	0.104
Mixed failure	0 (0)	0 (0)	1 (3)	0 (0)		
Cohesive failure	0 (0)	5 (17)	4 (14)	7 (23)		
Total	30 (100)	30 (100)	30 (100)	30 (100)		

83% of samples in Group 2 and Group 3 had undergone adhesive failure. In Group 4, however, 77 % samples had undergone adhesive failure. Cohesive failure was seen in 5 (17%), 4 (13%) and 7 (23%) samples in Groups 2, 3, and 4 respectively. Mixed failure was seen in only 1 (3%) sample in Group 3. No significant association was observed between the type of failure and the groups ($P > 0.05$) as adhesive failure.

DISCUSSION

For restoring multi surface carious primary teeth, full coverage restorations are often the reliable option. Since anterior teeth and posterior teeth are restored with SSCs, pediatric dentists have recognized the need for an esthetic alternative to SSCs for anterior teeth. As parental demand for esthetic for posterior teeth are rising day by day, so pediatric dentists are forced to look at more esthetic options such as preveneered or open-faced crowns. There are drawbacks with preveneered SSCs such as difficulties in shade matching, limited ability to crimp the crown, tendencies of fracture of the veneered surfaces, and fears over long-term clinical performance have prevented their universal acceptance by pediatric dentists. Esthetic acceptability has been questioned for open faced SSCs in spite of higher rate of clinical success have been reported. It has been found that mechanical modifications improve the bond strength between composites and SSC surfaces.

In the present study sandblasting was chosen as the method to improve the retention of the composite to the crown as the equipment was easily available in the dental lab and since it was less time consuming and easier to standardize when compared to methods such as creation of grooves manually with a bur or welding of orthodontic brackets. Also in a scanning electron micrograph study conducted by Salama and el-Mallakh in (1997),[8] they found that sandblasting creates irregular and rough surface with many undercut areas in which the adhesive could wet and penetrate the SSCs surfaces creating micromechanical retention.

In the present study, after application of composite resin on the SSCs, all the samples were subjected to thermocycling. This technique was used to simulate the thermal changes occurring in the oral cavity due to intake of different kind of food articles. Similar technique has been used in many previous studies (Waggoner *et al.* 1995, De Araujo *et al.* 1997).[9,10]

The present study tested the bond strength of commercially available nanocomposite resins to. Pre-trimmed pre-contoured posterior SSCs (KIDS crowns) using a new single-bottle adhesive system, i.e. Bond Plus manufactured by Medicept UK Ltd. The bond strength obtained was compared to that of using two currently available dentin bonding agents, Adper Single Bond 2 (3M ESPE) and Prime and Bond NT (dentsply).

To avoid any chance of incompatibility of bonding agent with composite, each bonding agent was tested with a resin manufactured by the same manufacturer. However, since Medicept UK Ltd. does not manufacture any nanocomposite resin, Bond Plus was used with composite resin manufactured by dentsply. As explained in the methodology earlier, all samples were embedded in acrylic base and the shear strength of composite to the SSC was measured using UTM with a force of 10 N. Similar methodology was used by authors such as Khatri *et al.* in 2007 and Hattan *et al.* in 2013.[11,12]

The results of the present study showed that the control group (without any bonding agent) had significantly lower

shear bond strength to composite than the groups that utilized bonding agents. This finding was in confirmation with all the previous studies reported.[8,11,12] This may be due to insufficient bonding between nanocomposite and metal surface of the crown.

The shear bond strength obtained with conventional single bottle adhesives used in the study, i.e., Adper Single Bond 2 and Prime and Bond NT were 0.48 MPa and 0.99 MPa respectively.

These values were significantly less when compared to the values obtained in previous studies using similar adhesives.[8,11,12] The new single-bottle adhesive used in the present study, i.e., Bond Plus showed shear bond strength of 1.10 MPa which was higher than the values obtained with the conventional single bottle adhesives. A recent study suggested using self-etching adhesives that utilize 10-methacryloloxydecyl dihydrogen phosphate (MDP) form self-assembled nanolayers at the tooth-bond interface, which could be the reason for their higher bond strengths to tooth.[13] However, both the presence of this layer and the feasibility of this explanation with regards to metal bonding need further evaluation.

Three types of bond failures were recorded in our study: (a) Adhesive failure at the resin SSC interface, (b) cohesive failure within the resin, and (c) mixed failure located at the resin SSC as well as within the resin.

The results of the present study showed that Bond Plus recorded lower incidence of adhesive failure (77%) when compared to Adper Single Bond 2 (83%) and Prime and Bond NT (83%).

The control group on the other hand showed 100% adhesive failures. The less adhesive failure may be because of self-assembled nanolayers at the metal bond interface formed by 10-MDP, which could be the reason for their higher bond strengths to tooth. Cohesive failure found in Bond Plus group was 23% when compared to 17% in Adper Single Bond 2 and 14% in Prime and Bond NT. Mixed failure was found only in 3% of Group 3 adhesive while Group 1, 2 and 4 did not show any mixed failures. The type of bond failure has been used as a measure of the success of the bonding between SSC and adhesive restoration. Cohesive failures have been considered ideal, mixed failure acceptable and adhesive failures unacceptable. In this context the significantly fewer adhesive failures and finding of cohesive failure in the group that bonded with the Bond Plus are of significance. However, it must be noted that even the group that bonded with Bond Plus bonding agent showed incidence of adhesive failure, suggesting that clinical trials of this material are needed to validate the findings of this study.

It is often seen that there is loss of space and plaque retention due to fracture of the veneering of the preveneered SSCs as reported in studies done by Ram *et al.* (2003) [14] and Shah *et al.* (2004).[15] Furthermore, the repair of fractured veneer has been unsuccessful mainly because of its inadequate bonding to the metal surface. The results of this study also suggest that the higher shear bond strengths of Bond Plus could indicate the need to assess their possible use in the repair of fractured veneers of esthetic SSCs.

CONCLUSION

The new adhesive agent, Bond Plus was found to be having higher shear bond strength and less adhesive failure. Therefore, it can be recommended as a better material for those who need esthetically modified crowns and can also be used for repair of fractured veneers of esthetic SSCs. Further studies are however needed to validate the results of the current study.

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Original Article

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Efficacy of Centrifuged Liquid-Based Cytology over Conventional Cytology in Oral Squamous Cell Carcinoma: A Diagnostic Augmentation

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Abstract

Background: Oral exfoliative cytology is the cost effective and perhaps the best approach for the initial evaluation and diagnosis of the oral lesion. Centrifuged liquid-based cytology (CLBC) offers high-quality smears compared to the conventional cytology enhancing sensitivity and quality of smear with limited available resources.

Aims: The aim was to determine the efficacy of CLBC over conventional cytology technique by quantitative analysis of smears of patients with oral squamous cell carcinoma (OSCC).

Materials and Methods: In this prospective comparative study, smears were obtained from lesions of OSCC with a soft toothbrush after obtaining prior written consent. One smear was made using the conventional technique and another with the CLBC. For CLBC, sample was centrifuged with a prepared reagent following which a smear was made from the cell pellet. Both the smears were stained by Papanicolaou method. Smears from both the techniques were analyzed with respect to cellularity, background clarity, uniform distribution, elongation, and overlapping.

Statistical Analysis: Qualitative analysis of smears obtained by the two techniques was evaluated by Chi-square test.

Results: CLBC presented smears with a clear background, adequate cellularity, and improved cell morphology compared to the conventional technique.

Conclusion: The clarity of the background offers a better prospect of slide observation and its application in advanced procedures in comparison to the conventional technique.

Keywords: Centrifuged liquid-based cytology, Conventional exfoliative cytology, Liquid-based cytology, Papanicolaou method, Squamous cell carcinoma

INTRODUCTION

Oral cancers are a major health problem in India, and it constitutes for most common cancers in males and the third most common in females.[1] Early diagnosis greatly increases the probability of cure with minimum impairment and deformity.[2]

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Exfoliative cytology is the microscopic examination of the shed or desquamated cells from the epithelial surface usually the mucous membrane and is a simple, safe and reliable method. But limitations are seen as clumping, overlapping of cells along with the smears being obscured by blood, mucus, and other debris which potentially leads to an increase in false-negative results.[3]

Oral exfoliative cytology is the cost effective and perhaps the best approach for the initial evaluation and diagnosis

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of the oral lesion.[4,5] Montgomery and Von Haam were first to examine the usefulness of cytology in the oral cavity.[6] Since, 1990 liquid-based cytology (LBC) has been designed to improve the quality and quantity of conventional cytology.[7,8]

LBC was initially developed for cervical uterine cancer screening.[4] LBC reduces the problem related to sampling, helps in preparation of smears with high cellularity dispersed in a homogenous thin layer, reduction in false negative rates, clear background and thereby enhances sensitivity and quality of smear.[4]

LBC has acquired a wide range of acceptance in non- cervical cytology specimen, including oral cavity but it requires expensive automated devices and materials, which might not be affordable for many cytopathology laboratories in country with limited resources.[9,10]

Hence, a modified technique called centrifuged LBC (CLBC) which is cost effective method of LBC, which reduces inadequate smears and background staining. Thus, in this study the efficacy of CLBC is compared with conventional cytology method in patients with oral squamous cell carcinoma (OSCC).

MATERIAL AND METHOD

In this prospective comparative study, a total of 40 cases of histologically proven OSCC carcinoma were investigated in the Department of Oral Pathology and Microbiology. The study protocol was approved by the Institutional Review Board of SDM College of Dental Sciences and Hospital, Dharwad, Karnataka, India. The subjects were informed with regard to research objectives, methods, possible benefits and potential risks, and a written consent was obtained from all patients. Two cytological smears were obtained from the lesion using a soft toothbrush. One smear was made using the conventional technique and fixed immediately in 95% ethyl alcohol. Second sample was flushed out in a suspending solution composed of 20 ml of 95% ethanol, 6 ml acetic acid and 74 ml of normal saline. This was centrifuged for 10 min at 2000 rpm. The obtained cell pellet was resuspended in 95% alcohol, and smear was prepared with the help another slide and left for 2 h following which both smears were stained by Papanicolaou method.

Evaluation of Smears

Qualitative analysis of the smear obtained through conventional brush cytology and CLBC were made. Comparison between these two techniques was carried out with respect to cellularity, cell distribution, cellular clumping, cellular morphology, presence of blood, mucus, inflammatory cells and microbial colonies. All the slides were evaluated blindly by two independent observers and information obtained was subjected statistical evaluation by means of Chi-square test. The $P < 0.005$ was considered significant.

RESULT

The overall observations were as follows (Table 1, Figures 1-4, Graph 1):

Cellularity

Significant difference was observed between two techniques, CLBC technique showed high cellularity (70%) than a conventional technique (37.5%) ($P < 0.004$).

Back Ground Clarity

Clear background was obtained in all smears using CLBC (92.5%) compared to conventional technique (7.5%) ($P < 0$).

Table 1: Comparison of parameters between CLBC and conventional technique

Criteria	Conventional	Conventional (%)	CLBC	CLBC (%)
Cellularity	15	37.5	28	70
Clear background	3	7.5	37	92.5
Uniform distribution	2	5	20	50
Cellular overlap	19	47.5	17	42.5
Cellular elongation	6	15	4	10
Blood	4	10	0	0
Microbial colonies	13	32.5	12	30
Inflammatory cells	38	95	35	87.5
Mucous	37	92.5	0	0

CLBC: Centrifuged liquid based cytology

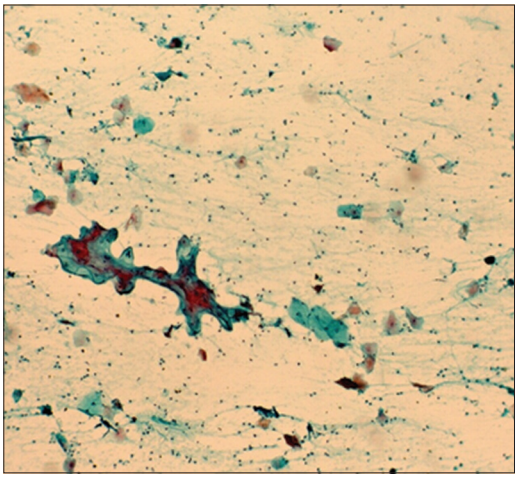


Figure 1: Photomicrograph of smear obtained with a conventional technique showing less cellularity, unclear background, clumped cells, cellular elongation and moderately diffuse inflammatory infiltrate

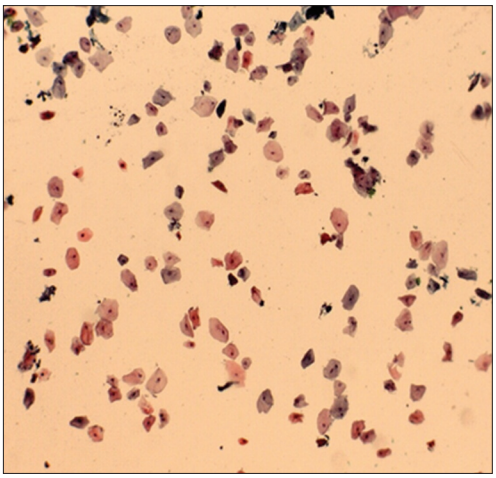


Figure 2: Photomicrograph of smear showing obtained with centrifuged liquid-based cytology technique showing adequate cellularity, clear back ground, less cellular clumping and sparse inflammatory infiltrate

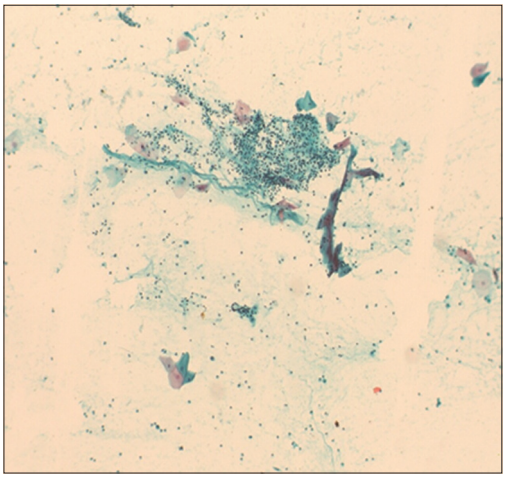


Figure 3: Photomicrograph of smear obtained with conventional technique showing less cellular areas of epithelial cells with unclear background with dense localized collection of inflammatory cells obscuring the details of the epithelial cells, cellular clumping can also be seen

Uniform Distribution

CLBC smears offered better uniform distribution of cells (50%), whereas conventional technique (5%) smears showed uniform distribution ($P < 0.000$).

Presence of Blood and Mucous

Smears made by conventional technique showed the presence of blood in 10% of cases and 92.5% showed presence of mucous, whereas none of the smears made by CLBC technique showed the presence of blood ($P < 0.040$) and mucous ($P < 0.000$).

Cellular Overlapping and Elongation

No statistically significant difference was obtained in both the techniques for cellular overlapping and elongation.

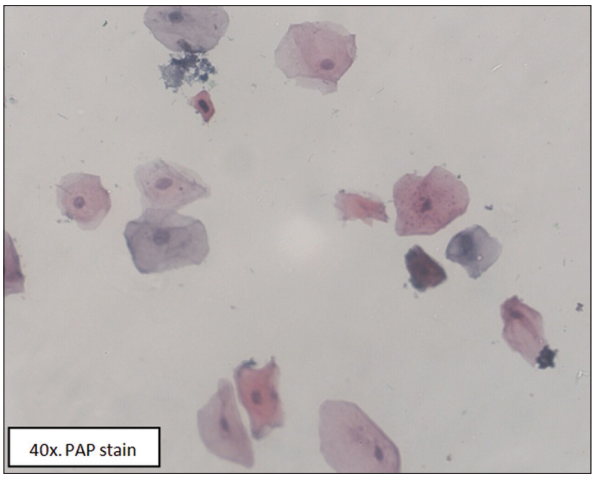
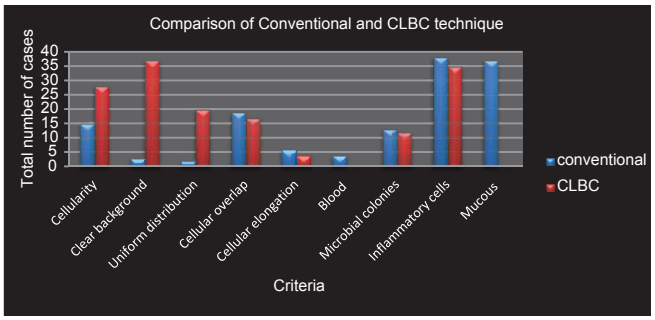


Figure 4: Photomicrograph of smear obtained with centrifuged liquid-based cytology technique showing uniformly distributed epithelial cells in clear background. Less of cellular clumping sparse inflammatory cells can also be seen



Graph 1: Various parameters compared between conventional and centrifuged liquid-based cytology technique

Presence of Inflammatory Cells

Smears which showed dense amount of inflammatory cells in conventional technique were reduced to moderate levels in CLBC smears, and those smears showed moderate inflammatory cells in conventional technique were reduced to a minimum in CLBC technique. But overall no statistically significant difference was obtained in both the techniques.

DISCUSSION

The seminal work by Papanicolaou and Traut in studying the cells from precancerous and cancerous lesions of the cervical mucosa paved the way for oral cytology.[6,11] Their work proved an effective tool for screening gynecologic malignant disease. In the second half of the nineteenth century, the morphology of malignant cells in sputum was first described from an oropharyngeal carcinoma.[6,12] This was followed by work of Morrison *et al.* in which they used Papanicolaou staining to diagnose nasopharyngeal carcinoma.[6,13]

Montomery and Von Haam who were the first to examine the usefulness of oral cytology in the oral cavity.[6,14] But

over a period of time, as the field of oral cytology started to grow, they experienced the limitations of oral cytology and therefore felt the need for improvements. They devised numerous modifications which were intended to procure larger amount of cells, to sample a large area and also to improve the quality of cell staining.[6]

Incidence of oral cancers and oral premalignant lesions is very high in India as compared with the western population. Though scalpel biopsy followed by histopathology is considered as gold standard in diagnosing these lesions, it may not be feasible in all suspected cases (the patient may be medically compromised or may refuse to undergo scalpel biopsy).[15]

Exfoliative cytology is an advantageous diagnostic procedure because it is non-invasive, relatively painless and inexpensive and requires minimum technical skills. Despite its advantages, it has certain disadvantages like inadequate sampling and false-negative results. It is well established that only small percentage of the harvested epithelial cells obtained during conventional cervical smear are transferred to the glass slide, and there is always a possibility of potential false-negative smears. It is shown that a maximum of only 20% of cells collected on a variety of collection devices can be mechanically transferred to the flat surface of a glass slide.[15] Study conducted by Oden GR, they compared cytobrush and wooden spatula for exfoliative cytology, they found cytobrush was found to be significantly more efficient than the wooden spatula, in terms of both cell yield ($P < 0.005$) and cell dispersion ($P < 0.005$).[16] But in our study, soft toothbrush was used because of cost effectiveness and easy availability.

LBC offers significant advantages over the conventional exfoliative cytology.[4] LBC technique removes most mucus, protein and red cells from the sample collected, distributes cells evenly, improves cell morphology, maintains diagnostic clusters, optimizes sample fixation, provides improved and unbiased sampling, controls cellular density, enhances nuclear detail, reduces scanty preparations and eliminates air-drying artifacts in oral samples.[9,17] But LBC requires expensive automated devices and materials, and trained users for interpretations, which might not be affordable for many cytopathology laboratories in countries with poor resources.[9]

The revolutionary modification of the conventional smear method by using LBC with a significant improvement in cytodiagnostic accuracy with increased sensitivity is CLBC.

In this study, we have evaluated the efficiency of the inexpensive CLBC method relying on cytocentrifugation. Here, mixture of isopropyl alcohol, glacial acetic acid, and normal saline was used as a reagent for the study in CLBC method. Isopropyl alcohol acts as a good fixative in cytological smears. This is important to preserve the morphology of the cells.[4] Glacial acetic acid acts as a lysing agent and helps in lysing of erythrocytes and enhances the clarity of the background. Physiological saline is iso-osmolar which maintains the cells in a proper osmolarity in order to avoid any osmotic shock and prevent the destruction of the epithelial cells.[18]

We found statistically significant results with various parameters like adequate cellularity, clear background, uniform distribution of cells, cellular overlapping and cellular elongation with CLBC in comparison with the conventional technique.

CLBC technique (70%) offered smears with adequate cellularity than the conventional technique (38%). This is attributed to the CLBC technique where sample collected through brush was flushed out, followed by centrifugation of the sample which resulted in pellet with better concentration of cells in comparison with the conventional method. Less cell yield obtained in a conventional technique may be due to loss of cells to the brush. Kujan *et al.* in his study on apparently normal oral mucosa using LBC technique found adequate cellularity in 98% of the cases. However, as LBC is expensive, the present method can be adopted where limited resources are present as it provides better cellularity than the conventional smear technique.[19] Ahmed *et al.* in his study on oral lesions using CLBC technique found optimal cellularity and concluded that this method gave better diagnostic accuracy when compared to the conventional method.[9] Thus, this method could replace the expensive LBC. Shah and Deshmukh also obtained 80% smears with high cellularity with cytocentrifugation technique in oral and premalignant lesion and concluded that high cellularity can be achieved with cytocentrifugation preparation.[20]

Most of the samples of CLBC (93%) showed clear background with minimum mucus, inflammatory cells and microbial colonies as compared to the conventional method (8%). Optimum results obtained in CLBC are due to the reagent used and centrifugation of the sample. There was no evidence of erythrocytes in any of the slides (0%) present in CLBC as compared to the conventional technique (10%). This result is similar to the study done by Dwivedi *et al.* and is attributed to glacial acetic acid used in the suspending reagent which will lyse all the erythrocytes.[4] CLBC also showed complete removal of mucus (0%) from the smears than conventional technique because of the reagent used in CLBC technique helps in removal of mucus from the smears and enhances clarity and brings about less cohesiveness of cells. Mucin, debris, and microbial colonies formed a supernatant solution in the cytocentrifugation

technique which were eliminated and hence increased the background clarity and cellular details. Shah and Deshmukh also concluded that cytocentrifugation reduces the amount of debris which is an integral part of exfoliative cytology.[20]

Conventional method does not have a liquid media for uniform spreading of cells; hence, scant cells were present in the center and most of the cells accumulated in the periphery. According to Dwivedi *et al.* the process of resuspending the cell pellet in alcohol and then pouring it over a horizontally placed glass slide led to sedimentation of cells and prevented uniform distribution of cells in CLBC method which they followed.[4] In our method, CLBC technique (50%) offered smears with uniform distribution than the conventional technique (5%) which can be attributed to a small amount of sample taken per slide which was evenly spread with the help of a glass slide.

In terms of cellular overlapping and cell elongation, no significant results were appreciated in both, conventional and CLBC technique.

Microbial colonies and inflammatory cells were present in dense amount in conventional smears which were drastically reduced in CLBC technique. This has been attributed to discarding the supernatant fluid which contained microbial colonies and debris. But no statistical significant difference was observed between both the techniques.

In a similar study conducted by Dwivedi *et al.*, CLBC technique scored better in terms of clear background, no other parameters were statistically significant in both the technique.[4]

But, in our study CLBC technique gave significant results in all the parameters except for cellular overlapping, cellular elongation and presence of inflammatory cells.

CONCLUSION

Results of our study concluded that, CLBC offered significant results over conventional smear preparation and thus, recommended for routine diagnostic purposes. Good clarity of background with adequate cellularity with evenly dispersed cells can be useful for diagnostic augmentation and for advanced procedures like immunochemistry especially in laboratories where automated devices are not accessible. Further implementation of this study on larger sample size with the help of more skilled professionals this technique can be modified to overcome the drawbacks obtained in this technique. CLBC method is strongly advocated in the best interest of public health as it improves the sample quality and reduces the likelihood of false negative results. As this method is relatively technique sensitive, improvement in this front can yield better results.

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Original Article

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Different Methods of Detection of Metallobetalactamase Producing *Pseudomonas Aeruginosa* from Tertiary Care Center

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Abstract

Background: Metallobetalactamase (MBL) producing *Pseudomonas aeruginosa* have emerged which have the capacity to hydrolyze virtually all beta lactam agents including the carbapenems. Detection of *P. aeruginosa* is crucial for optimal treatment of patients and control the spread of resistant bacteria in the hospital scenario.

Aim: The present study was undertaken to evaluate the various techniques for detection of MBL producing *P. aeruginosa* from a large tertiary care center in Western Maharashtra.

Methods: Totally, 100 imipenem (IM) resistant strains of *P. aeruginosa* form a study group. These IM resistant strains were subjected to the modified Hodge tests (MHT), IM-ethylenediaminetetraacetic (EDTA) disc diffusion test, IM-2 mercaptopropionic acid (MPA) double-disc synergy test and epsilometer-test strips.

Result: MHT picked all the MBL producers. IM-EDTA disc diffusion test was 100% sensitive for MBLs whereas the IM-2MPA showed the least sensitivity i.e. 69%.

Conclusion: Early detection of MBL producing *P. aeruginosa* is crucial for optimal treatment of patients and to control the spread of resistant bacteria in the hospital scenario. Simple methods i.e. MHT and IM-EDTA should use routinely for detection of MBL from various clinical isolates.

Keywords: Metallobetalactamases, Modified Hodge test, *Pseudomonas aeruginosa*

INTRODUCTION

Pseudomonas aeruginosa is a dreaded pathogen in the hospital environment. It could originate from the endogenous flora of patients or from moist environmental sites such as medical devices rinsed with the contaminated water. Indirect contact with contaminated surfaces via health worker hands could also act as a source of infection. It is a formidable opportunistic pathogen causing infections in hospitalized immunocompromised patients and most frequently recovered pathogen from intensive care unit patients. The spectrum of infection cause by these pathogens ranges from urinary tract infections to severe sepsis.[1]

A relatively narrow spectrum of antimicrobials is effective against *P. aeruginosa* including carboxypenicillin, ureidopenicillins, monobactam, carbapenems, quinolones, and aminoglycosides. Almost all strains are resistant to penicillins, cephalosporins, including ampicillin, cefuroxime, and cefotaxime. Thus, treatment of *P. aeruginosa* infections can be difficult.[1]

The introduction of carbapenems into clinical practice was a great step forward in treating such resistant infections. Recently, metallo-beta-lactamase (MBL) producing bacteria have emerged which have the capacity to hydrolyze virtually all β lactam agents including the carbapenems.[2]

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The new challenge thus is the detection and management of the emergent strains of *P. aeruginosa*, which are resistant to all conventionally used antibiotics including carbapenems.[2] Early detection could result in the introduction of effective control measures to prevent the spread of such multi-drug resistant infections in the hospital environment.

Detection of MBL producing *P. aeruginosa* is crucial for optimal treatment of patients and to control the spread of resistant bacteria in the hospital scenario. However, no Clinical and Laboratory Standard Institute or any other standard guidelines exist for MBL detection and reporting. Various methods have been used for detection of MBL strains such as double-disc synergy test, combined disc method, modified Hodge technique, dilution methods, epsilometer (E-test), and polymerase chain reaction.

Hence, the present study was undertaken to evaluate the various techniques for detection of MBL's from *P. aeruginosa*.

MATERIALS AND METHODS

A total of 100 imipenem (IM) resistant strains of *P. aeruginosa* were collected and formed the study group. The IM resistant strains of *P. aeruginosa* were screened for MBL production using the following different phenotypic methods:

Modified Hodge Test (MHT) (Figure 1)[3,4]

Procedure

The surface of Mueller-Hinton agar plate was inoculated evenly using a cotton swab with an overnight culture suspension of ATCC *Escherichia coli* 25922. Which was adjusted to 0.5 McFarland standard. After brief drying, an IM disc was placed in the center of the plate, and IM resistant test strain from overnight culture plate was streaked heavily from the edge of the disc to the periphery of the plate. The plate was incubated overnight at 37°C.

Interpretation

When the test strain produces the enzyme carbapenemase, it allows the growth of a carbapenem susceptible strain (*E. coli* ATCC 25922) toward a carbapenem disc. The positive result was taken to be a characteristic cloverleaf indentation. Cloverleaf type indentation occurred at the intersection of the test strain and the standard strain.[4]

IM-Ethylenediaminetetraacetic (EDTA) Disc Diffusion Test (Figure 2)[5]

Procedure

The suspected strains were inoculated into sterile peptone broth and the turbidity adjusted to 0.5 McFarland.

- Sterile cotton swab were dipped in the above broth and plated as a lawn culture on Mueller-Hinton agar
- After drying, two 10 µg IM disc was applied firmly on the surface of the agar
- To one of the IM disc, 4 µl of 0.5 M EDTA was added and plates were incubated for 16-18 h at 35°C.

Interpretation

EDTA is a chelating agent which removes zinc ions from the active site of the MBL enzyme. This makes the enzyme inactive and thus the organism become sensitive to carbapenems.

The zone diameter of two IM discs was measured and compared. Difference in the inhibition zones between the two discs by ≥7 mm was considered as a positive.

Double Disc Synergy Test[6] - IM with a Thiol Compound i.e. 2 Mercaptopropionic Acid (MPA) (Himedia) (Figure 3)

Procedure

- The suspected strain was inoculated into sterile peptone broth and turbidity adjusted to 0.5 McFarland.
- Sterile cotton swab was dipped in above the broth and a lawn culture made on Mueller-Hinton agar.
- After drying two 10 µg IM disc were applied firmly on the agar and filter paper disc was placed near one of the IM disc.
- Filter paper disc was placed 1-1.5 cm away from the IM disc.
- Then add 3 µl of 2-Mercapto-propionic acid on the filter disc
- The plate was incubated for 16-18 h at 37°C.

Interpretation

Inhibition of activity of the enzyme is demonstrated by the use of Thiol compounds i.e. 2 MPA. The presence of synergistic zone was interpreted as positive. Synergistic zone means MBL positive *P. aeruginosa* shows distinct extension of the zone of inhibition toward 2MPA filtered paper disc.

E-test (Biomerieux, France) (Figure 4)[6,7]

The E-test MBL strip consists of double-sided dilution range of IM in one side and IM-EDTA dilution on the other side. The E-test strip determines the minimum inhibitory concentration (MIC) of the antimicrobial agent.

Procedure

- The individual colonies of strain were suspended in liquid broth to attain a turbidity matching to 0.5 McFarland
- With sterile cotton swab a lawn culture was made in the same way as for disc diffusion
- Then E-test strip was placed on the agar with a sterile applicator
- Then plate was incubated for 16-18 h at 37°C and results of MIC of IM and IM-EDTA read directly from the strip.

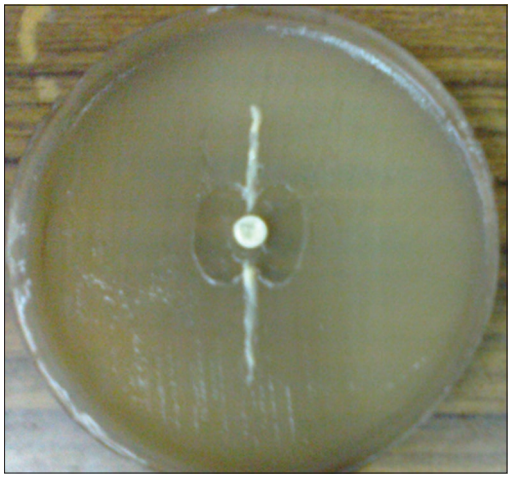

Figure 1: Modified Hodge test showing clover-leaf type indentation at the intersection of the test strain and the standard strain

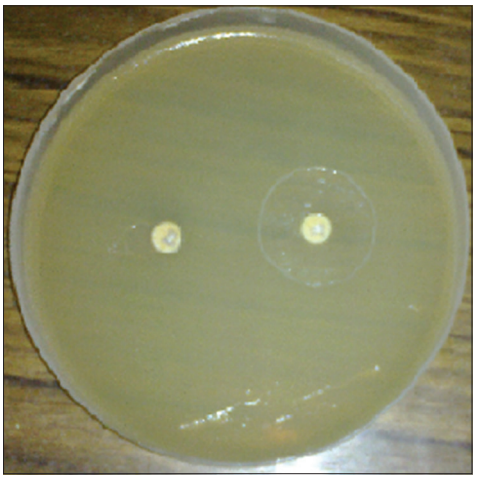

Figure 2: Imipenem-ethylenediaminetetraacetic double disc diffusion test showing difference in the inhibition zones between the two discs is >7 mm represents metallobetalactamase production

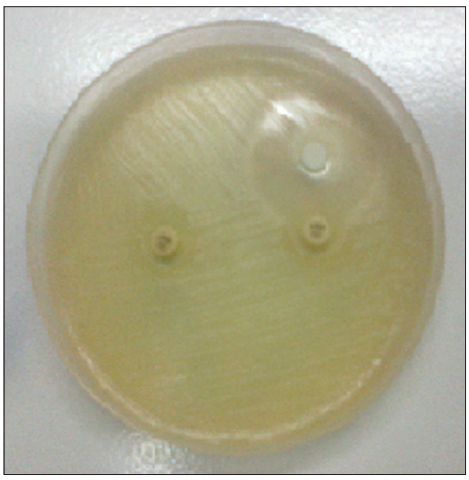

Figure 3: Imienem-2 mercaptopropionic acid (MPA) double-disc synergy test showing distinct extension of zone of inhibition toward 2MPA

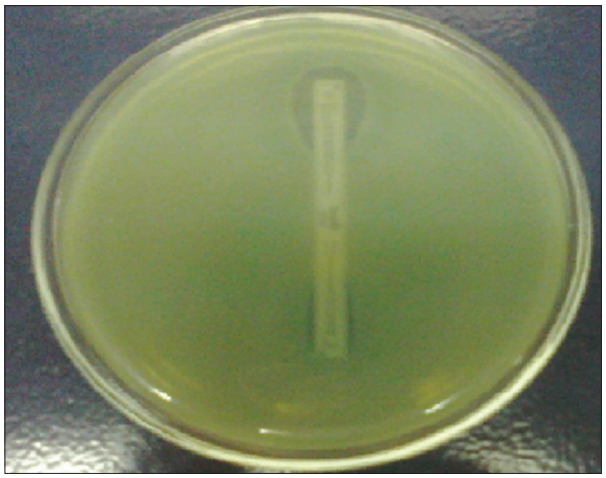

Figure 4: Metallobetalactamase (MBL) E-test showing minimum inhibitory concentration ratio of imipenem (IM)/IM-EDTA of 8 i.e. MBL producing strain of *Pseudomonas aeruginosa*

Interpretation

Ratio of IM/IM-EDTA ≥8, presence of the phantom zone, and distortion of ellipse were interpreted as positive results. This test was taken as the gold standard for detection of a MBL producer.

RESULTS

All the 100 *P. aeruginosa* isolates showing carbapenem resistance by modified Kirby-Bauer disc diffusion test were further screened by different phenotypic methods for detection of MBL. Many reports suggest that using the meropenem resistance rather than IM may increase the detection of MBL production but in the present study we used IM resistance to preliminary detect MBL producers.[8] Since MIC measurements are more accurate and quantitative method so E-test was taken as the gold standard[9] for evaluating three different phenotypic methods for screening for MBL production which can be routinely performed in most laboratories. Four isolates were E-test negative. Thus, 96% of IM resistant isolates were definite MBL producers.

All 96 isolates which are definite MBL producers by E-test, all those were picked up by MHT as well as IM-EDTA individually. Whereas the IM-2MPA double-disc synergy test picked only 69 MBL producers (Table 1).

DISCUSSION

MHT

This test is used to detect carbepenemase production. Evaluating this test, we found that for detecting MBL production 100 IM resistant strains of *P. aeruginosa* gave 100% positivity by MHT. For this test, we were using *E. coli* ATCC

Table 1: Performance of the different phenotypic methods for detection of MBL

	GOLD standard E-test (*n*=100)	MHT (% sensitivity) (*n*=100)	IM-EDTA disc diffusion test (% sensitivity) (*n*=100)	IM-2MPA double-disc synergy test (% sensitivity) (*n*=100)
Positive	96	100 (100)	100 (100)	69 (69)
Negative	04	00	00	31

MHT: Modified Hodge test, EDTA: Ethylenediaminetetraacetic, IM: Imipenem, MPA: Mercaptopropionic acid

25922 as a strain which gives 100% sensitivity. The four isolates which were demonstrated to be negative for MBL by E-test were found to be false positive by the MHT test. Pasteran *et al.* showed that using ATCC *E. coli* 25922 strain only 78% of sensitivity was obtained.[10] When they replaced the indicator strain with *Klebsiella pneumoniae* ATCC 700603 an improvement in performance was obtained. However, Bhongle *et al.* report a 100% positivity by using *E. coli* ATCC 25922.[11] Another similar study by Attal *et al.* shows all 16 MBL positive *P. aeruginosa* isolated by them were MHT positive.[3] Similar results were reported by Prakash *et al.*[12] Thus, MHT is a good screening test for detection of carbapenemase and MBL production but needs to be confirmed by a more specific test.

IM-EDTA Double Disc Diffusion Test

Another test recommended for detection of MBL production is the IM-EDTA double disc diffusion test. This test has also been reported to be 100% sensitive in detecting MBL producing *P. aeruginosa.*[13] This method is described by Yong *et al.*[14] They tried various concentrations of EDTA along with 10 μg IM disc in their study. The concentration of EDTA varied from 150 to 1500 μg. They concluded that 750 μg of EDTA gave excellent results. In this study, we used 750 μg disc of EDTA and the difference in zone of inhibition between two discs of ≥7 mm taken was taken as positive. The study done by Qu *et al.* shows 90.5% sensitivity with 750 μg EDTA and ≥7 mm zone diameter but gives 100% sensitivity if ≥6 mm zone difference was taken as the end point. They also used different concentration of EDTA like 290 μg, 750 μg, 930 μg. But 750 μg EDTA gave a higher sensitivity.[15] Another study by Irfan *et al.*[13] reported 100% sensitivity and 91% specificity of the IM-EDTA double disc diffusion test.

According to Yong *et al.* the IM 10 μg-EDTA 750 μg combined disc test was only 95.7% sensitivity for detection of MBL in MBL producing *Pseudomonas* spp. and *Acinetobacter* spp. Galan *et al.* have reported the utility of the same combination for *Enterobacteriace* with 80% sensitivity for detection of MBL.[16]

IM with 2MPA Double Disc Synergy Test

This test showed 69% sensitivity in our study. A similar study by Anwar et al showed a detection rate of 83% with IMP-2MPA DDST.[17] Another report describes that the distance between the two discs is important in the performance of the test. It shows sensitivity 53.6% when distance between the IM disc and filter paper disc with 2MPA was 2.5 cm. It also showed that as the distance between two discs goes on decreasing, the sensitivity of the test goes on increasing i.e. for 1 cm, 1.5 cm, 2 cm the reported sensitivity was 89.3%, 89.3%, 85.7%, respectively.[18]

E-test

In our study, we used the E-test as a gold standard. It detected 96 MBL positive strains out of 100 IM resistant *P. aeruginosa.* There are conflicting reports regarding the performance of MBL E-test in literature, It is reported to give only 36.7% sensitivity in MBL positive strain. Another study by Walsh *et al.* gives 94% sensitivity.[7] Studies by Lee *et al.* shows 100% sensitivity for detection of MBL in *P. aeruginosa.*[19]

In our study, four strains of IM resistant *P. aeruginosa* gave negative results by the E-test. In these four strains, two strains gave MIC ratio 2.6, one strain gives MIC ratio 3, and one strain gives MIC 1.5.

Evaluating the different phenotypic methods for detection of MBL in *P. aeruginosa*, we found that MHT and IM-EDTA disc diffusion test were equally sensitive and performed better than 2MPA double-disc synergy test. In the 2MPA, double disc synergy test 2MPA was seen to be a very volatile and corrosive substance so it could be dangerous to use it routinely.

The IM-EDTA double disc diffusion test and MHT gave four false positive results. This may be because of both the test are very subjective to interpretation The E-test is a very expensive test., so the MHT and IM-EDTA double disc diffusion test could be routinely used in all laboratories as a screening test. They are sensitive, less expensive, and easy to perform routinely.

CONCLUSION

Thus, we recommend that IM discs should be routinely used in laboratories for preliminary screening of MBLs. Every IM resistant *P. aeruginosa* should be subjected to the screening test for MBL either the MHT or the IM-EDTA double disc diffusion test. The latter test was easier to perform. If the results of the test are immediately informed to the clinician proper antibiotics effective against MBL+ve *Pseudomonas* could be start immediately.

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Case Report

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Prepubertal Periodontitis: A Rare Case Report

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Abstract

Periodontal diseases of destructive form in children are very rare. It still unclear to most of the clinicians that the pre-pubertal periodontitis is completely a separate entity which differs from juvenile periodontitis as the former occurs in the primary set of teeth while the later in the permanent. The underlying cause for pre-pubertal periodontitis is still hazy. It can be associated with the systemic disease, however; it can also be seen in clinically normal child. A 4.5-year-old female child reported to the Department of Pedodontics had clinical evidence of early exfoliation of primary teeth. Her family as well as medical history gave no contribution for the diagnosis. The treatment objective was to prevent the progress of the condition to the permanent dentition and also to restore the functional and esthetic of the child which would add to the psychological benefit to the patient.

Key words: Early-onset periodontitis, Premature dental loss, Prepubertal periodontitis, Primary dentition

INTRODUCTION

The classic definition of periodontosis is "a disease of the periodontium occurring in an otherwise healthy adolescent and is characterized by a rapid loss of alveolar bone involving more than one tooth of the permanent dentition. The amount of destruction is not manifested commensurate with the amount of local irritants present."[1] The rate of destruction is 3-4 times faster than that of adult periodontitis. One form affects the first permanent molars and incisors, and a more generalized form may affect most of the permanent dentition. Most of the dental community now refers to periodontosis as juvenile periodontitis. Page *et al.* has established a specific diagnostic criteria to distinguish true periodontosis (juvenile periodontitis), as defined by Baer,[1] from periodontosis of the primary dentition in young children, which he termed as pre-pubertal periodontitis (PP).[2] It is a term suggested for a form of periodontitis that starts soon after the eruption of primary teeth as reported by Hurt *et al.* in 1986.[3]

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The onset of PP is during or immediately after the eruption of the primary teeth. The prevalence is unknown, but probably rare, and there is a possibility of a genetic basis for some types of the disease. PP may be followed by severe periodontitis of the permanent teeth or by a normal permanent dentition.

PP can broadly be classified as generalized form and localized form which can be differentiated from each other on the basis of clinical feature, defect in the neutrophil, monocyte and microbiologically. In the localized form of PP, some but usually not all of the primary teeth are affected. The onset of the disease occurs around or even before the age of 4 years. The gingival tissue manifests only minor inflammation if any, and microbial plaque is minimal. Functional defects are present in either neutrophils or monocytes, but not in both. The hallmarks of generalized PP include a fiery red, acute inflammation involving the marginal and attached gingiva around all the teeth, gingival proliferation, and cleft formation. Recession onset is at the time of or soon after tooth eruption. Both neutrophils and monocytes are profoundly abnormal in this form of the disease, and the peripheral blood white cell count is elevated markedly.[4]

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In 1986, the American Academy of Periodontology (AAP) in its glossary of terms defined PP as, "periodontitis that starts soon after the eruption of the primary teeth." In the following year, the AAP published a position paper and defined the disease based on the publication of Page *et al.* with the additional criterion that patients with the following diseases are excluded from the definition of PP: Neutropenia, agranulocytosis, aplastic anemia or other traditional blood dyscrasias, and Papillon–LeFevre syndrome.[3]

There are two broad categories into which the etiology of aggressive periodontitis may be broadly divided, and they are bacterial plaque with highly pathogenic bacteria and other being impaired host defense mechanism.[5] *Aggregatibacter actinomycetemcomitans* previously known as *Actinobacillus actinomycetemcomitans* in combination with *Prevotella intermedia*, *Treponema denticola,* and *Porphyromonas gingivalis* are the most important pathological microflora responsible for the disease though presence of other bacteria are also reported.[6] Genetic predisposition for periodontal disease has been observed, and their transmission among the family members or between children and their caregivers has also been observed.[7,8] Thin cementum areas in the teeth of patients with PP could be a major determinant of disease progression as it increases the risk of pathogen invasion.[9]

Here, presented is a rare case report of 4.5-year-old female child diagnosed with PP showing all the classical features of the disease. This paper highlights not only the elimination of the diseased condition but also the rehabilitation of its function and esthetics.

CASE REPORT

A 4.5-year-old female was referred to the Department of Pedodontics and Preventive dentistry. The patient was reported because of the parental concern for the early exfoliation of her teeth. The patient was in no apparent distress, and there was no history of recurrent infections. Neither of the parents had any periodontal pathology, and both were healthy. The patient had not received any treatment for this condition before. According to her mother, her deciduous teeth had erupted normally but early mobility and exfoliation of teeth had occurred. On examination, gingiva was apparently normal and missing teeth were 51, 52, 61, 71, 72, 81, 82 and Grade II mobility in relation to 62 (Figure 1). Halitosis was present. Blood counts were within normal ranges, except for an elevation in the number of white blood cells. Erythrocyte sedimentation rate was also elevated. Serum biochemistry results were within normal ranges and were consisted with her age.

The initial treatment of the case included extraction of teeth with Grade II mobility, i.e. 62 (Figure 2). Rest of the primary teeth were scaled, root planed, and subgingival irrigation with 0.2% chlorhexidine was performed. Furthermore, the topical application of metronidazole in chlorhexidine base was prescribed for a period of 2 weeks. A program of 3 months maintenance, scaling and oral hygiene index reinforcement was followed. Upper and lower space maintainer was delivered for functional and esthetic rehabilitation (Figure 3).

Figure 1: Missing 51, 52, 61, 71, 72, 81, 82 due to prepubertal periodontitis

Figure 2: Extraction of involved primary teeth i.e. 62

Figure 3: Functional and esthetic rehabilitation

DISCUSSION

Severe, rapid periodontal destruction and tooth loss occur infrequently in children and teenagers and can be classified into two groups according to the age of onset: Prepubertal forms; which occur before 11 years of age, although they may exist after this age too, and the pubertal and adolescent forms; which are seen approximately between the age of 11 and 19. The term juvenile periodontitis is used to refer to the second group.[10] PP is essentially a periodontitis of primary teeth and may include inflammation of the gingiva, early loss of primary teeth as well as bone loss. In the localized form of PP, some but not all of the primary teeth are affected. The disease may occur around or even before the age of 4 years. The gingival tissue manifests only minor inflammation if any, and microbial plaque is minimal. Alveolar bone destruction is more advanced and faster than that of adult periodontitis or chronic periodontitis in teenagers. The presented case also manifests the similar finding i.e. early loss of primary teeth with minor gingival inflammation around the age of 4 years. Therefore, the diagnosis best fits into localized PP due to its classical clinical manifestations.

Existing evidences show that PP tends to occur in families. In some patients, a clear history of recurrent infections, early loss of primary teeth can be traced through previous generations.

In view of Baer,[1] periodontitis per se does not occur in young children but when present, it can be a manifestation of some systemic disease like agranulocytosis or hypophosphatasia.

However in some other studies, there was no reported history of skin lesions, although patients may have recurrent, sometimes life-threatening infections. Generalized as well-localized PP have been reported in otherwise clinically normal children but these children may have some systemic disease that may remain undetected.[3]

Similarly, this case exhibited early-onset periodontitis involving the primary teeth only in a pre-pubertal child with no systemic diseases and family history.

Tinanoff *et al.*, Preus and Gjermo have proposed a treatment protocol consisting of not only local removal of the irritant factors, but also of extraction of teeth, either primary or permanent that are involved in the pathology.[11,12] This should be done before the appearance of the remaining permanent teeth and be combined with administration of antibiotics.

This protocol was also followed in this case. Treatment included extraction of the teeth which were affected by the pathologic condition. Other teeth were scaled, root planed and subgingival irrigation with 0.2% chlorhexidine was performed. For the maintenance of the condition, the topical application of metronidazole in chlorhexidine base was prescribed for a period of 2 weeks. A regular follow-up schedule at the interval of 3 months was recorded. Repeated treatment by local chemicals for short periods was done instead of a wide spectrum systemic antibiotic therapy as reported by most of the authors.[13-16]

This treatment plan not only gave a moral boost and psychological benefit to the parent but also to the patient thereby delivering a positive dental attitude in the child.

CONCLUSIONS

PP is probably a rare disease affecting primary dentition. It was concluded that the elimination of the pathogenic microflora during primary dentition by early extraction of the teeth involved, also daily local, mechanical, and chemical control of the irritant factors may prevent subsequent damage to remaining teeth in PP. This disease not only affects primary dentition but also lowers the confidence of the patient as there is earlier exfoliation of anterior teeth. Therefore, our aim should not only be to treat the disease but also to raise her confidence by delivering her upper and lower removable functional space maintainers to restore her function and esthetics.

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Case Report

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Male Breast Carcinoma: A Rare Case Report

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Abstract

Breast cancer is one of the most frequent tumors of the female population and is basically considered a disease of women. Though males do not develop milk-producing breasts, a man's breast cells and tissue can still develop cancer. Male breast cancer (MBC) is a relatively rare disease with an incidence of <1% of all breast cancers, mostly occurring at an older age. Though rare, it carries a higher mortality than women do, primarily because awareness among men is less causing a delay in seeking treatment, secondarily due to less amount of breast tissue the spread occurs faster thus presenting with an advanced disease. Due to its rarity, MBC is not well-understood, current knowledge is based mainly on population-based or descriptive studies that assess a limited number of patients. Its optimal treatment is not known, and the general recommendation is to use current guidelines for female breast cancer. Most MBC show positivity for hormonal receptors *viz*.; estrogen, progesterone, and HER-2, rarely triple negative cancers are seen which are even more aggressive and difficult to treat. We report a rare case of highly aggressive and recurrent - triple negative carcinoma left breast in a 60-year-old male.

Key words: Breast neoplasms, Female, Hormone receptors, Male

INTRODUCTION

Male breast cancer (MBC) is rare and tends to be diagnosed at an older age than women. The majority of breast cancers are sporadic, but in both genders in 25% of cases a positive family history due BRCA-1 and BRCA-2 germline mutations is present.[1] MBC presents late at an advanced stage and is highly recurrent resulting in poor prognosis. Invasive ductal carcinoma is the most prevalent histological type, with an incidence varying from 65% to 95%.[2] Due to rarity of this disease, there have only been retrospective analyses performed in evaluating treatment options for MBC at this point in time. Treatment choices are similar to the options available for female breast cancer (FBC) and include surgery, neo-adjuvant and adjuvant therapy, radiation and chemoprevention.[3] But, even though, more data are emerging; more efforts to understand risk factors, treatment options, and survival benefits are needed. Thus, a case report and review.

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CASE REPORT

A 60-year-old male patient presented with a painless lump over upper, anterior aspect of left chest of 6 months duration with no history of nipple discharge, eczema or distortion. There was a history of significant weight loss, generalized weakness, easy fatigability, and low-grade fever. No significant medical, surgical, and family history was recorded. He was a non-smoker and consumed alcohol occasionally. There was no history of any intake of drugs or anabolic steroids, his systemic examination apart from revealing anemia and cachexia was unremarkable. Examination of the chest revealed a solitary, non-tender, non-mobile, hard lump (5 cm × 4 cm × 3 cm) on upper anterior aspect of left side of the chest, about 6 cm from left nipple-areolar complex (Figure 1). The overlying skin was edematous, with erythema and multiple ulcerated patches, basal induration was present indicating the infiltration into pectoral muscles. Ipsilateral nipple-areolar complex showed no structural or the positional abnormality and failed to exude any serous or bloody discharge on compression of the lump, and no axillary lymphadenopathy was noted. No other palpable lump was noted in the opposite breast, axilla or supraclavicular fossa. Blood investigations were unremarkable. Chest radiograph was normal and showed no osseous, cardiopulmonary,

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pleural, or pericardial pathology. Ultrasound of the left breast revealed a well-circumscribed mass with complex internal echotexture and partial infiltration of deep planes with axillary lymph node enlargement suggestive of malignancy. Fine-needle aspiration and a core biopsy of the lesion were performed, and the diagnosis was invasive ductal carcinoma with triple negative hormone receptor status. Karyotyping showed a normal male genotype, and metastatic workup was normal. A left modified radical mastectomy was performed; flaps could not be approximated throughout the length resulting in a small raw area inferomedially on which a split skin graft was placed. Graft was taken up well. Histology revealed it to be highly invasive infiltrating ductal carcinoma with metastasis to four axillary groups of lymph nodes, negative margins, and triple receptor negativity. Adjuvant chemoradiation was planned, but patient was lost to follow-up, to return after 8 months with cervical, bilateral axillary and local recurrence (Figures 2 and 3) along with a history of shortness of breath. Excision of the local recurrence was done (Figure 4), and base of the wound was kept open and one dose of systemic chemotherapy was given along with local instillation of 5FU. However; there was local recurrence again within 1 week of surgery and patient developed chest metastasis. Unfortunately, the patient was again lost to follow-up.

DISCUSSION

MBC, as described earlier is a rare tumor and accounts for <1% of breast cancers, but the incidence seems to be increasing.[4] It has unimodal age-frequency distribution with a peak incidence at 71 years old. Conversely, FBC has a bimodal age-frequency distribution with early-onset and late-onset peak incidences at 52 and 72 years old, respectively.[5] Mostly, sporadic and genetic in 25% cases other risk factors are cirrhosis,[6] testicular trauma, obesity, radiation therapy exposure, Klinefelters syndrome, and the use of exogenous estrogen.[7]

Figure 1: Solitary lump over upper anterior aspect of the left side of the chest

Figure 2: Axillary lymphadenopathy

Figure 3: Local recurrence

Figure 4: Raw area over the chest post excision of local recurrence

Invasive ductal carcinoma is the most common histological type seen in men as described earlier and presents with peculiar features. About 42% of breast cancer cases in men are diagnosed in Stage III or IV,[8] due to delayed presentation. Proximity to the skin allows for quicker invasion of lymphatic vessels and spread to regional lymph nodes as well as development of distant disease.[9]

Painless lump is the most common mode of presentation. Estrogen and progesterone receptors have been suggested to play a key role. MBC has a higher rate of positivity for hormonal receptors than FBC, the estrogen receptor being positive in 81% of cases as well as the progesterone receptor in 74%, with positivity in female cases being 57% for both receptors.[10] Expression of progesterone and estrogen and HER-2 nuclear receptors predicts for lesser rates of recurrence and improved survival rate.[11] Triple negative breast cancers are very rare and associated with poor clinical outcome being highly aggressive and therapy resistant as in our case; currently possess almost no molecular targets for therapeutic option in this horizon.[12] Overexpression of the proto-oncogene, HER-2 has been shown to present the worst prognosis for a patient.[13] Other markers that have been recently studied are p27, MIB-1, and Bcl-2 genes. Earlier detection of MBC is associated with higher success rates of treatment similar to women. Investigation consists of a combination of a clinical examination, mammography, cytology, and percutaneous biopsies.[14,15] The core needle biopsy is important because it enables a definitive diagnosis of invasive breast cancer and the evaluation of estrogen receptors, progesterone receptors, and HER-2 status.[16] The mainstay of breast cancer surgery for men is modified radical mastectomy. Neoadjuvant and adjuvant chemotherapy with cytotoxic agents has been shown to favorably influence survival in men with lymph node-positive cancer. Radiation is generally indicated when the risk of locoregional recurrence following mastectomy and systemic treatment exceeds 15% or 20%. The pathologic features that predict local recurrence rates in excess of 15% include: (1) T3 or T4 primary disease, (2) involvement of four or more axillary lymph nodes, and (3) involvement of one to three axillary lymph nodes and either extracapsular extension of disease measuring over 2 mm or 10 mm or fewer lymph nodes recovered from the axillary dissection. In women, radiation has been shown to decrease locoregional recurrences by two-thirds, which translates into an improvement in survival in selected patients.[17]

Unlike in females, the use of aromatase inhibitors in men (anastrozole, letrozole, and exemestane) may be problematic because the testicular production of estrogen is independent of aromatase and accounts for approximately 20% of circulating estrogens. The remaining 80% of circulating estrogens in men result from the conversion of androgens through aromatase.[18]

The most important independent prognostic factors are tumor size, grade, lymphatic invasion, axillary node status, and stage. Due to late presentation; men have more advanced disease at diagnosis than women. Sites of metastases are similar to those in women and include bone, lung, liver, brain, and others. Median survival from the time of presentation with metastatic disease is approximately 26.5 months.[17]

CONCLUSION

Men are not spared of carcinoma of the breast. Though rare, MBC is more aggressive than FBC and has a worse prognosis especially the triple negative type. Due to lack of self-awareness, these patients usually present late with delayed diagnosis, and larger tumor size resulting in a higher morbidity and mortality. Possibility of this rare entity should always be considered in the presence of a nodule or mass in chest region, so that early diagnosis can be made, leading to better patient survival rates, as is the case in women.

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Case Report

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Giant Cell Tumor Involving the Proximal Phalanx of Ring Finger: A Rare Case Report

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Abstract

Giant cell tumor (GCT) of bone arising from a phalanx is extremely rare. We hereby report a case of GCT arising from a phalanx of left ring finger. He initially presented with swelling over the proximal phalanx of ring finger. He was diagnosed as GCT and was treated primarily by intralesional curettage and autogenos bone graft. At his follow-ups patient presented with recurrence for which he was successfully treated with ray amputation (en block resection). At his most recent follow-ups, he is recurrence-free and had returned to his previous occupational and recreational activities. GCT of phalanx is locally aggressive and highly recurrent tumor so primary aim of treatment should been block removal of tumor mass. Patient should be under regular follow-up for detection of early recurrence appropriate treatment.

Key words: Bone graft, Curettage, Giant cell tumor, Ray amputation

INTRODUCTION

Giant cell tumor (GCT) of a phalanx of a finger is extremely rare. Only 2% of all reported GCTs are found in the hand.[1] The metaphysical region of the metacarpals and phalanges has been found to be the common site of GCTs in most of the reported cases.[2-4] Though GCT is not a sarcoma, its relatively high recurrence rate.[5] Coupled with local aggressiveness after simple curettage often requires extensive en bloc excision.

The recurrence of GCT of hand is higher than for other locations. Local recurrence following curettage and bone grafting has been reported to be as high as 90%.[1,4,6,7] Wide resection and reconstruction with structural bone grafting is also reported to have a high local recurrence rate.[6] Multiple procedures such as excision (local or wide), ray amputation, and amputation are used to eradicate the disease completely. Even with single- or double-ray resection for primary or recurrent tumors, local tumor control may not be absolute. Here, we report one case GCT proximal phalanx of ring finger noting the rarity of a lesion at this site, and also high chances of recurrence and need for multiple procedures.

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CASE REPORT

A 38-year-old male presented with a painless swelling of the left ring finger of 6 months duration without any history of trauma or fever (Figure 1). Examination revealed a fusiform swelling, hard in consistency, in the proximal phalanx of ring finger. The overlying skin was stretched and pigmented without adherence to the underlying mass. The adjacent joints had normal ranges of movement. Regional lymph nodes were not palpable. Serum biochemistry was within normal limits. Radiographs demonstrated an expansile lytic lesion involving the entire phalanx with a cortical break (Figure 2a). The articular margins were found to be intact. Radiograph of the chest was normal. Fine needle aspiration cytology revealed multinucleated giant cells with stromal cells in the background. Under general anesthesia, curettage of the lesion was performed with cancelous bone grafting from the iliac crest (Figure 2b). The recovery was uneventful. Histology confirmed the diagnosis of a GCT, demonstrating osteoclastic giant cells admixed with stromal cells.

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On regular follow-up, patient presented with progressive swelling. At 6th-month follow-up on examination, the swelling was globular in shape, firm in consistency, and tender. The overlying skin was found to be fixed and markedly stretched (Figure 3a1 and a2). Regional lymph nodes were not palpable. A radiograph revealed an expansile lytic lesion in the remaining part involving the entire phalanx including the articular surface and was associated with soft tissue swelling (Figure 3b1 and b2). A radiograph of the chest was normal. There were no signs of the disease elsewhere in the body. Results of laboratory studies were within normal limits.

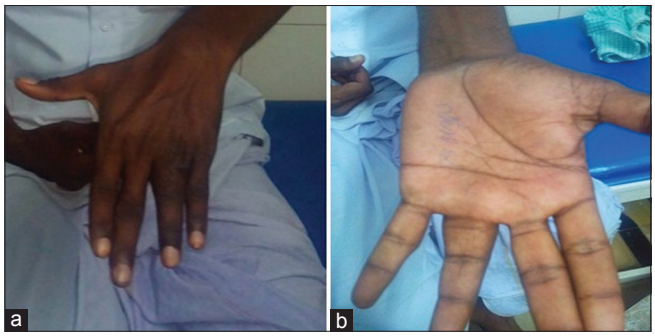

Figure 1: Clinical photograph of swelling over proximal phalanx of ring finger

Figure 2: (a) X-ray showing an expansile lytic lesion with break in the cortex, (b) X-ray after curettage and bone grafting

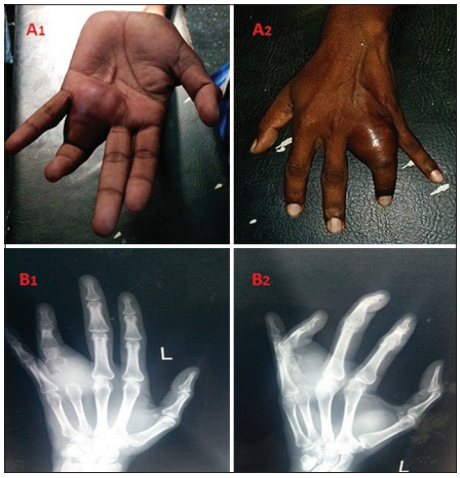

Figure 3: (a1 and a2) Clinical photograph showing recurrence of tumor, (b1 and b2) X-ray anterior-posterior and oblique showing lytic lesion of proximal phalanx of ring finger

Ray resection of the ring finger was performed under brachial block taking consent from the patient. Resected tumor tissue was found to involve the entire base of the proximal phalanx, including the articular cartilage. Histopathological examination reconfirmed that it was a GCT of proximal phalanx with extension into 3rd aintermetacarpal space. The patient had an uneventful recovery [Figure 4].

At his most recent follow-up (1 year), neither clinical nor radiological evidence of local recurrence was seen [Figure 5].

RESULT

After proper ray excision of ring finger for GCT of proximal phalanx, there was no recurrence of the tumor at 1-year follow-up. There was no limitation on the strength or motion of the uninvolved digits or wrist. He was able to perform normal activities of daily life except that the patient started wearing his ring in the middle finger.

DISCUSSION

GCT of the hand is rare and seems to be different from conventional GCT, which occurs at other sites in the

Figure 4: (a1-a4) Ray excision of ring finger of the left hand, (b) postoperative day 15 after suture removal, (c) immediate post-operative X-ray

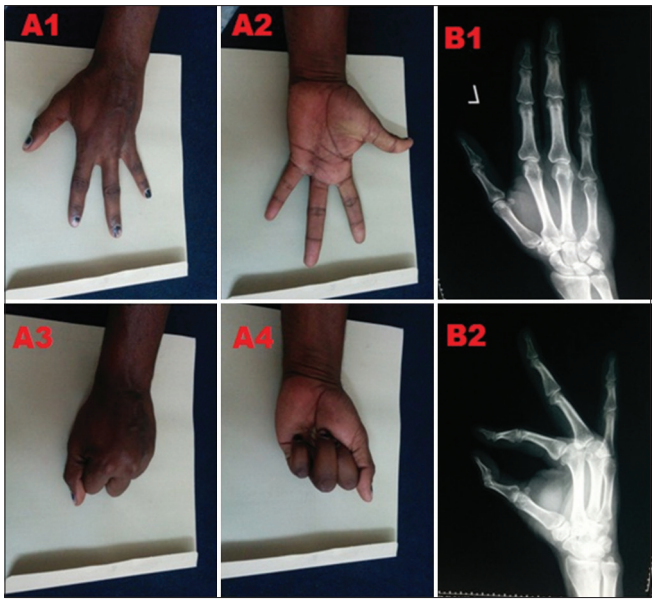

Figure 5: At 1 year months follow-up: (a1-a4) Clinical photos showing finger movements, (b1 and b2) X-ray showing no recurrence of the lesion

skeleton. GCTs recur more rapidly in the hand than they do in other locations. It is even rarer to encounter a GCT arising from the phalanges. Of the more than 2400 skeletal GCTs reported in the literature, <50 were found to involve the phalanges of the hand.[7,8] Coley *et al.*[9] reported only two cases of GCT arising from the phalanges in their series of 108 cases. Goldenberg *et al.*, in their analysis of 218 cases of GCT, reported six cases involving the phalanges.[10] In another two large series of 568 and 327 cases of GCT, authors found only four and one cases of phalangeal involvement, respectively.[11,12] Yasuda *et al.*[13] reported a multicentric GCT of the hand involving a finger and the wrist. Benign metastasizing tumor of hand has also been reported. GCT of the hand has also been reported.[14] GCTs of the hand have been treated with curettage and cancelous bone grafting, wide resection, and structural bone grafting or ray amputation.[1,4,6,7,15] High local recurrence rates have been reported with these treatment modalities.[1,4,6,7]

Daniel *et al.*[16] reported a GCT of the middle phalanx treated with curettage and bone grafting, which recurred at 9 months and was successfully treated by excision and allograft replacement.Wittig *et al.*[17] reported three cases of phalangeal GCT treated with curettage, cryosurgery, and cementation. Resection-iliac graft and double arthrodesis for GCT of the proximal phalanx of the thumb has also been reported.[18] Most local recurrences of GCT cases of the hand are reported to occur within 1 year of primary surgery.[1,6] Patel *et al.*[7] treated three cases of GCT of the hand with curettage and bone grafting, two of which had local recurrence and required ray resection.

Most of the GCT cases with recurrent tumors require ray amputation to prevent recurrence. There are reports of success with ray resection or amputation at the cost of the loss of a functional finger.[7,15] We chose ray resection of the amputated ring finger with the aim of preventing recurrence. The recurrent tumor in our patient expanded eccentrically, leading to increase in size of swelling. Histology of the lesion also revealed osteoid formation. Kumar and Tuli[19] and Dahlin[11] reported similar histological findings in their series. Following ray resection of the ring finger, there was no functional loss of the hand in our patient. The patient was satisfied with a cosmetically improved hand. In view of the comparative rarity of a tumor arising from the phalanges of the finger, the present case was considered worth reporting.

CONCLUSION

GCT of phalanx is locally aggressive and highly recurrent tumor so primary aim of treatment should be block removal of the tumor mass. Patient should be under regular follow-up for detection of early recurrence if any. Here we have treated a case of GCT phalanx which recurred with primary treatment of curettage; recurrence was detected early and treated appropriately with ray excision.

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Case Report

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Rapidly Enlarging Swelling of Upper Lip: A Rare Case Report

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Abstract

Squamous cell carcinoma (SCC) is a malignant tumor which arises from the keratinizing cells of the epithelium or epidermis. It grows slowly, shows local invasion with the potential to metastasize other organs of the body. We report an unusual case of a rapidly enlarging swelling on the upper lip of a 56-year-old male patient, which was suspected to be malignant melanoma on the basis of clinical presentation. But, it was histopathologically confirmed as moderately differentiated SCC. Rapidly enlarging skin lesions pose great challenges in the management. As the lesions are rapidly increasing in size, they eliminate the first-line reconstructive options that can compromise aesthetic and functional outcomes. Accurate histological diagnosis prior to surgery is important, as it has an impact on the excision margins. Early referral to a specialist is essential to avoid any need for a more invasive procedure and associated morbidity.

Keywords: Dissection, Lesion, Reconstruction

INTRODUCTION

Lips reveal a heterogeneous group of lesions ranging from developmental, inflammatory, ulcerative and neoplastic conditions. The neoplastic conditions include papilloma, fibroma, lipoma, salivary gland tumors, hemangioma, keratoacanthoma, squamous cell carcinoma (SCC), melanoma and Kaposi's sarcoma etc.,[1] Most common benign tumor of upper lip is canalicular adenoma and lower lip is mucocele. Most common malignant tumor of upper lip is basal cell carcinoma and lower lip is SCC.[2] We are reporting a case of rapidly enlarging ulcerative swelling of upper lip in a 56-year-old male patient which was thought to be melanoma due to its location and color, but histopathologically was diagnosed as moderately differentiated SCC.

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CASE REPORT

A 56-year-old male patient presented to us with a chief complaint of swelling of the upper lip since 2 months. Patient complained of a painless small swelling of the upper lip 2 months back, which gradually increased to present size. The medical history was non-contributory. Patient had the habit of khaini eating with a frequency of 6-7 times a day since 20 years. Now, patient had discontinued the habit.

Local examination showed a solitary, ill-defined swelling, oval in shape, in the center of upper lip measuring 3.5 cm × 3 cm in dimension, extending from midline till the left commissures and intraorally into gingivobuccal sulcus, without involving gingival mucosa. Surface of swelling was covered by a blackish brown slough, which on removal revealed ulcerated mucosa.

The swelling was non-tender and painless, hard in consistency, non-fluctuant, indurated, and fixed to underlying structures. Submandibular and deep cervical lymph nodes were palpable and enlarged, hard in consistency and fixed to underlying structures (Figures 1 and 2).

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Radiological findings of computerized tomography (CT) scan revealed an ulcerative ill-defined lesion involving upper lip measuring 3.5 cm × 3.5 cm × 1.8 cm. Lesion extended into gingivobuccal sulcus but did not involve gingival mucosa. No bony erosion of maxillary alveolar arch was noted. Left Level I, II and III nodal lesion with peripheral enhancement and central necrosis seen measuring 2.8 cm × 1.8 cm × 1.6 cm (Figure 3).

Differential diagnosis included keratoacanthoma as it is the most common lesion of upper and lower lip. Canalicular adenoma was also considered as it commonly involves the upper lip. Basal cell carcinoma was also included. But it mostly involves upper 1/3rd of the face. Melanoma is pigmented lesion with rapid growth, and since the present case also had rapid growth, with pigmented appearance. Oral SCC though mostly involves the lower lip was also considered based on the habit of khaini eating and age of the patient. Based on the clinical and radiographic finding, provisional diagnosis of malignant melanoma was made.

An incisional biopsy was initially done, which histopathologically diagnosed it as well differentiated SCC. Later, excision of the lesion along with healthy margins with functional neck dissection followed by lip reconstruction using a double layer flap was done under general anesthesia. The excised specimen was sent to the department of oral pathology (Figure 4).

Gross examination revealed a soft tissue piece measuring 4 cm × 3 cm in diameter, irregular in shape, firm in consistency, grayish black in colour. Histopathologically, H and E stained section showed sheets of highly anaplastic epithelial cells with vesicular and pleomorphic nuclei. Few epithelial and keratin pearls were seen. Ortho-keratinized stratified squamous epithelium with hair follicle and sebaceous gland was also seen. The overall histopathological features were diagnostic of moderately differentiated SCC.

Post-operative findings showed clear margins and the patient recovered well. He maintained oral competence without microstomia and his speech was not affected (Figure 5).

Figure 1: Pre-operative picture of patient

Figure 3: Computed tomography showing an ulcerative lesion involving upper lip measuring 3.5 cm × 3.5 cm × 1.8 cm

Figure 2: The close-up of lesion

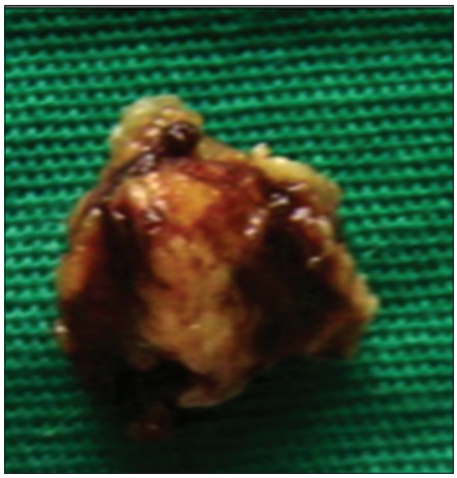

Figure 4: Removed specimen after surgery

Figure 5: Post-operative picture of patient

DISCUSSION

SCC is defined as a malignant epithelial neoplasm exhibiting squamous differentiation as characterized by the formation of keratin and presence of intercellular bridges as defined by Pindborg (1997). Most common malignant neoplasm of the oral cavity. SCC of the lip is a disease of elderly men.[2] SCC of upper lip are histologically more undifferentiated and grow more rapidly, and lymphatic metastasis occurs earlier and is more diffuse in carcinoma of upper lip than lower lip.[3] Age affected is between 55 and 75 years of age with a mean of 62 years. SCC of lower lip affects 95% males while as in upper lip SCC - females are affected more often compared to males. Upper lip SCC occurs with a frequency of 3.3 %.[4]

Variation in clinical appearance of lip cancer depends on duration of lesion and nature of growth. Begins on the vermillion border of the lip to one side of the midline as a small area of thickening, induration, and ulceration. As the lesion becomes larger, it produces small crater like defect or exophytic, proliferative mass.[4] Lymphatic drainage through upper lip proceeds from periparotid trunk to pre-auricular, post-auricular, infra parotid and submandibular nodes. Metastasis from carcinoma of upper lip is frequently found in pre-auricular and infraparotid nodes.[3] In the present case tumor/node/metastases grading was T2 N1 M0. CT and magnetic resonance imaging supplement the clinical evaluation, staging of the primary tumor and inform about the local extent of the disease and to identify lymph node metastases. But, final diagnosis is made by a histopathological evaluation only.[5,6]

Histopathologically classified as following according to broder:[7]

Grade I: Well-differentiated tumors - 75-100% of cells are differentiated
Grade II: Moderately differentiated tumors - 50-75% of cells are differentiated
Grade III: Poorly differentiated tumors - 25-50% of cells are differentiated
Grade IV: Anaplastic tumor - 0-25% of cells are differentiated.

Treatment can be surgical excision or X-ray radiation depending on duration and extent of lesion and presence of metastasis.[8] Early stage lesions can be treated with surgical or radiation therapy with similar 5 years survival rates. Late stage lesions fare poorly with radiation alone. Some drawbacks to radiation therapy, however, include a prolonged treatment course and the potential for whistle deformity of the lips after wound contracture. Osteoradionecrosis is also a potential complication from primary radiotherapy.[9] Cure rate of patient with lip cancer treated by surgery is 81%. Cases treated with X-ray radiation have 83% cure rate.[10]

CONCLUSION

Early diagnosis is the key to optimal management of cancer of the lip. For carcinomas of the lip, surgical resection with adequate margins is the preferred treatment. Any suspicious lesion should be biopsied to establish the diagnosis.

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Case Report

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Primary Genital Tuberculosis of Ovary: A Rare Case Report

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Abstract

Tuberculous (TB) oophoritis is uncommon and usually secondary to TB salpingitis and present in 10% of cases of pelvic TB. Patients with ovarian TB commonly present with complaints of infertility, pelvic pain and bleeding. Unilateral or bilateral adnexal masses, in some cases accompanied by an elevated CA-125 level, may clinically simulate an ovarian tumor. On macroscopic inspection, the ovaries are typically adherent to the tubal ampullae. Grossly visible caseation is rare. On histologic examination, the tubercles are typically confined to the cortex of the ovary and show multiple caseating or non-caseating granulomas. We report a case of primary TB of ovary in a 26-year-old nulliparous married female, present with the complaints of 3 months - history of pelvic pain. Histopathological examination of ovarian tissue confirms the diagnosis of TB oophoritis.

Key words: Genital tuberculosis, Non-caseating granuloma, Ovary

INTRODUCTION

Genital tuberculosis (TB) in females is not uncommon, particularly in communities where pulmonary or other forms of extragenital TB are endemic. TB can involve any organ system in the body and can present without any clinical manifestation.

TB is a major health problem in many developing countries. Genital TB is one of the most important causes of the infertility in females of reproductive age group.[1] An estimated 30 million people have active TB, and 7-10 million persons die every year due to TB of various organ.

It is estimated that almost one-half of the population of India has infected by *Mycobacterium* TB and one person dies every minute from TB. It has been estimated that approximately 5% of females presenting complaint of infertility have genital TB worldwide.[2]

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Female genital TB is a disease of young women in the age group of 20-40 years with 80-90% of cases diagnosed during the workup for infertility.[2]

Genital TB is almost always develops from dissemination of *Mycobacterium* from other site of the body usually pulmonary and sometimes renal, gastrointestinal, bone, joint, or it may be a part of a generalized miliary disease process.

The criteria necessary for a diagnosis of primary genital TB incudes are: (1) The genital TB lesions should be the first TB infection in the body, and (2) regional lymph nodes should demonstrate the same stage of TB development as do the genital organs.

CASE REPORT

A nulliparous married female, aged 26 years, visited gynecologic out-patient department of the P.B.M. Hospital with the complaint of pain in the pelvic region since 3 months. She also complained of low-grade fever on and off, weakness and anorexia with weight loss of 6 kg in previous 8 months. She was also complaining of infertility since 3 years. She had received the bacille Calmette–Guerin vaccination at birth and there was no history of contact with any case of TB. No long-term history of medication was present.

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Per abdominal examination revealed a right pelvic mass with tenderness.

On vaginal examination, a mass was palpated on the right side which is cystic and firm in consistency. The mass was tender on palpation. Blood tests showed a moderate microcytic hypochromic anemia with a hemoglobin 8.5 g/dL, total leukocyte count 14,500/mm^3, platelet count 16,300/mm^3 and erythrocyte sedimentation rate 60 mm at the end of 1 h. Bleeding and clotting time were normal. Liver and kidney function test were normal. HIV, hepatitis B antigen and venereal disease research laboratory were non-reactive.

CA-125 was markedly elevated (360/μl). X-ray chest was clear and did not show any opacity. Abdominal X-ray was normal and did not show any fluid or gas in the peritoneal cavity.

Ultrasonography of whole abdomen reveals a heterogeneous right pelvic mass adjacent to adnexa of the uterus measuring 6 cm × 4 cm. The provisional diagnosis of ovarian tumor was made.

Patient underwent exploratory laparotomy. This revealed an isolated partially solid and partially cystic mass of the right ovary that was fully excised. The fallopian tube, uterus and peritoneum were normal.

Specimen was sent for histopathological examination to our department.

Gross

Received specimen of oophorectomy measuring 6 cm × 4 cm in size. Outer surface is smooth gray-white. Cut surface was partially solid and partially cystic in consistency and grey white in colour. At places, necrotic material was present.

Histopathological examination showed granuloma formed by epithelioid cells, lymphocytes, Langhans' giant cells and central caseous necrosis (Figure 1).

Epithelioid cells are round to oval with elongated spindle or slipper shaped nucleus with vesicular chromatin and nucleoli (Figure 2). Langhans' giant cells have multiple nuclei which are arranged in a horseshoe shaped pattern (Figures 1 and 3). In surrounding ovarian stroma, lymphocytic infiltration was present.

There was extensive caseous necrosis in the ovarian stroma (Figures 4 and 5).

There was no sign of malignancy of ovary, and the diagnosis was revised to ovarian TB. No other focus of TB was found. Hence, a diagnosis of TB of ovary was made on the basis of histopathological examination.

Anti-tubercular treatment was given to the patient according to RNTCP guideline.

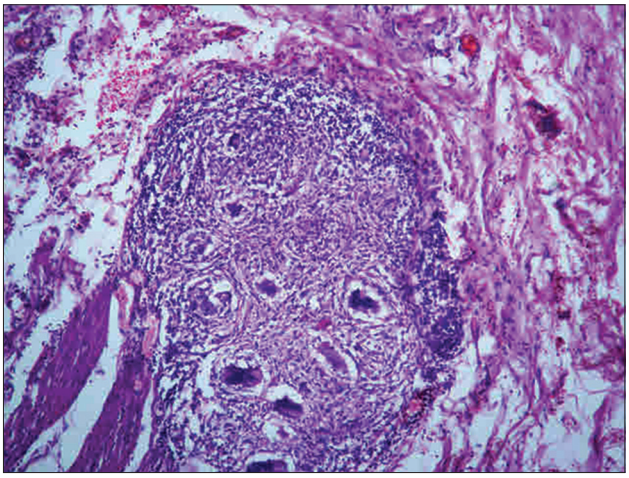

Figure 1: Granuloma with central caseous necrosis (low power)

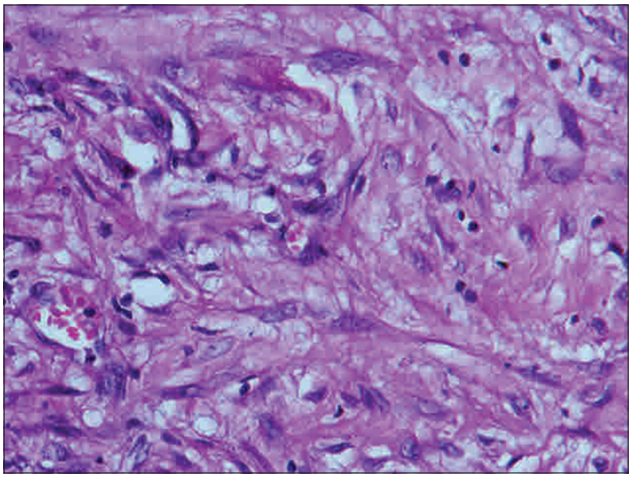

Figure 2: Multiple epitheloid cells and lymphocytes (high power)

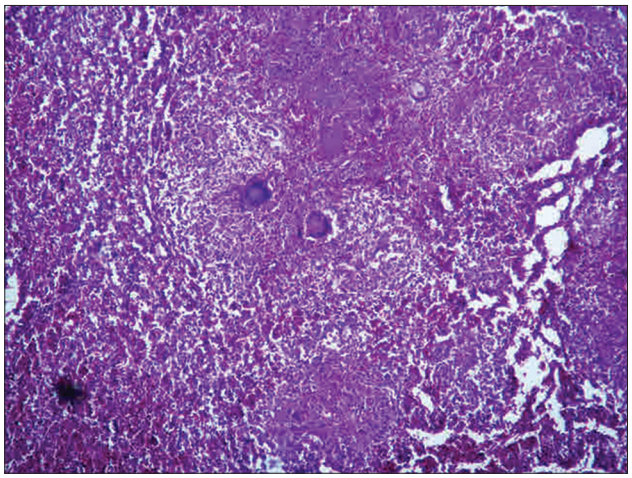

Figure 3: Langhan's type of giant cells (low power)

After the treatment, patient was improved.

DISCUSSION

More than 5.8 million new cases of all form of TB were reported to the World Health Organization in 2009. About 95% of the cases were reported from the developing countries.[3]

In order of frequency, the extrapulmonary sites, most commonly involved in TB are the lymph nodes, pleura, genitourinary tract, bones, joints, meninges, peritoneum, and pericardium. However, virtually any organ system may be involved by TB. In HIV-infected patients, extrapulmonary TB is more common due to hematogenous dissemination.

Genital TB in females is not uncommon in developing countries like India, particularly in communities where pulmonary or other forms of extragenital TB are common.

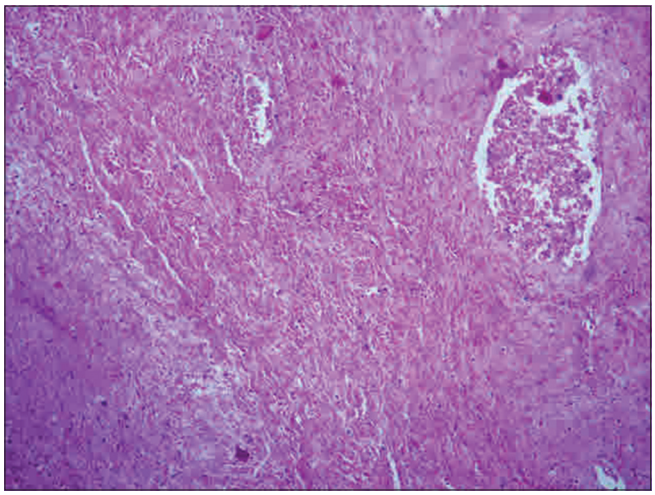

Figure 4: Granuloma with caseous necrosis (low power)

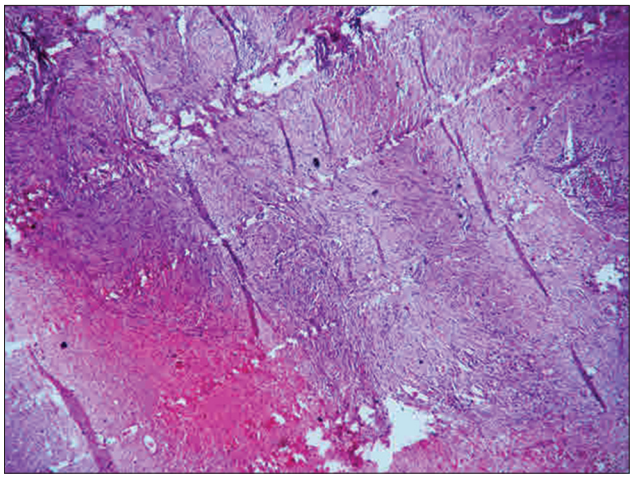

Figure 5: Ovarian stroma with epithelioid cell, lymphocytes and caseous necrosis (low power)

In the literature, the frequency of TB with which the genital organ are involved are ranged from 11 to 30.[4]

Ovary is usually involved bilaterally. Although this cannot always be recognized with certainty at laparotomy. Ovarian TB can be present in two forms. First one is pure arthritis in which the ovary is surrounded by adhesions and studded with tubercles caused by direct extension from the tube, and the second is arthritis, in which infection starts in the stroma of the ovary presumably from a homogeneous source that produces a caseating granuloma within the parenchyma.[2,5]

The clinical diagnosis of genital TB requires a high index of suspicion and mostly it is difficult. About 20% of patients with genital TB give a history of TB in their family member.[2] Approximately 50% of patients might have had pulmonary TB, TB pleurisy, peritonitis, erythema nodosum, or renal, osseous TB. A history of primary infertility in a woman in whom examination reveals no apparent cause and who gives a family history or personal history of TB of any organ should arouse suspicion of genital TB.

According to most series, approximately 30-50% patients have extragenital TB in patient who were suffering from genital TB.[2,6]

The most common initial symptom of genital TB is infertility.[5,7-9] Lower abdominal pain and menstrual disorders are the next most common symptoms after infertility. 10-40% patient of genital TB have abnormal uterine bleeding. Menorrhagia, menometrorrhagia, intermenstrual bleeding, oligomenorrhea, and postmenopausal bleeding may be present.[10,11]

Infertility for which no obvious cause can be found, chronic pelvic inflammatory disease refractory to standard antibiotic therapy, or adnexal disease with ascites in virgin females should alert the clinician to look for TB of the genital tract.

For proper management of a case of genital TB, one must consider that: (1) Is there an active TB present elsewhere? (2) What is the extent of the genital tract lesion? (3) Will medical management cure genital TB? (4) When is surgical management needed? (5) Is pregnancy possible after treatment?

Hence, according to patients' symptom and extent of TB drug or surgical treatment is advised.

CONCLUSION

Genital TB in females is one of the most important causes of infertility so the possibility of TB infection of the genital

tract should always be considered especially in a patient from an area where TB is endemic.

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Case Report

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Renal Cell Carcinoma as a Second Malignancy in Treated Case of Seminoma of Testis: A Case Report

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Abstract

Major advances in the treatment of testicular cancer have resulted in increased cure rates. However, accompanying this success has been the concern about long-term side effects of treatment such as renal and pulmonary damage, ototoxicity, and the occurrence of second primary malignancies. Leukemia following chemotherapy and development of solid tumors following radiotherapy has been documented. However, the development of a second primary malignancy in the kidney has rarely been reported and is even more unlikely in the absence of previous adjuvant radiotherapy. We report a case of second primary renal cell carcinoma, in a treated case of seminoma testis.

Key words: Metastasis, Renal cell carcinoma, Second primary, Seminoma testis

INTRODUCTION

Advancement in treatment of testicular malignancies resulted in better cure rates, increased disease-free survival, progression-free survival, and distant recurrence-free survival. Major recurrences in testicular malignancies occur within 2 years of completion of therapy.[1] Late relapse is defined as tumor recurrence more than 2 years after complete remission following primary treatment. Many years after successful treatment, second primary malignancies can occur.[2] Here, we report a case of clear cell carcinoma of the left kidney as a second malignancy after 8 years of completion of treatment for seminoma of left testis.

CASE REPORT

A 26-year male had a history of left-sided testicular swelling and underwent high inguinal orchidectomy. Post-operative histopathology revealed it to be seminoma of the testis of classical variant (Figure 1). Contrast-enhanced computed tomography (CECT) scan revealed significant left para-aortic and also left inguinal lymphadenopathy (Figure 2). The patient was treated with four cycles of injection bleomycin, etoposide, and cisplatin combination chemotherapy, followed by external beam radiotherapy of 45Gy in 25 fractions to para-aortic, pelvic, and left inguinal lymph nodes in dog leg portal. Patient was on regular follow-up without any evidence of disease. The patient presented with hematuria, left-sided flank pain, and irregular left hypochondriac mass after 8 years of follow-up. CECT scan of abdomen and pelvis revealed enhancing, solid mass lesion in the left kidney involving whole of the kidney without any evidence of enlarged retroperitoneal lymph nodes or free fluid collections (Figure 3). Right kidney was normal and there was no evidence of hepatic metastasis or free fluid collection in the peritoneal cavity. Serum markers, alpha fetoprotein, beta human chorionic gonadotropin, and lactate dehydrogenase were within normal limit. The patient was treated with left side radical nephrectomy. Post-operative histopathology revealed features of renal cell carcinoma (Figure 4). Immunohistochemistry revealed positive for cytokeratin, vimentin, EMA, and CK8/18, negative for placental alkaline phosphatase and CD10, favoring renal cell carcinoma.

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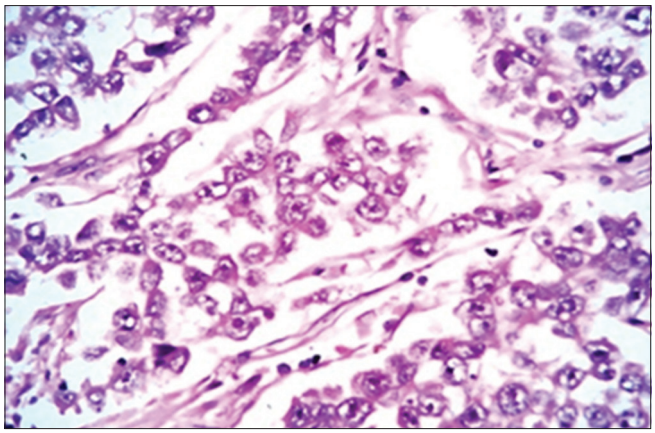

Figure 1: Tumor cells are present in clusters separated by fibrous septa and infiltrated with lymphocytes in H and E ×400 magnification

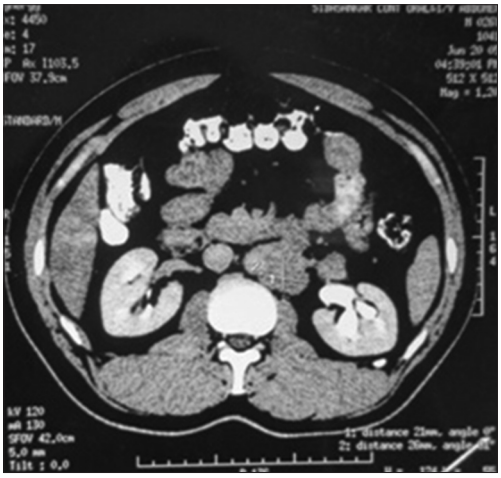

Figure 2: Contrast-enhanced computed tomography scan revealed significant left para-aortic lymphadenopathy

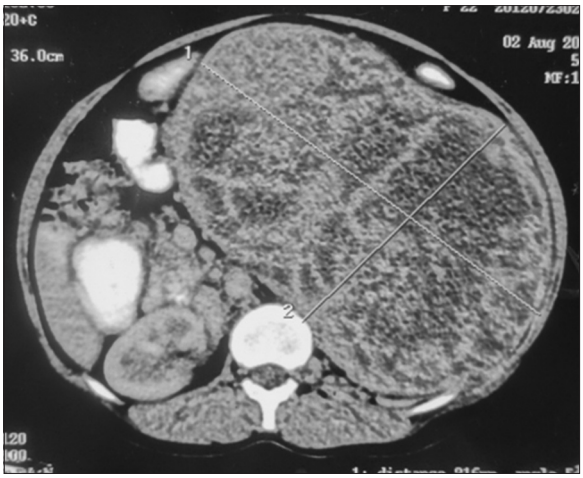

Figure 3: Contrast-enhanced computed tomography scan of abdomen and pelvis revealed mixed attenuated mass arising from the left kidney

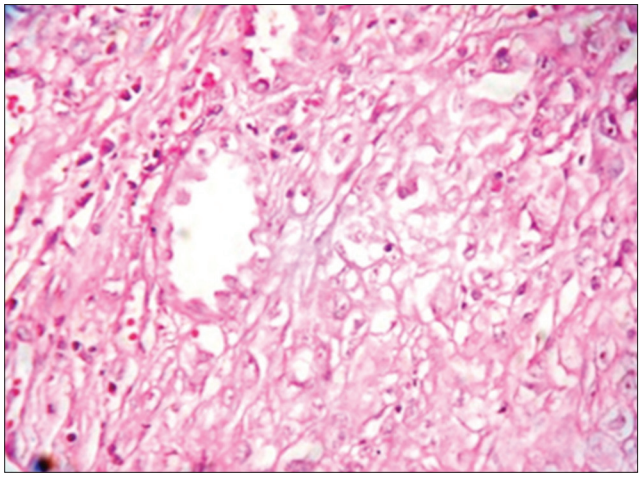

Figure 4: Presence of tumor cells in diffuse sheets. Cells are round to polygonal having clear cytoplasm, with round nucleus and prominent nucleolus. Section shows the presence of normal tubular structures (H and E, ×400)

DISCUSSION

Testicular cancer is the most common solid malignancy in men 20-35 years of age.[3] Renal cell carcinoma represents up to 3% of all adult visceral tumors, commonly occurring in the 5th and 6th decade of life.[4] Most recurrences and relapse in testicular malignancies occur within 2 years of curative treatment. Most common sites of relapse are retroperitoneal space. Lungs and mediastinal lymph nodes are also rarely affected.

There are 12 reports of patients having simultaneous testicular and renal malignancies.[5,6] Metachronous malignant neoplasms which develop after treatment for testicular germ cell tumors are very uncommon, but the development of a renal cell carcinoma after a previous testicular tumor is particularly found to be rare.

Appearance of second primary malignancy after treatment of germ cell tumor testis is a rare entity. The possibility of a new lesion in a kidney, in the setting of testicular tumor, raises the chances of metastatic disease. These tumors rarely present clinical evidence of spread to the kidney, although autopsy studies available in literature have found that up to 25% of non-seminomatous tumors to have progressed to renal metastasis, thus this condition needs to be excluded.[6] An analysis of population-based registries in Europe and North America included 28,843 patients treated between 1935 and 1993 with germ cell tumors. The observed-to expected ratio of second cancers in this population compared to the general population was 1.43 and which was supported by Møller *et al.*[7,8] According to Bokemeyer and Schmoll, patients cured of testicular cancer have been shown to be at greater risk of developing a second primary malignancy.[9]

An increased incidence of renal cancer in long-term survivors of testicular cancer has been suggested.[7] Possible contributing factors to this risk of second malignancy include radiation-induced solid tumors and chemotherapy-induced leukemia.[9] Møller *et al.* suggested that the relative risk of renal cancer was estimated at 2.3, with the increased risk thought most likely to be due to radiation.[8] Current treatment protocols now aim to minimize carcinogenic exposure, with the relative risk of second malignancy being lower today than the past studies.[3] However, if one examines the time to development of renal cell carcinoma, the majority of cases occurred outside of when one would be doing follow-up or surveillance of a tumor.

CONCLUSION

Development of second primary renal cell carcinoma in a case of seminoma testis is a rare entity. In this case, the second primary renal mass detected 8 years after completion of treatment for seminoma. Therefore, late follow-up in patients with testicular cancer is important and may need annual follow-up evaluations throughout their life because of the possibility of second primary malignancies. Whether the second primary malignancy is treatment-related or genetic needs to be verified.

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Case Report

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Syringocystadenoma Papilliferum of Scalp: A Rare Case Report

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Abstract

Syringocystadenoma papilliferum also known as naevus syringocystadenomatosus papilliferus is an exuberant proliferating lesion, commonly seen on the scalp in association with an organoid naevus, and showing predominantly apocrine differentiation. It is a benign adnexal skin tumour of the apocrine or the eccrine type. It is relatively a rare neoplasm. These lesions may be present at birth or in childhood, but the majority are seen on the face and scalp of young adults. There is frequently a history of papillomatous expansion of a small pre-existing lesion at or around puberty and lesions often occur in a pre-existing organoid naevus. The lesion is composed of multiple warty papules, some of which are translucent and pigmented. The microscopic appearance is characteristic and shows ducts connecting to the surface, containing papillary processes and lined by two epithelial cell layers. Treatment of this tumor includes local excision in most of the cases. We report a case of syringocystadenoma papilliferum of the scalp in a 12-year-old female, which was clinically diagnosed at first as squamous cell carcinoma of the scalp but was later histologically confirmed as syringocystadenoma papilliferum.

Key words: Child, Scalp, Syringocystadenoma papilliferum

INTRODUCTION

Syringocystadenoma papilliferum is a rare benign hamartomatous adnexal tumour which originates from the apocrine or the eccrine sweat glands. It is relatively a rare neoplasm, predominantly a childhood tumour. In about 50% of those who are affected, it is present at birth, and in a further 15-30%, the tumour develops before puberty.[1] Syringocystadenoma papilliferum occurs with equal frequency in both sexes.[2]

Syringocystadenoma papilliferum occurs most commonly on the scalp or the face. Presentation with multiple lesions is rare; those arising outside the head and neck region are even more uncommon. The lesion of syringocystadenoma papilliferum usually measures between 1 and 3 cm and <4 cm in diameter.[3] The tumour has varied clinical presentations.

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There is frequently a history of papillomatous expansion of a small pre-existing lesion at or around puberty and lesions often occur in a pre-existing organoid naevus. The lesion is composed of multiple warty papules, some of which are translucent and pigmented.

We present a case of syringocystadenoma papilliferum in a 12-year-old female child presented with an ulcer on scalp.

CASE REPORT

A 12-year-old female child presented with the complaint of an ulcerative lesion with alopecic patch over scalp associated with itching and bleeding. Initially, the patient had a nodule of around 1 cm over the right side of the parietal region of the scalp, which did not increase in size. There was no growth of hair over the swelling. The nodule turned into a 1.5 cm ulcer in the past 1 year, which gradually increased in size. There was no regional lymphadenopathy. No other skin lesions were noted elsewhere. Skin sensations were normal. A presumptive clinical diagnosis of squamous cell carcinoma was made. The patient was worked up. Her routine investigation were normal.

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Patient underwent excision reconstruction under general anaesthesia. The lesion was excised completely with a normal margin of around 1 cm and with a depth up to the subcutaneous plane. Gross sample was sent to our department for histopathological examination.

Pathologic Finding

Gross

Single gray white soft tissue mass measuring 5.5 cm × 2 cm × 1.5 cm along with skin attach on one side. Skin is irregular. On cut surface gray white verruciform growth measuring - 2.5 cm × 1 cm present.

Microscopic

Section shows epidermis and dermis. At one place, ulcerative area is present in the epidermis. The epidermis shows varying degrees of papillomatosis. Cystic invaginations extend downwards from the epidermis, with numerous villous projections extending into the lumen of the cyst (Figure 1).

The upper portion of the invaginations and large segments of the cystic invaginations are lined by squamous, keratinizing cells similar to those of the surface epidermis (Figure 2). In the lower portion of the cystic invaginations, numerous papillary projections extend into the lumina of the invaginations. The papillary projections and the lower portion of the invaginations are lined by glandular epithelium consisting of two rows of cells (Figure 3). The luminal row of cells consists of high columnar cells with oval nuclei and eosinophilic cytoplasm. The outer row of cells consists of small cuboidal cells with round nuclei and scanty cytoplasm. Dense plasma cell infiltrate is present in the stroma of the papillary projections (Figures 3 and 4).

Beneath the cystic invaginations, deep in the dermis, groups of tubular glands with large lumina are present. The cells lining the large lumina are flattened showing evidence of active decapitation secretion (Figures 1 and 3).

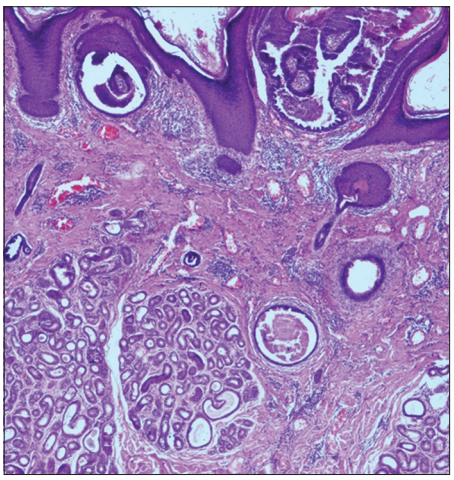

Figure 1: Epidermis with ulceration, papillomatosis with cystic invaginations downward from epidermis, with numerous villous projections extending into the lumen of the cyst

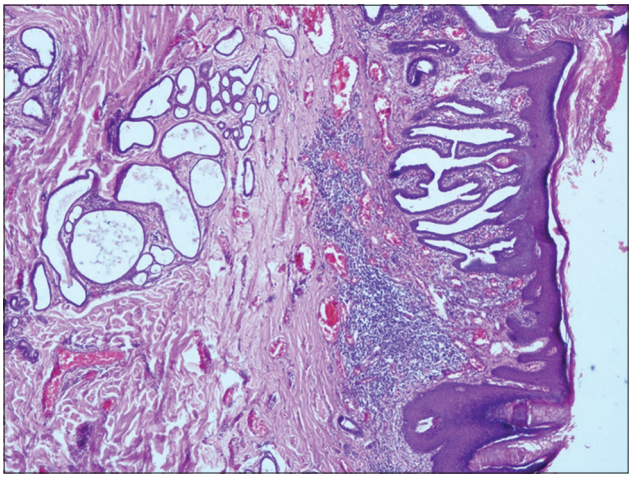

Figure 2: Cystic invaginations lined by squamous, keratinizing cells

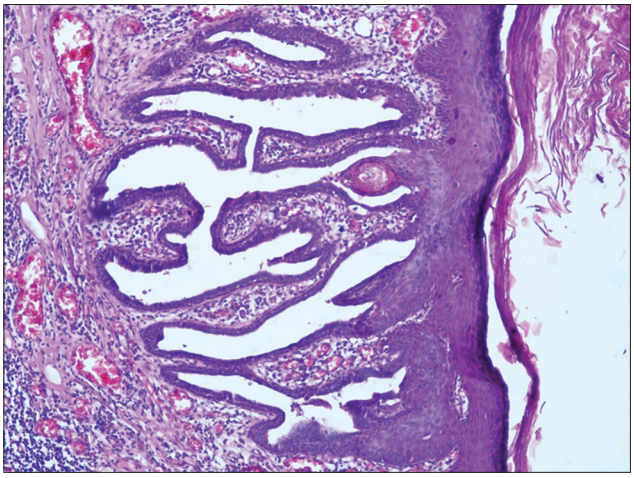

Figure 3: Papillary projections lined by glandular epithelium consisting of two rows of cells inner columnar and outer cuboidal cells. Stroma shows dense plasmacytic infiltrate

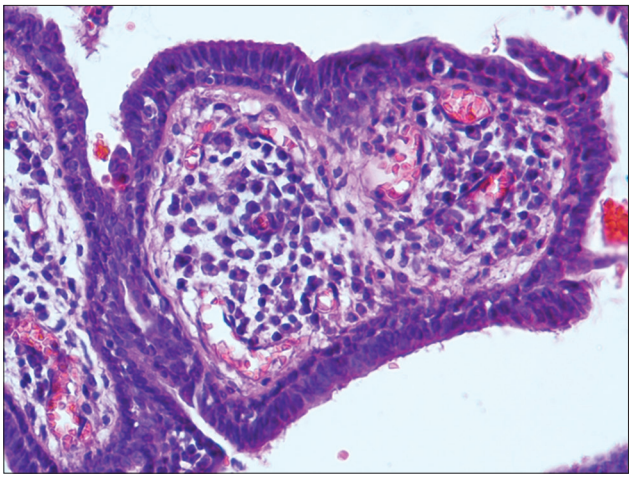

Figure 4: Plasma cell infiltration and tubular glands in the dermis with secretion

On the basis of gross and histopathological examination, a diagnosis of syringocystadenoma papilliferumwas offered.

DISCUSSION

Syringocystadenoma papilliferum is a rare non-malignant adnexal sweat gland neoplasm characterized by asymptomatic, skin-colored to pink papules or plaques with a highly variable appearance, most commonly in the head and neck area. Syringocystadenoma papilliferum occurs most commonly on the scalp or the face; however, tumours may be seen in other locations including the vulva,[4] external ear,[5] lower leg,[6] scrotum[7] and breast[8] in about one fourth of the cases. It is usually first noted at birth or in early childhood and presents as a papule or several papules in a linear arrangement or as a plaque. The lesion increases in size at puberty, becoming papillomatous and often crusted. On the scalp, syringocystadenoma papilliferum frequently arises around puberty within a nevus sebaceous that has been present since birth.

Three clinical types have been described:

a. Plaque type: Presenting as an alopecic patch on the scalp and may enlarge during puberty to become nodular, verrucous or crusted
   Plaques commonly tend to be associated with a naevus sebaceous of Jadassohn in one-third of the cases
b. Linear type: Consists of multiple reddish pink firm papules or umbilicated nodules 1-10 mm in size commonly occurring over face and neck
c. Solitary nodular type: They are domed pedunculated nodules 5-10 mm in size with a predilection for the trunk shoulder and axillae

Approximately one-third of cases of syringocystadenoma papilliferum arise in organoid naevi which is a precursor lesion for it.[2]

Yamamoto *et al.*[9] postulated an origin in pluripotent cells on immunohistochemical and ultrastructural grounds. Böni *et al.*[10] showed mutations in PTCH or P16 tumour suppressor genes in syringocystadenoma papilliferum. Kazakov *et al.* noted an overlap with tubular adenoma.[11]

Histopathologically, the epidermis shows varying degrees of papillomatosis. One or several cystic invaginations extend downward from the epidermis.

Frequently, there are malformed sebaceous glands and hair structures in the lesions of syringocystadenoma papilliferum. In about one-third of the cases, syringocystadenoma papilliferum is associated with a nevus sebaceous. In about 10% of the cases, a basaloid epithelial proliferation resembling basal cell carcinoma develops, but this is noted only in lesions that also exhibit a nevus sebaceous.

A few instances of transition of a syringocystadenoma papilliferum into an adenocarcinoma with regional lymph node metastases have been reported.[12]

Additional studies syringocystadenoma papilliferum can exhibit both apocrine and of eccrine differentiation. For example, positive immunoreactivity for gross cystic disease fluid proteins 15 and 24 and zinc-2 glycoprotein demonstrates evidence of apocrine differentiation.[13] On the other hand, immunohistochemical analysis of cytokeratins in syringocystadenoma papilliferum demonstrates similarities to eccrine poromas and the ductal component of eccrine glands.[14] In addition, light and electron microscopic features of some lesions show evidence of eccrine differentiation. It is probable that syringocystadenoma papilliferumarises from undifferentiated cells with the potential to exhibit both apocrine and eccrine modes of epithelial secretion. Most lesions of syringocystadenoma papilliferum exhibit apocrine differentiation; however, some demonstrate eccrine features. Studies have demonstrated loss of heterozygosity for patched and p16, a negative regulator of the cell cycle, in syringocystadenoma papilliferum, suggesting that these molecules may play a role in the pathogenesis of these lesions.[10]

The only treatment for syringocystadenoma papilliferum is excision biopsy, which also confirms the diagnosis. CO_2 laser excision of syringocystadenoma papilliferum of the head and neck is a clinical treatment option in anatomic areas unfavorable to excision and grafting. Syringocystadeno carcinoma papilliferum has been successfully treated with Moh's micrographic surgery.

CONCLUSION

Syringocystadenoma papilliferum is a rare neoplasm, present most commonly on head and neck area. In the present case, it was clinically diagnosed at first as squamous cell carcinoma of the scalp, but later, it was histologically confirmed as syringocystadenoma papilliferum. Such a presentation of this tumour may include multiple differential diagnoses on clinical background so it must be sent for a histopathological examination to confirm the diagnosis. The excision of the tumor is sufficient in most of the cases.

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Case Report

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Posterior Vaginal Wall Fibroid in a Postmenopausal Lady: An Unusual Case Report

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Abstract

Vaginal tumors are rare and include papilloma, hemangioma, mucus polyp, and rarely leiomyoma. Vaginal leiomyomas remain an uncommon entity. We met upon one such case in our institute. A 70-year-old postmenopausal woman was admitted to our institute complaining of pain in the right iliac fossa for a month. It was suspected to be appendicitis. ultrasonography (USG) whole abdomen showed the presence of a hypoechoic space occupying lesion in the posterior vaginal wall/anterior rectal wall of size 44 mm × 30 mm. USG guided fine needle aspiration cytology reports from two laboratories showed conflicting results. As the patient was symptomatic, operative management was carried out. After putting the patient in lithotomy position, on giving an incision on the posterior vaginal wall, a mass which looked like a degenerated posterior vaginal wall fibroid, was seen, which was removed piecemeal. The post-operative histopathology showed that the mass was a leiomyoma.

Keywords: Leiomyoma, Post-menopausal, Vaginal

INTRODUCTION

Vaginal tumors are rare and include papilloma, hemangioma, mucus polyp, and rarely leiomyoma. Vaginal leiomyomas remain an uncommon entity, and there are about 300 reported cases only. The first case was detected way back in 1733 by Denis de Leyden.[1] Bennett and Erlich, two investigators, found that there were only nine cases in 50,000 surgical specimens. Moreover, they found only one case out of 15,000 autopsies which they reviewed at Johns Hopkins Hospital.[2] Here, we are reporting a case that was previously suspected as appendicitis based on her clinical features but came out to be a posterior vaginal wall fibroid after thorough investigations and post-operative histopathology.

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CASE REPORT

A 60-year-old lady, a resident of Murshidabad district in West Bengal, was admitted to our hospital on March 17, 2014. She was complaining of pain in the right iliac fossa for about 1 month, which was not associated with fever, nausea or vomiting. Her bowel and bladder habits were regular. She had attained menopause 12 years ago. Coming to her obstetric history, she was a P5 + 0, and all her children were delivered vaginally at home. Her last child was born 30 years ago. She was a known hypertensive for the last 15 years. The medicines she was taking at the time of admission were tablet amlodipine 10 mg 1 tablet once daily, tablet torsemide 10 - ½ tablet once daily, and tablet clonazepam 1 mg 1 tablet once daily at bedtime. There was nothing significant in her past surgical or family history. She had a personal history of occasional allergic reactions to shellfish for which she took tablet cetirizine on a SOS basis.

Investigations: The following investigations were done:

- Ultrasonography (USG) whole abdomen: This was done at our institute on admission for pain lower abdomen suspecting appendicitis. It showed the presence of a hypoechoic space occupying lesion in

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the posterior vaginal wall/anterior rectal wall of size 44 mm × 30 mm. The other organs were normal.

- A USG-guided fine-needle aspiration cytology was also carried out. The histopathology reports came as - Fibrosarcoma/cellular leiomyoma. Simultaneously, the sample was also sent outside to a reputed pathological laboratory. The histopathology reports from the laboratory came out to be a proliferative spindle cell tumor.
- A two-dimensional echocardiography was done which showed mild grade left ventricular hypertrophy with diastolic dysfunction of left ventricle, which were within normal limits for a chronic hypertensive.

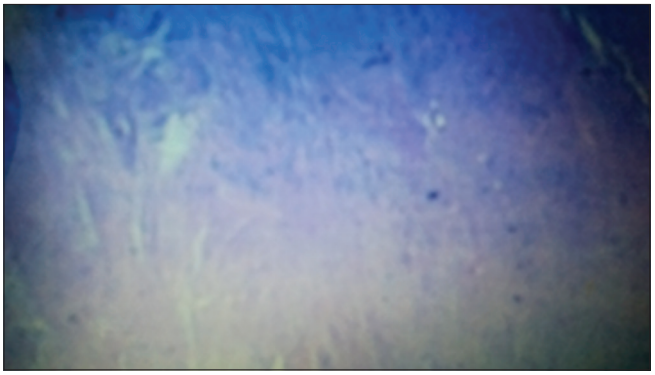
Based on these findings, we decided to go for surgical removal of the tumor. Pre-operative investigations done came out to be normal.

Per-operative findings were as follows:

- Under spinal anesthesia bladder was catheterized, ASS and ASD were done. The patient was put in lithotomy position. A small incision of about 2-3 cm was given over posterior vaginal wall. The posterior vaginal wall flap was separated from the mass by a gradual separation and the mass that resembled a degenerated fibroid was found. It was taken out in piecemeal and sent for histopathological examination. Hemostasis was secured, the posterior vaginal wall repaired, and betadine wash was given.

The per-operative images are depicted in Figures 1-3.

Histopathology



Histopathology reports of the mass were as follows:

Gross: Multiple pieces of greyish white tissue, the largest measuring 1.5 cm in its greatest axis. All the pieces embedded.

Microscopic examination: Sections show a lesion composed of interlacing fascicle of spindle-shaped cells with elongated nuclei having blunt ends. The tumor cells show nuclear pleomorphism and exhibit occasional mitotic activity. Focal areas of hyaline degeneration are seen. There is no evidence of malignancy.

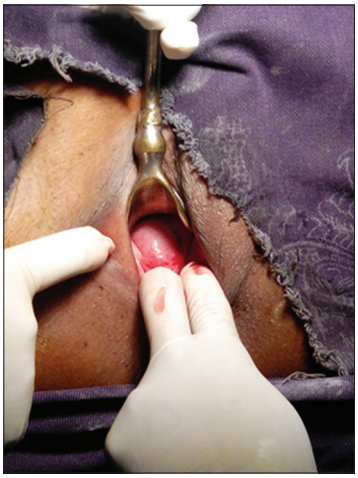


Figure 1: A bulge showing on the exposed posterior vaginal wall

Figure 2: The posterior vaginal wall being separated from the mass

Figure 3: The mass after removal piecemeal

Impression: Leiomyoma. The sutures healed and the patient was discharged on the 7th post-operative day in good health.

DISCUSSION

Most leiomyomas are benign myometrial tumors, though, at times, uncommon loci may be found in the round ligament, broad ligament, renal pelvis, spermatic cord, urinary bladder, urethra, and rarely the peritoneum.[3] Vaginal fibromas are rare benign neoplasms; approximately 300 have been reported previously.[4,5] The clinical presentation is variable, and the consistency of the mass on pelvic examination may be misleading. A mass can originate anywhere along the vagina. It is generally localized, mobile, non-tender, and circumscribed. Its consistency can vary from solid to cystic. These lesions are at times asymptomatic. However, they can also give rise to variable symptoms such as pain or urinary tract symptoms, dyspareunia, and obstruction to the birth passage. Occasionally, they may just be present as a swelling in the vagina.[6] In our patient, the presentation was pain in right iliac fossa. They are generally slow growing. They commonly arise from the anterior and lateral vaginal wall, and rarely are found to originate from the posterior vaginal wall.[7,8]

Transabdominal and intravaginal sonography along with needle biopsy are valuable in making the pre-operative diagnosis of a benign smooth-muscle tumor. The treatment of choice is vaginal enucleation, and generally it is easily done due to the availability of good cleavage plane.[6,9] Some cases require an abdominal[7] or abdominopelvic[9] approach. Operative management should include evaluation of the urethral and vesical support and possible reconstruction, such as placation of the bulbourethral ligament.

If a diagnosis is possible pre-operatively, a gonadotropin-releasing hormone analog can be used intramuscularly to reduce the size of these tumours.[4,6] Otherwise, a pre-operative embolization can be performed to reduce intra-operative blood loss.[10]

CONCLUSION

Vaginal leiomyomas that present as a mass are most often diagnosed clinically and readily treated by surgery. As our case had an uncommon presentation, we performed some investigations to decide on the mode of treatment. The patient was successfully treated.

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Case Report

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Central Odontogenic Fibroma of Maxilla: A Rare Case

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Abstract

Central odontogenic fibroma (COF) is a rare benign odontogenic tumor characterized by variable amounts of inactive-looking odontogenic epithelium embedded in a mature fibrous stroma corresponding to 0-5.5% of all odontogenic tumors. COF may be seen at any age, but it is diagnosed most frequently in patients between the second and fourth decades of life. The lesion is asymptomatic except the swelling of the jaw. It occurs slightly more often in the mandible, and the prevalent site in the mandible is the molar-premolar region whereas in maxilla it occurs anterior to the first molar. The periphery usually is well defined where smaller lesions are usually unilocular, and larger lesions show a multilocular pattern. The internal septa may be fine and straight, as in odontogenic myxomas, or it may be granular, resembling those seen in giant cell granulomas. COF may cause expansion with maintenance of a thin cortical boundary or on occasion can grow along the bone with minimum expansion, similar to an odontogenic myxoma. Tooth displacement is common, and root resorption has also been reported. Here, we present a rare case of COF in the left premolar area of the maxilla in a 14-year-old male.

Key words: Anterior maxilla, Central odontogenic fibroma, Maxilla

INTRODUCTION

Central odontogenic fibroma (COF) is a rare benign odontogenic tumor characterized by variable amounts of inactive-looking odontogenic epithelium embedded in a mature fibrous stroma[1] which corresponding to 0-5.5% of all odontogenic tumors recorded in various studies.[2-4] COF may be seen at any age, but it is diagnosed most frequently in patients between the second and fourth decades of life.[5] The lesion is asymptomatic except the swelling of the jaw.[6] It occurs slightly more often in the mandible, and the prevalent site in the mandible is the molar-premolar region whereas in maxilla it occurs anterior to the first molar. The periphery usually is well-defined where smaller lesions are usually unilocular, and larger lesions show a multilocular pattern. The internal septa may be fine and straight, as in odontogenic myxomas, or it may be granular, resembling those seen in giant cell granulomas. COF may cause expansion with maintenance of a thin cortical boundary or on occasion can grow along the bone with minimum expansion, similar to an odontogenic myxoma. Tooth displacement is common, and root resorption has also been reported. Here, we present a rare case of COF in the left premolar area of the maxilla in a 14-year-old male.

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CASE REPORT

A 14-year-old male patient reported to the department of oral medicine and radiology with a chief complaint of swelling on the left side of the face since 6 months (Figure 1). The patient first noticed the swelling 6 months back, and it was increasing in size gradually. The swelling is not associated with pain. There was no history of trauma or any decayed teeth in that region. The patient's medical history and other histories were non-contributory.

On general physical examination, the patient was moderately built and nourished; all his vital signs were within normal limits. Extraoral examination revealed asymmetry of the face with a diffuse swelling on the left

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middle third of the face measuring around 6 cm × 6 cm in size, extending from the left ala of the nose till 5 cm anterior to the tragus of the left ear anteroposteriorly and from the left infraorbital margin till the left corner of the mouth. The overlying surface was normal. The swelling was firm to hard in consistency with diffuse borders and was non-tender on palpation (Figure 1).

On intraoral examination, swelling measured around 4 cm × 3 cm in size, extending from left maxillary lateral incisor till the left maxillary second molar causing expansion of the cortical plate and vestibular obliteration. The swelling was non-tender and non-fluctuant on palpation. Clinically, left maxillary canine was missing (Figure 2).

Based on patient's history and clinical findings, working diagnosis of dentigerous cyst involving left maxillary canine was made. Clinical differential diagnosis of adenomatoid odontogenic tumor and fibrous dysplasia - monostotic type was considered.

Figure 1: Extra oral photograph with swelling on the left side of the face

Figure 2: Intra oral photograph showing buccal cortical expansion

Patient was subjected to chair side investigations like electric tooth vitality test which revealed positive response in all teeth of the second quadrant and all routine blood investigations were within normal limits. Aspiration could not be performed as there was no yielding point for needle insertion.

Patient was the subjected to radiographic examination. Orthopantomograph revealed a multilocular radiolucency extending from left maxillary central incisor till the second premolar anteroposteriorly and from the crest of the maxillary arch from the region of missing left canine till the left infraorbital margin (Figure 3). The left canine was displaced superiorly till the infraorbital margin and the left maxillary sinus was obliterated.

Intraoral periapical radiograph showed an area of multilocular radiolucency with missing left maxillary canine (Figure 4). Thin, fine, straight bony septa intersecting at certain angles were also seen.

Occlusal radiograph showed an area of multilocular radiolucency extending from the left maxillary lateral incisor till the second premolar anteroposteriorly (mediolaterally) and impacted canine could be noted (Figure 4). Based

Figure 3: Orthopantomograph showing lesion in the left maxilla

Figure 4: Intraoral periapical radiograph and occlusal radiographs showing internal structure of the lesion

on the all the radiographic findings, differential diagnosis of dentigerous cyst, keratocystic odontogenic tumor, ameloblastoma, odontogenic myxoma was considered.

Further to know the extent of the lesion computed tomography (CT) of the head was advised which showed a multilocular lesion (Figure 5). Expansion and thinning of buccal cortical plate with thin and straight septa were also noted.

Following CT examination, an incisional biopsy was performed which was evaluated histologically. The features were suggestive of odontogenic fibroma, following which partial maxillectomy was done, and the specimen was evaluated histologic again. The biopsy specimen revealed highly cellular connective tissue stroma made-up of mature collagen fibers interspersed with plump fibroblasts (Figure 6). Few odontogenic islands were evident. The feature was again suggestive of odontogenic fibroma.

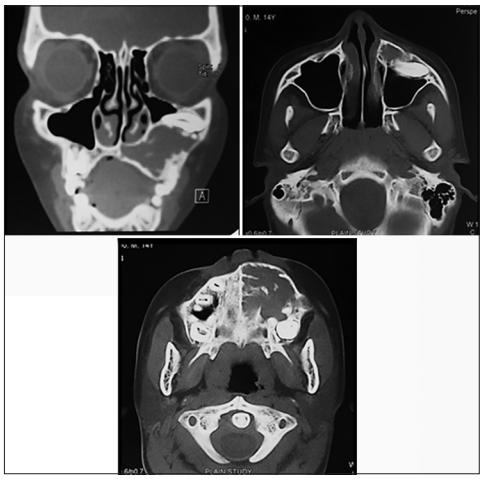

Figure 5: Computed tomography showing lesion in sagittal and coronal sections

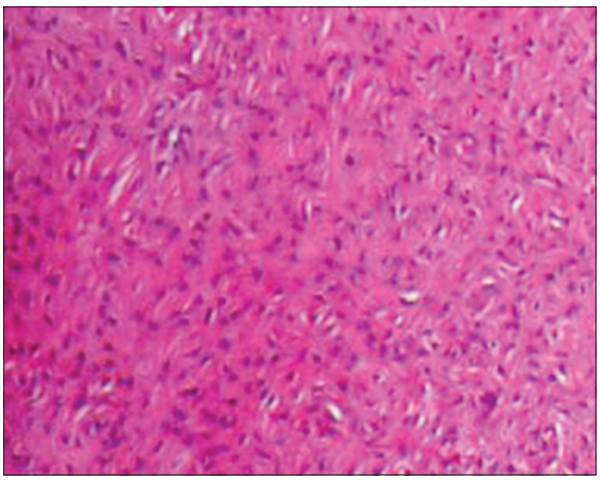

Figure 6: Photo micrographic picture (×40)

Based on clinical, radiological, and histological findings, a final diagnosis of COF was made. The prognosis of the lesion was good, and the patient is still under follow-up.

DISCUSSION

COF is defined as a fibroblastic neoplasm containing varying amounts of apparently inactive odontogenic epithelium.[7] It can originate from the mesenchymal tissues of dental origin that includes dental follicle, dental papilla or periodontal ligament.[5,8] COF is a benign odontogenic neoplasm which is not completely understood.[9] Revised WHO histological typing of odontogenic tumors by Kramer (1992) included this entity under "odontogenic ectomesenchyme with or without included odontogenic epithelium."[10] The WHO panel decided to consider the simple type of odontogenic fibroma under the heading of myxoma. It is the most collagenous variant of the histologic spectrum of odontogenic myxomas, myxofibromas, and odontogenic fibromas.[11] It is suggested that the terminology "odontogenic fibroma WHO type" can be renamed as "odontogenic fibroma complex type" or "fibroblastic odontogenic fibroma" which could be considered as a more appropriate name.[11]

The literature review showed that COF is a very rare odontogenic neoplasm which accounts for only 0-5.5% of all odontogenic tumors.[7] It is seen in wide age ranges and frequently diagnosed in patients between the second and fourth decades of life and in the current case the patient was in the second decade. Female predilection is observed in many reports, but equal distribution has also been reported between males and females by Kaffe *et al.*; Mosqueda-Taylor *et al.*; Veeravarmal *et al.*[5,7,8] According to the literature available both the jaws have been affected equally, in the maxillary arch it involves anterior segment as seen in the present case, and mandibular lesions affect the premolar and molar areas. The present case manifested as a slow growing lesion in the anterior region of the maxilla. COF causes bony expansion and displacement of the adjacent teeth.[10,12]

Radiographically, the lesions are associated with the crown of an unerupted molar, premolar, or incisor tooth. COF usually has well-defined borders, but may also present with scalloped margins as seen in the present case. The internal structure normally appears as a unilocular radiolucency which may exhibit a multilocular appearance as seen in the present case.[5,7,8] The presence of calcifications in the form of flecks is interpreted as a mixed lesion with a characteristic "ground glass" appearance. The lesion and the surrounding normal bone interface may be well-demarcated with sclerotic borders. The appearance may suggest encapsulation, but the presence of a capsule has

not been reported. In spite of that, many cases appeared to be infiltrative.[5,8,10-12]

The mode of treatment of COF is enucleation and curettage, but in cases with large lesions excision of the lesion can be performed. Recurrence is uncommon. But on the evidence of cases of recurrence, it is suggested that these patients must be followed up post-operatively. There has not been any recurrence in the present case 3 months after surgery, and the patient is still under follow-up.

CONCLUSION

As the occurrence of COF is very rare, the purpose of this report is to present an additional case of COF as well as to highlight the significance of clinical, radiological, and histological features which helps in differentiation of the lesion from other lesions and to understand the need of long-time post-operative follow-up and to develop a better understanding of COF.

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Case Report

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Non-Surgical Endodontic Approach for Management of Periapical Lesions

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Abstract

Due to pulp tissue necrosis the pulp chamber is transformed into unprotected environment. This unprotected environment becomes susceptible to colonization by numerous microorganisms. Development of periapical lesions is associated with the presence of microorganisms in the root canal system. To treat such cases there are surgical and non-surgical methods and the healing of periapical lesions will not be achieved through surgical removal of the periapical lesion without proper root canal disinfection and obturation. Through proper cleaning, shaping, asepsis, and proper obturation of the root canal system aids in the success of non-surgical endodontic treatment. This clinical case reports highlights follow-up results of two cases demonstrating the resolution of periapical lesion through nonsurgical approach, confirms that periapical lesions respond favorably to non-surgical treatment.

Keywords: Calcium hydroxide, Healing, Periapical lesion

INTRODUCTION

Periapical lesions of endodontic origin are produced by an inflammatory response at the root apices of teeth with nonvital pulps.[1,2] After pulp necrosis, the root canal system becomes increasingly susceptible to colonization by the microorganisms. Due to close physiopathological relationship between the pulp and the periapical region, bacteria, fungi, and cell components may trigger an inflammatory process in periapical tissues, progressively affecting them through the resorption phenomenon. Subsequently, immunopathological mechanisms lead to the formation of abscesses, granulomas, and periapical cysts.[2-5] Seltzer, Soltanoff, and Bender[6] observed in a series of studies, that pulpo-periapical lesions have the potential for healing without surgical intervention. Cvek, heithersay, messer, and stock have demonstrated successful clinical management of large periradicular lesion by the use of calcium hydroxide used as an interim dressing. Only when there are persistent signs and symptoms and/or no radiographic evidence of healing of periapical lesion, a surgical method of treatment should be considered.[7]

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CASE REPORTS

Case 1

A 19-year-old male patient was reported to the Department of Conservative Dentistry and Endodontics, Mamata Dental College, Khammam with discolored fractured mandibular incisors. Patient gave a history of trauma 5 years back. Medical history was noncontributory. Thermal and electric pulp tests were performed to determine the vitality of all the anterior teeth. Both the mandibular central incisors were found non-vital showing no response to thermal and electric pulp tests. On intra-oral periapical radiograph of the involved teeth was taken, which demonstrated a periapical lesion involving 31 and 41 (Figure 1) and hence conventional root canal therapy was initiated. Access cavity was prepared on the mandibular central incisors and the working length determined (Figure 2).

Canals were cleaned and shaped using K-files by the conventional method. 3% sodium hypochlorite was used as the intra-canal irrigant. The canal was enlarged to an apical size of ISO #40. Calcium hydroxide dressing was

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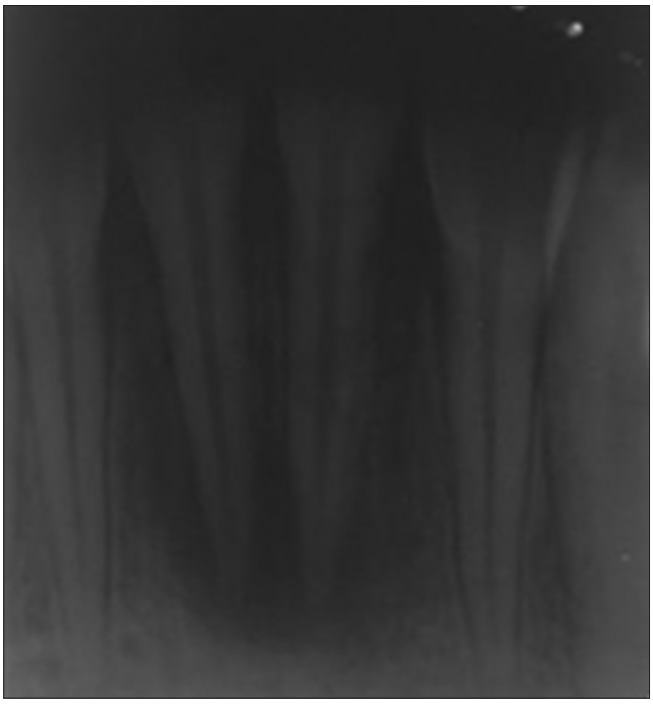

Figure 1: Intraoral periapical radiograph showing periapical lesions in relation with 31 and 41

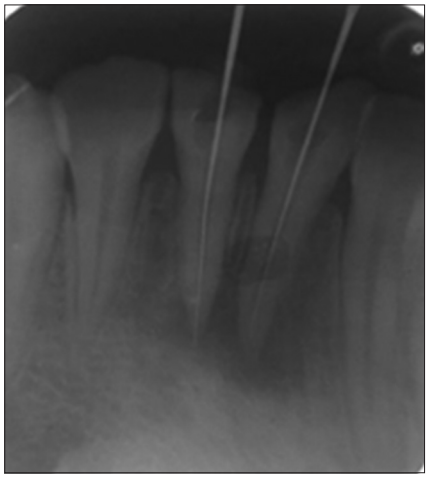

Figure 2: Working length determination

placed in the canal as the intra-canal medicament, and the access cavity was closed with temporary cement. Patient was recalled a week later and received a fresh dressing of calcium hydroxide, following thorough irrigation, and drying of the canal. This procedure was repeated again after 1 week. In the fourth visit, the canals were cleaned and dried using paper points. Master cone selection was done corresponding to ISO #40 size. The obturation was completed by lateral condensation technique using gutta-percha and zinc oxide eugenol root canal sealer (Figure 3). A post-operative follow-up radiograph after 14 months showing complete healing of periapical lesion (Figure 4).

Figure 3: Radiograph showing obturation of 31 and 41

Figure 4: 14 months post-operative radiograph showing complete healing of periapical lesion

Case 2

A 30-year-old female patient was reported to the Department of conservative dentistry and endodontics, Mamata Dental College, Khammam with swelling and discolored mandibular incisors. Patient gave a history of trauma about 7 years back. Medical history was noncontributory. Thermal and electric pulp tests were performed to determine the vitality of all the anterior teeth. The mandibular central incisors and a lateral incisor were found non-vital showing no response to thermal and electric pulp tests. Intraoral periapical radiograph of the involved teeth was taken which demonstrated a periapical lesion involving 31, 32 and 41 (Figure 5) and hence conventional root canal therapy was initiated. Following the isolation with a rubber dam, the access cavity was prepared on the mandibular central incisors, and a lateral incisor, and the working length determined (Figure 6).

Canals were cleaned and shaped using K-Files by the conventional method. 3% sodium hypochlorite was used

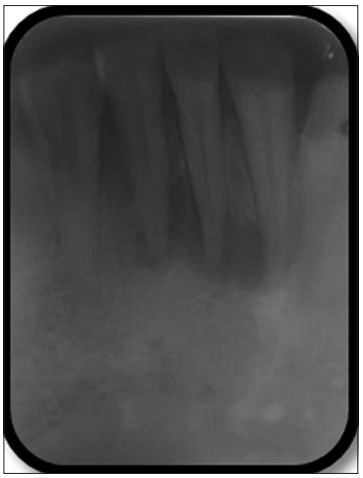

Figure 5: Intraoral periapical radiograph showing large periapical lesions in relation with 31, 32 and 41

Figure 7: Master cone selection

Figure 6: Working length determination

Figure 8: Radiograph showing obturation of 31, 32 and 41. 12 months post-operative radiograph showing healing of periapical lesion

as the intra-canal irrigant. The canal was enlarged to an apical size of ISO #45. Calcium hydroxide dressing was placed in the canal as the intra-canal medicament, and the access cavity was closed with temporary cement. Patient was recalled a week later and received a fresh dressing of calcium hydroxide, following thorough irrigation and drying of the canal. This procedure was repeated after 1 week. In the 5th visit, the canals were cleaned and dried using paper points. Master cone selection was done corresponding to ISO #45 size. The obturation was completed by lateral condensation technique using gutta-percha and zinc oxide eugenol root canal sealer (Figure 7). After 12 months of post-operative follow radiograph showing complete healing of periapical lesion (Figure 8).

DISCUSSION

Root canal treatment primarily aimed at the elimination of bacteria as completely as possible. To manage large periapical lesions treatment options range from non-surgical root canal treatment and/or apical surgery to extraction.[8] When root canal treatment is not successful in resolving the periapical lesion, then additional treatment in the form of surgical intervention should be carried out. Necrotic pulps harbors pathogenic bacteria, necrotic pulp provide nutritional supply for these bacteria which leads to the development of periapical lesion. Conventional root canal treatment is primarily based on the removal of this microbial infection from the root canal system. Irrigants and intra-canal medicaments aid in reducing the microbial flora of infected root canals. In the present case reports, calcium hydroxide was used as the intra-canal medicament. Use of calcium hydroxide as dressing for 1 week has been shown efficiently eliminates bacteria from the root canals.[9]

It has also been reported that especially in young patients treatment with Ca (OH) 2 resulted in a high frequency of periapical healing.[10] It may takes many months for

healing of lesions. Caliskan and Sen[4] have reported that high frequency of periapical healing showing completed resorption of the periapical defect is observed with the treatment of calcium hydroxide. The exact mechanism of action of calcium hydroxide is still speculative. The efficacy of calcium hydroxide, owing to its antiseptic, anti-exudative, and mineralization inducing properties depends on the sustained release of calcium and hydroxyl ions to the root canal and periapical region. Regular renewal of the root canal dressing is fundamental in reducing the intensity of the periapical inflammatory process as they are progressively resorbed by the periapical fluids. Root canal dressing transforms the inflammatory granulation tissue into reparative granulation tissue, and simultaneously the differentiation of undifferentiated mesenchymal cells into reparative cells.[5]

Ghose *et al.*[11] have advocated that for osteoinductive reasons there should be direct contact between the calcium hydroxide and the periapical tissue. It is suggested that if calcium hydroxide is confined to the root canal, it is possible that the inflammation created by the diffusion of calcium hydroxide through the apical foramen may be sufficient to cause breakup of the cystic epithelial lining, thereby allowing a connective tissue invagination into the lesion with ultimate healing.

CONCLUSION

The clinical cases showed excellent healing of periapical lesions through a non-surgical approach. It is achieved through debridement, disinfection and three dimensional obturation of the root canal system. Healing of periapical lesion is effectively achieved through calcium hydroxide interim dressing. It is necessary to observe and monitor the prognosis of periapical lesions.

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Case Report

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Midgut Carcinoid Tumor in an Elderly Female: A Rare Case Report

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Abstract

Neuroendocrine tumors arise from diffuse endocrine system of the gastrointestinal system. They arise from amine precursor uptake decarboxylation cells, which can be found distributed throughout the gastrointestinal system. They show differential growth pattern varying from benign and well differentiated (tumors) to poorly differentiated malignant (carcinomas). Those arising from the gut have been collectively termed as carcinoid tumors. They are mostly asymptomatic. They may be detected incidentally or present as mass abdomen. The secreting tumors present with symptoms of hormone they secrete. They are rare (1.9/1,00,000 population) and overall form <2% of gastrointestinal tumors. We present one such rare case of midgut carcinoid in an elderly female who presented with mass abdomen.

Keywords: Carcinoid tumor, Elderly female, Midgut, Neuroendocrine tumor

INTRODUCTION

Carcinoids are usually slow-growing neuroendocrine tumors arising in the gastrointestinal tract, respiratory tract, thymus, testis or ovary. They are APUDOmas with cells of origin in argentaffin cells (dark stain with silver stain) or enterochromaffin cells (yellowish brown stain with chromate salts), which are found in a small intestine. They are mostly asymptomatic. Initial presentation may be in the form of mass or secretory symptoms of carcinoid syndrome due to secretion of serotonin (5-hydroxytryptamine) mainly, which is metabolized in liver, lung and brain to 5-hydroxyindoleacetic acid (5-HIAA), and excreted in urine. The measurement of 24 h urinary 5-HIAA and chromogranin (Cg A) are important tools for initial diagnosis and later follow-up of carcinoid tumor. Unusual manifestations of gastrointestinal carcinoids may be excessive gastrointestinal bleeding or cardiac manifestations.[1] Surgical excision forms the cornerstone of therapy, curative in early stages, and cytoreductive in later stages. Endoscopic resection of the tumor may be done in selected cases.[2] Radio-active ablation and chemotherapy have some role in controlling metastatic disease. Somatostatin analogues (Octreotide and lanreotide) are used to control symptoms of carcinoid syndrome.[3] Hepatic artery embolization has been used to control hepatic metastasis.[4,5] With increasing diagnosis, newer modalities of treatment have come into practice with better control of the disease.[6]

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CASE REPORT

A 72-year-old female presented with frequent episodes of loose stools and pain abdomen of about 2 years duration and mass abdomen of 1-year duration. She had no other symptoms attributable to cardio-respiratory system or history of flushing. General physical examination was unremarkable. A 12 cm × 10 cm size globular freely mobile non-tender, cystic intra-abdominal mass with a nodular surface was found occupying umbilical region mainly and extending to epigastric and left hypochondriac regions. Liver and spleen were not palpable and no ascites was found. Abdominal ultrasonography (USG) and computed tomography (CT) scan revealed a well-defined

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thick walled predominantly cystic intraperitoneal mass of 10 cm × 09 cm size in close proximity to jejunum and its mesentery, extending into root of small intestinal mesentery (Figure 1).

Exploratory laparotomy revealed a large mass in small intestinal mesentery and another smaller mass in close proximity to intestine. There were no metastatic deposits in the liver. Complete excision of mass along with about 70 cm of a small intestinal coil and its mesentery was carried out (Figure 2). Abdomen was closed after peritoneal toilet. Post-operative recovery was uneventful. Cut surface of the intestine showed a well-circumscribed grey-white soft to firm tumor mass. Cut surface was grey-white to grey brown. Section studied showed a tumor composed of cells arranged in an organoid, trabecular, and ribbon-like pattern separated by thin fibrovascular sepatae. Tumor cells were round and uniform with a moderate amount of eosinophilic granular cytoplasm, which was vacuolated at places. The tumor cells were seen to form pseudorosettes at places. Sections from adjoining mass showed a tumor with similar features.[7] Section studied from mesenteric lymph nodes showed hemorrhagic areas extensively infiltrated by tumor cells with similar morphology. Also seen were areas of lymphovascular invasion.

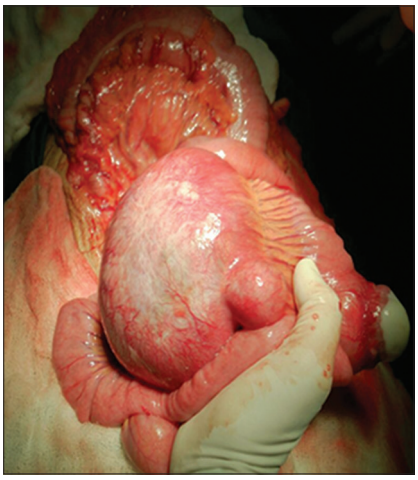

Figure 1: Per-operative appearance of the tumor arising from the jejunum with mesenteric lymph node metastasis

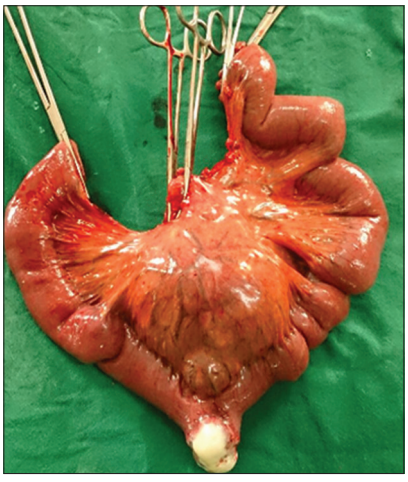

Figure 2: Specimen of the tumor along with coil of small gut after resection

Patient is planned for further follow-up with biological markers with the help of higher centers.

DISCUSSION

Siegfried Oberndorfer, a German pathologist (1907) coined the term "Karizinoide" (carcinoma like), unique benign growing tumors, for their benign growth in spite of their malignant appearance microscopically.[8] Incidence reported is 1.9/1,00,000 and form 0.25% of total oncology load. They are found in 1 in 300 autopsies. They usually have a benign course, but some become aggressive and resistant to treatment. 40% of carcinoids occur in a small intestine, 96% of these in jejunum.[9,10] In 2006 and 2010, Canadian consensus guidelines were published by a Canadian net expert group.[11,12] Furthermore, in recent years, a number of European and North American groups have developed consensus guidelines for the diagnosis and management of well-differentiated gastroenterohepatic nets.[13,14] Improvement in diagnostic modalities and management has improved the survival (67% - 5 years survival). They may be functioning (hormone secreting) or non-functioning. Functioning tumors produce carcinoid syndrome characterized by flushing, diarrhea, wheezing and peripheral edema due to secretion of serotonin.[15,16] Our patient did not have classical symptoms of carcinoid syndrome except attacks of diarrhea. Associated attacks of pain abdomen in our patient may have been due to the fibrotic changes producing gut ischemia, (abdominal cramps) that are known to be caused as a result of desmoplastic reaction in mesentery due to excess of serotonin secretion.[17] They may also give rise to intestinal obstruction, intussusceptions.[18] or even distant fibrotic changes in the form of endomyocardial fibrosis, tricuspid insufficiency and pulmonary valvular disease giving rise to carcinoid heart failure which may be fatal. In addition to serotonin several other biologically active substances such as kallikrein, histamine, prostaglandins, adrenocorticotropic hormone, gastrin, calcitonin, and growth hormone among others are secreted. As compared to carcinoids elsewhere, midgut carcinoids tend to produce carcinoid syndrome more often than others. Severity of symptoms depends on the size of tumor and extent of metastasis especially access of hormone to the systemic circulation bypassing portal circulation. Non-functioning tumors are asymptomatic and detected incidentally. Our patient did not have liver metastasis.

Biochemical markers are important tools in the diagnosis and follow-up of these patients. 5-HIAA, serotonin metabolite and Cg A are the two biochemical markers used for diagnosis and follow-up of these patients.[19,20] 24 h urinary 5-HIAA is normally 3-15 mg and up to 45 mg is taken as normal by some laboratories. It has 73% sensitivity and 100% specificity. Cg found in the walls of vesicles containing serotonin and glucagon is elevated in 85-100% of patients with carcinoid tumors with a specificity of 98% and sensitivity of 62%.[21] Ki 67 antigen protein present in the nucleus of proliferating cells is used as a prognostic marker along with mitotic index. Tumors with high value >2% of Ki 67 are likely to respond than those with low values (<2%). Antibodies to Ki 67 are reliable markers of cell proliferation. In our patient, biological markers could not be assessed due lack of facilities in our center. However, these studies are planned to be undertaken with the help of higher centers during follow-up of the patient.

Conventional imaging (USG, CT and magnetic resonance imaging) can be used to locate site and extent of tumor. Abdominal USG and CT scanning revealed the location and extent of tumor in our case. ^{111}In pentetreotide scintigraphy and ^{123}I or ^{131}I Meta iodobenzylguanidine (MIBG) scintigraphy are used for identifying and staging.[22] MIBG scans may be positive in 10% of cases with negative pentetreotide scan. Somatostatin analogue scans for tumor detection, are also used to control symptoms of carcinoid syndrome.

As per the recommendation, a basal octreoscan should be done before treatment and thereafter yearly, after curative resection. 03 monthly urinary 5-HIAA during 1st year and 6 monthly in 2nd year with yearly Cg A levels is also recommended along with imaging studies for follow-up.

WHO has classified gastrohepatic neuroendocrine tumors as:[23]

- Well-differentiated NETs
  - Benign
  - Uncertain malignant potential
- Well differentiated neuroendocrine carcinomas
- Poorly differentiated neuroendocrine carcinomas.

Well-differentiated nets are often considered the "classical carcinoid" NETs and demonstrate a trabecular, insular, or ribbon-like architecture, minimal cellular pleomorphism and sparse mitotic activity. Well-differentiated neuroendocrine carcinomas (sometimes called "malignant carcinoids") have increased cellular pleomorphism and mitotic activity and may have punctate necrosis. Poorly differentiated neuroendocrine carcinomas show marked cellular pleomorphism, fields of necrosis, and brisk mitotic activity. These can be histopathologically similar to small-cell lung carcinoma.

Surgical treatment is curative for loco-regional disease. Tumor debulking provides good palliation in control of large tumors and metastatic disease. Prophylactic cholecystectomy should be considered in every patient undergoing surgery for NETs of the digestive tract. Our patient had already undergone cholecystectomy. This procedure mitigates the biliary toxicity of sulfosalicylic acid therapy and avoids chemical cholecystitis if transcatheter arterial chemoembolization is required to be performed in the future.[24]

Medical management consists of administration of somatostatin analogues (octreotide) for functioning tumors. Interferon alfa helps in control of angiogenesis and improves immunity. Chemotherapy consisting of streptozocin with doxorubicin or fluorouracil have been used with limited effect in poorly differentiated carcinomas.[25]

CONCLUSION

A rare case of midgut carcinoid in an elderly female with lump abdomen is reported. Whereas symptoms of diarrhea and abdominal cramps were only symptoms in addition to lump abdomen. Complete classical carcinoid syndrome was not noted in our patient. Hence, the possibility of carcinoid was not considered in our patient. The diagnosis was clear only after the histopathological examination. Studies of hormonal markers could have given more information about the functional status of the tumor. Since the tumor has been completely resected, further follow-up with imaging studies and biological markers need to be done to detect any recurrence or metastasis.

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Case Report

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Mullerian Developmental Defect Along with Multisystem Abnormalities: A Rare Case with Rare Association

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Abstract

A mullerian abnormality encompasses a wide range of systemic abnormalities which throws a real challenge to the gynecologists for chalking out the appropriate strategy for their diagnosis and management. The most basic classification of mullerian duct defects consists of agenesis and hypoplasia, defects of vertical fusion, and defects of lateral fusion. Mullerian abnormalities are often associated with other systemic abnormalities. In the reported case, we encountered at least four systemic abnormalities in the same patient. The mullerian, gastrointestinal, and cardiological abnormalities were corrected on subsequent intervals. On the follow-up, the patient was seen to be heading towards a healthy life.

Keywords: Mullerian defects, Rectal agenesis, Ventricular septal defect

INTRODUCTION

Mullerian developmental defects are some of the most fascinating disorders that gynecologists encounter. The Mullerian ducts are the primordial analog of the female reproductive trac t which differentiates to form the fallopian tubes, cervix, body of the uterus, and the upper part of the vagina. Frequently associated abnormalities are those of renal, cardiac, and axial skeletal system.[1]

Embryology

At 6 weeks of development, the male and female genital systems are indistinguishable in appearance, constituting two sets of paired ducts: the paramesonephric (Mullerian) ducts and the mesonephric (Wolffian) ducts. In the absence of the testis-determining factor of the Y chromosome, the mesonephric ducts begin to degenerate and form a matrix for the developing paramesonephric ducts. Synchronously, the paramesonephric ducts develop bi-directionally along the lateral aspects of the gonads. The proximal segments of the uterovaginal canal, derived from coelomic epithelium, remain unfused and open into the peritoneal cavity to form the fallopian tubes. The distal segments, induced by or derived from the adjacent mesonephric ducts, progress caudomedially and join each other before contacting the posterior aspect of the pelvic urethra at the level of the sinusal tubercle. These distal segments of the uterovaginal canal give rise to the uterus and upper 4^{th}-5^{th} of the vagina.

Initially separated by a septum, at 9 weeks the paramesonephric ducts fuse at their inferior margin forming the single lumen of the uterovaginal canal. Regression of the uterine septum has been proposed to be a result of apoptosis, mediated by the Bcl2 gene. Absence of this gene has been implicated in the persistence of the septum. The classic theory of unidirectional regression hypothesizes that the septum regresses from the caudal to cranial aspect of the uterovaginal canal, with the uterus initially bicornuate in configuration. However, an alternative bi-directional theory has been proposed in which it is hypothesized that the process proceeds simultaneously in both the cranial and the caudal directions. This would explain anomalies such as a complete septum with a duplicated cervix or

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isolated vertical upper vaginal septum in an otherwise unremarkable uterus.

At week 12, the uterus exhibits its normally developed configuration: A fused external uterine contour of the myometrium and a triangular-shaped endometrium. Because, the fallopian tubes are derived from a different cellular origin than are the uterus and mid- to the upper vagina, they are rarely involved in mullerian duct anomalies.

During the formation of the uterovaginal canal, the sinusal tubercle thickens and forms the sinovaginal bulbs of the primitive urogenital sinus, which gives rise to the lower 20% of the vagina. The uterovaginal canal remains separated from the sinovaginal bulbs by the horizontal vaginal plate. The vaginal plate elongates during the 3rd-5th month, and its interface with the urogenital sinus forms the hymen, which usually ruptures during the perinatal period.

The urinary and genital systems both arise from a common ridge of mesoderm arising along the dorsal body wall, and both rely on normal development of the mesonephric system. The ureters, renal calices, and collecting tubules are formed from the ureteral bud, which arises from the mesonephric ducts, which also induce formation of the kidneys. Hence, abnormal differentiation of the mesonephric and paramesonephric ducts may also be associated with anomalies of the kidneys. Renal agenesis is the most common associated anomaly, although crossed renal ectopia, cystic renal dysplasia, and duplicated collecting systems have all been described.

The ovaries arise from the mesenchyme and epithelium of the gonadal ridge and are not influenced by the formation of the mesonephric or paramesonephric ducts. The undifferentiated gonads are induced to develop by primordial germ cells that migrate from the yolk sac to the dorsal mesenchyme at 5 weeks. These germ cells induce cells of the mesonephros to form genital ridges, which in turn form primitive sex cords. If germ cells do not develop in the region of the gonads, the gonads do not form. Hence, ovarian development is a separate process from the formation of the uterovaginal canal and is not usually associated with mullerian duct anomalies.[2]

CASE REPORT

A 19-year-old girl came to the outpatient department on 20/1/2009 with the chief complaints of chronic lower abdominal pain for 3-4 years. Her pain was mainly located on the right hypochondrium, progressive in nature and had exacerbations during her menstruation. Her menarche was at the age of 14 years and her menstrual history revealed that her periods were regular with mild to moderate flow and was associated with progressive dysmenorrhea.

Regarding her past history, it was revealed she was previously diagnosed with a high type of rectal atresia which was treated initially by colostomy and finally through the definite modality of posterior sagittal anorectoplasty at the age of 18 months. She also had a history of having a ventricular septal defect which was repaired between 6 and 12 months of her age.

On examination, there was a lower abdominal mass of 14-16 weeks of uterine size felt at the right hypochondrium which was later diagnosed as a chocolate cyst of right ovary. Ultrasonography of whole abdomen also gave the hint of renal agenesis on the right side with along with unicornuate uterus. Intravenous pyelography confirmed the absence of right kidney and ureter.

The patient underwent laparoscopy on 24/1/2009 which finally made the diagnosis of the case as unicornuate uterus with the left uterine horn communicating with the cervix. The right non-communicating horn had a collection inside (hematometra) with a right chocolate cyst. As a definitive management procedure, laparotomy was performed on 1/04/2009 where removal of right-sided non-communicating horn along with right ovary with chocolate cyst was performed. The left horn of the functional uterus with ipsilateral tubes and ovaries were found to be absolutely normal hence left undisturbed. Her post-operative recovery was uneventful and she was discharged on the 7th postoperative day. Her subsequent scans and follow-up were smooth and regular (Figures 1-4).

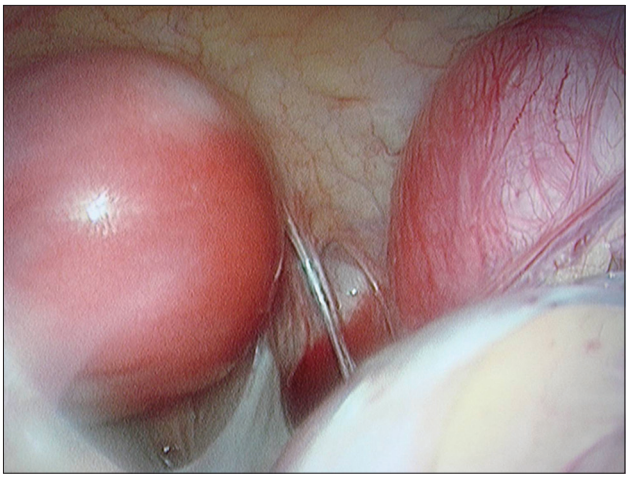

Figure 1: Right side hematometra & chocolate cyst with left side normal functional uterine horn

Figure 2: Scar of initial colostomy (before posterior sagittal anorectoplasty)

Figure 3: Scar of sternotomy (ventricular septal defect repair)

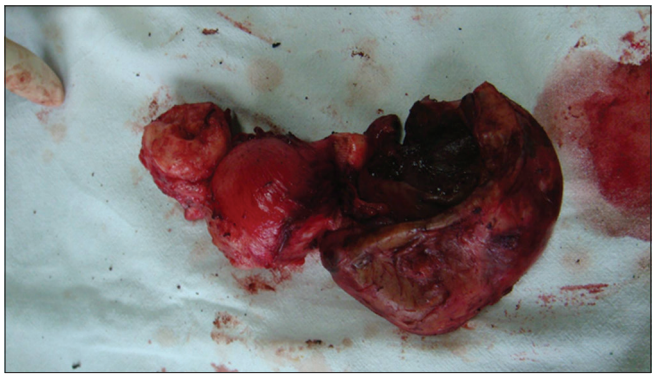

Figure 4: Uterus with cervix along with chocolate cyst

DISCUSSION

Abnormalities in the formation or fusion of the mullerian ducts can result in a variety of anomalies of the uterus and vagina. Close developmental relationship of the mullerian and the wolffian ducts explain the frequency with which anomalies of the female genital system and urinary tract are associated. Jones and Rock have pointed out that failure of lateral fusion of the mullerian ducts with unilateral obstruction is associated consistently with absence of the kidney on the side of obstruction, which was exactly the similar scenario of the reported case.[3] Reports have also described several patients with functioning endometrial tissue in one or both rudimentary uterine bulbs. These patients can develop a large hematometra because of the cyclic accumulation of trapped blood which was also one of the main features of the abovementioned case. Pittock *et al.* reported a substantial incidence of cardiac defects (16%) when reviewing a group of 25 patients with Mullerian abnormalities.[4] The reported case also had a history of large ventricular septal defect. According to the study done by Oppelt of Germany in 2007 there is an association of rectal atresia with mullerian abnormalities which is about 2%.[5]

CONCLUSION

The uniqueness of the reported case lies in the fact that there was the presence of multiple abnormalities of the cardiac, renal, genital and gastrointestinal system in a single affected person. Most of these anomalies were treated comprehensively. Hence, it is recommended that in every case of Mullerian anomaly, associated cardiac, renal, and gastrointestinal system should be investigated in thorough so that any other associated abnormality do not escape the examiners vision.

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Case Report

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Benign Intracranial Hypertension Secondary to Prolonged Steroid Usage: A Case Report

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Abstract

Benign intracranial hypertension (BIH), also known as idiopathic intracranial hypertension or Pseudotumor cerebri, is a syndrome of signs and symptoms of increased intracranial pressure without causative mass or hydrocephalus identified. We report a case of 21-year-old male who was a known asthmatic since 11 years, on oral steroids without any medical supervision presented with diplopia and blurring of vision of 10 days duration with recent onset of squint and cushingoid features. Case was diagnosed as BIH based on clinical and radiological criteria. Treatment was initiated with Tab. Acetazolamide 250 mg twice daily for 2 weeks along with gradual tapering of steroids. On the follow-up after 4 weeks, a dramatic improvement in visual symptoms with resolution of papilledema was observed. BIH is commonly associated with sudden withdrawal of steroids. We report this case as it was resulted from prolonged steroid usage and which improved after gradual tapering of the steroid along with acetazolamide therapy.

Keywords: Benign intracranial hypertension, Diplopia, Papilledema, Steroids

INTRODUCTION

Benign intracranial hypertension (BIH) is a disorder defined by clinical criteria that include symptoms and signs isolated to those produced by increased intracranial pressure (ICP) (e.g. headache, papilledema, vision loss), elevated ICP with normal cerebrospinal fluid composition, and no other cause of intracranial hypertension evident on neuroimaging or other evaluations.[1] While once called BIH, to distinguish it from secondary intracranial hypertension produced by a neoplastic malignancy, it is not a benign disorder. Many patients suffer from intractable, disabling headaches, and there is a risk of severe, permanent vision loss. The presence or absence of findings on magnetic resonance imaging (MRI) does not appear to predict visual outcomes.[2] Recurrence of symptoms may occur in 8-38% of patients after recovery from an episode of BIH or after a prolonged period of stability.[3] A subset of individuals with idiopathic intracranial hypertension (IIH) have a more malignant or fulminant course with rapid development of vision loss within a few weeks of symptom onset which is referred to as fulminant IIH.[4] To limit the severity of permanent vision loss, more aggressive surgical treatment measures are considered at the outset, often with temporizing measures (e.g. serial lumbar punctures, lumbar drain, and/or corticosteroids) employed until surgery can be performed. BIH is a disorder that primarily affects women of childbearing age who are overweight.[5] Review of literature shows that BIH is commonly associated with withdrawal of steroids. Development of BIH, while on maintenance steroid therapy or increase in its dose is an uncommon phenomenon in adults.

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CASE REPORT

A 21-year-old male patient admitted with a complaint of headache and diplopia of 10 days duration. He was born to a non-consanguineous parents and developmental history was also normal. There was no family history of neurological

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disorders. He reported that he was a known case of asthma for the past 11 years, and taking oral prednisolone therapy since then without any medical supervision till the date of presentation. He had weight gain with retarded growth for the past 5-6 years. He had intermittent blurring of vision with new onset squint of 10 days duration.

On physical examination, he was noticed to have retarded growth with central fat distribution, Buffalo hump. He had delayed development of secondary sexual characters with absent axillary and pubic hair with a hypoplastic penis.

The neurological examination was noteworthy for diplopia with right-sided 6th nerve paresis. Laboratory evaluations including a complete blood count, blood electrolytes, urea, creatinine, and liver enzymes gave results at normal range.

Ophthalmologic evaluation revealed acute bilateral papilledema and diminished visual acuity. Cerebrospinal fluid pressure (CSF) pressure manometry records an increased CSF pressure of 50 mm of water. CSF analysis was normal.

CT scan cranial MRI was normal. MR venogram shows multiple collaterals and reformation of distal venous sinuses seen at sigmoid sinus and dominant right jugular vein. Since the plain study does not suggest any thrombosis, this appearance most likely represents BIH.

Following the diagnosis of BIH with cushing's syndrome, acetazolamide 250 mg twice daily was prescribed for 2 weeks along with gradual tapering of the steroids. His sixth nerve palsy resolved gradually over 1 month. On the review, 2 months later his optic disc had returned to normal and he had remained asymptomatic. After tapering the drug, patient's visual improvement and the resolution of the papilledema were very dramatic. Such a causal relationship strongly suggests prolonged steroid to be the cause of the BIH [Figures 1-5].

DISCUSSION

The first report of BIH was by the German physician Heinrich Quincke, who described it in 1893 under the name serous meningitis.[6] The term "pseudotumor cerebri" was introduced in 1904 by his compatriot Max Nonne.

BIH or pseudotumor cerebri is a syndrome that is defined by increased ICP, absence of ventriculomegaly, no evidence of intracranial extensive lesion and normal CSF composition.

The main symptoms are headache, nausea, and vomiting, as well as pulsatile tinnitus, double vision and other visual symptoms. If untreated, it may lead to swelling of the optic disc in the eye, which can progress to vision loss. The increased pressure leads to compression and traction of the cranial nerves that arises from the brainstem. Most commonly, the abducens nerve (sixth nerve) is involved.

Modified Dandy criteria[7]

Symptoms of raised ICP (headache, nausea, vomiting, transient visual obscurations, or papilledema)
No localizing signs with the exception of abducens (sixth) nerve palsy
The patient is awake and alert
Normal CT/MRI findings without evidence of thrombosis
LP opening pressure of >25 cm H_2O and normal biochemical and cytological composition of CSF
No other explanation for the raised ICP

CT: Computed tomography, MRI: Magnetic resonance imaging, CSF: Cerebrospinal fluid pressure, ICP: Intracranial pressure

Our case satisfies all the six modified Dandy criteria, and hence labeled as BHI.

The strongest evidences for the association with BIH exists for young age, female sex, obesity or weight gain, prolonged use of tetracyclines or vitamin A. Steroid withdrawal and Addison's disease are clearly associated with BIH.[8]

BIH is most commonly associated with abrupt withdrawal of steroids and it was evident from the literature that symptoms were attenuated after reintroduction of steroid therapy. However, the presentation of BIH during steroid therapy and regression of symptoms after tapering of steroids was a very rare phenomenon in adults as evident in our case.

On average, BIH occurs in about one per 100,000 people and can occur in children and adults. The median age at diagnosis is 30.[9] BIH occurs predominantly in women, especially in the ages 20-45, who are 4-8 times more likely than men to be affected. Overweight and obesity strongly predispose a person to BIH: Women who are more than 10% over their ideal body weight are 13 times more likely to develop BIH, and this figure goes up to 19 times in women who are more than 20% over their ideal body weight. In men this relationship also exists, but the increase is only five-fold in those over 20% above their ideal body weight.

A theory for the mechanism of BIH posits that either increased blood flow to the brain or increase in the brain tissue itself may result in the raised pressure. Another suggested theory was restricted venous drainage from the brain may be impaired resulting in congestion. Many patients with IIH have narrowing of the transverse sinuses.[10]

The treatment goal for patients with BIH is to preserve optic nerve function while managing increased ICP. Weight control is recommended for obese patients.[11]

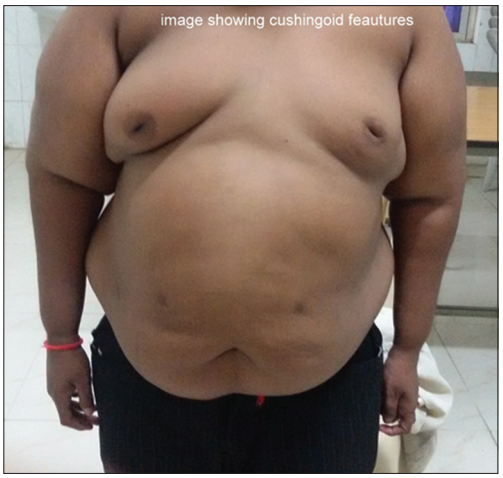

Figure 1: Cushingoid features

Figure 2: (a) right lateral rectus palsy (b) complete resolution after treatment

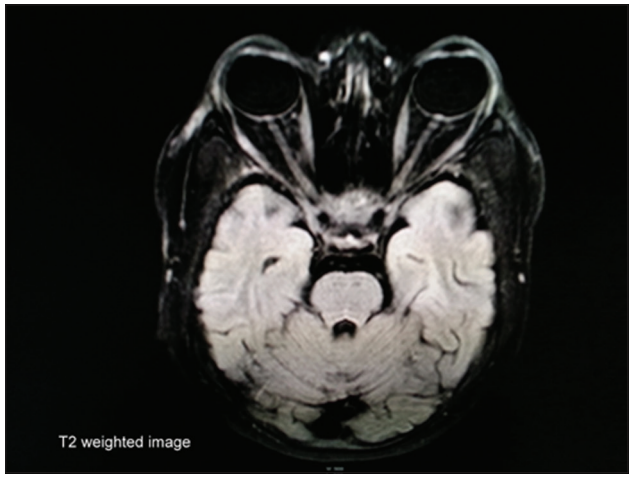

Figure 3: Magnetic resonance imaging T2 W imaging

As our patient has blurring of vision with decreased visual acuity he is treated with acetazolamide therapy along with gradual tapering of steroids.

Figure 4: Magnetic resonance imaging T1 W imaging

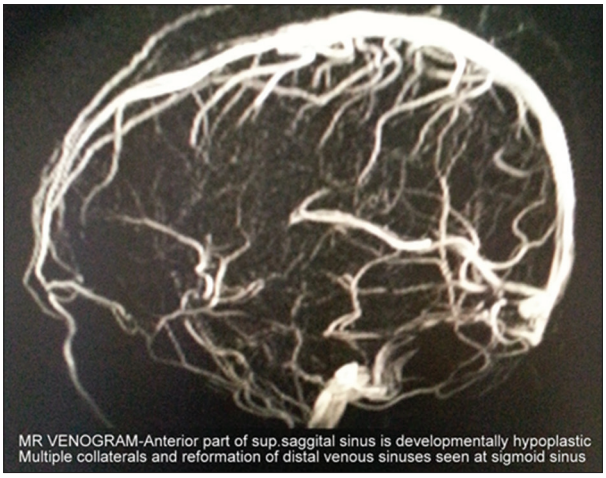

Figure 5: Magnetic resonance venogram

Patients without visual loss most often are treated with a carbonic anhydrase inhibitor like acetazolamide,[12] furosemide to lower the ICP. The mechanism of action of acetazolamide is likely multifactorial. It has been found to reduce CSF production. Furthermore, it changes the taste of foods and sometimes causes anorexia aiding in weight loss. Furosemide has also been used to treat BIH. It has been well documented that furosemide can lower ICP. It appears to work by both diuresis and reducing sodium transport into the brain primary headache prophylaxis with amitriptyline, propranolol, or other commonly prescribed migraine prophylaxis agents, or with topiramate. Topiramate has also been used to treat BIH since it has carbonic anhydrase inhibitor activity and weight loss commonly occurs. In studies to date, it appears comparable to acetazolamide.[13]

If visual function deteriorates, surgical or other invasive interventions may be considered. Interventions include the following. Optic nerve sheath fenestration (decompression).[14]

Cerebrospinal fluid diversion (i.e. via a lumboperitoneal or ventriculoperitoneal shunt).[15] Intracranial venous sinus stenting.[16]

CONCLUSION

Headache and visual symptoms after prolonged steroid usage should prompt the evaluation of BIH. The etiological factor for BIH in our case includes prolonged steroid therapy and treatment was initiated with acetazolamide along with gradual tapering of steroids. Increased awareness of this adverse effect among physicians is important, as steroids are widely used medications for varied conditions.

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Case Report

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Neurothekeoma of Oral Cavity: A Rare Case Report

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Abstract

Neurothekeoma is a benign soft tissue tumor with a clinical presentation as a solitary slow-growing painless mass. It is seen most commonly in the central area of the face, neck, and upper extremities. The mean age of occurrence is 25 years with a slight female predilection. Three histologic variants include myxoid, mixed, and cellular. The histogenesis of this tumor is controversial. The occurrence in the oral cavity is extremely rare. This article describes a case report of cellular neurothekeoma in the tongue of a 51-year-old male patient. The lesion was excised during biopsy and has shown no recurrence to date. This is the 7th case reported in the literature on cellular neurothekeoma presenting in the oral cavity.

Key words: Nerve sheath myxoma, Neurothekeoma, Oral cavity, Tongue

INTRODUCTION

Neurothekeoma is an uncommon benign soft tissue tumor. Gallagher and Helwig coined the term neurothekeoma.[1] The term cellular neurothekeoma was coined by Rosati *et al.* in 1986.[2] It is seen most commonly in the central area of the face, neck, and upper extremities. The mean age of occurrence is 25 years with a slight female predilection (1.8: 1).[3] Three histologic variants include myxoid, mixed and cellular.[4] Histopathologically, these lesions show a circumscribed tumor mass composed of epithelioid and spindle cells, arranged in well-formed micronodules.[5] A recent study of 37 cellular neurothekeoma showed cytological atypia in about 50% of cases.[6] The histogenesis of this tumor is controversial. Earlier it was believed to be a type of nerve sheath myxoma.[7] Gene expression profile study of neurothekeomas have shown that it may be a variant of fibrous histiocytomas.[8]

Oral involvement is extremely rare. The most common intraoral site is tongue.[9] This article describes a case report of cellular neurothekeoma in the tongue of a 51-year-old male patient.

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CASE REPORT

A 51-year-old male patient presented with the chief complaint of swelling in the right side of the tongue since 1 year. The swelling was asymptomatic, insidious in onset, first noticed 1 year back, and has slowly increased to its present size. No relevant medical or family history was present.

On examination, a swelling of size 1 cm × 1 cm × 0.4 cm was noticed on the right side of the dorsum of the tongue. It was firm in consistency, non-fixed with limited mobility. The overlying mucosa appeared relatively normal. The provisional diagnosis was fibroepithelial hyperplasia or granular cell tumor. The swelling was excised during biopsy.

Microscopic examination of hematoxylin and eosin stained section showed stratified squamous epithelium and an underlying lamina propria with tumor mass (Figure 1). The proliferating tumor mass was arranged as lobules (Figure 2). Under ×40 magnification, ovoid to spindle cells and epithelioid cells with bland, vesicular nuclei, and a light eosinophilic cytoplasm, arranged like staves of a barrel were seen (Figure 3). Immunohistochemical analysis showed positivity of tumor cells for NKI/C3, vimentin; and were

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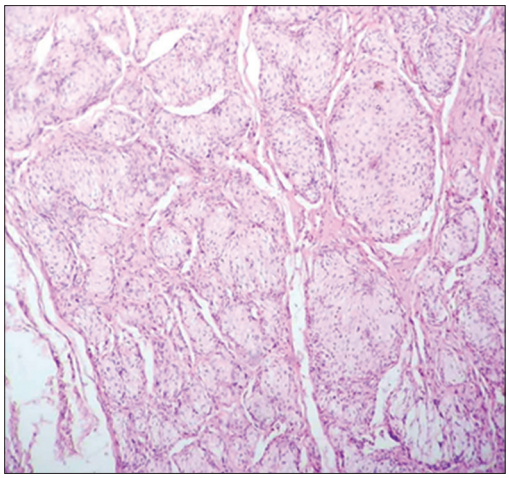

Figure 1: Tumor mass separated from the epithelium by a condensed fibrous connective tissue, H and E stain, under ×4 magnification

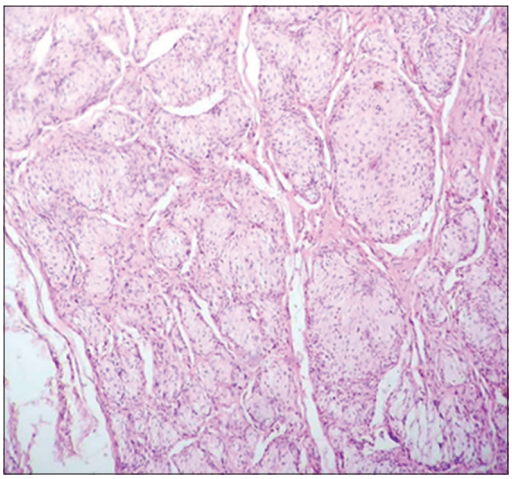

Figure 2: Lobules of tumor cells separated by fibrous connective tissue, H and E stain, under ×10 magnification

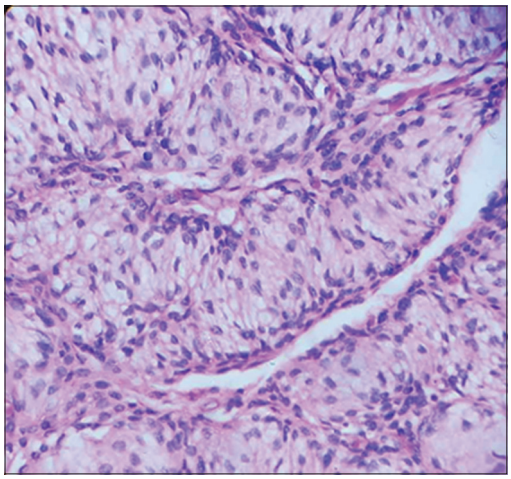

Figure 3: Ovoid to spindle cells with bland nucleus and light eosinophilic cytoplasm, H and E, under ×40 magnification

negative for S100. A diagnosis of cellular neurothekeoma was arrived.

DISCUSSION

Neurothekeoma is a benign cutaneous tumor with rare mucosal involvement. Oral involvement of neurothekeoma is extremely rare with only six reported cases of cellular neurothekeomas.[5,10] A slight female predilection was reported. Tongue was the most common site.

In earlier days, the term nerve sheath myxoma and neurothekeoma were used interchangeably. Husain *et al.* considered these tumors as either ends of the morphologic spectrum of neurothekeoma.[7] Various immunohistochemical studies showed neural differentiation of myxoid neurothekeoma.[11,12]

The histogenesis of cellular neurothekeoma is controversial. Fetch *et al.* proposed an origin from fibroblastic cells with the ability to differentiate into myofibroblasts and a tendency to recruit histiocytic cell.[2] Sheth *et al.* studied microarray-based gene expression profile of dermal schwannomas, dermal nerve sheath myxomas, cellular fibrous histiocytomas and myxoid/mixed/cellular neurothekeomas. They found that neurothekeomas and cellular fibrous histiocytomas showed upregulation of genes encoding various metalloproteinases and glycoproteins involved in growth and remodeling of extracellular matrix; whereas genes encoding neuronal cell intercellular signaling were differentially expressed between nerve sheath myxomas and schwannomas.[8]

Histopathologically, neurothekeomas are seen as multinodular, lobular, or plexiform patterns surrounded by bands of dense collagen. Cells are epithelioid or spindle-shaped with light eosinophilic cytoplasm, and contain bland, ovoid nuclei. Myxoid areas are frequently seen in the stroma which may mimic nerve sheath myxoma. Osteoclast like giant cells may be seen.[13]

Neurothekeomas are variably immunoreactive for smooth muscle actin, PGP 9.5, NKI/C3, CD10, CD68, microphthalmia transcription factor, podoplanin; and negative for S100, glial fibrillary acidic protein, and melan A.[14,15]

Complete excision is the treatment of choice. Recurrence may occur with incomplete removal. The differential diagnosis includes plexiform fibrohistiocytic tumors, reticulohistiocytoma, epithelioid fibrous histiocytoma, and melanocytic tumors.[13] Plexiform fibrohistiocytic tumors show diffuse, nodular, and plexiform growth pattern of either spindle or epithelioid cells, but plexiform pattern being the predominant. Giant cells are more in number and with more nuclei than cellular neurothekeoma. Expression of microphthalmia transcription factor

helps in differentiating neurothekeoma from plexiform fibrohistiocytic tumors. Reticulohistiocytoma lacks the plexiform or whorling growth pattern seen in neurothekeoma and the epithelioid cells are CD163 positive. The epithelioid variant of fibrous histiocytoma shows a diffuse pattern of epithelioid fibroblasts rather than the multi-nodular pattern of neurothekeoma.[16] Melanocytic tumors show positive expression of S100 and melanocytic markers such as HMB45 and Melan-A.[13]

CONCLUSION

The present case was that of a male patient with tongue involvement. Histopathology of our case was that of a clear-cut cellular neurothekeoma. The lesion was excised during biopsy. Patient is on follow up and has shown no recurrence to date. This is the 7th case reported in the literature on cellular neurothekeoma presenting in the oral cavity.

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Case Report

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Pulmonary Tuberculosis with Mediastinal Lymphadenopathy and Superior Veno Caval Obstruction, Mimicking Lung Malignancy: A Case Report

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Abstract

Pulmonary tuberculosis may present as a mass-like lesion can mimic lung cancer and can also coexist with it. We report a case of pulmonary tuberculosis in middle-aged female with right upper lobe lesion, mediastinal adenopathy and with superior vena cava obstruction mimicking lung malignancy. X-ray chest, multi detector computed tomography chest, fiberoptic bronchoscopy, and thoracotomy findings are consistent with malignancy. Imaging findings alone are not sufficient to distinguish tuberculosis from malignancy. Ultimately open biopsy revealed tuberculous granulomatous pathology. We reviewed our case with existing literature.

Keywords: Biopsy, Lung malignancy, Pulmonary tuberculosis, Superior vena cava obstruction

INTRODUCTION

Tuberculosis continues to be a health problem despite efforts at eradication and control, and a total of 9.2 million cases of tuberculosis are reported World Wide annually.[1] Pulmonary tuberculosis exhibits variable radiological findings, mimicking all the other pathological formations of the lung and clinical difficulties for diagnosis.[2] Bacterial pneumonias, fungal infections, and bronchogenic carcinoma are such common diseases among others which can be mistaken as tuberculosis because of non-specific symptoms and similar radiological findings. Over-reliance on clinical findings and imaging may lead for misdiagnosis.[3]

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Keeping endemicity of the disease in India, knowledge of typical and atypical radiological patterns is necessary. This case report is about pulmonary tuberculosis that mimicked lung cancer in the way it had presented which required open biopsy for final diagnosis.

CASE REPORT

A 30-year-old female presented with chest pain, cough and sputum since 1-month. Chest X-ray (Figure 1) showed soft tissue opacity right upper lobe with peripheral haziness extending medially to mediastinum and below with upward displacement of minor fissure: Suggestive of right upper lobe mass with mediastinal invasion or mediastinal mass with partial collapse of right upper lobe.

Routine lab investigations were unremarkable. Sputum for acid-fast bacilli (AFB) negative, HIV non-reactive. Patient was managed as a community acquired pneumonia and discharged. Patient was not presented for follow-up. After 1-year, she was readmitted with chest pain, cough

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and hemoptysis. Routine blood chemistry and lab tests were unremarkable and sputum for AFB negative and HIV non-reactive.

Second plain X-ray chest (Figure 2) showed well-defined homogenous mass lesion in right upper lobe with upward displacement of minor fissure with mild displacement of distal trachea suggestive of right upper lobe mass (or) mediastinal mass. In comparison with old X-ray, the same findings are noted.

Contrast-enhanced computed tomography (CT) chest findings (Figure 3a-d) in axial, coronal views in mediastinal and lung window showed large non homogenously enhancing, lobulated heterogenous soft tissue mass lesion in anterior superior mediastinum extending to apical segment of right upper lobe (measuring 8.1 cm × 7.1 cm × 7.5 cm) with encasement of superior vena cava, right pulmonary artery, abutting trachea with mild displacement toward left. The lesion seen extending up to the right hilum encasing right upper lobe bronchus with collapse, consolidation of right upper lobe suggestive of malignant mediastinal mass (or) lymphoma (or) carcinoma lung.

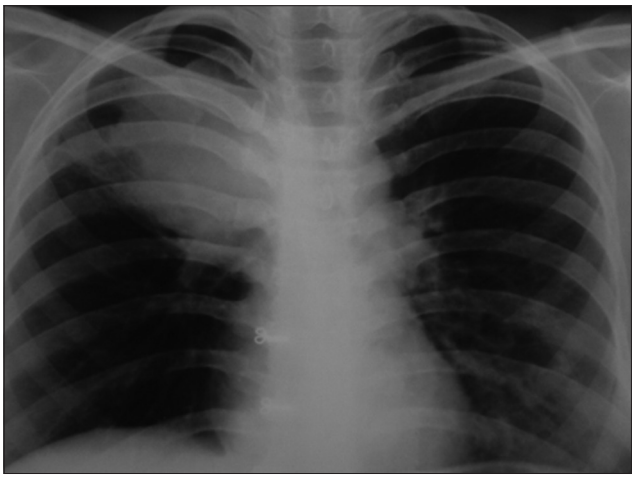


Figure 1: Plain X-ray chest posteroanterior view - large soft tissue opacity in right upper lobe with peripheral haziness extending to mediastinum and inferiorly to minor fissure with upward displacement of minor fissure

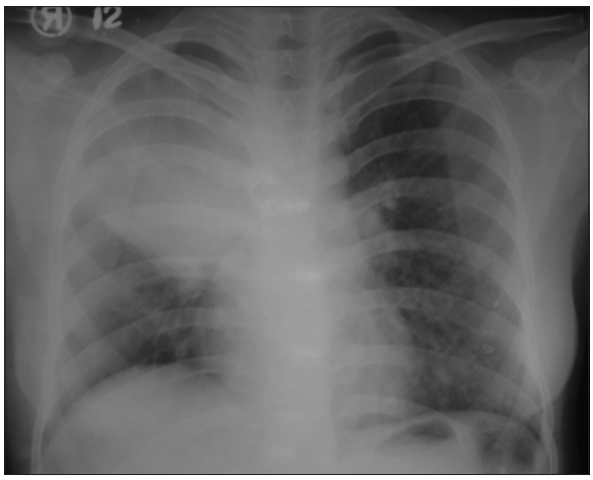


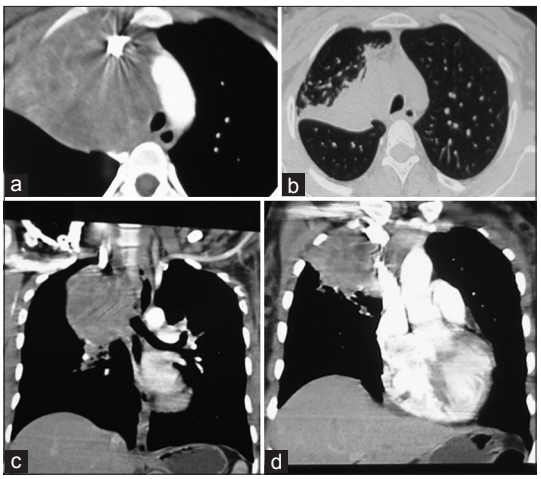
Figure 2: Plain X-ray chest posteroanterior view - large soft tissue opacity in right upper lobe with peripheral haziness extending to mediastinum and inferiorly to minor fissure

Next, patient was subjected for fiberoptic bronchoscopy (FOB) which revealed pedunculated fleshy growth in lower end of the trachea, extending to right main bronchus. Biopsy was taken from pedunculated growth showed lymphocytes, multinucleated giant cells prominent neutrophils, macrophages, Langerhans type giant cells with epithelioid cells with no evidence of malignancy suggestive of tuberculosis.

Still with high radiological suspicion of malignancy and pedunculated growth in trachea and right main bronchus in FOB, patient was referred to the cardiothoracic surgeon for thoracotomy and open biopsy to rule out malignancy.

Per-operative findings showed a mass lesion occupying right upper lobe and mediastinum with plenty of right para and pre tracheal lymph nodes. After incising, the lesion showed contents with loculated pus. Biopsy was taken from mass lesion and sent for histopathological examination (HPE).

HPE report of open biopsy specimen revealed lymphoid tissue replaced by caseation necrosis, granulomas with epitheloid cells and Langerhans foreign body giant cells suggestive of tuberculous pathology (Figure 4).



Figures 3: (a-d) Contrast-enhanced computed tomography chest mediastinal and lung window - axial and coronal views - large non homogenous enhancing soft tissue density mass lesion in anterio superior mediastinum extending to apical segment of right upper lobe, encasing superior vena cava, right pulmonary artery and mild displacement of distal trachea. The lesion is extending to the right hilum encasing right main bronchus with collapse consolidation of right upper lobe

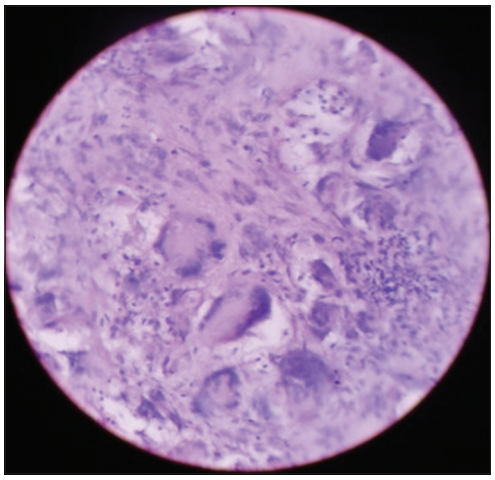


Figure 4: Open biopsy of the lesion showing lymphoid tissue replaced by caseation necrosis, granulomas, with epithelioid cells, Langerhans and foreign body giant cells suggestive of tuberculous pathology

DISCUSSION

Among pulmonary infections mimicking lung malignancy, tuberculosis plays major role approximately in one quarter of cases[4] Cherian *et al.*[5] in his study of atypical pulmonary pattern of tuberculosis found that the most common unusual pattern of pulmonary tuberculosis was mass-like lesion, most of which are initially and mistakenly diagnosed as neoplasms.

Lung tuberculosis is often seen radiographically in the forms of cavitary, micro and macronodular and miliary types, fibro-calcification and pleural involvement. In our study, the above typical findings were absent. Parenchymal lesion and associated mediastinal pathology in X-ray chest could not be distinguished from malignancy or any mediastinal mass.

The chest CT patterns of pulmonary Koch's described are bronchial narrowing or obstruction without a central mass-like lesion (Pattern 1), central mass-like lesion with distal atelectasis or obstructive pneumonia (Pattern 2), peripheral nodule or mass including mass-like consolidation (Pattern 3), and cavitary lesion (Pattern 4).[6] In our case study, the above patterns are not appreciated. Our findings are mass lesion extending onto right upper lobe with encasement of superior vena cava (SVC) and other vascular structures and trachea, right upper lobe bronchus, strongly suggesting lung malignancy or invasive mediastinal mass and on contrast study there is non-homogenous enhancing pattern, which is attributed to the thoracotomy findings of encrypted abscess with peripheral inflammation.

FOB findings in our case are pedunculated fleshy growth in lower end of the trachea extending into right upper lobe bronchus is feature of epithelial malignancy of airways with submucosal spread. These findings can be correlated with study of Chung and Lee[7] on endobronchial tuberculosis which explains that tuberculous granulations tissue may be observed to erupt through bronchial mucosa to form a tumor-like mass. The caseous tracheo-bronchial lymph node can produce ominous irregular swelling on the trachea or main bronchus which suggest malignant invasion of lymph node. Finally, bronchial biopsy will reveal the tissue situation. Similar pattern was observed in our study.

Despite biopsy on bronchoscopy suggesting tuberculosis, the symptom of persisting haemoptysis, clinical features of SVC obstruction which are most common with malignancies and non responsiveness to conservative treatment patient was subjected to thoracotomy and open biopsy to rule out associated malignancy. As pulmonary malignancies are common in our place, and surgery is now safe, thoracotomy should not be withheld if there is clinical suspicion of malignancy.[8]

Contrary to CT findings and gross findings on FOB and thoracotomy suggesting malignant mass-like lesion in our case, the biopsy report turned out to be chronic tuberculous granulomatous pathology. In developing countries like India, keeping endemicity of the disease, as many patterns of pulmonary tuberculosis mimic malignancy,[9,10] the disease should be kept in the differential diagnosis of controversial lesions. Clinical, radiological, and pathological correlation is necessary to initiate appropriate therapy.

CONCLUSION

As pulmonary tuberculosis is known for its ability to masquerade other infectious and disease processes, when combined efforts of clinical, laboratory, imaging findings do not help to exclude malignancy, biopsy can lead to a timely diagnosis. This helps to initiate appropriate therapy.

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Case Report

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Aspergillosis Causing Delayed Implant Loosening in a Case of Total Hip Arthroplasty: A Case Report with Review of Literature

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Abstract

Aspergillus is an ubiquitous opportunistic saprophytic fungus which exists as spores and hyphae. In an immunocompromised host, the inhaled spores primarily affect the respiratory system resulting in superficial or invasive disease forms. Other less commonly affected sites include skin, brain and eye. Fungal prosthetic joint infection (PJI) after total hip arthroplasty is a very rare, but serious complication warranting prolonged medical and surgical care. We describe a case of PJI by aspergillus in a diabetic patient who presented with limb length shortening and pain in the affected joint, diagnosed on histopathology. This is only the second documented case of aspergillus infection after total hip arthroplasty.

Keywords: Aspergillus, Hip pain, Prosthetic joint infection, Total hip arthroplasty

INTRODUCTION

With the ever expanding advancement in medical science related to joint replacement surgeries, the associated comorbidities have been steadily rising. One of the most debilitating complication of arthroplasty is prosthetic joint infection (PJI). The incidence of PJI for primary hip or knee replacements and after revision surgeries varies around 1-2.5% and 2.1-5.8%, respectively.[1,2] The most common pathogens implicated in PJI are coagulase negative *Staphylococci* and *Staphylococcus aureus*, accounting for up to 65% of all the cases.[3] Fungal PJIs are rare, constituting only approximately 1% of all the PJIs, with candida being the most common offender.[1] In the last 22 years, there have been total of four case reports documenting aspergillus as the offending organism in PJI after total knee arthroplasty.[4] However, only a single documented case of hip prosthesis infection has been attributed to aspergillosis.[5] To the best of our knowledge, this is only the second case of aspergillus causing PJI after total hip arthroplasty (THA).

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CASE REPORT

A 45-year-male patient, known case of diabetes and hypertension since 4 years, who had a total hip replacement done 12 years back for avascular necrosis and revision arthroplasty 3 years back, presented to our hospital's outpatient department with pain in the left hip since 4 months and was walking with crutch support. On examination, there was mild shortening of left lower limb with restriction of movements at left hip joint. There was no obvious soft tissue swelling or local rise of temperature. No redness or discharging sinus was seen. Modified teleoroentgenogram revealed limb length discrepancy with shortening of left femoral length by 1.5 cm with Ficat Arlet Stage II Avascular necrosis of right femoral head (Figure 1). Laboratory investigations were within normal limits except for mildly elevated C-reactive protein (3.4 mg/lt) and erythrocyte sedimentation rate (23 mm/h). Repeated arthrocentesis for cultures did not yield any growth even after 48 h.

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Figure 1: Modified teleoroentgenogram revealed limb length discrepancy with shortening of left femoral height

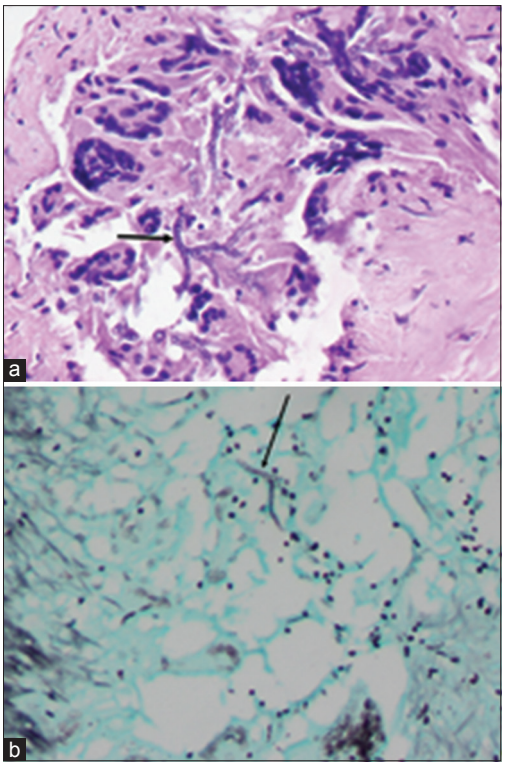

Figure 2: Septate fungal hyphae of Aspergillus (black arrow). (a) H and E (×400) and (b) methenamine silver (×400)

Based on clinicoradiological findings of implant loosening, left hip revision arthroplasty was undertaken and debrided tissue was sent for histology. The patient tolerated the procedure well and was ambulated on day 4 and subsequently discharged under antibiotic cover.

Histopathology of the debrided tissue showed shards of devitalized bone with granulomatous inflammation and enmeshed septate, dichotomous branching hyphae morphologically consistent with aspergillus (Figure 2a and b). As the diagnosis was not suspected during the surgery, no specimen was submitted for fungal culture.

In the light of histopathology report, the patient was counseled for two-stage revision surgery, which he refused because of the involved complexities and also because he was pain-free, instead he opted for prolonged systemic antifungal therapy. On 3 months follow-up, the patient is pain-free and has started walking without crutch support.

DISCUSSION

PJI is a rare but devastating complication of arthroplasty fraught with grave consequences as it is difficult to diagnose and equally difficult to treat. Among the rare cases of PJI caused by *Fungal organisms*, *Candida albicans* accounts for the majority, with other rarely reported entities being *Aspergillus fumigatus*, *Pichia anomala,* and *Rhodotorula minuta*.[1,6]

Aspergillus is a ubiquitous opportunistic saprophytic fungus which develops hyphae only in the pathogenic state. The risk factors usually associated with fungal infections are immunosuppressed states, rheumatoid arthritis, diabetes mellitus, malignancy, tuberculosis, malnutrition, prior native joint infections, and renal impairment.[1,3]

The presentation of fungal PJIs closely resembles that of chronic bacterial infection, having an indolent course with local swelling and pain without any other inflammatory features. Radiographic spectrum for fungal PJIs ranges from being normal to frank bony destruction. Serial radiographs with comparative analysis for features like radiolucency >2 mm at bone-implant interface and component migration helps diagnose implant loosening, with the limb length shortening being the most reliable criteria for prosthesis loosening. Presence of femoral periosteal reaction and associated soft tissue may help favor a diagnosis of infective over aseptic joint loosening.[7] However, no specific radiographic feature has been described to differentiate fungal from bacterial PJIs.

Diagnosis of fungal PJI is essentially made by histopathological examination and culture in concert

with clinical and radiological findings.[8,9] It is postulated that in samples obtained for PJI, any cultured fungal species should be considered pathogenic, and not as contaminant.[1]

Newer diagnostic techniques which can also be employed for diagnosis of fungal PJIs include the sonication of the removed implant and polymerase chain reaction, which are supposed to increase the diagnostic yield.[1,8]

Most effective treatment for fungal PJI is two-staged procedure with delayed reimplantation arthroplasty after adequate systemic antifungal therapy ranging from 6 weeks to 3 months depending on the patients' clinical profile.[1,6]

CONCLUSION

High index of suspicion is warranted for fungal etiology in the setting of PJI, as a delayed diagnosis can be catastrophic for both the patient and the treating surgeon. Clinical examination and radiological investigations play an important albeit ancillary role in the management of fungal PJIs, whereas histopathology and culture remains the gold standard for diagnosis.

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Case Pictorial

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Chronic Myelogenous Leukemia in a Patient of Sickle Cell Anemia: A Rare Case Report

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Hematologic malignancies in patient with sickle cell anemia are rare. Very few cases have been reported worldwide.[1,2] This is the first case report on sickle cell anemia with chronic granulocytic leukemia which comes to our knowledge in the region of Chhattisgarh.

A 30-year-old female reported to the medical ward complaining of a huge lump in the abdomen with 6-month history of low-grade fever, fatigue, night sweats. She had remarkable pain in the abdomen and left hypochondrium for 4 months. She had past history of vaso-occlusive crisis. She received approximately 10 unit of whole blood transfusion during last 2 years and under medication of hydroxyurea form local doctor for the treatment of her disease. Her physical examination revealed huge splenomegaly mild hepatomegaly, bilateral axillary lymphadenopathy, Pallor, and mild jaundice. Complete blood count through five part Hematology Analyzer Pentra-60 (Horiba-ABX, Span) showed Hemoglobin 7.8 g/dl and high leukocyte count 82,000/cu mm, Hematocrit 28.8%, MCV 88/f l, MCH 23.7 pg, MCHC 26.9 g/dl, platelets 373000/μL.

When the patient`s leukocyte count was elevated and was found positive for sickle cell test by Sodium Meta bisulfate oxygen reduction test, then the patient was examined and investigated in detail. Spleen was enlarged up to pelvis and liver was enlarged up to the costal margin in Sonography. Liver enzymes were elevated. High-performance liquid chromatography (HPLC) conducted through D-10 (Biorad, USA) for hemoglobin shows Sickle Hemoglobin 30.4%, Fetal hemoglobin <0.8% Hb A1 C 4.8% and Hb

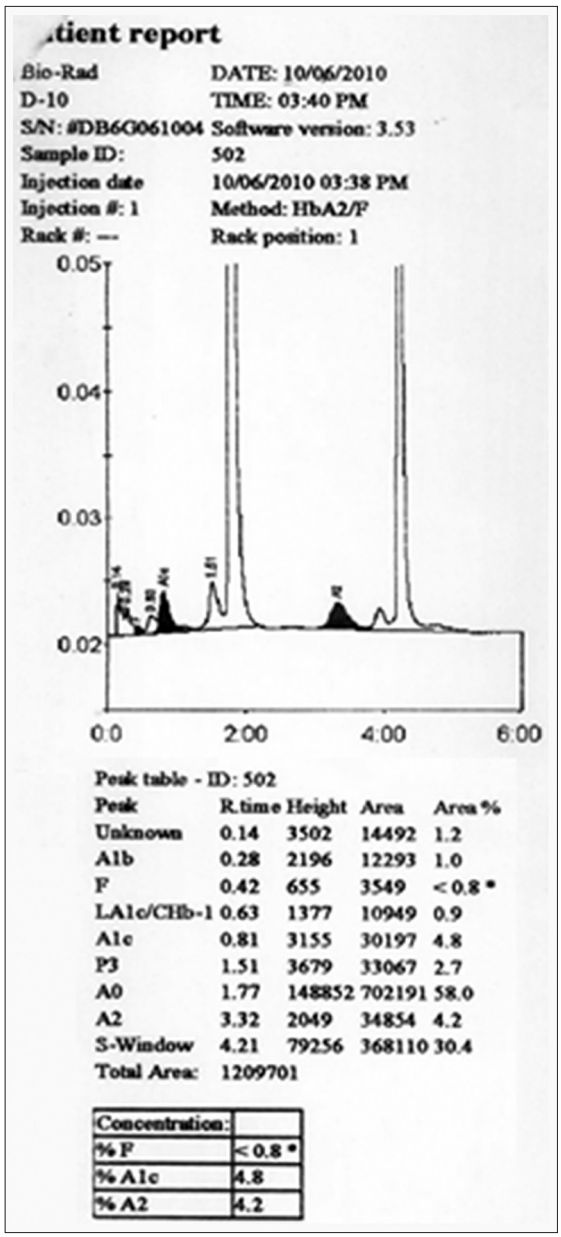

Figure 1: High-performance liquid chromatography graph shows s window

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Lab No.- S10502 DATE:- 05-Oct
Name:- SMT RESHMA
Age/Sex- F/26
Ref. By MODERN PATHO LAB

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY [HPLC]
D-10 Bio-Rad Analyser

Result -

Hb-A 0	58	HbA1c	4.8
Hb-S	30.4	Others	2.2
Hb-A2	4.2	Others	0.9
Hb-F	<0.8	Others	2.7

Conclusion -
Hemoglobin genotype :-Hb A-S PATTERN

History of recent blood transfusion may be taken into account, if applicable.

DR.AJAY SHESH,MD DR.B.P.SINGH,MD D.DIAB

Figure 2: High-performance liquid chromatography report shows Hb A-S pattern

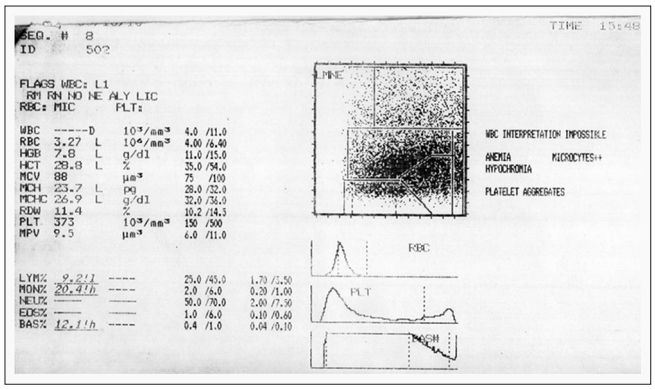

Figure 3: Hemogram picture

A2 4.2%, Peripheral Blood picture showed marked red cell anisopoikilocytosis, drepanocytes, with fare number of normoblasts (7NRBC/100 RBC) (Figures 1-3).

White Blood cell series presented with fair number of metamyelocytes 17% promyelocytes 07% and Band cells 14%, myeloblasts 04%, myelocytes 11%, basophils 12% monocytes 20%, lymphocytes 09%, and mature neutrophils

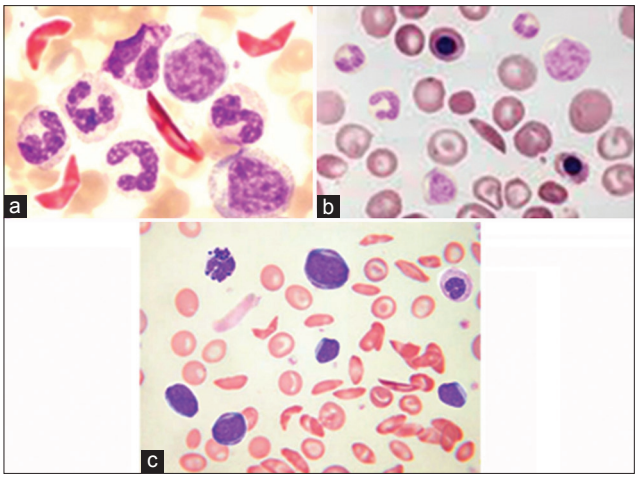

Figure 4: (a-c) Photomicrographs shows red cell anisopoikilocytosis, moderate hypochromasia, drepanocytes, normoblasts, myeloblasts, and basophils

06%. Bone Marrow aspiration and examination revealed depressed erythropoiesis, leukocytes hyperplasia with shift to left predominantly promyelocytes, metamyelocytes, and myeloblasts promotion diagnosis of chronic myeloid leukemia (CML). Cytological evaluation of peripheral blood sample confirmed a Karyotype of 46 XX T (9,22) (q 34;q 11.2); confirming the diagnosis of chronic myelogenous leukemia (Figure 4a-c).

Points to Ponder (2 striking points - this is a compulsory field)

- Diagnosis of CML in a patient of sickle cell anemia is one of the rarest findings in laboratory. Karyotyping performed to confirm the CML and HPLC for SCD apart from Peripheral smears examinations.
- The Association of CML in patients of Sickle cell is one of the rarest combinations. Before this case 10th case was reported by Sallam *et al.* in 2011.

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