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Prognostic Significance of Posturally Induced Crackles as a Predictor of in - Hospital Mortality and Morbidity in Patients with Acute Myocardial Infarction

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Abstract

Background: Myocardial infarction (MI) is a major cause of morbidity and mortality in contemporary populations. Several 2-dimensional echocardiographic biochemical electrophysiological predictors of mortality have been described. However, significance of clinical examination in estimating the prognosis of patients with MI is understudied.

Materials and Methods: This is a prospective cross-sectional study that included adult patients (age >25 years) who had been diagnosed with acute MI and were treated at our hospital between January 2016 and June 2016. All consecutive patients with acute MI admitted during the study period were included in the study.

Results: A total of 302 patients were diagnosed as acute MI (144 - ST-segment elevation MI [STEMI] and 158 - non-STEMI) treated during this period in our hospital. 167 patients are excluded from the study (30 = known case of coronary artery disease 26 = history of lung disease 11 = did not give their consent for study 12 = already on diuretics for various indications 88 = patients with persistent crackles). A total of 135 patients are included in the study (64 are posturally induced crackles [PIC] positive = study group, and 71 are PIC negative = control group).

Conclusion: In conclusion, the presence of PIC is a simple bedside examination finding which helps us determining the prognosis of patients admitted with acute MI. It is independent predictor of in hospital death and significantly associated with longer hospital stay. Thus, Killip class 1 group of patients is heterogeneous group prognostically.

Key words: Morbidity, Mortality, Myocardial infarction, Posturally induced crackles, Predictor

INTRODUCTION

Myocardial infarction (MI) is a major cause of morbidity and mortality in contemporary populations. Several 2-dimensional (2D) echocardiographic^{1,2} biochemical,³⁻⁵ electrophysiological (ECG)⁶⁻⁸ predictors of mortality have been described. However, significance of clinical

examination in estimating the prognosis of patients with MI is understudied.

Crackles are rare in healthy persons during normal tidal breathing^{9,10} Fine crackling sounds, however, may appear in up to 60% of healthy persons, especially over the anterior chest, if the person first exhales as much as possible and breathes in the from residual volume instead of functional residual capacity.¹¹ Bilateral fine crackles are discontinuous adventitious lung sounds and are important in the clinical detection of left-sided heart failure (HF). Killip and Kimball have classified the severity of acute MI according to the extent of fine crackles.¹²

Baseline demographic characteristics of population are shown in Table 1. The mean age in the study group is 55.2 ± 12.3 years and in control group is 56.6 ± 13.1 years.

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Table 1: Definition of PIC*

	Sitting	Supine	Leg Elv
PIC negative	-ve	-ve	-ve
PIC positive	-ve-ve	+ve-ve	+ve+ve
Persistent crackles	+ve	+ve	+ve

*+ve: Crackles heard and -ve: Crackles not heard. PIC: Posturally induced crackles

The study group has 62.5% males (40) as compared to control group 59.2 (42). There were no significant differences ($P > 0.05$) between the two groups in age, sex distribution, and in comorbid conditions.

The term posturally induced crackles (PIC) describes crackles that appear when the patient is in the supine position disappear when the patient is in the sitting position. They are produced mainly due to airway closure at the base of the lungs secondary to increased pulmonary capillary wedge (PCW) pressure which in turn correlates with left ventricular filling pressures.¹³

Therefore, this study aimed to evaluate the in hospital prognostic significance (i.e. length of hospital stay, for death and in hospital adverse clinical events) of postural crackles in patients with acute MI.

MATERIALS AND METHODS

Study Population

This is a prospective cross-sectional study that included adult patients (age >25 years) who had been diagnosed with acute MI and were treated at our hospital between January 2016 and June 2016. All consecutive patients with acute MI admitted during the study period were included. Inclusion criteria were (a) history of chest pain at rest or other symptoms suggestive of an ACS with the most recent episode occurring within 24 h of admission and (b) compatible ECG changes and positive cardiac biomarkers.

The patients were excluded if they have (a) history of lung disease, (b) valvular heart disease, (c) already on diuretics for various indications, and (d) known the case of coronary heart disease.

Baseline variables

Anthropometric measures such as blood pressure, weight, height, and body mass index were measured. Fasting blood was tested for blood glucose, serum lipid levels. Chest X-ray, 2D echocardiography, and ECG parameters were recorded.

Examination technique for PIC

To elicit the finding, the clinician listens to the lower chest wall near the posterior axillary line with the patient in three sequential positions: Sitting, supine, and supine with legs

elevated 30 degrees.^{14,15} At first the patient is seated on a bed for 3 min. Then, the lungs are auscultated by stethoscope at the 8th, 9th, and 10th intercostal spaces along the posterior axillary line and the presence or absence of fine crackles is noted during at least five consecutive breaths during which special attention is paid to the end-inspiratory phase of deep respiration without forced expiration. Then, the patient assumes the supine position. 3 min after the patient has maintained the supine position, the patient's lungs are again auscultated. Then, the patient has both legs elevated passively to an angle of about 30 after 3 min in this position, the patient's lungs are auscultated again. If crackles are absent when the patient is upright but appear when the patient either is supine or has the legs elevated, the test is positive (i.e., the patient has PIC).

Definition of In-hospital Adverse Clinical Events

The adverse clinical events were defined as any one of the followings: (a) Development of any malignant ventricular arrhythmias (ventricular tachycardia or ventricular fibrillation) (b) development of hemodynamic instability needing catecholamine or inotropic support and/or ventilatory support (noninvasive or invasive positive pressure ventilation).

Ethical Approval

Ethical approval was obtained by the Ethics Review Committee of MGM Hospital, Warangal. An informed consent was obtained from all study participants and those who did not give consent were excluded in the study.

Study Design

All the patients presenting to cardiology department with a diagnosis of acute MI (ST-segment elevation MI [STEMI] or non- STEMI [NSTEMI]) are considered for study and patients are examined at admission. Patients having persistent crackles are excluded from the study, patients with PIC negative are selected as control population and patients with PIC positive are selected as case population.

All auscultatory findings were performed by two independent internal medicine residents who were blinded to patient information. To estimate intra- and inter-observer variability, 30 randomized patients were re-examined by second, independent investigator who was blinded to the results obtained by the first investigators, the inter- and intra-observer coefficients of variation were 2.1% and 1.3%, respectively. Patients baseline demographic characteristics, chest X-ray, 2D echocardiography parameters, and daily ECGs are recorded and analyzed for statistical analysis.

Statistical Analysis

Statistical analyses were performed using SPSS 17.0 (IBM, Armonk, NY). Categorical and numerical variables were expressed in percentage and mean (\pm standard deviation), respectively. Numerical variables were tested with

independent samples *t*-test, and categorical variables were tested using Fisher's exact test or Chi-square test, whichever was suitable. Multivariate logistic regression analysis was performed to determine the predictors of in-hospital outcomes. This analysis included variables with statistical significance in the univariate logistic regression analysis and those with a known clinical impact. The statistical significance was considered for a $P < 0.05$.

RESULTS

A total of 302 patients were diagnosed as acute MI (144 - STEMI and 158 - NSTEMI) treated during this

period in our hospital. 167 patients are excluded from the study (30 = known case of coronary artery disease 26 = history of lung disease 11 = didn't give their consent for study 12 = already on diuretics for various indications 88 = patients with persistent crackles). A total of 135 patients are included in the study (64 are PIC positive = study group and 71 are PIC negative = control group). Baseline demographic characteristics of population are shown in Table 2. The mean age in the study group is 55.2 ± 12.3 years and in control group is 56.6 ± 13.1 years. The study group has 62.5% males (40) as compared to control group 59.2 (42). There were no significant differences ($P > 0.05$) between the two groups in age, sex distribution and in comorbid conditions.

Table 2: Baseline demographic characteristics of control (PIC-ve) and case population (PIC+ve)

Variable	Case/PIC+ve population n=64 (%)	Control/PIC-ve population n=71 (%)	P (NS)
Age			
40 years	21 (32.8)	21 (29.6)	0.7130
40 years	43 (67.2)	50 (70.4)	0.7130
Mean (in years)	55.2±12.3	56.6±13.1	0.5245
Sex			
Male	40 (62.5)	42 (59.2)	0.7266
Female	24 (37.5)	29 (40.8)	0.7266
Comorbid conditions			
Hypertension	21 (32.8)	22 (31)	0.8548
Diabetes mellitus	33 (51.2)	30 (42.2)	0.3038
Alcohol	21 (32.8)	28 (39.4)	0.4758
Smoking	18 (28.1)	15 (21.1)	0.4234
Obesity	5 (7.8)	6 (8.4)	1

NS=Not significant statistically. PIC: Posturally induced crackles

Clinical, electrocardiographic and biochemical parameters in two groups are depicted in Table 3. The proportion of the type of acute MI does not vary significantly ($P > 0.05$) between the two groups, as is the management (conservative vs. thrombolysis [$P > 0.05$]). Biochemical parameters, such as random blood glucose and total leukocyte count, are also significantly higher ($P < 0.001$) in study (PIC +ve) group compared to control (PIC -ve) group.

Even the ejection fraction of patients in the study (PIC +ve) group is significantly lower than control (PIC -ve) group. Other serum biochemical findings, such as serum lipid levels and serum creatine kinase MB levels, did not differ significantly in both groups ($P > 0.05$). However, diastolic blood pressure and heart rate at admission differ significantly in both groups ($P < 0.05$).

Table 3: Clinical, electrocardiographic, echocardiographic and biochemical characteristics of both groups

Variable	Case/PIC+ve population (n=64)	Control/PIC-ve population (n=71)	P
Hemodynamic variables*			
SBP (mmHg)	122.5±14.7	126.8±16.8	0.11
DBP (mmHg)	78.5±7.4	81.4±8.9	0.04
HR (bpm)	87.1±8.2	81.6±9.1	<0.001
Acute MI group			
NSTEMI (%)	35 (54.7)	32 (45)	0.3030 (NS)
Thrombolysed STEMI (%)	18 (28.1)	26 (36.7)	0.3587 (NS)
Not thrombolysed STEMI (%)	11 (17.2)	13 (18.3)	1 (NS)
Lab findings*			
TLC	10439±1210.2	8243.6±1450.5	<0.001
Random glucose	179.8±14.1	163.3±19.6	<0.001
Hemoglobin	10.6±1.8	11.2±2.1	0.0786 (NS)
CK-MB	76±4.5	75±5.6	0.2445
ECG variables			
NSTEMI (%)	35 (54.7)	32 (45)	0.3030 (NS)
AW-STEMI (%)	17 (26.5)	23 (32.4)	0.5716 (NS)
IW-STEMI (%)	6 (9)	9 (12.6)	0.5937 (NS)
PW-STEMI (%)	2 (3)	2 (2.8)	1 (NS)
Global STEMI (%)	4 (6)	5 (7)	1 (NS)
2D echo variables			
LVEF	50.2±7.4	55.9±6.3	<0.001
E/A ratio	1.02±0.35	0.99±0.40	0.6452 (NS)

E/A ratio: Ratio of mitral E and A wave diastolic velocities at discharge. *Findings at admission. AW: Anterior wall, IW: Inferior wall, PW: Posterior wall, Global: More than one territory, NS: Not significant, ECG: Electrophysiological, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, HR: Heart rate, LVEF: Left ventricular ejection fraction

As seen in Table 4, significantly higher proportion ($P < 0.05$) of PIC +ve patients suffer with in hospital adverse events compared to PIC -ve patients.

Duration of hospital stay is significantly higher ($P < 0.001$) in PIC +ve patients than compared to PIC -ve patients, even in hospital mortality is significantly higher ($P < 0.05$) in PIC +ve group compared to control group as shown in Figures 1 and 2.

In binary univariate logistic regression analysis diastolic blood pressure, heart rate, white blood cell (WBC), random plasma glucose, left ventricular ejection fraction (LVEF), presence of PIC, increased the risk angiotensin converting enzyme (ACE). However, only LVEF and presence of PIC increased the risk of in hospital ACE as shown in Tables 5 and 6. On multivariate logistic regression analysis WBC, random plasma glucose, presence of PIC, reduced LVEF are independent predictors of in hospital mortality.

DISCUSSION

This study showed that presence of PIC is an independent predictor of in hospital adverse clinical effects and death.

Table 4: Comparison of in-hospital adverse events (ACE) in study and control groups

ACE	PIC+ve n=64 (%)	PIC-ve n=71 (%)	P
Malignant ventricular arrhythmias	7 (10.9)	4 (5.6)	0.3490 (NS)
Ionotropic support	9 (14)	2 (2.8)	0.0250
Ventilator support	4 (6.2)	2 (2.8)	0.4222 (NS)
Total number of patients	15 (23.4)	4 (5.6)	0.0053

1 patient may experience >1 ACE. PIC: Posturally induced crackles, ACE: Angiotensin converting enzyme, NS: Not significant

Table 5: Multivariate regression analyses for the predictors of ACE in the entire population

Variable	OR (95% CI)	P
LVEF	0.87 (0.65-1.04)	0.02
Presence of PIC (n)	1.94 (1.7-2.18)	0.001

PIC: Posturally induced crackles, ACE: Angiotensin converting enzyme, LVEF: Left ventricular ejection fraction, OR: Odds ratio, CI: Confidence interval

Table 6: Multivariate regression analyses for the predictors of mortality in the entire population

Variable	OR (95% CI)	P
TLC	2.8 (2.6-2.9)	0.001
RPG	1.34 (1.2-1.45)	0.012
Presence of PIC	2.1 (1.9-2.2)	0.014
LVEF	0.87 (0.66-1.04)	0.02

RPG: Random plasma glucose, PIC: Posturally induced crackles, OR: Odds ratio, CI: Confidence interval, TLC: Total leukocyte count, LVEF: Left ventricular ejection fraction

The length of hospital stay is also significantly higher in this group of patients. In addition to PIC, WBC and random plasma glucose levels are also found to be independent predictors of morbidity in patients with acute MI in accordance to previous studies.¹⁶⁻¹⁸ An extensive study done by Yasuda *et al.*¹⁹ found that PIC crackles are predictor of latent congestive HF and associated with increased mortality in patient with HF. In another study by Deguchi *et al.* found that PIC was the third most important prognosticator after recovery from MI and the number of diseased coronary vessels and the PCW pressure ranked first and second, respectively. Hemodynamically Iida *et al.*²⁰ found that PCW pressure is significantly higher in the PIC-positive group than in the PIC negative group thus causing alveolar collapse and reducing lung compliance. Hence, the patients presenting with acute MI can be prognostically separated by

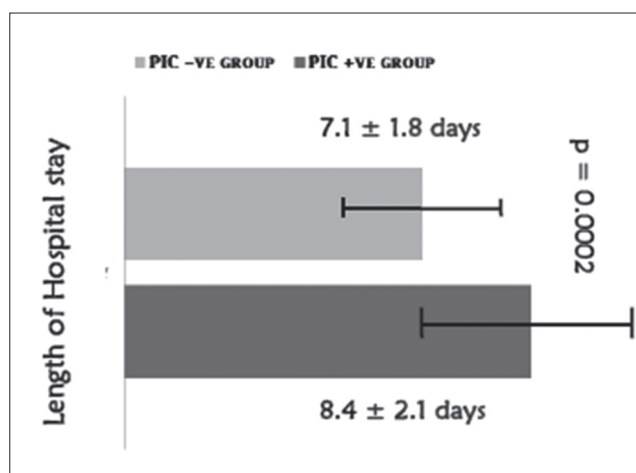


Figure 1: Showing difference in length of stay in study group (posturally induced crackles [PIC] +ve) and control group (PIC -ve) group is statistically significant ($P < 0.001$), higher in PIC +ve group

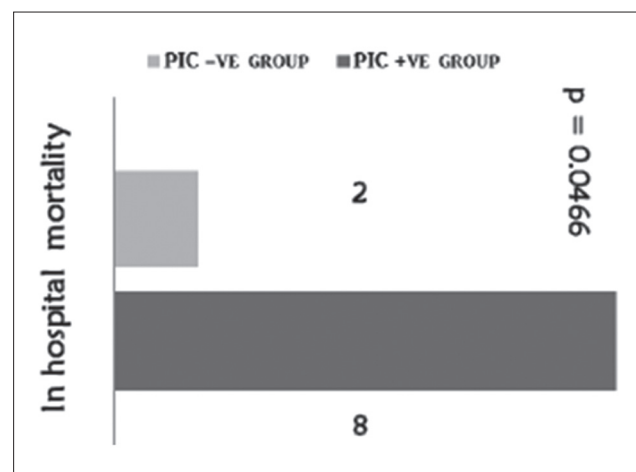


Figure 2: Showing difference in "in-hospital mortality" in study group (posturally induced crackles [PIC] +ve) and control group (PIC -ve) group is statistically significant ($P < 0.05$), higher in PIC +ve group

examining for the presence of PIC, thus helps in delivering improved medical care and reducing in hospital mortality. This study in fact proves that Killip class 1 population is a heterogeneous group prognostically.

Limitation

The primary limitations of this study are that it was a single-centred study and that it examined a limited number of patients in a specific period (no long-term follow-up of patients is done).

CONCLUSION

In conclusion, the presence of PIC is a simple bedside examination finding which helps in determining the prognosis of patients admitted with acute MI. It is an independent predictor of in-hospital death and is significantly associated with longer hospital stay. Thus Killip class 1 group of patients are a heterogeneous group prognostically.

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Sociodemographic and Clinical Profile of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome Patients Visiting a Tertiary Care Hospital in Kerala - A Cross-sectional Study

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Abstract

Introduction: Human immunodeficiency virus (HIV) infection prevalence in India varies geographically. Understanding the epidemic at the specific regional level (i.e., at the inter-state and intra-state levels) will provide useful insights on suspecting atypical presentation of the disease at the earliest and accelerate the progress toward the elimination of new infections and acquired immune deficiency syndrome-related deaths.

Materials and Methods: This cross-sectional study included subjects who had come to the tertiary health care hospital from February 2015 to July 2016. It is a record based cross-sectional study.

Results: Out of the 3506 patients screened over 1 year, 30 patients were found to be HIV positive. Males outnumbered females with 19 (63%) and 11 (37%), respectively. Mean CD4 count for all HIV-infected individuals was 206.84 cells/ μ l and for asymptomatic HIV-infected individuals was 278.57 cells/ μ l. There were 22 (73.4%) symptomatic and 26.6% asymptomatic participants. The most common clinical presentation was a loss of weight (23.3%), cough (13.3%), and weakness/fatigue (13.3%). 26.67% of patients were asymptomatic at the time of screening. The most common route of transmission was through heterosexual contacts 22 (73.3%) and 6 (20%) got the infection which was unknown. Maximum incidence of infection seen in age group more than 49 years, 12 (40%) and the next common age group was 30-39 years 10 (33.3%). 60% of patients were from rural background and 40% from urban area. Laborer occupation found to have maximum incidence 6 (31.5%) in males and housewives were found to be maximum among females 6 (54.5%). 70% of the population belong to below poverty line. Mean CD4 count for all HIV-infected individuals was 206.84 cells/ μ l and for asymptomatic HIV-infected individuals were 278.57 cells/ μ l. There were 22 (73.4%) symptomatic and 26.6% asymptomatic participants.

Conclusion: Our study found a regional lesser prevalence (<0.2%) of infection and a change in the clinical presentation of HIV patients. Moreover, this study gives the distribution of disease in different social patterns and provides information regarding necessary changes to be taken in the screening tools in a regional set up and promote awareness.

Key words: Acquired immune deficiency syndrome, Clinical profile, Human immunodeficiency virus, Socio-demographic

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INTRODUCTION

The human immunodeficiency virus (HIV) infection is a global pandemic. India has the third largest HIV epidemic in the world. National adult (15-49 years) HIV prevalence is estimated to be 0.26% (0.22-0.32%) in 2015. In 2015, adult HIV prevalence is estimated to be 0.30% among

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males and 0.22% among females.¹ India has the third-highest number of people living with HIV in the world with 2.1 million Indians accounting for about 4 out of 10 people infected with the deadly virus in the Asia-Pacific region, according to a United Nation (UN) report. The report by UN programme on HIV/acquired immune deficiency syndrome (AIDS) (UNAIDS), the UNAIDS, said that 19 million of the 35 million people living with the virus globally do not know their HIV-positive status and so ending the AIDS epidemic by 2030 will require smart scale-up to close the gap. The first-ever UNAIDS “Gap Report” said after sub-Saharan Africa, the region with the largest number of people living with HIV is Asia and the Pacific. Six countries - China, India, Indonesia, Myanmar, Thailand, and Vietnam - account for more than 90% of the people living with HIV in the region. The proportions of people who do not have access to antiretroviral therapy treatment are 64% in India.²

HIV prevalence in India also varies geographically. Understanding the epidemic at the specific regional level (i.e., at the inter-state and intra-state levels) will provide useful insights on suspecting atypical presentation of the disease at the earliest and accelerate the progress toward the elimination of new infections and AIDS-related deaths. Among the states/UTs, in 2015, Manipur has shown the highest estimated adult HIV prevalence of 1.15%, followed by Mizoram (0.80%), Nagaland (0.78%), Andhra Pradesh and Telangana (0.66%), Karnataka (0.45%), Gujarat (0.42%), and Goa (0.40%). Besides these States, Maharashtra, Chandigarh, Tripura, and Tamil Nadu have shown estimated adult HIV prevalence greater than the national prevalence (0.26%), while Odisha, Bihar, Sikkim, Delhi, Rajasthan, and West Bengal have shown an estimated adult HIV prevalence in the range of 0.21-0.25%. All other States including Kerala/UTs have levels of adult HIV prevalence below 0.20%. The adult HIV prevalence at national level has continued its steady decline from an estimated peak of 0.38% in 2001-2003 to 0.34% in 2007 and 0.28% in 2012 to 0.26% in 2015. India is estimated to have around 86,000 (56-129) new HIV infections in 2015, showing 66% decline in new infections from 2000 and 32% decline from 2007, the year set as a baseline in the National AIDS Control Programme-IV children.¹

In India, HIV testing is done as a voluntary test or as a diagnostic procedure in symptomatic individuals. In antenatal clinics, HIV screening test is done as a mode of prevention of parent to child transmission. It is also done in all tuberculosis (TB) patients due to the strong association between HIV and TB.¹ Various strategies have been developed by the WHO and National AIDS Control Organisation (NACO) to promote awareness of HIV and AIDS which aims in early diagnosis of HIV infection

which facilitates better care, ameliorates clinical outcomes and improves strategies by health-care delivery systems.³ Studies show that a person diagnosed and counselled for HIV infection avoids high-risk behavior which is beneficial to the society by limiting the transmission of the virus.⁴ Triangulation and analysis of data from different sources and different regions, especially at state and district level, will allow drawing useful lessons on what works in programmes and what instead needs improvement.¹

This study was conducted in an urban tertiary health care hospital in South India with the objective to assess the sociodemographic and clinical profile of HIV/AIDS patients. This study brings out the sociodemographic and clinical profile of patients attending a tertiary health care hospital in South India.

MATERIALS AND METHODS

This record based cross-sectional study was a tertiary care teaching hospital in Kochi, Kerala, South India, from February 2015 to July 2016. The permission from concerned authorities was obtained. Medical records of patients who attended the tertiary care center and who were referred to Integrated Counseling and Testing Center (ICTC) to check HIV status were included in the study. Children were excluded from the study. Over the retrospective study period of 1-year and 5-month, it was found that total of 3506 patients were screened at ICTC, out of which 32 were found to be seropositive. Of the total 32 patients, 6-year-old child and a 30-year-old pregnant woman was also excluded, since she has been previously diagnosed at other ICTC and was on antiretroviral drugs. The NACO guidelines for the diagnosis of HIV were followed. First HIV test was carried out with HIV - Coombs test (COMBAIDS-RS). As per the NACO guidelines, if the sample is reactive in the first test, it is confirmed by second (HIV-Trio-LF) and third AIDSCAN (SD-Bioline) test.

For these patients, a pro forma was made about sociodemographic characteristics such as age, sex, literacy status, marital status, occupation, socioeconomic status, and clinical presentation ensuring confidentiality. Data required were extracted from the records maintained by the counselors and clinicians who attended the patients and entered into this pro forma. Standard protocols were followed to ensure confidentiality of the information collected.

The data were entered in Excel sheets, and statistical analysis was performed using Statistical Package for Social Sciences (SPSS, Inc. Chicago, IL) 22.0 version.

In this analysis, ELISA for HIV test result (positive/negative) was considered as a dependent variable. The signs, symptoms and risk factors reported were considered as possible covariates. The data were analyzed using mean, standard deviation, and Chi-square test. Association between CD4 count and clinical symptom was analyzed using Chi-square test; $P < 0.05$ was considered to be significant.

RESULT

A total of 3506 individuals were tested for HIV in 2015-2016 at the ICTC clinic in the tertiary care hospital, situated in Kochi region of Kerala, state of India, from Feb 2015 to July 2016. Children (<18 year) as well as individuals with indeterminate ELISA test result were excluded from the study and data were analyzed for the remaining 30 individuals tested (Table 1).

Males outnumbered females with 19 (63%) and 11 (37%) respectively (Figure 1). Maximum incidence of infection seen in age group more than 49 years, 12 (40%) and the next common age group was 30-39 years 10 (33.3%). 60% of patients were from rural background and 40% from urban area. Table 1 includes the description socio-demographic factors of seropositive patients including age, sex, education, occupation, marital and socioeconomic status. Labour were found to have maximum incidence 6 (31.5%) in males, which included migrant labourers as well. Housewives were found to be maximum among females 6 (54.5%). 60% of the population belong to below poverty line and more than half of the patients had education status was only up to primary school level (Figure 2). Maximum incidence of infection seen in married people (76.7%) than unmarried or divorced.

The most common route of transmission was through heterosexual contacts 22 (73.3%) and 6 (20%) got the infection which was unknown. There was no incidence of blood transfusion associated seropositivity. 21% males and 18.8% females were not aware of the route of the infection (Tables 2 and 3, Figures 3 and 4). Number of patients acquiring disease due to blood transfusion was nil. 20 % patients did not know about their routes of transmission (Figure 4). Children were not included in the study. In the present study injectable drug abuser was only one patient.

The most common clinical presentation was loss of weight (23.3%), cough (13.3%), weakness/fatigue (13.3%). 26.67% of patients were asymptomatic at the time of screening (Table 4). They were screened routinely for surgery as well as for their clinical symptom they presented with and was found to be seropositive.

Table 1: Sociodemographic profile of HIV positive patients

Sociodemographic factors	Male	Female	Total
	n=19 (%)	n=11 (%)	n=30 (%)
Age group (years)			
20-29	3 (15.78)	0 (0)	3 (10)
30-39	6 (31.57)	4 (36.36)	10 (33.33)
40-49	3 (15.78)	2 (18.18)	5 (16.67)
>49	7 (36.84)	5 (45.46)	12 (40)
Setting			
Rural	12 (63.15)	6 (54.55)	18 (60)
Urban	7 (36.84)	5 (45.45)	12 (40)
Education			
Illiterate	-	-	-
Primary school	10 (52.63)	6 (54.55)	16 (53.33)
Secondary school	6 (31.57)	5 (45.45)	11 (36.67)
College and above	3 (15.79)	-	3 (10)
Occupation			
Laborer	6 (31.57)	2 (18.18)	8 (26.67)
Farmer	1 (5.26)	0 (0)	1 (3.33)
Business	3 (15.78)	1 (9.9)	4 (13.33)
Driver	3 (15.78)	0 (0)	3 (10)
Services	1 (5.26)	2 (18.18)	3 (10)
Housewives	0 (0)	6 (54.54)	6 (20)
Unemployed	1 (5.26)	0 (0)	1 (3.33)
Professional	4 (21.05)	0 (0)	4 (13.33)
Marital status			
Married	15 (78.95)	8 (72.73)	23 (76.67)
Widower/widow	1 (5.26)	3 (27.27)	4 (13.33)
Divorced	-	-	-
Separated	-	-	-
Unmarried	3 (15.78)	-	-
Socioeconomic status			
APL	6 (31.58)	3 (27.27)	9 (30)
BPL	13 (68.42)	8 (72.73)	21 (70)

APL: Above poverty line, BPL: Below poverty line, HIV: Human immunodeficiency virus

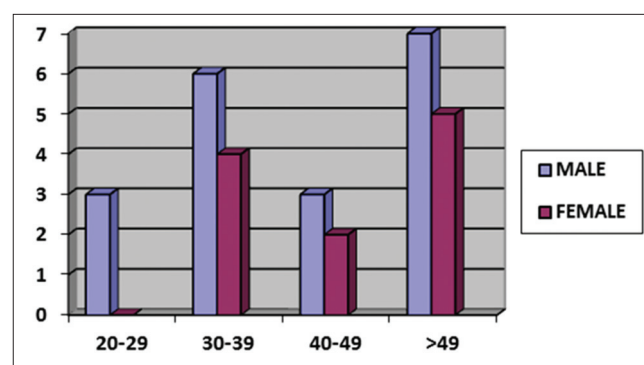


Figure 1: Age profile of patients in the human immunodeficiency virus study group

The CD4 cell count was available for HIV infected individuals. Mean CD4 count for all HIV infected individuals was 206.84cells/ μ l and for HIV infected asymptomatic individuals ($n = 7$) was 278.57cells/ μ l (Table 5). The CD4 count was categorized as <50, 51-200, 201-350 and >350 cells/ μ l and associated with their clinical presentation status (Figure 5). It was observed that a high proportion of individuals who had CD4

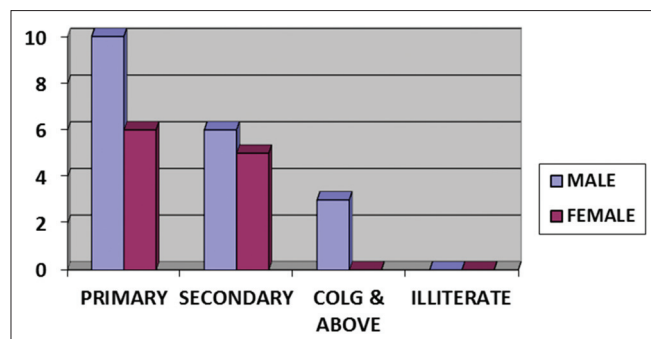


Figure 2: The educational status of patients in the human immunodeficiency virus study group

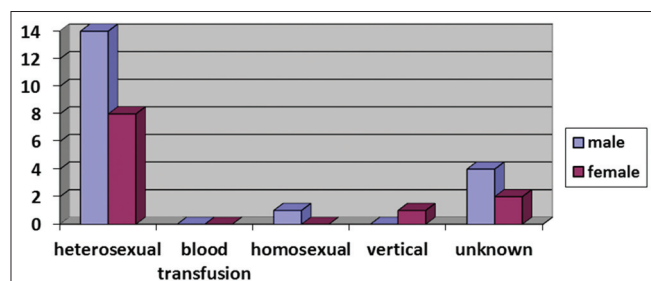


Figure 3: The exposure profile of patients in the study group

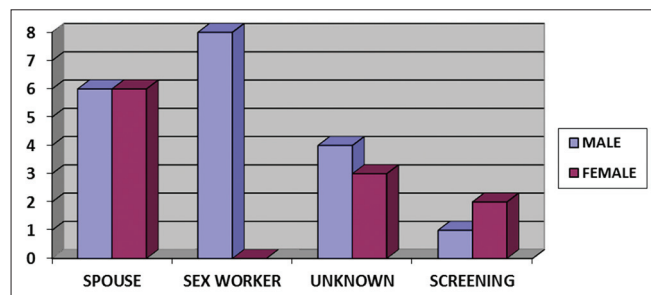


Figure 4: The type of exposure among the patients in the study group

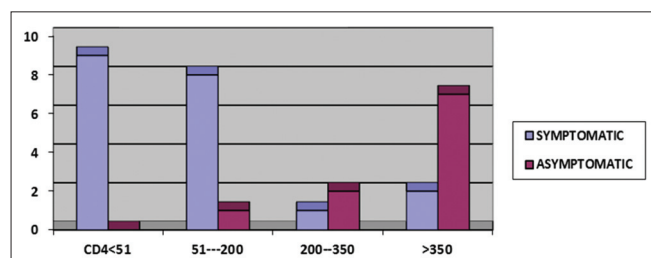


Figure 5: The CD4 count of the patients in the study group at the time of screening

count >350 cells/ μ l were asymptomatic or with subtle clinical complaints. Association between CD4 count and clinical symptom was analyzed using chi-square test; $P < 0.05$ was considered to be significant (Tables 6 and 7). The proportion, severity of symptoms associated with disease and CD4 counts were inversely proportional. As compared to individuals with higher CD4 counts, those

Table 2: Routes of transmission

Routes of transmission	Male	Female	Total
Heterosexual	14 (73.68)	8 (72.73)	22 (73.33)
Blood transfusion	0 (0)	0 (0)	0 (0)
Homosexual	1 (5.26)	0 (0)	1 (3.33)
Vertical	0 (0)	1 (9.09)	1 (3.33)
Unknown	4 (21.06)	2 (18.18)	6 (20)
Total	19	11	30

Table 3: HIV exposure profile

Sex	Spouse-n (%)	Sex worker n (%)	Unknown n (%)	Screening n (%)
Male	6 (31.57)	8 (26.67)	4 (21.05)	1
Female	6 (31.57)	0	3 (27.27)	2
Total	12 (63.15)	8 (26.67)	7 (23.33)	3 (10)

HIV: Human immunodeficiency virus

Table 4: Presenting complaints among patients

Complaints	Male n=19 (%)	Female n=11 (%)	Total n=30 (%)
Fever	1 (5.26)	1 (9.09)	2 (6.67)
Loss of weight	4 (21.05)	3 (27.27)	7 (23.33)
Cough	3 (15.78)	1 (9.09)	4 (13.33)
Diarrhea	1 (5.26)	0 (0)	1 (3.33)
Weakness	2 (10.52)	2 (18.18)	4 (13.33)
Itching	2 (10.52)	0 (0)	2 (6.67)
Pain abdomen	3 (15.78)	0 (0)	3 (10)
No complaints	3 (15.78)	5 (45.45)	8 (26.67)

Table 5: CD4 category wise distribution of HIV infected individuals tested in the study group

CD4 category	Symptomatic (n=21)	Asymptomatic (n=7)
<50	9 (42.85)	-
51-200	8 (38.09)	1 (14.28)
201-350	3 (14.29)	2 (28.57)
>350	2 (9.52)	4 (57.14)

HIV: Human immunodeficiency virus

with CD4 count within the range of <50 cells/ μ l had more symptoms; almost 42.8% of all symptomatic patients ($n = 21$) had CD4 count <0 cells/ μ l (Tables 8 and 9).

DISCUSSION

This study demonstrates the importance of sociodemographic and clinical features and initial CD4 count of HIV/AIDS patients who were attending a tertiary care hospital. The overall male patients outnumbered the female patients and male to female ratio was 1.73:1. Male predominance was also observed in study done by Zaheer *et al.*⁵ and Singh *et al.*⁶ The majority (81.40%) of patients were within the age group of 20-39 years which is sexually active and productive

Table 6: Statistical analysis-sex versus occupation

Sex×Occupation cross-tabulation							
Sex×Occupation	Occupation						Total
	Labourer	Businessman	Driver	Services	Housewives	Unemployed	
Sex							
Male							
Count	7	3	4	1	0	1	19
Expected count	5.7	2.5	3.2	0.6	3.8	0.6	19.0
Female							
Count	2	1	1	0	6	0	11
Expected count	3.3	1.5	1.8	0.4	2.2	0.4	11.0
Total							
Count	9	4	5	1	6	1	30
Expected count	9.0	4.0	5.0	1.0	6.0	1.0	30.0

Table 7: Statistical analysis-sex versus occupation

Chi-square tests			
Sex×Occupation	Value	df	Asymptomatic significant (2-sided)
Pearson Chi-square	13.397 ^a	6	0.037
Likelihood ratio	15.893	6	0.014
Linear-by-linear association	1.696	1	0.193
Number of valid cases	30		

^a13 cells (92.9%) have expected count<5. The minimum expected count is 0.37

Table 8: Statistical analysis-presentation×CD4 count

Clinical presentation×CD4 count cross-tabulation						
Presentation×CD4 count	CD4 count					Total
	0	<50	51-200	201-350	>350	
Clinical presentation						
Fever						
Count	0	0	0	1	1	2
Expected count	0.1	0.5	0.6	0.5	0.3	2.0
Loss of weight						
Count	0	3	2	1	1	7
Expected count	0.5	1.6	2.1	1.9	0.9	7.0
Cough						
Count	0	2	2	0	0	4
Expected count	0.3	0.9	1.2	1.1	0.5	4.0
Diarrhea						
Count	0	1	0	0	0	1
Expected count	0.1	0.2	0.3	0.3	0.1	1.0
Weakness						
Count	2	0	2	0	0	4
Expected count	0.3	0.9	1.2	1.1	0.5	4.0
Itching						
Count	0	1	1	0	0	2
Expected count	0.1	0.5	0.6	0.5	0.3	2.0
Pain abdomen						
Count	0	0	2	1	0	3
Expected count	0.2	0.7	0.9	0.8	0.4	3.0
No complaints						
Count	0	0	0	5	2	7
Expected count	0.5	1.6	2.1	1.9	0.9	7.0
Total						
Count	2	7	9	8	4	30
Expected count	2.0	7.0	9.0	8.0	4.0	30.0

age group. These findings are very much similar to the national level statistics in which NACO has reported that 89% of the cases were in the age group of 15-44 years. This age group of the population is more affected because they are economically productive, sexually more active and the social structure is patriarchal.⁷

Nearly 60% patients were from rural areas. The rural predominance of HIV seropositive patients in a study done at suburban area is believed to be an indication of spread of HIV from the urban to the vast rural areas. Similar findings were reported by Joardar *et al.*³ It may be because of the fact of location of tertiary care hospital in suburban area. With regard to the level of education, 56%, 36% and 10% patients were up to primary, secondary and college and above level of education, respectively. These findings were similar to study conducted by Joshi *et al.*⁴ and the national data from NACO.²

From this study, it shows the level of education and incidence of HIV seropositivity is inversely proportional. Lack of school education and knowledge predisposes individuals to lack of awareness from protecting himself or herself from STDs including HIV/AIDS (Figure 2).

In this study, maximum number of patients (26.67%) were laborers among males (31.57%) and housewives among females (54.54%). The study area is a suburban area. Most of the laborers were involved in carpentry, masonry, and agriculture related activities and/or industries which also have migrant laborers from neighboring states and North Indians as well. As these migrant laborers should have to stay away from family for a longer time, it increases the risk of sexual promiscuity. This shows that the laborers are working as a link population and spreading the disease to general population. In females, the most affected group was housewives (54.54%) who are at mercy of their counterpart and are ignorant of their spouse illness. They do not have the right to ask for contraception and suffer

Table 9: Statistical analysis-presentation×CD4 count

Chi-square tests			
Presentation×CD4 count	Value	df	Asymptomatic significant (2-sided)
Pearson Chi-square	42.068 ^a	28	0.043
Likelihood ratio	43.436	28	0.032
Linear-by-linear association	2.065	1	0.151
Number of valid cases	30		

^a40 cells (100.0%) have expected count<5. The minimum expected count is 0.07. There was a statistical significance between the clinical presentation at onset and the initial CD4 values ($P=0.043$). Patients with lesser CD4 counts were more prone to develop clinical presentations as expected

from deadly disease just because of their partners. The financially well-off patients involved in the occupations like business, services constitute a totally different group they have more money and get involved in high-risk behavior when away from family. Therefore, they act as a bridging population and spread the disease from urban to rural area. The variation in occupations between this study and Joardar *et al.*³ could be due different occupations in different geographical areas. With regard to marital status, the majority of patients were married (76.67%), in both males and females. The high number of married persons having HIV/AIDS was also reported by Jayarama *et al.* (70.3%).⁸

The predominant mode of transmission was through unprotected heterosexual intercourse (73.33%). More or less similar findings were reported by Gupta *et al.* (97%).⁹

As far as the most common presenting complaint is concerned, loss of weight was only second preceded by no specific complaints. This may be due to the fact that screening is done for patients posted for surgery and this being a tertiary care hospital, doctors suspect and screen for the disease even before the clinical presentation of AIDS.

The ICTC aims at increasing awareness about HIV/AIDS through group meetings as well as a couple or one-to-one counseling, resulting in early detection of HIV infection even during asymptomatic phase. The maximum numbers of individuals were between 26 and 49 years. In the Indian setting, this is important since this age group is economically productive and about 80% of newly HIV-infected individuals are believed to have acquired the infection during unprotected sex.¹⁰

The mean CD4 count observed in this study was 206.84.57 cells/ μ l, which was lower when compared to a similar study conducted in Pune in 1996-1997 (mean CD4 count 238 cells/ μ l).^{11,12} The asymptomatic individuals presented with a mean CD4 count of 278.57 cells/ μ l.

This indicates that the trend toward earlier diagnosis of HIV infection is increasing due to effective screening. The most common symptoms reported by the individuals who came for HIV testing were different as compared to data reported in studies conducted at Pune and Varanasi but differed in proportion, since they had more patients with TB and those presenting with opportunistic infections.^{9,11,13}

CONCLUSION

It can be concluded from the results of this study that the proportion of individuals getting detected at an early stage of their infection has increased as compared to previous studies. The signs and symptoms strongly associated with HIV infection can be used for vigilance and early detection of HIV. The majority of the seropositive population in this study was from lower socioeconomic class and between age group, i.e., 20 and 49 years. As this is the major part of reproductive age group, it significantly affects the development of the community. It increases the financial burden of the family and affects the overall progress of the country. Laborer which was the most common occupation found to be affected, as observed in other studies is the major link population between high-risk groups to general population and between urban to rural areas. Since the majority of females affected are housewives, it implies that marital life is a risk factor for those women who get infected by their HIV positive spouse.

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Prevalence of Prehypertension among the Medical Students and its Correlation with Body Mass Index

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Abstract

Introduction: Hypertension is a major risk factor for cardiovascular diseases (CVD), chronic renal diseases, cerebrovascular diseases, and many others. The root cause of hypertension may present since childhood. Obesity itself is a risk factor for CVD such as hypertension, dyslipidemia, and many other diseases. Early diagnosis of prehypertension can help to prevent a development of hypertension and other CVDs by adopting preventive measures such as lifestyle modification, yoga, and meditation.

Aim and Objectives: This study aims to measure the prevalence of prehypertension among the medical students of Jorhat Medical College and Hospital, Jorhat, Assam and also to find any correlation between body mass index (BMI) and prehypertension. So that preventive measures can be adopted by medical students to prevent the development of hypertension and other CVDs related to hypertension.

Materials and Methods: A total of 136 medical students were selected randomly for this study. Blood pressure (BP) was measured using standard mercury sphygmomanometer. Height and weight were measured using standard instruments.

Results: Out of 136 students, 62 were male and 74 were female. Overall, the prevalence of prehypertension was 68.38% which is again more in males (35.29%) than females (33.09%). We have also found a strong correlation between BMI and BP.

Conclusion: The prevalence of prehypertension among the medical students of Jorhat Medical College and Hospital is 68.38%, which is again more in male than female and there is a correlation between BMI and BP.

Key words: Body mass index, Medical students, Prehypertension

INTRODUCTION

Hypertension is a major risk factor for cerebrovascular disease, myocardial infarction, vascular disease, and chronic renal disease. Several studies supported that the roots of essential hypertension may extend back to childhood.¹ Obesity is an independent risk factor for cardiovascular disease (CVD) including hypertension, dyslipidemia, glucose intolerance, and impaired homeostasis.² The Joint National Commission 7 (JNC 7) on prevention, detection, evaluation and treatment of high blood pressure (BP),

released in May 2003, introduces the classification of BP. According to this systolic BP (SBP) <120 and diastolic BP (DBP) <80 is considered as normal and SBP 120-139 or DBP 80-89 is defined as prehypertension. Early identification of prehypertension plays an important role in identification of modifiable factors required for prevention of cardiovascular accidents.

Several research papers, meta-analyses, review articles, etc., have been published on the prevalence of prehypertension in several groups and its association with other cardiovascular risk factors and CVD and treatment benefits.³⁻⁸ Studies from India have given varied prevalence of prehypertension, ranging from 20% to 80%.⁹⁻¹⁵

There are not many studies reported from this part of the country which estimates the prevalence of prehypertension among medical students and hence this study was undertaken.

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Aims and Objectives

To determine the prevalence of prehypertension among the medical college students of Jorhat Medical College and Hospital, Jorhat, Assam, and to study the association between prehypertension and body mass index (BMI).

MATERIALS AND METHODS

This study was conducted in the year of 2016 at the Department of Physiology of Jorhat Medical College, Jorhat, Assam, India.

The participants were interviewed, and information regarding age, sex, personal habits such as smoking, alcohol intake, exercise profile, and dietary habits were collected using questionnaire.

A written informed consent was obtained from all the participants who responded to the questionnaire survey. The study protocol was approved by the Institutional Ethics Committee before the start of the study.

A total of 136 medical students of first to final year MBBS were selected randomly for this study. The students who are already diagnosed as hypertensive and under medication were excluded from this study.

Each participant's data were collected by questionnaire method, (which includes age, sex, family history) followed by anthropometric measurements, recording of BP.

BP was measured with a mercury sphygmomanometer, as per JNC 7 guidelines.¹⁶ Two measurements were obtained, and the average was taken as BP.

Weight and height were measured with standard instruments.¹⁷

Statistical Analysis

SPSS Version 16 was used for all data processing and analysis. A significant association between two variables were determined via sample *t*-tests and correlation tests, $P < 0.05$ was considered significant.

RESULTS

A total of 136 medical students were examined. Out of these, 74 (54.4%) were female and 62 (45.4%) were male. The overall prevalence of prehypertension among the whole group was 68.38% as 93 out of 136 students were prehypertensive while 43 (31.62%) were normotensive. Out of these 93 (68.38%), prehypertensive students 45 (33.09%) were female and 48 (35.29%) were male. This distribution of students according to BP and sex is showing in Table 1.

When the students in both groups (normotensive and prehypertensive) were categorized based on their BMI, an equal number of obese students are prehypertensives as normotensives ($P = NS$), as shown below. About 1.47% (2/43) of normotensives and 1.47% (2/93) of prehypertensives were obese. Most of the subjects were in the normal BMI category (Table 2).

However independent sample test, test of significance shows that there is a significant correlation (significant - 0.049) between BMI and BP. It is shown in Tables 3 and 4.

We have tried to correlate BMI and BP and it is seen that BMI is more strongly correlated index is more strongly correlated with DBP than SBP.

It is shown in Tables 5 and 6.

DISCUSSION

This study included 136 medical students from different socioeconomic background. Out of these, 74 (54.4%) were female and 62 (45.4%) were male. The overall prevalence of prehypertension in the entire group was

Table 1: Distribution of students according to sex and BP

Sex	BP (%)		Total
	Normotensive	Prehypertensive	
Female	29 (21.32)	45 (33.09)	74 (54.4)
Male	14 (10.29)	48 (35.29)	62 (45.4)
Total	43 (31.62)	93 (68.38)	136

BP: Blood pressure

Table 2: The distribution of normotensive and prehypertensive students according to BMI categories

BMI	BP (%)		Total	P value
	Normotensive	Prehypertensive		
Normal	27 (19.85)	71 (52.21)	98 (72.1)	0.07
Obese	2 (1.47)	2 (1.47)	4 (2.94)	
Over weight	9 (6.62)	12 (8.82)	21 (15.4)	
Under weight	5 (3.68)	8 (5.82)	13 (9.36)	
Total	43 (31.62)	93 (68.38)	136	

BP: Blood pressure, BMI: Body mass index

Table 3: Group statistics

BP	n	Mean	SD	SEM
BMI				
Normotensive	43	21.72	3.548	0.541
Prehypertensive	93	21.65	3.074	0.319

BP: Blood pressure, BMI: Body mass index, SD: Standard deviation, SEM: Standard error of mean

Table 4: Independent samples test

BMI	Levene's test for equality of variances		t-test for equality of means						
	F	Significant	t	df	Significant (Two tailed)	Mean difference	Standard error difference	95% confidence interval of the difference	
								Lower	Upper
Equal variances assumed	3.943	0.049	0.127	134	0.899	0.076	0.596	-1.102	1.254
Equal variances not assumed			0.121	72.242	0.904	0.076	0.628	-1.176	1.327

BMI: Body mass index

Table 5: Correlations Between BMI and SBP

SBP	SBP	BMI
SBP		
Pearson Correlation	1	0.042
Significant (two-tailed)		0.629
N	136	136
BMI		
Pearson correlation	0.042	1
Significant (two-tailed)	0.629	
N	136	136

BMI: Body mass index, SBP: Systolic blood pressure

Table 6: Correlations Between BMI and DBP

BMI	BMI	DBP
BMI		
Pearson correlation	1	0.112
Significant (two-tailed)		0.194
n	136	136
DBP		
Pearson correlation	0.112	1
Significant (two-tailed)	0.194	
n	136	136

BMI: Body mass index, DBP: Diastolic blood pressure

68.38%. The prevalence was more in boys than girls 48 (35.29%) and 45 (33.09%), respectively. The prevalence of prehypertension in this study is higher than the 21.7% prevalence reported from a study in a medical college in Puducherry.¹¹ A study of 100 medical students in Davangere showed a prevalence of prehypertension is 64%¹⁸ while two studies of 100 boys + girls and 150 girls in a medical college in Wardha showed a prevalence of prehypertension in 52% and 58%, respectively.^{19,20} The third study from a medical college in Dehradun among 400 students also revealed an overall prevalence of prehypertension of 58.75%.²¹ There was a significant association between excess weight and prehypertension in our study, similar to findings in other studies.^{14,18-20} A study from Israel concluded that BMI was the strongest predictor of prehypertension among males and females.²² A study among medical students in coastal Karnataka has found a significant correlation between prehypertension and BMI in boys¹⁴ while a study in Jamaica found a relation

to overweight/obesity and waist circumference among younger prehypertensives.²³

CONCLUSION

It can be concluded that in our study among healthy medical students prevalence of prehypertension is 93 (68.38%) which is again more in males than females. We have found a correlation between BMI and BP. There is more correlation between BMI and DBP than SBP. A lifestyle enhancement with yogic intervention in medical colleges may be the answer to reduce weight, BP, etc.

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Relationship between Awareness of Tardive Dyskinesia and Awareness of Illness in Schizophrenia

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Abstract

Background and Objective: One interesting addition to the growing literature on the multidimensional nature of insight or awareness deficits are recent studies which point to a relative unawareness of tardive dyskinesia (TD) in schizophrenia in spite of its debilitating consequences. This study was aimed to study the relationship between awareness of TD and awareness of illness in schizophrenic patients.

Methodology: Consecutive patients with schizophrenia on treatment at the Department of Psychiatry, Kilpauk Medical College, Chennai, with TD were chosen and rated for extent and severity of abnormal movements by the abnormal involuntary movement scale (AIMS). Insight was measured by the scale for unawareness of mental disorders. Awareness of abnormal movements was rated on a five-point severity scale (item 10 of AIMS) and a correlation between the scores was done. The influence of negative symptoms on awareness of abnormal movements was also studied.

Results: Awareness of TD was poor and was correlated with severity of dyskinesia, negative symptoms, and certain aspects of insight.

Conclusion: Unawareness of dyskinesia in schizophrenia is common, and hence active examination for early signs of TD is advisable. This unawareness may be associated with negative symptom severity and unawareness of illness symptoms.

Key words: Insight, Scale for unawareness of mental disorders, Schizophrenia, Tardive dyskinesia

INTRODUCTION

Schizophrenia is characterized by a loss of awareness of illness or insight (Carpenter *et al.*, 1976).¹ Studies also point to a relative unawareness of tardive dyskinesia (TD) in schizophrenia in spite of its debilitating consequences. Loss of awareness is related to the presence of cognitive deficits (Myslobodsky, 1985)² and may be a feature of frontal lobe dysfunction in schizophrenia (Sandyk *et al.*, 1993)³ or parietal lobe related agnosia (Arango *et al.*, 1999).⁴

Poor insight and anosognosia for dyskinesia may share a common biological basis (Amador *et al.*, 2004).⁵

TD is a common side effect of long-term neuroleptic treatment (Kane, 1982; Lieberman *et al.*, 1985).^{6,7} Edentulousness increases the risk for neuroleptic-induced orofacial dyskinesias (Sandyk *et al.*, 1993).³ Age and female gender is associated with TD (Turrone, 2000).⁸

Many studies have reported that schizophrenic patients exhibit unawareness of abnormal movements (Alexopoulos, 1979).⁹ Other patients with abnormal movements (e.g. Parkinson's disease) are aware of their movements. Unawareness of TD is persistent despite feedback (Caracci *et al.*, 1990)¹⁰ and is a cross-cultural finding. A lack of awareness of TD is greater for orofacial than limb-kinetic movements. The patients with cognitive deficit and negative symptoms have been found to be associated with lack

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of awareness of TD (Macpherson, 1992; Caracci *et al.*, 1990).^{10,11} This finding is contradicted by some studies (Chiu *et al.*, 1993).¹² Unawareness of TD has not been related to any sociodemographic or clinical variable such as severity or duration of TD though right-handedness has been associated (Amador *et al.*, 1997).¹³

Insight is multidimensional with awareness of illness, acceptance of need for treatment, and awareness of symptoms and consequences as its components. Awareness of dyskinesia is related to certain insight domains such as social consequences of the mental disorder (Arango *et al.*, 1999)⁴ and unawareness of symptoms (Amador *et al.*, 1997).¹³ These findings are contradicted by other studies (Cuesta and Peralta, 1994).¹⁴

Aim

To study the relationship between awareness of involuntary movements and awareness of illness in patients with schizophrenia and to study the relationship between “negative” symptoms and the degree of awareness into dyskinesia.

METHODOLOGY

An observational prospective study conducted in the Department of Psychiatry, Kilpauk Medical College, Chennai. All the patients with a clinical diagnosis of schizophrenia and on follow-up treatment were screened for abnormal movements by the abnormal involuntary movement scale (AIMS) (Guy, 1976)¹¹ according to criteria proposed by Schooler and Kane in 1982.¹² The Ethical Committee Approval and informed consent from the patients were obtained. Data about sociodemographic variables and relevant clinical variables were obtained from the patients and caregivers at the time of the study. In selected patients, insight in different domains was assessed with the scale of unawareness of mental disorder (SUMD; Amador *et al.*, 1993).⁵ A similar approach to assess insight has been adopted by other authors (Arango *et al.*, 1999).⁴ The patients’ awareness of their TD was assessed by another interviewer who was blind to the patients’ score on insight into their mental disorder. Awareness of dyskinesia was measured by two methods. (i) Unawareness of symptom rating as per SUMD and (ii) the awareness item of AIMS. The severity of negative symptoms was rated by the negative symptom assessment - 16 (NSA - 16; Alps and Axelrod, 1993).¹³ The proportion of the population screened who had TD was determined. The correlation between awareness of TD and clinical insight dimensions, negative symptoms, and other variables were analyzed by appropriate statistical methods using the Statistical Package for Social Sciences Version 20 (SPSS-20.0).

RESULTS

A total of 356 patients were screened, and 33 patients were identified to have TD giving an observed prevalence rate of 9.3%. All the patients with TD were taken for further evaluation. The average age of the sample was 43.75 years (SD 10.5). The proportion of women in the sample was 33%. The majority of the sample (51.5%) had <5 years of schooling. Most of the patients were unemployed or working as unskilled laborers (cumulative 90.9%). 28 of the 33 patients studied (84.8%) had been ill for more than 10 years. About a quarter of all the patients had a positive family history of mental illness. Four patients (12.1%) had an early onset of illness (<18 years). There were no patients who had a late onset (>45 years). Most of the patients (72.7%) had been on prescribed both typical and atypical drugs at some point in time. All the patients in the sample were right handed. The frequencies are tabulated. There was no significant correlation between sociodemographic variables, clinical variables, and awareness of TD (Table 1).

Orofacial dyskinesias were more common than limb dyskinesia. Of these, jaw ($n = 23$) and oral ($n = 21$) were the most common. Six patients had loss of teeth and all of them had oral dyskinesia, they also had in addition minimal to mild facial and limb dyskinesia. Many patients had dyskinesia of multiple body areas. Most of the sample (75%) had a mild severity of dyskinesia. Distress due to dyskinesia was absent or minimal in most cases. The severity of dyskinesia was significantly associated with its awareness (Table 2).

The average unawareness scores obtained on SUMD ranged between 3.78 for achieved effects of medication to 4.30 for social consequences of illness. Thus, the most of the patients had a score on the higher range for unawareness. The average score for unawareness of TD was 4.39. The analysis for correlation between unawareness of illness and TD revealed a significant correlation between current unawareness of achieved medication effects and awareness of TD and current unawareness of symptoms and awareness of TD (Table 3).

The average global negative symptom score was 4.39 indicating that most patients had severe negative symptoms. Awareness of TD was significantly correlated with all domains of the NSA 16 except motivation. Awareness of TD was significantly correlated with global negative symptom scores (Table 4).

DISCUSSION

The overall prevalence of TD was 9.3%. This was lesser than that described by other studies which report

Table 1: Sociodemographic characteristics

Demographic details	Frequency (%) n (%)
Sex	
Male	22 (66.7)
Female	11 (33.3)
Education in years	
<5	17 (51.5)
5-10	9 (27.3)
>10	6 (21.2)
Occupation	
Unemployed	14 (42.4)
Unskilled	16 (48.5)
Skilled	3 (9.1)
Duration of illness (years)	
0-5	6 (0)
6-10	5 (15.2)
>10	28 (84.8)
Age at onset	
<18	4 (12.1)
18-45	29 (82.9)
>45	0 (0)
Family history	
Yes	8 (24.2)
No	25 (75.8)
Medication	
Typical	7 (21.2)
Atypical	2 (6.1)
Combined	24 (72.7)

a prevalence of up to one-third of the patients on treatment (Waln O, 2013; Kane JM, 1982).^{6,15} The lower prevalence could be due to the relatively younger age of the population.

Orofacial dyskinesia was the more common than limb dyskinesia as has been reported previously.¹⁵ All the patients who were edentulous had oral dyskinesia, suggesting that the two might be associated as reported (Sandyk *et al.*, 1993).³ In our sample, more male patients were observed contradictory to the view that older women are prone to develop dyskinesia (Waln O, 2013).¹⁵ This finding may be influenced by sample demographics. Mild level of symptom severity and dyskinesia of multiple regions was commonly noted.

Most patients were unaware of abnormal movements as has been previously noted (Amador *et al.*, 1997).¹³ There was no relation between sociodemographic correlates and awareness of TD. This is in line with previous studies.³ The severity of dyskinesia was correlated with awareness, indicating that the patients with more severe dyskinesia had better awareness of symptoms. This was contradictory to results of the previous research.⁴

Poor insight into symptoms and unawareness of medication effects were significantly correlated suggesting that insight

Table 2: Distribution and frequency of TD and its awareness

Body area	Grading	Frequency (n)	Total	Percentage (%)	Cumulative Percent
Face	Mild	8	14	24.2	42.4
	Moderate	4		12.1	
	Severe	2		6.1	
Lips	Mild	14	21	42.4	63.6
	Moderate	7		21.2	
	Severe	0		0	
Jaw	Mild	14	23	42.4	69.7
	Moderate	8		24.2	
	Severe	1		3	
Tongue	Mild	10	12	30.3	36.4
	Moderate	2		6.1	
	Severe	0		0	
Upper limb	Mild	8	10	24.2	30.3
	Moderate	2		6.1	
	Severe	0		0	
Lower limb	Mild	0	2	0	6.1
	Moderate	2		6.1	
	Severe	0		0	
Trunk	Mild	2	2	6.1	6.1
	Moderate	0		0	
	Severe	0		0	
Severity	Mild	25	33	75.8	100
	Moderate	6		18.2	
	Severe	2		6.1	
Incapacitation	Mild	12	16	36.4	48.5
	Moderate	3		9.1	
	Severe	1		3	
Edentulous	Yes	6	33	18.2	100
	No	27		81.8	
Awareness	Not aware	20	33	60.6	100
	Aware, no distress	11		33.3	
	Aware, mild distress	2		6.1	
	Aware, severe distress	0		0	

TD: Tardive dyskinesia

Table 3: Correlation of unawareness of illness with awareness of TD using Pearson's correlation coefficient

Insight item	Mean score	Correlation coefficient	P value
Current unawareness of illness	4.27	-0.339	0.054
Unawareness of effects of medication	3.78	-0.366	0.036
Unawareness of social consequences	4.3	-0.123	0.495
Unawareness of symptoms	3.84	-0.511	0.022
Attribution of symptoms	4.24	-0.278	0.117
Unawareness of TD	4.39	-0.784	0.001

TD: Tardive dyskinesia

into illness is related to awareness of dyskinesia. We did not find any association between unawareness of social consequences and unawareness of dyskinesia as has been

Table 4: Correlation of negative symptom scores with awareness of TD

Symptom	Correlation coefficient	P value
Emotion	-0.385	0.027
Motivation	-0.296	0.094
Communication	-0.472	0.036
Social dysfunction	-0.35	0.046
Motor retardation	-0.457	0.017
Global	-0.415	0.016

TD: Tardive dyskinesia

suggested.⁴ The results might have been influenced by the skew of the sample toward poor insight hiding any statistically significant differences.

Poor awareness of TD was significantly correlated with all domains of the NSA 16 except motivation. The strong association between negative symptoms and unawareness has already been shown by various authors (Chiu *et al.*, 1993).¹²

CONCLUSIONS

Unawareness of abnormal movements is common in patients undergoing treatment for schizophrenia; hence active examination for early signs of TD is advisable during follow-up. The patients who are edentulous are at particular risk. Lack of awareness of dyskinesia is correlated with both negative symptom severity and unawareness of illness symptoms.

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Incidence of Various Types of Gallstones in Patients of Cholelithiasis in Belagavi

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Abstract

Background: Cholecystitis is a very common disease for which patients come to Surgical Department. There are various causes for cholecystitis. Out of which gallstones are very common cause. The development of gallstones depends on dietary habits and lifestyle. The various components of gallstones are cholesterol, bile pigment, and calcium salts in the form of phosphate, carbonate palmitate. Composition of gallstones is important to understand the pathophysiology of gallstone formation in the gall bladder. The object of this study was to find out as to the frequency of different types of gallstones in the population and various signs/symptoms in these patients of cholelithiasis.

Materials and Methods: The gallstones of 143 patients who underwent cholecystectomy were collected over a period of 2-year. A detailed history of all the patients was taken with reference to dietary habits, sex, and stature of patients. The gallstones were analyzed with chemical and enzymatic methods.

Results: The disease had the highest incidence in the age group of 41-50 years of age. There were 38 cases out of 143 in this age group followed by 35, 29, 20, 9 and 9 in the age group of 51-60, 31-40, 61-70, 21-30 and >70 years of age groups, respectively. One case was of more than 70 years of age and one was below 20 years of age. The common complaint was flatulence (64 cases), dyspepsia (63 cases), epigastric pain in 45, and pain in the right hypochondrium in 44 patients. Murphy's sign was positive in 38 cases; 31 patients had complaint of nausea. Mixed stones were the most common, present in over 80.7% cases followed by cholesterol and pigment stones in the form of 13.5% and 5.8%, respectively.

Conclusion: In this study, most of the patients fell in the age group of 41-50 years of age with 38 out of 143 cases, i.e., 26.57% followed by the age group of 51-60 years of age with 24.48% cases. In the age group of 31-40 years, there were 29 cases and 61-70 years 20 cases. There was female predominance with 111 out of 143 patients and 32 males with a female-male ratio of 3.47:1.0. The most common presenting symptoms were flatulence, dyspepsia, epigastric pain, and pain in the right hypochondrium. 31 patients complained of nausea. The most common gallstones were mixed stones with 81.12%, followed by cholesterol stones with 13.29% and pigment stones with 5.59%.

Key words: Cholelithiasis, Cholesterol, Gallbladder, Gallstone, Pigment

INTRODUCTION

One of the common diseases of gallbladder is cholecystitis for which people come to Surgical Department. Cholecystitis is caused by various factors. Gallstones are very common cause for the development of cholecystitis.

Dietary habits and lifestyle of the patient are going to influence the formation of gallstones. Components of gallstones are cholesterol, bile pigment, and calcium salts, in the form of phosphate, carbonate and palmitate. The composition of gallstones is important. To understand the pathophysiology of gallstone formation depends on the composition of the gall stones. Gallbladder stones are one of the major surgical problems in many hospital admissions and surgical interventions.¹ High-risk factor for the cholesterol dominant gallstones is the obese individuals with a body mass index - 30 kg/sq.m² calculus cholelithiasis is a disorder with changing prevalence, reflecting the increasing life expectancy, and changes in lifestyle in Westernized societies.³ There is increased

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incidence of gallstone cholecystitis particularly cholesterol stones with the change in lifestyle and food they consume.⁴ This study was aimed at studying the frequency of various types of gallstones and the epidemiology as regards the most common age group and sex prevalence including the common signs and symptoms.

MATERIALS AND METHODS

The gallstones of 143 different patients were taken after they underwent cholecystectomy for cholelithiasis. History of these patients was taken including age, sex, residence, and signs and symptoms. The gallstones were dried and crushed to make powder, 500 mg of powder of each sample was taken which was dissolved in 5 ml of distilled water. This was then filtered and filtrate was analyzed for bilirubin, cholesterol, calcium and phosphate.

RESULTS

The most interesting finding of this study was that the females were far more prone to gallstone disease than the males in a ratio of female: male as 3.47:1.0. The disease had the highest incidence in the age group of 41-50 years of age. There were 38 cases out of 143 in this age group followed by 35, 29, 20, 9 and 9 in the age group of 51-60, 31-40, 61-70, 21-30 and >70 years of age groups, respectively. One case was of more than 70 years of age and one was below 20 years of age (Table 1). The common complaint was flatulence (64 cases), dyspepsia (63 cases), epigastric pain in 45, and pain in the right hypochondrium in 44 patients. Murphy's sign was positive in 38 cases; 31 patients had a complaint of nausea (Table 2). Mixed stones (Figure 1) were the most common, present in over 80.7% cases followed by cholesterol and pigment stones in the form of 13.5% and 5.8%, respectively (Table 3).

DISCUSSION

Cholecystitis⁵ is an inflammatory condition of the gall bladder characterized by the inflammation of the gallbladder wall, which may be due to retention of bile in gallbladder or secondary to infection by microorganisms, predominantly *Escherichia coli*, *Klebsiella*, *Enterobacter*, and *Bacteroides* species.⁶ In Westernized societies,³ there is change in the lifestyle of the people, increase in the life expectancy which has led to increase in the incidence of cholesterol predominant gallstone disease. In particular, the increase of lifestyle-related risk factors was assumed to result primarily in an increase of cholesterol gallstones.⁴ One of the common diseases of gallbladder is cholecystitis for which people come to Surgical Department with

Table 1: Relationship between age and incidence of gallstone

Age group	Number of patients		Percentage
	Male	Female	
<20 years	01	02	2.09
21-30 years	01	08	6.29
31-40 years	06	23	20.27
41-50 years	07	31	26.57
51-60 years	06	29	24.48
61-70 years	08	12	13.99
>70 years	03	06	6.29
Total	32	111	100

Table 2: Presenting sign/symptoms

Sign/symptom	Frequency (%)
Epigastric pain	45 (43.3)
Pain right hypochondrium	44 (42.3)
Flatulence	64 (60.5)
Dyspepsia	63 (60.5)
Nausea	31 (29.8)

Table 3: Types of gallstones according to composition

Type of stone	Stone frequency (%)
Mixed stone	84 (80.7)
Cholesterol stone	14 (13.5)
Pigment stone	6 (5.8)
Total	104 (100)



Figure 1: Showing specimen with solitary gall stone

complaints of flatulence, dyspepsia, and upper abdominal pain. There are various causes for cholecystitis. Out of which gallstones is very common cause. Dietary habits and lifestyle of the people are going to influence the formation of gallstones. The various components of gallstones are cholesterol, bile pigment, and calcium salts. In the form of phosphate, carbonate palmitate. However, the studies

from the 1960's and 1970's have shown the prevalence of pigment stones of 23-30%.^{7,8} The chemical composition of gallstones is essential for etiopathogenesis of gallstone disease.⁹ This study was aimed to know the prevalence of various types of gallstones and pattern of complaints including the age and sex variations. In our study, there was female predominance with 111 patients being females out of a total of 143. The most common age group was 41-50 years followed by 51-60 years with 26.57 and 24.48% patients, respectively, and male to female ratio is 3.47:1.0, whereas Shrestha and Bajracharya.¹⁰ found the higher incidence of cholelithiasis among younger age group of 20-30 years with male-to-female ratio 1:4. In a study of Maskey *et al.*,¹¹ various signs/symptoms were presented as epigastric pain, pain in right hypochondrium, flatulence, dyspepsia, positive Murphy's sign and nausea in 45, 64, 63, 44, 38, and 31 patients, respectively. Two patients had complained of occasional vomiting, and two had previous jaundice the cause of which could not be ascertained. Four patients had given a history of some periodicity of symptoms. The most common gallstones were of mixed variety constituting 80.7%, while cholesterol and pigment stones were 13.5 and 5.8%, respectively. The gallstones in Tamil Nadu and Pondicherry, South India, are probably due to the infection rather than supersaturation as evidenced by the predominance of pigment stones, whereas in Sikkim and North Bengal cholesterol stones were found.¹²

CONCLUSION

The disease of the gallstone has been found to be the most common cause of cholelithiasis in the age group of

31-60 years of age with more than 70% of the patients falling in this age range. The female-male ratio was 3.47:1.0. Mixed types of gallstones were in the majority of patients, i.e. in 80.7% while cholesterol and pigment stones constituted 13.5 and 5.8%.

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Accuracy of Pre-operative Imaging Predictors of Shamblin Grades in Carotid Body Tumors

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Abstract

Background and Purpose: Magnetic resonance imaging (MRI) is both sensitive and specific imaging modality in the diagnosis and surgical planning of carotid body tumors (CBTs). Radiological criteria to predict Shamblin grades has been described based on MRI, however, literature validating the same is sparse. The purpose of this study was to evaluate the accuracy of radiological criteria used to predict Shamblin grades in correlation with pre-operative grading.

Materials and Methods: MRI images of 11 patients diagnosed to have CBTs during April 2014 to July 2016 at our institution were correlated with per-operative Shamblin grade. Radiologically, the tumors were classified into 3 types based on the arc of vascular contact with the internal carotid artery (ICA); contact $\leq 180^\circ$ was categorized as Type I, Type II tumors had more than 180° and $< 270^\circ$, and Type III tumors had a maximum circumference of contact of 270° or more.

Results: Of the 11 patients, two patients were excluded from our study, one had bilateral carotid tumors on imaging and was operated elsewhere, and the other two, histology of one was vagal schwannoma, and the others were a nodal metastatic adenocarcinoma. Of the eight, six were Type II, one was Type I, and one was Type III. Pre-operative prediction of Shamblin grades correlated accurately with per-operative Shamblin group in all the 8 operated tumors.

Conclusions: MRI can accurately predict Shamblin group preoperatively based on the degree of circumferential contact of the CBT with the ICA on axial images.

Key words: Carotid Body Tumors, Shamblin grade, MRI

INTRODUCTION

Carotid body tumors (CBT's) are slow-growing hypervascular tumors classically sited at the bifurcation of the common carotid artery and accounts for more than 50% of head and neck paraganglioma. These tumors are also known as glomus caroticum or chemodectoma; they arise from the carotid body, which is located in the adventitia of carotid bifurcation. Histologically, the carotid body comprises of both ectoderm and mesodermal tissue and has two types of glomus cells, namely Type I (chief

or paraganglion cells) and Type II (sustentacular cells), physiologically it functions as a vascular chemoreceptor and is sensitive to hypoxia, hypercapnia, and acidosis.^{1,2}

CBTs are mostly benign in etiology and run an indolent course and present anywhere between the third and fifth decade. The exact etiology of CBT is unknown, although its higher incidence among people living at high altitudes or those with chronic obstructive pulmonary disease suggests role of chronic hypoxia.¹³ Mostly unilateral in occurrence, can be bilateral in 5% of sporadic cases, and in 33% of familial cases. Familial cases have been shown to be caused by germline mutations in three of the four succinate dehydrogenase subunit genes. Incidence of malignancy varies between 5% and 7% and usually in familial cases.^{3,11} Mostly nonfunctional, however, occasionally they secrete catecholamines and can present with hypertension and tachycardia.

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Surgical excision is the mainstay of treatment for CBT. Surgical morbidity and mortality is secondary to injury to the internal carotid artery (ICA) or the nerves at the time of resection. Meticulous pre-operative planning and careful patients' selection is essential for a successful surgical outcome. Shamblin *et al.*⁴ graded these tumors based on clinicopathological studies to predict vascular morbidity. Arya *et al.*⁵ proposed criteria based on arc of contact with ICA on axial magnetic resonance imaging (MRI) sequences for preoperatively prediction of Shamblin grades. Involvement of external carotid artery or the common carotid artery is not assessed, as morbidity is mainly related to ICA encasement. The purpose of our study is to validate the accuracy of these imaging criteria in correlation with per-operative Shamblin grade.

MATERIALS AND METHODS

MRI images of 11 patients diagnosed to have CBT during April 2014 - July 2016 on imaging were included for the study. Patients with no operative records or with a histological diagnosis other than CBT were excluded from the study as all tumors histologically confirmed.

Computed tomography (CT) was done in two patients and MRI was done in 10 patients. The surgical records were blinded to the radiologists while they reviewed the MRI. Radiologically, the tumors were classified into 3 types based on the arc of vascular contact with the ICA; contact $\leq 180^\circ$ was categorized as Type 1, Type II tumors had more than 180° and $< 270^\circ$, and Type III tumors had a maximum circumference of contact of 270° or more.

Imaging Protocol

Contrast enhanced CT angiography was performed on 128 slice CT with bolus tracking, helical acquisitions of 0.625 mm from the level of aortic arch to the level of frontal sinus was done following injection of iodinated contrast media. Iohexol (Omnipaque 300 mg/ml) was injected at a rate of 3.5 ml/sec followed by saline chase using the dual head CT pressure injector. Axial images were reconstructed at 1 mm thickness with coronal and sagittal reformations.

Multiplanar and multiple sequence pre- and post-gadolinium contrast enhanced MRI was done on Philips 3 tesla MRI using a dedicated neck coil with three-dimensional (3D) time of flight angiography MR angiography.

Imaging Criteria as Proposed by Arya *et al.*⁵

Radiological classification was based on the arc of contact; the angle suspended between two intersecting

lines passing from the center of the ICA to the tumor. The degree of circumferential contact of the ICA with the tumor (Figure 1) was noted. Large tumors, wherein arc of contact with ICA exceeded 180° , the angle was assessed on the rest of the tumor, circumferential contact was inferred following subtraction by 360° . Based on this methodology, the tumor was radiologically classified into 3 types, Type I, $\leq 180^\circ$; Type II, $> 180^\circ$ and $< 270^\circ$; Type III, $\geq 270^\circ$ (Figure 1).

Angle measurements were made on T2-weighted axial images and correlated with post-contrast T1-weighted sequences using the inbuilt angle measurement tool available on Philips 3 Tesla MRI workstation. Two patients, one underwent a routine CT neck protocol and another was planned for CT angiography. Measurements could not be obtained on the former as the enhancement of ICA and CBT equaled in the delayed arterial phase. However, accurate depiction of tumor and ICA was possible on the angiography protocol, in this patient the same principle of measurement were used. This patient could not undergo MRI as she was claustrophobic.

Per-operative Shamblin Grades

According to the currently applied Shamblin's classification⁴ CBTs, based on the relationship between the mass and the carotid artery wall, are classified into three types: Type I, referring to those without encasement of the vessel wall, tumor size < 5 cm, no widened carotid bifurcation, and easy for surgical removal; Type II, referring to those attached to the blood wall, but without encasement; Type III, referring to those located inside the blood vessel with encasement of the blood wall, tumor size larger than 5 cm with widened carotid bifurcation.⁴ The Shamblin group of the tumor was classified based on at least 2 of the following criteria: (1) The extent of circumferential encasement of the carotid vessels by the tumor as seen intraoperatively; (2) the feasibility of obtaining a plane of dissection between tumor and the vessel; (3) the presence of adventitial infiltration on gross examination.

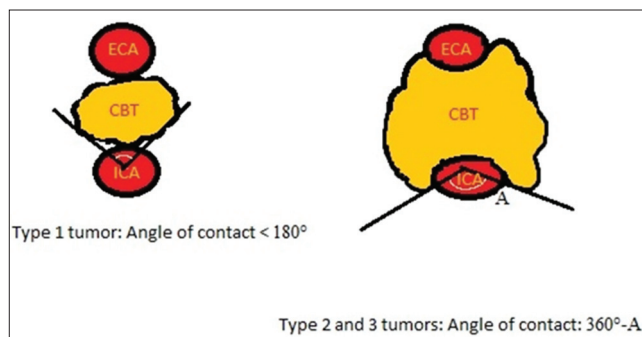


Figure 1: Schematic representation: Measuring circumference of tumoral contact with internal carotid artery

RESULTS

Of the 11 patients, one lady bilateral carotid tumors on imaging and was operated elsewhere, and the others, one was diagnosed to be a vagal schwannoma and the other as metastatic nodal adenocarcinoma; three were excluded from the study

Of the eight, seven were female and one a male. The youngest was 18 years old and the oldest was 80 years. In this study, there was a definite female predominance as opposed to literature that documents male to female ratio of 2.5:1 was observed. Three tumors were on the right and five on the left. However, few other studies state that females are more frequently affected as seen in our study. All were sporadic cases, no predisposing etiology was observed.

In all the 8 patients, imaging appearances were classical for CBT. T2-weighted fat suppressed sequences depicted all of the tumors as hyperintense elliptical masses splaying the CCA bifurcation and with punctuate flow voids with the classical “lyre sign” (Figure 2). On CT, intensely enhancing hypervascular tumor splaying the CCA was seen. Five tumors splayed the CCA in the mediolateral direction, and three in the anteroposterior direction. The size of the tumor varied between 3 cm and 5 cm in the axial dimension.

Based on imaging criteria, six were Type II, one was Type 1, and one was Type III, this was concordant with per-operative grading. Per-operative grading Shamblin I tumor encased the vessels partially and could be easily dissected from the vessels, and did not show adventitial infiltration. Shamblin II tumors were difficult to dissect from the vessels, which had partial or focal adventitial infiltration. Shamblin III tumors encased the vessels almost completely, and despite meticulous dissection, plane between the tumor and vessels could not be obtained due to adventitial infiltration leading to incomplete resection (Figure 3).

It was possible to preserve, the ICA in all the cases and none of the patients we evaluated had post-operative neurological deficits or nerve injury. The radiological classification proposed by Arya *et al.*, was found to be accurate in all the cases with 100% positive predictive value.

DISCUSSION

Our small case series reiterate the accuracy of pre-operative imaging prediction of Shamblin grades based on the criteria proposed by Arya *et al.* In this small series of

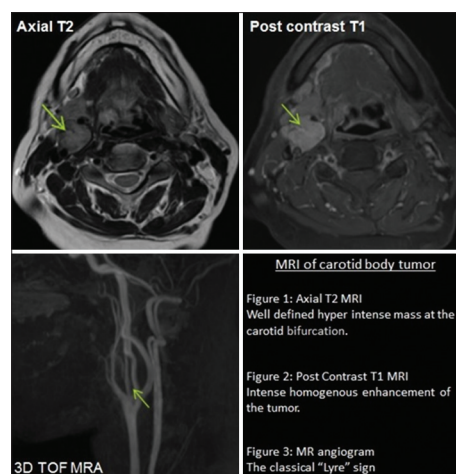


Figure 2: Magnetic resonance imaging of carotid body tumor

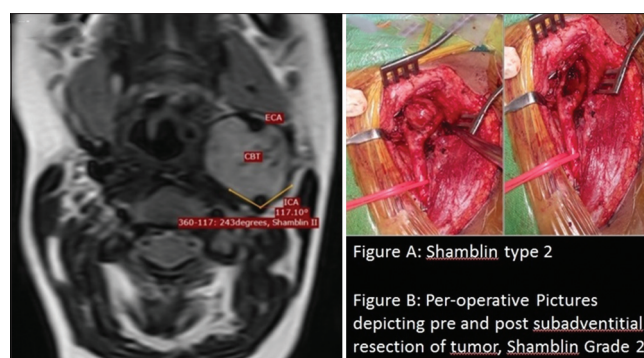


Figure 3: Shamblin Grade II: Axial T2-weighted magnetic resonance imaging versus per-operative picture

CBTs are mostly benign in etiology and run an indolent course. Usually unilateral, bilateral occurrence is rare, varies between 5% and 10% and is usually seen in the familial type. Incidence of malignancy varies between 5% and 7%. The incidence of CBTs is <1 in 30,000.^{1,11}

Lushka¹ first described tumors arising from the carotid body in 1862. Etiopathogenesis of the tumor is largely unknown. The tumor mostly occurs in sporadic form while a minority of patients had a familial type which is thought to be related to genetic factors. They can occur at any age but are usually more common in the third to sixth decade of life. A higher incidence has been reported in those living higher altitudes typified by relative hypoxia.⁶ Recent biogenetic discoveries reveal that mutations in oxygen sensing genes may also be responsible, accounting for approximately 35% of cases, these two etiologies are probably additive.^{6,7} The tumor is usually nonfunctional but occasionally tumors capable of catecholamine secretion are diagnosed with symptoms similar to pheochromocytoma such as hypertension and tachycardia.

Carotid arterial angiography in decades past was the mainstay for diagnosis of these tumors. It aided in detecting

the tumor size, vascularity, blood supply, and presence of multiple tumors. The main vascular supply of the tumor is from bifurcation and external carotid artery, through the ligament of Meyer but may have contributory blood supply from ICA, vertebral artery, and thyrocervical trunk. A biopsy is contraindicated owing to tumoral vascularity.^{7,8}

Color Doppler study, panoramic imaging with 3D sonography, CT angiography, and MR angiography are now the modalities for pre-operative imaging. Color Doppler study highlights vascularity of the tumor at the level of carotid artery bifurcation and is the first diagnostic tool, and this can be coupled with panoramic imaging as well as 3D sonography for optimal delineation of the tumor.^{9,12} CT or MR angiography is imperative prior surgery as they aid in surgical planning.^{14,15,17}

Rapid evolution of imaging techniques has replaced angiography in the present decade. Invasive angiography is resorted to only in patients planned for pre-operative embolization to reduce tumor vascularity; however, this too is not preferred as inflammatory response followed by fibrosis impedes sub-adventitial dissection preoperatively resulting in incomplete resection.^{18,19}

The tumor is a surgical challenge due to its location, high vascularity and potential morbidity, and mortality secondary to injury to ICA or nerve injury. Novel surgical techniques have evolved over the years, but meticulous sub-adventitial dissection described by Gordon Taylor as the “white line” has stood the test of time. Although surgical removal of the tumor is the treatment of choice, if patient is elderly and unfit for surgery, radiotherapy can also be tried.^{15,16}

Surgical classification by Shamblin *et al.* continues to be a predictor of vascular morbidity. Shamblin *et al.* classified these tumors into 3 groups based on the operative notes and gross specimen examination and established that the risk of surgical intervention depends mainly on the relationship of the tumor with the carotid vessels. According to Makeieff *et al.*,^{20,21} The rate of serious complications, i.e., permanent nerve palsy and vascular complications was 2.3% for Shamblin Class I/II tumors and 35.7% for Shamblin Class III tumors ($P < 0.001$) and O'Neill *et al.*¹⁰ found in his series that cranial nerve injury was more likely following the removal of larger tumors.

The importance of Shamblin classification increases significantly if pre-operative cross-sectional imaging can accurately predict the Shamblin group. CT and MRI is a frequently used imaging method in the diagnosis and pre-operative workup, however, most reports on the diagnosis and surgical management of CBTs do not mention specific or consistent imaging criteria to predict

this classification. Van der Mey *et al.* have stressed the need for a uniform classification system for these tumors so that the communication in the literature could be consistent.

Our study highlights the accuracy of radiological classification based on arc of contact of tumor to the ICA which can be easily inferred on the axial imaging, be it CT or MRI. We propose the use of this simplistic radiological classification to be incorporated in all reports of CBT so as to aid the surgeon in pre-operative planning.

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Soft Tissue Neoplasms: Distribution and Diagnostic Strategies Including Immunohistochemical Study

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Abstract

Introduction: Tumors arising in soft tissue form a varied and complex group which may show a wide range of differentiation. In the absence of a firm histological diagnosis, it is often dangerous to attempt to predict the likely clinical course of a soft tissue neoplasm.

Materials and Methods: The surgical specimens of the patients who underwent excision of soft tissue tumors during the period March 2011-February 2014 at KAPV Government Medical College, Tiruchirappalli, formed the material for this study. All the specimens are subsequently diagnosed as one of the soft tissue tumors by histopathological examination.

Results: A total of 11095 surgical specimens received in the Department of Pathology, KAPV Government Medical College, Tiruchirappalli, during the study period of which soft tissue tumor constitutes 260 (2.35%) cases. This study included those 260 soft tissue neoplasms, in which 27 were seen in pediatric patients and the remaining 233 in adults. In the 27 pediatric soft tissue neoplasms, 15 cases were seen in male children and 12 in female children. In adults, of 233 cases, 117 cases were seen in males and 116 were seen in females. Soft tissue neoplasms including both benign and malignant constituted 8.8% of total neoplasms during our study period.

Conclusion: Improving the knowledge of cytological appearance of individual tumors, through fine needle aspiration cytology as initial approach to the soft tissue neoplasms and in addition, molecular techniques could really improve the quality of diagnosis of soft tissue tumors, with which treatment modalities can be modified, and prognosis could be improved.

Key words: Histopathology, Immunohistochemistry, Soft tissue neoplasm

INTRODUCTION

Tumors arising in soft tissue form a varied and complex group which may show a wide range of differentiation. In the absence of firm histological diagnosis, it is often dangerous to attempt to predict the likely clinical course of a soft tissue neoplasm.¹⁻⁵ In this study, we analyzed the incidence and distribution of soft tissue neoplasm in relation to age, sex, and site. We also evaluated the role of immunohistochemistry (IHC) in the diagnosis and confirmation soft tissue neoplasm of critical histopathology.

Aim

1. To study the incidence of soft tissue neoplasm in adults and pediatric patients.
2. To analyze the distribution of soft tissue neoplasm anatomically, as per the guidelines provided by association of directors of anatomic and surgical pathology (ADASP).
3. To study the usefulness of special stains.
4. To evaluate the role of IHC in soft tissue neoplasm of critical histopathology.
5. To study rare soft tissue neoplasms arising at rarer sites and confirmation by IHC.

MATERIALS AND METHODS

The surgical specimens of patients who underwent excision of soft tissue tumors during the period March 2011-February 2014 at KAPV Government Medical College, Tiruchirappalli, formed the material for this study.

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All the specimens are subsequently diagnosed as one of the soft tissue tumors by histopathological examination.

A thorough clinical evaluation and gross descriptions, as per the guidelines recommended by ADASP was done in each case. A detailed history with particular attention to site, duration, depth of neoplasm and type of resection were also recorded. All lesions were placed in categories in accordance with the WHO classifications system and added to anatomical locations such as head and neck, upper extremities, trunk, lower extremities, and peritoneum.

Soft tissue neoplasms of either sex irrespective of the age group (both pediatric and adult neoplasms) were included in this study.

The specimens were received in 10% formalin and processed in the routine way small biopsy specimens (<0.5 cm) were submitted into whereas larger specimens were sampled at 1 cm intervals. Multiple bits were taken at different sites, paying particular attention to base margin, and necrotic areas.

After routine processing and paraffin embedding, 5-6 cm sections were cut. The sections were stained with hematoxylin and eosin (H and E) for evaluation of histopathological features.

Histochemical stains - such as Masson trichrome, periodic acid Schiff, Van Gieson, and reticulin - were also performed.

IHC with S100, neuron specific enolase (NSE), CD34, and CD99 was also performed in selective cases in arriving at a final diagnosis.

IHC was performed on one representative section per case on 4 µ thick, formalin fixed, paraffin embedded sections mounted on charged slides, and baked at 60°C for 1 h. All cases were stained in parallel with appropriate positive and negative controls. Staining extent was scored as negative, focally positive, and positive or diffusely positive.

RESULTS

A total of 11095 surgical specimens received in the department of pathology, KAPV Government Medical College, Tiruchirappalli, during the study period of which soft tissue tumor constitutes 260 (2.35%) cases.

This study included those 260 soft tissue neoplasms, in which 27 were seen in pediatric patients and the remaining 233 in adults.

In the 27 pediatric soft tissue neoplasms, 15 cases were seen in male children and 12 in female children.

In adults, out of 233 cases, 117 cases were seen in males and 116 were seen in females.

Soft tissue neoplasms including both benign and malignant constituted 8.8% of total neoplasms during our study period.

The incidence of benign and malignant soft issue neoplasms in our study are given in Table 1.

Of 260 cases, benign tumors constituted 87.65% and malignant tumors accounted for 10.7% of total soft issue neoplasms.

The rest being intermediate group of neoplasms. Table 1 showed that benign tumors outnumber malignant tumors. Intermediate categories constitute only 1.9%.

Among the malignant soft issue neoplasms, malignant fibrous histiocytoma (MFH) was the most common followed by malignant peripheral nerves sheath tumor. The third common malignant neoplasm was extraskelatal Ewing's sarcoma.

All soft tissue neoplasms were categorized into six groups according to their age as 1-10 years, 11-20 years, 21-30 years, 31-40 years, 41-50 years, and >50 years.

The overall incidences of soft tissue neoplasms were higher in the age group of 31-40 years (26.1%). Intermediate tumors were found in all age groups with the exception of 11-20 years.

Table 2 showed that most of the benign tumors were found in the age group of 31-40 years and malignant tumors were frequently seen in >50 years of age.

Table 3 shows the sex incidence of soft tissue neoplasms in adult and pediatric cases.

Table 1: Overall incidence of soft tissue neoplasms

Tumor types	Benign (%)	Malignant (%)	Intermediate (%)	Total
Lipomatous	149 (65)	2 (7.14)	-	151
Fibrous	18 (8.3)	3 (10.7)	4 (80)	25
Vascular	23 (10)	-	1 (20)	24
Fibrohistiocytic	2 (0.88)	6 (21.4)	-	8
Neural	36 (15.8)	4 (14.3)	-	40
Rhabdomyosarcoma	-	2 (7.1)	-	2
Synovial sarcoma	-	2 (7.1)	-	2
Extraskelatal	-	3 (10.7)	-	3
Ewing's sarcoma	-	2 (7.1)	-	2
Leiomyosarcoma	-	1 (3.6)	-	1
Epithelioid sarcoma	-	2 (7.1)	-	2
Olfactory	-	2 (7.1)	-	2
Neuroblastoma	-	-	-	-
Total	228 (87.7)	27 (10.4)	5 (1.9)	260

Benign tumors were typically found in females (51.5%), whereas malignant tumors were predilection toward males (56.5%). Most of the intermediate tumors were reported in adult males (60%). In out of 27 malignant neoplasms, 13 cases were seen in males, 11 cases in females, and 3 cases were seen in pediatric age group. Among the pediatric neoplasms, 15 cases were seen in males and 12 cases were seen in females.

A lipoma is commonly seen in females. Among the intermediate neoplasms, dermatofibrosarcoma protuberans was frequently seen in male persons. In malignant tumors sex prediction varies among different tumors.

The universal tumor lipoma was frequently encountered in trunk region followed by upper extremity, and the other histological types were usually encountered in head and neck region.

Fibrohistiocytic tumors were reported in the lower extremity.

The most frequent tumor encountered was MFH followed by malignant peripheral nerve sheath tumor (MPNST) and both the tumors were frequently encountered in the lower extremity. We encountered one case of leiomyosarcoma in labia majora and one case of epithelioid sarcoma in retroperitoneum.

In this study, 149 cases of lipoma were encountered which includes 122 conventional lipomas, 24 fibrolipomas, and 3 angiolipomas.

About 36 benign neural tumors were diagnosed which constitutes 23 neurofibromas, 11 schwannomas, 1 granular cell tumor (GCT), and 1 neurothekeoma.

Of 11 schwannomas, three cases were diagnosed as ancient schwannomas showed features of inflammatory cells, histiocytes, and increased vascularity.

We reported a rare case of neurothekeoma in medial malleolus. We encountered a case of GCT in hand.

About 18 benign fibrous tumors were observed which included 8 benign fibroma, 6 angiofibroma, 1 nodular fasciitis, 1 dermatofibroma, and 2 fibromatosis.

The malignant counterparts of fibrous tumor include 3 cases of fibrosarcomas.

One case of inflammatory myofibroblastic tumor which comes under intermediate group was found in the head and neck region (palate).

Microscopically, the tumor was composed of masses of spindle cells, inflammatory cells (mostly lymphocytes and plasma cells) against a collagenous and myxoid stroma.

The incidence of malignant tumors was shown in Table 4.

The biopsy specimens were subjected to histochemical stains in doubtful cases. For selective cases, the histochemical stains used were Masson's trichrome, Van Gieson, periodic acid Schiff, and reticulin. Masson trichrome stains were applied to five cases of MPNST, periodic acid Schiff for three cases extraskelatal Ewing's sarcoma, reticulin was applied for Kaposiform Hemangio endothelioma, and synovial sarcoma, Van Gieson was applied for desmoid tumor where diagnosis by light microscopy alone was difficult (Table 5).

In our study, of 260 cases, only six doubtful cases were subjected to IHC. The IHC markers applied were S 100, NSE, CD 34, CD 45, and CD 99 (Table 6).

Table 2: Age distribution of benign and malignant tumors

Adult	Benign (%)	Malignant (%)	Intermediate (%)	Total (%)
1-10	12 (5.2)	4 (14.3)	1 (20)	17 (6.5)
11-20	25 (11)	2 (7.1)	-	27 (10.5)
21-30	37 (16.2)	2 (7.1)	1 (20)	40 (15.5)
31-40	62 (27.2)	5 (18.5)	1 (20)	68 (26.1)
41-50	42 (18.4)	3 (10.7)	1 (20)	46 (17.6)
>50	50 (21.92)	11 (39.28)	1 (20)	62 (23.8)
Total	228	27	5	260 (100)

Table 3: Sex incidence of adult and pediatric soft tissue neoplasms

Type	Male (%)	Male (pediatric)	Female (%)	Female (pediatric)
Benign	101 (48.5)	11 (73.3%)	104 (51.5)	12 (100%)
Intermediate	3 (60)	1 (6.7%)	1 (20)	-
Malignant	13 (56.5)	3 (20%)	11 (43.5)	-
Total	117	15	116	12

Table 4: Incidence of histological types of malignant soft tissue neoplasms

Type	Total number	Percentage
MFH	6	21.42
MPNST	4	14.28
Extraskelatal Ewing's sarcoma	3	10.71
Liposarcoma	2	7.14
Rhabdomyosarcoma	2	7.14
Fibrosarcoma	3	10.71
Leiomyosarcoma	2	7.14
Epithelioid sarcoma	1	3.57
Synovial sarcoma	2	7.14
Olfactory neuroblastoma	2	7.14

Table 5: Histochemical stains

Initial diagnosis	Histochemical stain	Result	Final diagnosis
Extraskelatal Ewing's sarcoma (3 cases)	Periodic acid Schiff	(+)	Extraskelatal Ewing's sarcoma (3 cases)
MPNST (4 cases)	Masson tri chrome	(+)	MPNST (4 cases)
Desmoid tumor	Von Gieson	(+)	Desmoid
Kaposiform hemangio endothelioma	Reticulin	(+)	Kaposiform Hemangio endothelioma
Synovial sarcoma	Reticulin	(+)	Synovial sarcoma

MPNST: Malignant peripheral nerve sheath tumor

Table 6: IHC markers

Initial diagnosis in H and E	IHC marker	Final diagnosis
Extraskelatal Ewing's sarcoma/lymphoma	CD 45 (-)	Extraskelatal Ewing's sarcoma
Olfactory neuroblastoma/rhabdomyosarcoma	CD 99 (+) NSE (+)	Olfactory neuroblastoma
Epithelioid sarcoma,/malignant mesothelioma	CD 34 (+)	Epithelioid sarcoma
MPNST/MFH	S 100 (+)	MPNST
MPNST/leiomyo sarcoma	S 100 (-)	Leiomyosarcoma
MPNST/MFH	S 100 (-)	MFH

NSE: Neuron specific enolase, IHC: Immunohistochemistry, H and E: Hematoxylin and eosin, MPNST: Malignant peripheral nerve sheath tumor, MFH: Malignant fibrous histiocytoma

DISCUSSION

The 260 soft tissue tumors analyzed in this study reveals that the proportion of soft tissue neoplasms among the total neoplasms was found to be 2.35%.

According to the National Cancer Institute's surveillance, the incidence of soft tissue sarcomas ranges from 15 to 35/1 million population.^{1,2} In a study conducted by Necati Akisatal showed that 3% incidence of soft tissue sarcomas among all neoplasms, whereas Enginger *et al.*, showed that the incidence of soft tissue sarcomas was <1%. Our study correlates with the literature (1.27%).

The number of cases with soft tissue sarcomas has risen in recent years, which is in accordance with the data of soft tissue sarcoma in the USA between 1973 and 1993 analyzed by Pollock. According to the statistics of malignant tumors in Shanghai from 1963 to 1992, the incidence of soft tissue sarcomas is 0.75-1.85/1,00,000. In the USA, the annual incidence is 2/100,000.⁵⁻¹¹

The incidence of soft tissue sarcomas in our institute has also increased from 0.74% to 1.78% during the study period.

In general, benign soft tissue tumors occur 10 times more frequent than malignant ones.^{1,12,13} This study also shows

that benign tumors constituted 87.7% as against malignant soft tissue neoplasms (10.4%).

Among the benign soft tissue tumors lipoma was found to be the most common. Ashok reported that 16% neoplasms are lipomas, and they were commonly seen on trunk and extremities. In our study, the incidence of lipoma constituted 5% among all neoplasm and 65% ($n = 149$) among all benign soft tissue tumors, and the common site is trunk 22.36% ($n = 51$).⁹⁻¹¹

According to Sposto *et al.*, GCT was an uncommon benign neoplasm and it can occur between 4th and 6th decades of life, more common in women. The most GCTs are found in the head and neck region and the tongue was the most common location. In contrast with the literature, the site was hand.

The incidence of soft tissue neoplasm in trunk is a more frequent in our study (25.4% $n = 66$). This study also included the clinical presentation of soft tissue neoplasms in which most of the tumors presented as painless, capsulated swelling with restricted mobility. Most of the benign tumors are superficial in location, and their size is <5 cm (77%), in correlation with the literature whereas 55% of malignant tumors were >5 cm in diameter.¹⁴⁻¹⁹

The anatomic distribution of soft tissue sarcomas frequently occurred in the lower extremities (39.3% $n = 11$) in accordance with the literature followed by head and neck and trunk.¹⁻³

Soft tissue sarcomas can be observed in any age group, while different tumor types exhibit a significant age predilection.

The incidence of malignant soft tissue tumors is slightly more in males (56.5% $n = 13$) and benign is more common in females (51.5% $n = 104$) in accordance with the literature (Figure 1).^{2,4}

In this study, the gender ratio for soft tissue sarcoma was 1.02:1 MFH accounts for 20-24% of malignant soft tissue tumors, making it the most common soft tissue tumors occurring in late adult life.^{2,3,19} In analysis of 200 cases of soft tissue sarcomas, Enzinger *et al.* found that 2/3 of MFH occurred in men and the majority of cases were occurring in persons between 50 and 70 years.

According to the 1240 cases of soft tissue sarcomas study recorded by the sarcoma group of French federal cancer center MFH is the most frequent tumor followed by liposarcoma. Another study conducted in Japan, in 2002, also proved.^{15,16}

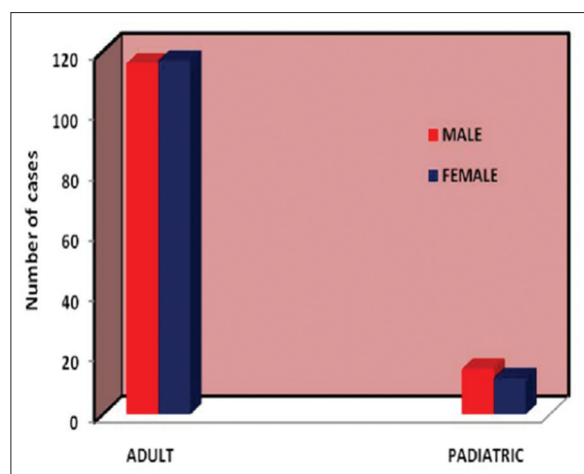


Figure 1: Sex distribution of soft tissue neoplasms

In accordance with the literature, MFH constituted the most common malignancy (21.4% $n = 6$) in this study, and the common site was lower extremity (thigh) 66.7%. The majority of them were in the sixth decade (20% $n = 5$). Most of the tumors are between 5 and 10 cm (66% $n = 4$).^{4,19}

The incidence of MPNST was 5-10% of all soft tissue sarcomas. In our study, MPNST accounts for 14.3% ($n = 4$), the common site is lower extremity (39.3% $n = 11$). In contrast with the literature males are more commonly affected than females.¹⁷

Although liposarcoma is considered to be a frequent tumor in adults by many articles like Fang-Zhi-Wei *et al.*, in our study liposarcoma contributed only 7.14%.^{3,7,8}

We reported two cases of liposarcomas, one was from thigh and another was from omentum, and the sex incidence was equal. Age group affected was >60 years.

Fibrosarcoma usually arises in the age group of 4-6th decades as per the literature.¹⁸ However, in our study, two cases of adult FS were diagnosed in the third decade.

In AFIP series, of 345 cases of synovial sarcoma 60% of cases were found to be in lower extremity and they were commonly encountered in 15-40 years of age.¹ In accordance with the literature our study shows the common site was knee (2/2 cases) and the age group was in the second decade. In contrast to the literature females were commonly affected in our study (2/2 cases).^{3,5,6}

Epithelioid sarcoma is a rare soft tissue sarcoma that occurs in the extremities, and they frequently occur in adult males.

In contrast with the literature, the incidence of epithelioid sarcoma in our study was 3.57% and the age group affected was 64 years and also the site was peritoneum.

The incidences of pediatric soft tissue neoplasms were also included in this study. In correlation with the literature, the most common benign pediatric tumor was hemangioma (54% $n = 13$) and the malignant tumor was rhabdomyosarcoma (66% $n = 2$).

Benign tumors were common in pediatric age group (88.8% $n = 24$) as against malignant tumors (11.2% $n = 3$).

Male children were more commonly affected than female children (56%). The most favorite age group in this study was <1.5 years. Males were more commonly affected (2/2 cases) and the site predilection was head and neck.⁴

CONCLUSION

In this study of 260 cases, which includes clinical findings, histopathological examination with routine H and E stains, special stain study and immunohistochemistry markers, the following conclusions are presented.

1. The incidence of soft tissue neoplasms is gradually increasing.
2. The incidence of benign tumors outnumbered malignant tumors in the both adult and pediatric age group.
3. As mentioned in the literature lipoma still appears to be there most common benign tumor.
4. In this study, in contrast to trunk appears to be the most common site for occurrence of soft tissue neoplasms.
5. The incidence of malignant soft tissue neoplasms one more in males, whereas benign tumors more in females.
6. Sarcomas of fibrohistiocytic origin outnumbered sarcomas of any other organ origin in our study.
7. In this study, in the pediatric age group, the embryonal RMS is the most common malignant tumor in correlation with the literature.
8. Most of the sarcomas presented as a mass lesion with size at least more than 5 cm.
9. Epithelioid sarcoma a rare soft tissue tumor usually occurs in extremities in adult age, but in our study, this tumor occurs in very rare site - peritoneum and the age group >2 years.
10. In doubtful case, immunohistochemical markers shall provide valuable tool in arriving at final diagnosis.

Our knowledge of the biology of the soft tissue tumors comes a long way from the time when they were classified based on gross morphology along to the present day when a combined multimodal approach using convectional histology, special histochemical stains, immune histochemistry, molecular biology, and cytogenetics are used to classify these tumors.

The time tested H and D section is still sufficient to diagnosis majority of the lesions.

In our study, we had attempted to describe the clinical and histomorphological profile of soft tissue neoplasms diagnosed in our institute.

The study of various pathological patterns of sarcomas helps in unraveling the natural history of these lesions. Without the knowledge of the tumor behavior, it would be difficult to decide treatment options. Prospective studies with adequate patient follow-up data are required for this purpose.

Improving the knowledge of cytological appearance of individual tumors, through fine needle aspiration cytology as initial approach to the soft tissue neoplasms and in addition, molecular techniques could really improve the quality of diagnosis of soft tissue tumors, with which treatment modalities can be modified and prognosis could be improved.

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Relationship between Psychosocial Stressors and the Intent and Lethality of Suicidal Behavior

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Abstract

Background: The increasing rate of suicide and suicidal attempts is a growing health problem worldwide. The majority of suicide attempts occur in the low and middle economic countries like India. Suicidal behavior occurs in response to interactions between biological, psychological, and socioenvironmental risk factors.

Aim: To determine the level of association between psychosocial stressors and intent and lethality of suicidal behavior.

Materials and Methods: Consecutive suicide attempters above the age of 15 years admitted to Kilpauk Medical College Hospital were assessed. 106 patients were selected, and they were administered a semi-structured socio-demographic pro forma, presumptive stressful life events scale, Beck's suicide intent scale, and Lethality assessment scale.

Results: Majority of the suicide attempters were female. The majority was married from a lower economic status and had some education. Individuals with higher psychosocial stressors had significantly higher suicidal intention and lethality of the suicide scores.

Conclusion: Psychosocial stressors are significantly correlated with the intention and lethality of the suicide. Female gender and marital conflicts had a major role as compared to other factors such as family conflicts, financial, and occupational problems in suicidal behavior. Early identification and intervention are needed to prevent the further suicide attempt.

Key words: Beck suicide intent scale, Lethality assessment scale, Presumptive stressful life events scale

INTRODUCTION

The increasing rate of suicide and suicidal attempts is a growing health problem worldwide. According to World Health Organization (WHO), suicide is the second leading cause of death between 15 and 29 years of age globally (2012). It is responsible for 1.4% of all deaths worldwide. According to WHO report, one person commits suicide every 40 s globally. The majority of suicide attempts occur in the low and middle economic countries. Worldwide, most suicides occur in the South-East Asia region. In

2012, India accounted for the most deaths by suicide in this region.¹

More than one lakh lives are lost every year due to reported (many being unreported) suicide in India. From 1975 to 2005, the suicide rate has increased by 43% (Government of India, 2005). The rates were approximately the same between 1975 and 1985; from 1985 to 1995 there was an increase of 35% and from 1995 to 2005, the increase was 5%.²

Suicidal behavior refers to directly self-injurious behavior that is engaged in with the intent to end one's life such as hanging/strangulation, severe cutting, and jumping from heights (Andover and Gibb, 2010).³ Suicidal behavior occurs in response to interactions between biological, psychological, and socio-environmental risk factors. Empirical research suggests that early and chronic life event stresses, particularly within the family context, are associated with suicidal behavior.

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The incidence of suicidal behavior is increased in young females and in lower socioeconomic status. Other risk factors include suicide attempts by family members or friends, chronic physical illness, family violence, and lower academic achievement (Lewinsohn *et al.*, 1994).⁴ Other potential risk factors for suicide attempts include psychopathology especially a major depressive disorder, previous suicide attempts, hopelessness, and recent stressful life events.

Stressful life events are associated with a high proportion of suicide attempts. Life changes could act as a stressor causing physiological arousal and enhanced susceptibility for suicidal risk. Suicide victims have experienced more changes in living conditions, work problems, and object losses than normal controls. Chronic physical illness also had a tendency to increase the suicidal behavior. Stressful life events and social problems happening in recent time may lead to suicide. A review of Indian studies on stressors in suicide has shown maladjustment with family members and domestic strife as the most important cause, followed by physical factors and mental illness (Ponnudurai *et al.*, 1986).⁵ Sometimes individuals with life event stressors attempt suicide immediately, often within a day of a stressor (Conner and Duberstein, 2004).⁶

Several recent studies have suggested that mental disorders are less important in the occurrence of suicidal behaviors in developing countries compared to developed countries. Studies in developed countries suggest that more than 90% of the suicide attempters had diagnosable mental disorder, but rates in developing countries were lower (Vijaykumar, 2007).⁷

The increase of suicide rates is much higher in adolescents than adults. The primary causes were identified as disturbed interpersonal relationships and psychiatric illness (Cohen *et al.*, 1982).⁸ Adolescents with the greatest risk of suicidal behavior had family and marital problems, poor parent child attachment, and sexual abuse in childhood (Fergusson *et al.*, 2000).⁹

Aim

To determine the significance of the severity of psychosocial stressors in relation to intent and lethality of suicidal behavior.

MATERIALS AND METHODS

The prospective observational study was conducted Department of Psychiatry, Kilpauk Medical College Hospital in patients referred after a suicidal attempt for psychiatric assessment and counseling. Patients who

were older than 15 years of age and who were willing to participate in the study by giving an informed consent (for minors, informed consent was obtained from a parent as well as subject) were included. The study was approved by the institutional ethics board. 115 suicide attempters above the age of 15 years reported to the psychiatry department during the above mentioned period. Among those, 4 patients were found to be very ill and 5 were not willing to participate, which resulted in 106 individuals being taken up for the study. A semi-structured pro forma was used to record sociodemographic and other relevant information. Life events and psychosocial stressors during the past year were assessed using presumptive stressful life events scale (PSLES). Suicidal intention and its lethality were assessed using Beck's suicidal intent scale and Lethality assessment scale, respectively. The presence of psychiatric disorders and substance use disorders were also diagnosed by clinical interview, according to ICD 10 but were not analyzed for this study. PSLES consists of 51 questions each having a separate score and is divided into 3 categories as low, medium and high depending on the total scores as <150, 150-300 and >300, respectively. Beck's suicidal intent scale was developed by Aaron Beck and his colleagues at the University of Pennsylvania to determine the severity after an unsuccessful suicide attempt. The range of scores is 0-21, divided into low intent 0-3, medium intent 4-10, and high intent 11 and above. Lethality assessment scale consists of 5 key ranges which apart from determining the lethality of the suicide attempt, also focuses on further imminent risk. In this study, the severity of the psychosocial stressors was analyzed in relation to the intent and lethality of the suicide attempt. Statistical analysis was performed using SPSS vision 20.0. Unpaired *t*-test, analysis of variance and Spearman's rank order correlation coefficient test were used.

RESULTS

In this study, 106 participants were analyzed and matched on age, sex, education, occupation, and marital status. Among those, 47.16% (*n* = 50) participants were males, 52.83% (*n* = 56) were females, 48.1% were single, and 51.9% were married. 64.15% had completed school level education like middle school, high school and higher secondary level and 24.52% (*n* = 26) had completed either a diploma or a degree. In income status, 66.98% had a monthly income of less than 10000, while 29.24% of them had a range of income from 10,000 to 25,000 per month, and only 3.77% of them had monthly income of above 25,000. Regarding occupational status, 13.20% (*n* = 14) of participants were students including school and colleges, 11.32% (*n* = 12) were housewives, 58.49% (*n* = 62) were employed, and 16.98% (*n* = 18) of them were unemployed (Table 1).

Table 2 shows that a significant association is observed between marital status and psychosocial stressors. The other indicators - such as occupation, education, and income status - were not significantly associated with any of the measured variables.

Table 3 shows that individuals with high psychosocial stressors had higher suicidal intention scores ($P = 0.028$) as well as the high scores on lethality of the suicide ($P = 0.020$). Individuals with high suicidal had higher lethality of the suicide ($P = 0.000$).

DISCUSSION

According to Ramdurg *et al.* (2012),¹⁰ 63% of the suicide attempts were by individuals with an educational level below matriculation and individuals with employment

had a higher suicidal rate than the unemployed persons and also the level of stressors were more in employed persons. Tara *et al.* (2014),¹¹ in her study, found that 55% of the suicide attempts were by individuals with unskilled work. According to Sudhir Kumar *et al.*¹² 58.1% of the participants came under lower socioeconomic status in their study. The results of our study are in broad agreement with this data with most attempters having some education and belonging to lower economic status.

Our findings suggest that psychosocial stressors had a major role in suicide attempts, and there was a direct relation between psychosocial stressors and suicidal intention/lethality. The score of the presumptive stressful life events was divided into low (<150), medium (150-300), and high (>300). Among those, suicide attempters in this study 72% ($n = 77$), 22% ($n = 24$), 4.7% ($n = 5$) of suicidal attempters were scores as low, medium, and high, respectively.

In our study, significant psychosocial stressors were present in married persons ($P = 0.027$), however, there was no significant relation between psychosocial stress score and other factors such as employment status, income status, or educational status. Osvath *et al.* (2004)¹³ have reported that the recent life events commonly noted in most suicide attempts were problems at work and family, somatic illness, and financial problem. Other studies have also reported that psychosocial stressors such as financial loss, family conflict, marital conflict, and broken engagement had a key role in suicidal behavior (Kumar and George (2013)).¹⁴

It is usually held that unmarried persons have a higher percentage of suicide (Ponnudurai *et al.*, 1986 and 1995; Latha *et al.*, 1996; Shivakumar and Shanmugasundaram,

Table 1: Sociodemographic data

Demographic details	Variables	Numbers (%)
Gender	Male	50 (47.16)
	Female	56 (52.83)
Marital status	Single	51 (48.1)
	Married	55 (51.9)
Education	Illiterate	12 (11.32)
	School education	68 (64.15)
	Degree/diploma	26 (24.52)
Income per month	<10000	71 (66.98)
	10000-25000	31 (29.24)
	>25000	4 (3.77)
Occupation	Students	14 (13.2)
	Home makers	12 (11.32)
	Employed	62 (58.49)
	Unemployed	18 (16.98)

Table 2: Association between socio-demographic variables and PSLES, Beck's suicide intent scale and LAS scores

Variables	PSLES	BECK'S	LAS
Gender	0.171	0.239	0.089
Marital status	0.027	0.603	0.116
Occupation	0.642	0.373	0.403
Education	0.547	0.712	0.134
Income	0.102	0.740	0.343

PSLES: Presumptive stressful life events scale, LAS: Lethality assessment scale

Table 3: Correlation between PSLE, Beck's and LAS

Variables	PSLES	
	Correlation coefficient	P
Beck's SIS	0.213	0.028
LAS	0.225	0.021

PSLES: Presumptive stressful life events scale, LAS: Lethality assessment scale

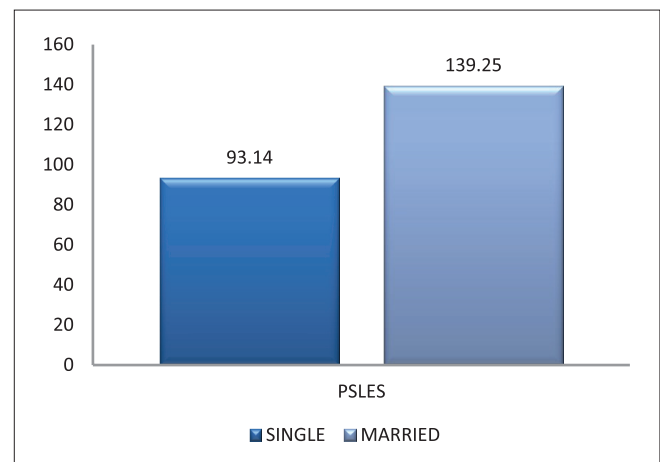


Figure 1: Relation between presumptive stressful life events scale and marital status

2003).^{5,15,16} The results of our study differed from the previous studies in this aspect. Fleischmann *et al.* (2005) have also reported that most of the suicide attempters were married than single in India (Figure 1).¹⁷

Our study shows that there was a correlation between psychosocial stressors and suicidal ideation similar to previous studies. Our study shows that individuals with high intent score had a high risk as well as high lethality. Hence, assessment of the suicidal intent should form a part of all suicide evaluation prevent the risk of further suicidal ideation or attempt (Vijayakumar, 2011).¹⁸ The risk of suicide among self-harm patients is highest within the first year following the episode of self-harm. In our study also recurrent suicide attempters had reattempted suicide within 1 year of the previous attempt. Harris *et al.* (2005)¹⁹ and Horrocks *et al.*, (2003)²⁰ have also shown that individuals with the high intent of suicide were more likely to die within 12 months of their index episode than those with low intent scores.

Our study shows that suicidal intent correlated significantly with lethality of the attempt. Compared to first-time attempters, patients with multiple attempts tended to show higher lethality. Similarly, planned suicide had a high lethality than impulsive attempts, though other studies have reported that impulsive attempts were associated with higher lethality compared to planned attempts (Kar *et al.* (2014)).²¹

Suicide attempts in psychiatric disorder, personality disorder and substance use disorders were not analyzed in this study. Being a cross-sectional study further follow-up could not be done.

CONCLUSION

Gender and interpersonal conflict have a major role in expression of suicidal behavior. Unlike in the developed countries, marital and other social stressors are frequently implicated in suicidal attempts as compared to existing psychiatric illness. The correlation between suicidal intent scores and stress scores suggest that the influence is direct. Suicidal intent evaluation should be included as a prominent part of suicide evaluation as it is associated with lethality and risk of further attempts.

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Incidence and Outcome of H1N1 Cases in a Tertiary Care Hospital in South India: A Retrospective Observational Study

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Abstract

Introduction: Influenza virus infection is a common, easily contagious, acute febrile illness which ranges from a mild fatigue to acute respiratory distress syndrome (ARDS), respiratory failure or death. H1N1 pandemic had its significantly great impact in India from April 2009 to August 2010. Those with comorbid illnesses get more severe and fatal illness. High mortality among young and healthy age group is a real matter of concern which also needs further studies.

Materials and Methods: The epidemiological data of patients admitted to the Medical College Hospital, Kalamassery, Ernakulam District of Kerala from 2009 April to 2016 July were analyzed from the medical records library and from the epidemiological data section.

Results: During 2009-2010 period, an epidemic of H1N1 fever about 32 cases was admitted to the special ICU of the nodal center. There were 3 deaths among the cases (9.4%). All of them were sick referred cases and in the age group 25-35 years. 2 of them were females. They all had viral bronchopneumonia and ARDS. Over the next 6 years until July 2016, no further cases have been recorded in the area. The monthly trend was plotted in multiple line diagrams and shows that the fever surge every year is almost similar with a clear-cut rise from the month of May with the beginning of the monsoon and lasting till the end of September with the close of the monsoon.

Conclusion: H1N1 influenza caused severe illness requiring admissions. The major cause of death was viral bronchopneumonia and ARDS. A high index of suspicion, prompt treatment with Oseltamivir and mechanical ventilation had a role in reducing the mortality. There was a definite peaking of H1N1 in the monsoon. Vaccination and special focus and studies of the young target population are mandatory.

Key words: Fever mortality, H1N1, Influenza, Oseltamivir

INTRODUCTION

Influenza virus infection is a common illness and very easily contagious. It causes an acute febrile illness which ranges from a mild fatigue to acute respiratory distress syndrome (ARDS), respiratory failure or death. H1N1

Influenza virus is a new virus which came up in late April 2009 in Kerala and probably originated in the pig farms in Mexico.¹⁻⁴ Hence, it was called swine flu. Inside the pigs a genetic reassortment occurred to the usual influenza viruses resulting in the new H1N1 virus. The virus was introduced to human beings and thereafter spread from man to man. H1N1 pandemic had its significantly great impact in India from April 2009 to August 2010. Kerala and Maharashtra were the most affected. It came like any other flu-like illness, and people were unprepared to face such a new epidemic especially with its similarity to usual flu-like illness but so different in its fiery complications.⁵⁻⁸ Morbidity and mortality is more among the elderly, children, and pregnant females. Signs and symptoms are similar

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to other flu viruses but much different in infectivity and virulence. The secondary attack rate in India ranged from 22% to 33%.⁹⁻¹² The overall mortality is 0.1-0.3%.² H1 indicates the type of hemagglutinin enzyme on the virus surface and N1 indicates the type of neuraminidase enzyme. H1N1 pandemic of 2009 caused maximum mortality among the young population. 2560 cases of swab positive reports occurred of which 80 died in Kerala State in 2009.¹ Of these 22 were associated with pregnancy or postpartum period. During the second attack in 2010 May to July, almost 946 swab-positive cases were reported of which 43 died and 14 were related to pregnancy.² H1N1 can cause asymptomatic infection or uncomplicated upper respiratory infection or severe pneumonia with multi-organ failure too. Diagnosis requires clinical, and epidemiological data as any other virus can cause influenza-like illness. It can be confirmed by laboratory data. Hence, the treatment should not be delayed at any cost. Those with comorbid illnesses get more severe and fatal illness. Rapid deterioration can occur in any patient in a few hours time.² High-risk groups include infants and young children, pregnant women, chronic respiratory illnesses, cardiac disease, diabetes, chronic kidney or liver failure or central nervous system diseases, immune suppression, hemoglobinopathies, and elderly.

Aims and Objectives

To look at the incidence and outcome of H1N1 patients over a 7-year period in a tertiary care center in South India compared to other specific causes of fever. A retrospective observational study.

MATERIALS AND METHODS

The epidemiological data of patients admitted to the Medical College Hospital, Kalamassery, Ernakulam District of Kerala from 2009 April to 2016 July were analyzed from the medical records library and from the epidemiological data section. The institution was a regional nodal center for admission and treatment of H1N1 cases in 2009 - 10. The total admissions, number of admissions with fever, total mortality and mortality of fever cases, and that of H1N1 were looked at.

Limitations

Under-reporting of many fever cases especially outpatient department (OPD) cases and those attending the casualty during non-OPD hours. Nonavailability of computer based data. This must have caused a certain amount of errors.

RESULTS

A total of about 54000 patients attended the hospital with fever in the medicine and allied departments during 2009

to 2016 July (Figure 1). Unidentified viral fevers, acute diarrheal diseases and simple respiratory infections topped the list. Other specific fevers were charted and found that pneumonias topped the list followed by tuberculosis, dengue fever, exanthematous fevers, hepatitis, typhoid, meningitis, and leptospirosis (Figure 2). During 2009-2010, there was an epidemic of H1N1 fever and along with other states especially Maharashtra, Kerala was one of the worst-hit states. This institution was one of the nodal centers in the middle part of Kerala and the cases admitted here during the time were included in the statistics. It was found that among the many number of cases which reported with suspected H1N1 fever about 32 cases were admitted to the special ICU of the nodal center (Figure 3). The throat swabs were sent and found to be positive. There were 3 deaths among the cases (9.4%). All of them were sick referred cases and in the age group 25-35 years. 2 of them were females. They all had viral bronchopneumonia and ARDS. Over the next 6 years until July 2016, no further cases have been recorded in the area. The monthly trend was plotted in multiple line diagrams (Figure 4) and shows that the fever surge every year is almost similar with a clear-cut rise from the month of May with the beginning of the monsoon and lasting till the end of September with

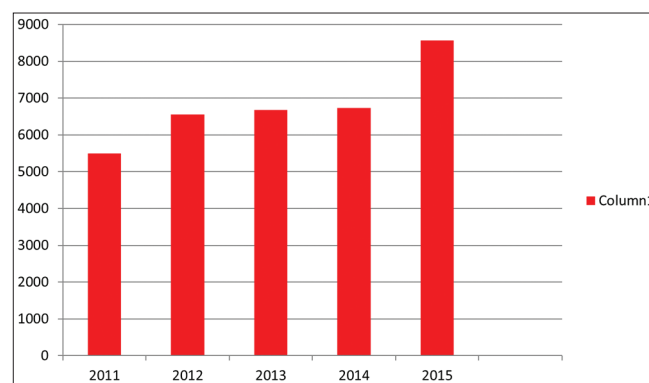


Figure 1: Bar chart showing the trend of total fever cases over last 5 years

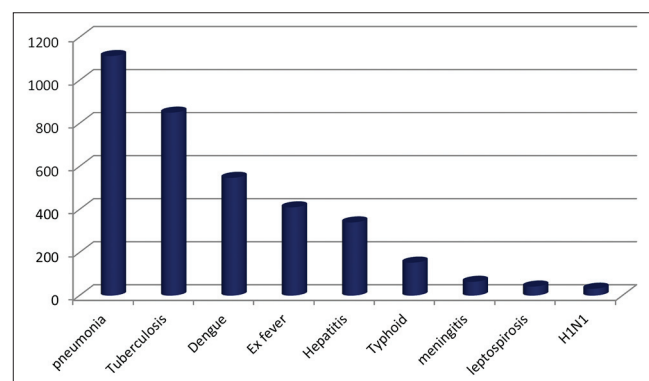


Figure 2: The incidence of different fevers excluding common viral fever, simple respiratory infection, UTI and acute diarrheal diseases

the close of the monsoon. The percentage of fever which needs IP care remained almost the same (13.5-15.5%) over the last 3 years (Figure 5). All H1N1 cases which came to the nodal center were given special ICU care.

The mortality pattern of different fevers was looked into and it was observed that complicated leptospirosis topped the list mostly due to delayed presentation (Figure 6).

DISCUSSION

During June 2009-2010 August H1N1 pandemic, Kerala was affected badly along with other states especially Maharashtra. Among the many number of cases which reported with suspected H1N1 fever about 32 cases were admitted to the special ICU of the nodal center. The

throat swabs were sent and found to be positive. There were 3 deaths among the cases (9.4%). All of them were sick referred cases and in the age group 25-35 years. 2 of them were females. One of them was a pregnant lady and all were without any other underlying health problems. They all presented late and had viral bronchopneumonia and ARDS. This is consistent with the state and national clinical profile.¹ The mortality was 9.4%. Bhatt *et al.* have described an in hospital mortality of 58.53%,² whereas Rama *et al.* have observed a mortality of 17.19% in a study in 2015.³ The overall mortality is only 0.3-0.5%.¹ The observed relatively high mortality percent compared to the state, and national mortality is probably because the statistics is from a nodal apex center. H1N1 has a high mortality rate even in the best institution. All patients were, however, treated with the existing oseltamivir regimen and supportive treatment including ventilation. All the exposed was also given oseltamivir and none of the contacts or caring staff who were on oseltamivir developed the disease despite closely working with the patients. This showed the efficacy of oseltamivir regimen during the pandemic both in prophylaxis as well as in treatment. Bhat *et al.* have identified poor prognostic factors as the development of ARDS, comorbid medical conditions and delay in starting antiviral therapy.² The epidemiologic hallmark of pandemic influenza is its early mortalities among young healthy individuals.⁸ Early identification, treatment, and isolation of ILI is important in spread of the disease as well as prevention of morbidity and mortality.³

Over the next 6 years until July 2016, no further cases have been recorded in the area. This shows that H1N1 has ceased spreading in the locality due to excellent and combined preventive measures taken by the honourable

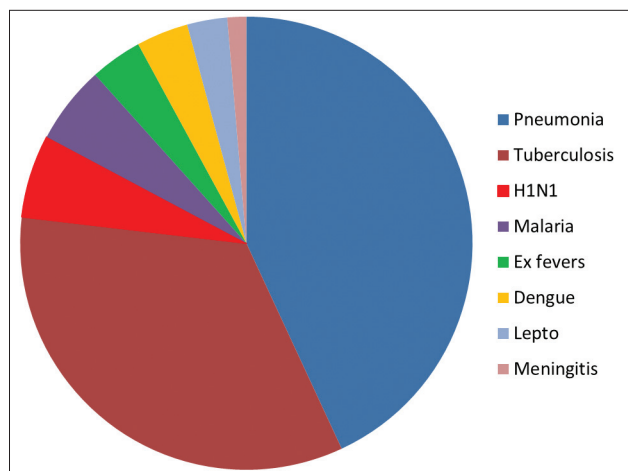


Figure 3: Pie chart showing the differential incidence of specific fevers during 2009 - 2010

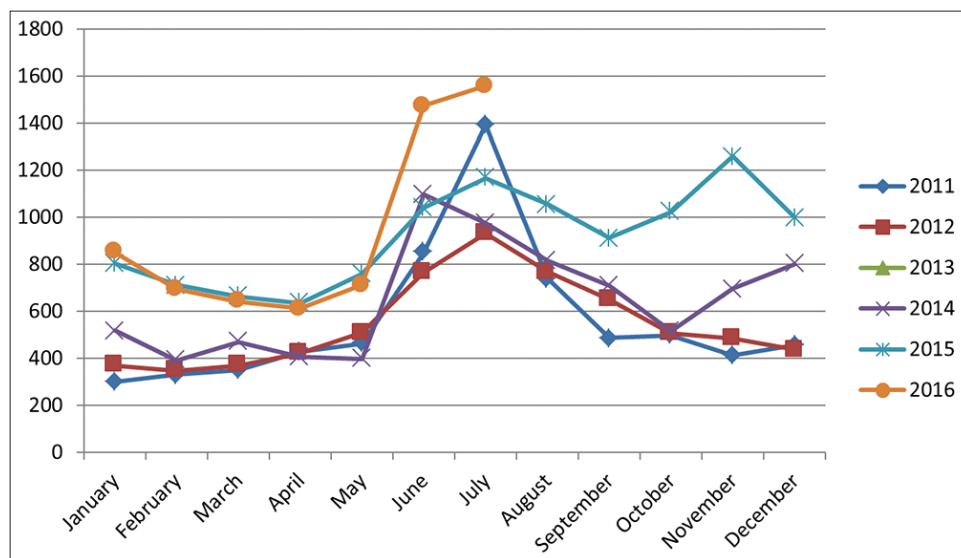


Figure 4: The monthly trend of fever cases over a 6 year period

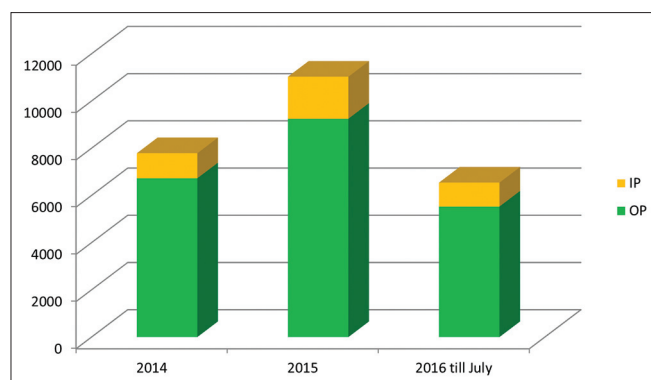


Figure 5: Bar diagram showing the OP-IP ratio of fever cases over the last 3 years

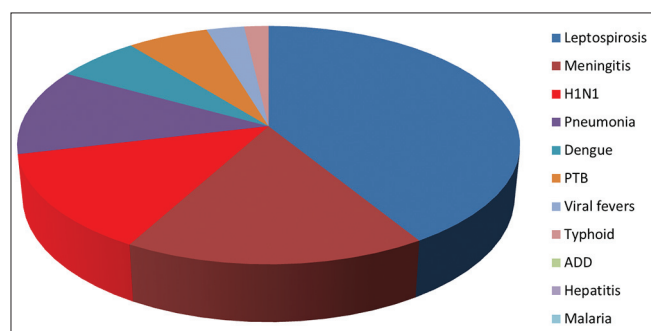


Figure 6: Pie chart showing the mortality pattern in the study

government agencies and the NGOs. Herd immunity attained during this period may be another important reason besides other epidemiological factors, why fresh cases have not occurred despite the epidemic running in other H1N1 naive areas of our country. The monthly trend of all fevers put together showed a definite peaking in the monsoon with the onset in May and return in September. This correlates with the mosquito breeding period especially because of the pooling of water in small or big collections. However, with the prompt use of effective medical as well as environmental measures, the epidemic in the area could be controlled and no further cases have been reported 5 years down the line. Unlike the average flu, H1N1 tended to kill younger people; 80 % were <60 years and almost the third were healthy with no underlying health problems.⁵ Kadam *et al.* have noted that young to middle-aged patients were commonly affected and common comorbidities were pregnancy, diabetes, hypertension, and obesity.⁶ In delayed presentations, there can be a 30 % mortality.⁵ There was no case reported in the region after August 2010. This may be due to screening of all immigrants, efficient surveillance, early detection and optimal treatment of cases and contacts, setting up of adequate laboratory facilities, provision of antiviral drugs in adequate quantities, isolation of cases and prophylactic measures including oseltamivir, anti mosquito measures, environmental sanitation and N 95 masks through the

best efforts of government and NGOs which brought the pandemic to a halt in India too. However, a revisit in other states of India after 6 years points to the possibility of further mutations or the naive nature of the susceptible populations.^{5,12-14}

CONCLUSION

During the evaluation period, H1N1 influenza caused severe illness requiring admissions. The major cause of death was viral bronchopneumonia and ARDS. A high index of suspicion, prompt treatment with oseltamivir, and mechanical ventilation had a role in reducing the mortality. There was a definite peaking of H1N1 in the monsoon. What worries an epidemiologist as well as the clinician most is the ability of the influenza virus to undergo frequent and unpredictable mutations which can result in the emergence of an even more virulent virus in future and epidemiological and clinical vigilance is warranted. Vaccination and special focus and studies of the young target population are mandatory.

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Correlation of Methods of Glomerular Filtration Rate Estimation - 24 h Urinary Creatinine Clearance, Predicted Creatinine Clearance Method (Cockcroft-Gault), and Camera Based TC-99m-diethylenetriaminepentaacetic Acid Renography in Patients of Diabetic Nephropathy

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Abstract

Introduction: Glomerular filtration rate (GFR) is the most important measure for early detection of deterioration of renal function. Patients with diabetic nephropathy need to be intensely monitored with GFR value. Many methods are used to estimate the GFR, all having their own advantages and constraints. The correlation of these methods with each other in patients with diabetic nephropathy needs to be studied.

Purpose: To correlate three widely used methods of GFR estimation, namely 24 h urinary creatinine clearance (CrCl), predicted CrCl method (Cockcroft-Gault [CG]), and camera based Tc-99m-diethylenetriaminepentaacetic acid (DTPA) renography (by Gates' protocol), in cases of diabetic nephropathy and to study the effect of duration of disease on renal function.

Materials and Methods: A total of 52 cases of diabetic nephropathy were studied, and GFR was estimated by all the above three methods simultaneously. Correlation between variables was performed using commercially available statistical software (Minitab 15). Bland-Altman recommendations were used to compare the GFR calculated with CG formula and 24 h CrCl with the TC-99m-DTPA renogram method. Pearson's correlation was used to assess the relationship between variables.

Results: The mean GFR obtained with 99mTc-DTPA renogram, 24 h CrCl, and CG method were 63.24 ml/min \pm 22.39 ml/min, 43.06 \pm 13.83 ml/min, and 54.87 \pm 18.25 ml/min, respectively. There was a significant correlation between GFR by 99mTc-DTPA versus endogenous CrCl ($P < 0.001$, $r = 0.830$) and 99mTc-DTPA versus CG formula ($P < 0.001$, $r = 0.919$).

Conclusion: There is a wide variation in the absolute values of GFR obtained by the three methods although all the three methods correlate well with each other. If the same method is used for follow-up, it is highly reliable in detecting the deterioration of renal function from the baseline value. However, these methods cannot be used interchangeably.

Key words: Cockcroft-Gault method, Creatinine clearance, Glomerular filtration rate, Renogram, Tc-99m-diethylenetriaminepentaacetic acid

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INTRODUCTION

Diabetic nephropathy is the leading cause of end-stage renal failure. Identification of early deterioration of renal function is most important in delaying the progression of renal damage.^{1,2} Glomerular filtration rate (GFR) is the best measure of renal function and serum creatinine

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concentration alone should not be used to assess the level of kidney function.³ There are many methods to estimate GFR. Inulin clearance is the gold standard; however, not performed in clinical practice, because of its technical complexity and limited availability. 99mTc-diethylenetriaminepentaacetic acid (DTPA) based plasma sampling methods are also very accurate but are very laborious involving multiple plasma samples.

Endogenous creatinine clearance (CrCl) estimation is widely used but is dependent on accurate collection of 24 h urine which is inconvenient and prone to collection failures and thus errors. It does not improve the estimate of GFR over that provided by prediction equations.³ The prediction equations to calculate GFR take into account serum creatinine concentration and some or all of the following variables: Age, gender, race, and body size. The modification of diet in renal disease (MDRD) formula and Cockcroft-Gault (CG) equations are the ones commonly used. However, these calculations also have intrinsic limitations in relation to all the variables used for calculation and the fact that these equations have been derived from Caucasian population.^{1,4,5}

Tc-99m-DTPA renography is being used very frequently for assessing renal function. It is a gamma camera based method simple to perform, reproducible, can assess individual kidney function and also detects additional abnormalities like obstructive uropathy. It does not require plasma sampling. The method introduced by Gate's is most commonly used.⁶ Most of the clinicians nowadays have started utilizing the gamma camera based method. However, the diagnostic accuracy of this has always been debated.⁷⁻¹⁵ There are studies comparing the formula based methods and Gate's method with the more accurate plasma sampling methods, each study having different conclusions.^{4,5,16,17} Simple and accurate determination of GFR still remains a challenge as was mentioned by Swan way back in 1997.¹⁸

In diabetics, in whom GFR value is the most important measure for early detection of deterioration of renal function, how do all these methods correlate? It is an important question to be answered. We undertook this study to correlate these three widely used methods of GFR estimation namely formula based CG method, 24 h urinary CrCl and Tc-99m-DTPA renography in cases of diabetic nephropathy.

MATERIALS AND METHODS

The study was conducted at a tertiary care hospital and cases of diabetic nephropathy as evidenced by microalbuminuria,

macroalbuminuria or raised creatinine levels, reporting to medical outpatient department or admitted in the wards over 6 months and who agreed to be part of the study were included. The patients with any other preexisting renal disease or with acute complications of diabetes were excluded from the study. A total of 52 cases were studied after obtaining their consent. In all the 52 patients, 24 h urine was collected and simultaneously blood samples for serum creatinine were collected. Serum and urine creatinine were measured using a kinetic alkaline picrate assay. Age, body weight, and height were recorded on the same day.

About 24 h urine CrCl was estimated using urine/plasma creatinine ratio (UV/P) formula, where U is the concentration of creatinine in urine in mg/dl and V is the volume of urine produced per minute and P is the plasma creatinine in mg/dl.

CG's method-predicted CrCl was calculated according to the equation of CG formula: $GFR (ml/min) = ([140 - \text{age (years)}] \times \text{body weight (kg)}) / [72 \times SCr (mg/dl)] \times 0.85$ for women).

Renography - GFR assessment by 99mTc-DTPA renography was done using Gates' protocol. The GFR was calculated using Gate's formula in renal software. The patient height (in cm) weight (in kg), age (in years), and sex were fed as input according to the program. Then, the percentage of injected dose (% ID) is calculated for each kidney.

$$\% ID = (K - B) \times 100 / I \times S \times D$$

Where, % ID = Percentage ID

I = Injected activity (in MBq)

S = Camera sensitivity (in Cts/min/MBq)

K = Kidney region (Cts/min)

B = Background region (Cts/min)

D = Depth correction.

$$GFR (ml/min/1.73 m^2) = (\% ID \text{ left} + \% ID \text{ right}) \times 9.8127 - 6.8252$$

The patients were advised to be on a normal diet and well hydrated before study. They were further asked to drink 5 ml/kg of water half an hour before the study and were asked to void before start of the study. 99mTc-DTPA was prepared 30-60 min before injection using a fresh elute and a DTPA kit (supplied by Board of Radioisotope Technology, Mumbai), 5 mCi of radiopharmaceutical was injected intravenously through antecubital vein and followed by infusion of 20 ml of normal saline after obtaining the pre syringe counts for 1 min under the camera. Supine posterior imaging was done. Images were

acquired initially as 2 s frames for 1 min and then 10 s frames for 25 min. Post syringe counts were then taken in the same way as pre syringe counts. A large field of view and low energy, all purpose, and parallel hole collimator was used. Photopeak - 15% window centered over 140 keV (^{99m}Tc). The region of interest (ROI) over each kidney was drawn on the composite frames for 3 min. Elliptical background ROI was drawn below and lateral to kidney avoiding scatter, liver, spleen, and gut. Gates protocol was used for depth correction and time activity curve was generated using computer software.

The results of the UV/P, CG, and ^{99m}Tc -DTPA GFR were corrected to body surface area (BSA) of 1.73 m^2 ($1.73/\text{BSA}$). BSA was estimated according to Mosteller formula.

The results from the three different methods of GFR estimation were analyzed statistically. Correlation between variables was performed using commercially available statistical software (Minitab 15). Bland-Altman recommendations were used to compare the GFR calculated with Cockcroft formula and 24 h endogenous CrCl with the renal clearance of ^{99m}Tc -DTPA (gamma camera based method - Gates method). Pearson's correlation was used to assess the relationship between variables, analysis of variance, and student's *t*-test was used to find a significance of GFR by DTPA, GFR by CG method and 24 h endogenous CrCl. Results are shown as mean \pm Standard deviation.

Classification of correlation of co-efficient: (a) Upto 0.1 - trivial correlation, 0.1-0.3 - small correlation, 0.3-0.5 - moderate correlation, 0.5-0.7 - large correlation, 0.7-0.9 - very large correlation, 0.9-1.0 - nearly perfect correlation and 1 - perfect correlation.

RESULTS

A total of 52 patients with diabetes mellitus (DM) with varying stages of nephropathy were included in the study. 48.1% ($n = 25$) were males, 51.9% ($n = 27$) were females, and the mean age was 56.85 ± 10.44 years (35-74 years). Their mean BSA was $1.69 \pm 0.09 \text{ m}^2$ and mean serum creatinine and blood urea nitrogen were $1.35 \pm 0.49 \text{ mg/dl}$ and $17.08 \pm 4.47 \text{ mg/dl}$, respectively. The distribution of cases based on duration of illness is given in Table 1.

The values of mean GFR ($\text{ml/min}/1.73 \text{ m}^2 \text{ BSA}$) by ^{99m}Tc -DTPA gamma camera based method, the endogenous GFR by 24 h urine CrCl and eGFR by Cockcroft-Gault equation, as well as other study variables, are given in Table 2.

Table 1: Distribution of cases of diabetic nephropathy based on duration of illness

Duration of illness	Number of patients (%)
1-5 years	21 (40.4)
5-10 years	21 (40.4)
>10 years	10 (19.2)
Total	52 (100.0)

Table 2: Descriptive statistics of study variables

Variables	Minimum	Maximum	Mean \pm SD
Age in years	35	74	56.85 \pm 10.44
Weight (kg)	6	76	62.00 \pm 9.41
BSA (m^2)	1.52	1.91	1.69 \pm 0.09
Duration of illness (years)	1	20	6.92 \pm 4.34
Serum creatinine (mg/dl)	0.6	2.8	1.35 \pm 0.49
eGFR-Cockcroft-Gault method	22	111.26	54.87 \pm 18.25
GFR-endo CrCl	17.52	76.56	43.06 \pm 13.83
GFR- ^{99m}Tc DTPA renogram			
Right kidney	12.60	58.00	31.06 \pm 10.45
Left kidney	10.00	70.00	32.16 \pm 13.26
Mean GFR	24.40	128.00	63.23 \pm 22.39

BSA: Body surface area, GFR: Glomerular filtration rate, DTPA: Diethylenetriaminepentaacetic acid, CrCl: Creatinine clearance, SD: Standard deviation

Table 3: Mean GFR of 24 h urine CrCl, CG method, and ^{99m}Tc -DTPA according to age

Age in years	Number of patients	GFR by 24 h endogenous CrCl	GFR-CG method	GFR by ^{99m}Tc DTPA clearance
35-40	5	51.73 \pm 17.45	78.23 \pm 20.27	81.20 \pm 29.96
41-50	12	43.75 \pm 11.77	56.51 \pm 17.31	65.20 \pm 24.46
51-60	15	48.98 \pm 15.48	60.06 \pm 18.58	71.01 \pm 21.53
61 and above	20	36.03 \pm 9.62	44.15 \pm 9.6	51.75 \pm 13.95
Total	52	43.06 \pm 13.83	54.87 \pm 18.25	63.24 \pm 22.39
P	-	0.015*	<0.001**	0.011*

*Moderately significant ($P: 0.01 < P \leq 0.05$). **Strongly significant ($P \leq 0.01$) GFR: Glomerular filtration rate, CrCl: Creatinine clearance, DTPA: Diethylenetriaminepentaacetic acid, CG: Cockcroft-Gault

To study the effect of age, the mean GFR obtained with ^{99m}Tc -DTPA, 24 h urine CrCl and Cockcroft-Gault formula were analyzed as per age (Table 3 and Figure 1). The GFR by ^{99m}Tc -DTPA was the highest in each group, followed by eGFR (CG formula) and the lowest was by 24 h urine CrCl. There was fall in GFR with an increase in age in the adult population and all the three methods correlated well with each other ($P < 0.001$) (Table 3 and Figure 1).

As disease duration of diabetes in a patient can affect renal function, the findings were analyzed for various disease durations of diabetes. The mean GFR obtained with ^{99m}Tc -DTPA, 24 h urine CrCl and CG formula according to disease duration between 1 and 5 years was $75.27 \pm 23.71 \text{ ml/min}$, $50.87 \pm 14.29 \text{ ml/min}$, and $66.78 \pm 18.43 \text{ ml/min}$, respectively; for disease duration

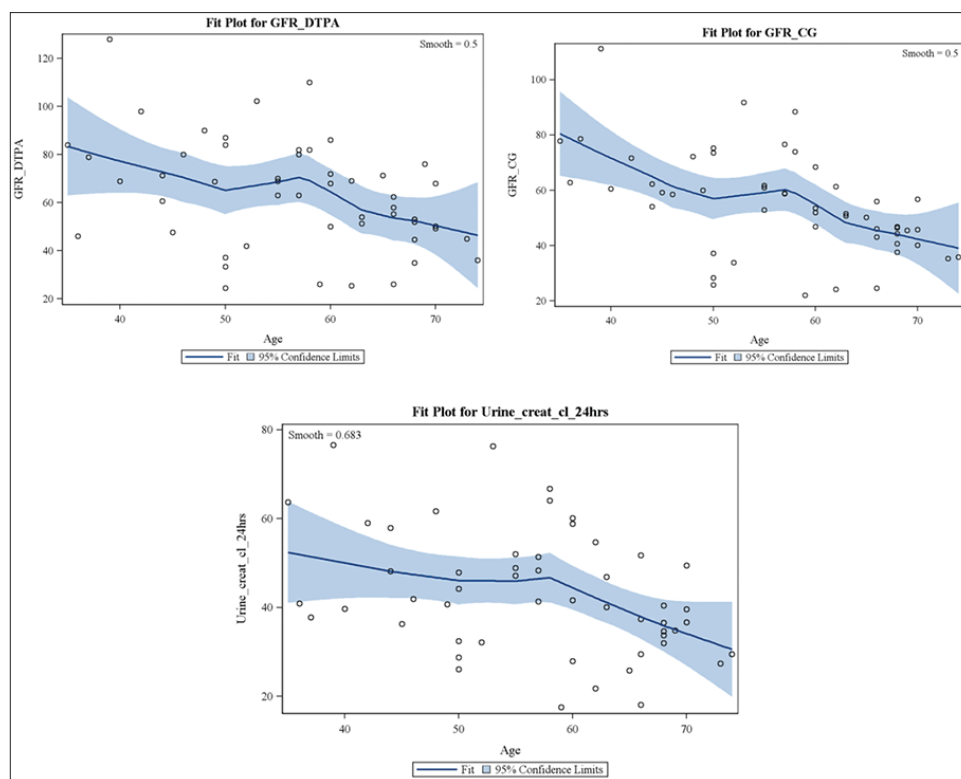


Figure 1: Fit plot graphs showing relation of glomerular filtration rate by ^{99m}Tc diethylenetriaminepentaacetic acid, Cockcroft-Gault formula, and 24 h urine creatinine clearance with age

between 5 and 10 years it was 57.61 ± 19.31 ml/min, 38.18 ± 11.07 ml/min, and 48.22 ± 14.16 ml/min, respectively and for disease duration >10 years was 49.79 ± 12.25 ml/min, 36.89 ± 10.89 ml/min, and 43.81 ± 10.84 ml/min, respectively (Table 4). The decrease in GFR with the duration of illness was significant in all the three methods.

The mean GFR obtained with ^{99m}Tc -DTPA camera based method was 63.24 ml/min ± 22.39 ml/min, whereas by 24 h urine CrCl was 43.06 ± 13.83 ml/min ($P = 0.015$) and by CG formula was 54.87 ± 18.25 ml/min (Tables 2-4). The mean values of eGFR by CG formula were nearer to the mean GFR obtained with ^{99m}Tc -DTPA camera based method. GFR from 24 h urine CrCl was the lowest. GFR values by ^{99m}Tc -DTPA (Gates method) were >15.2% compared to CG formula and GFR values by CG method were >21.5% compared to 24 h urine CrCl.

GFR by all the three methods was normally distributed by D'Agostino and Pearson omnibus normality test. There was a significant correlation between GFR by ^{99m}Tc -DTPA versus end CrCl ($P < 0.001$), ^{99m}Tc -DTPA versus CG formula ($P < 0.001$) (Figures 2 and 3). The coefficient of correlation (r) of ^{99m}Tc -DTPA (Gates' method) and endogenous CrCl was $r = 0.830$ (very large correlation)

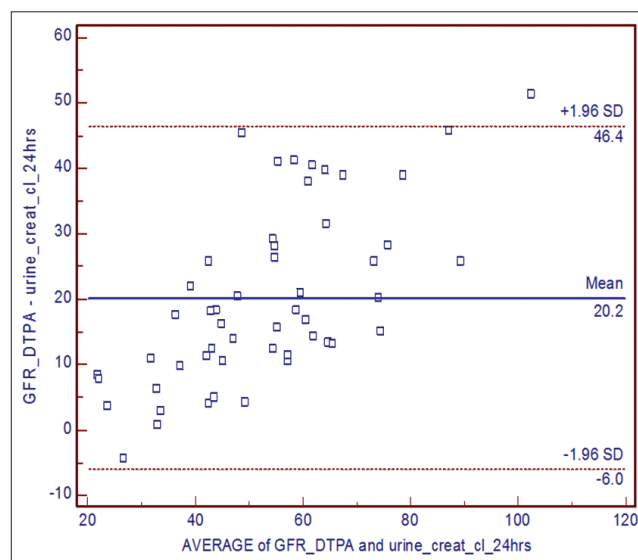


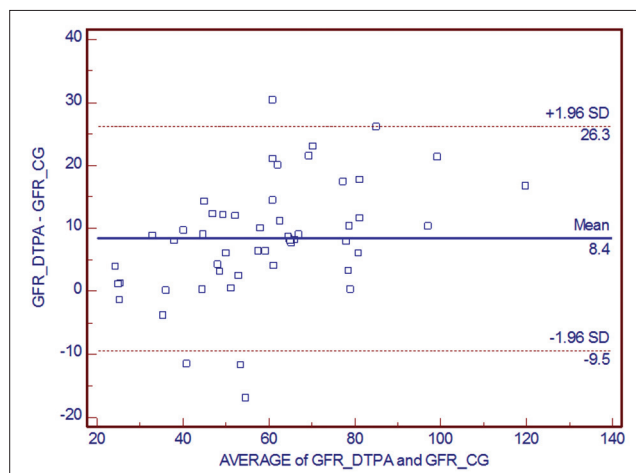
Figure 2: Bland-Altman plot for correlation of glomerular filtration rate by diethylenetriaminepentaacetic acid and 24 h urine creatinine clearance

and coefficient of correlation (r) of ^{99m}Tc -DTPA and Cockcroft formula, $r = 0.919$ (nearly perfect correlation). An assessment of the plots (Bland-Altman plot) of GFR estimation by Cockcroft-Gault formula and 24 h urine CrCl compared with Tc- 99m -DTPA clearance by camera based method (Gates method) showing that they correlate well (Figures 2-4).

Table 4: Mean GFR by 24 h urinary CrCl, CG method, and 99mTc-DTPA according to duration of illness

Duration of illness	Number of patients	GFR by 24 h urine CrCl	GFR-CG method	GFR by Tc-99m-DTPA scan
1-5 years	21	50.87±14.29	66.78±18.43	75.27±23.71
5-10 years	21	38.18±11.07	48.22±14.16	57.61±19.31
>10 years	10	36.89±10.89	43.81±10.84	49.79±12.25
Total	52	43.06±13.83	54.87±18.25	63.24±22.39
P	-	0.002**	<0.001**	0.003**

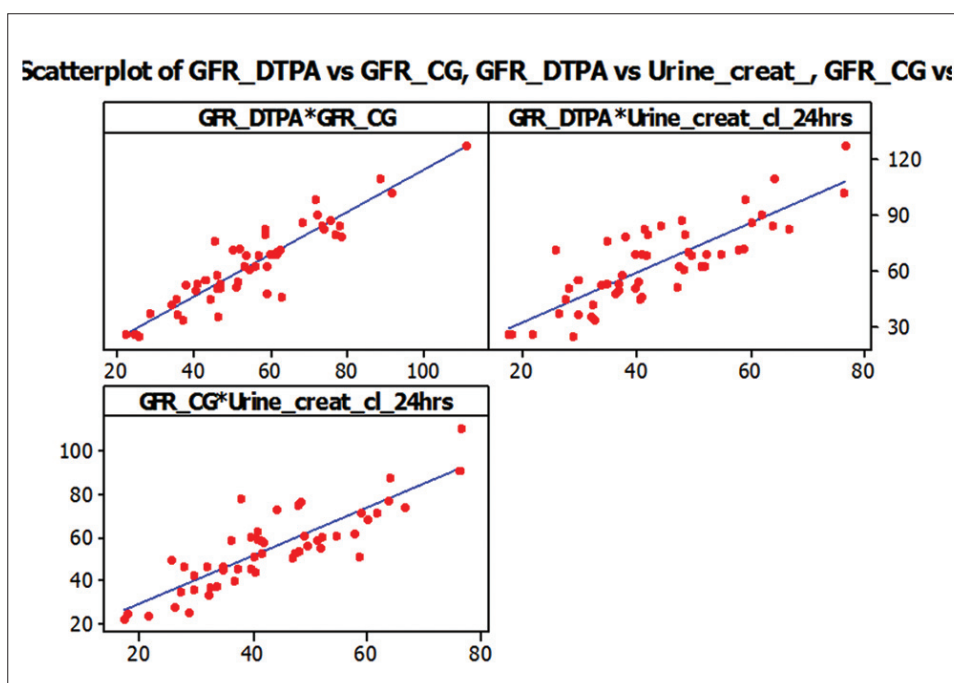
**Strongly significant ($P \leq 0.01$). GFR: Glomerular filtration rate, CrCl: Creatinine clearance, DTPA: Diethylenetriaminepentaacetic acid, CG: Cockcroft-Gault

**Figure 3: Bland-Altman plot for correlation of glomerular filtration rate by 99mTc diethylenetriaminepentaacetic acid and glomerular filtration rate by Cockcroft-Gault method**

DISCUSSION

Diabetic nephropathy is the leading cause of end stage renal failure. Approximately, 20-30% of all diabetics will develop evidence of nephropathy. GFR is generally considered the best measure of renal function in health and in disease.^{1,2} However, simple and accurate measurement of GFR still remains a challenge.¹⁸ The correlation of the commonly used methods of GFR estimation exclusively in the patients of diabetic nephropathy needs to be evaluated. We undertook this study, to correlate the three commonly used methods - 24 h CrCl, CG formula based method, and Tc-99m-DTPA renography in the patients of diabetic nephropathy.

Our results show that GFR value obtained by Tc-99m renography (Gates method) is highest, followed by the CG method with intermediate values and the 24 h clearance method showing the least values. This trend was seen in all the subsets of diabetics. The question remains as to which of these is the accurate value. We have not compared the values with any gold standard method to answer this question. However, all the three methods showed good correlation with each other. There was a significant correlation between GFR by 99mTc-DTPA versus 24 h CrCl ($P < 0.001$), 99mTc-DTPA versus CG formula ($P < 0.001$). The coefficient of correlation (r) of 99mTc-DTPA (Gates' method) and endogenous CrCl was $r = 0.830$ (very large correlation) and coefficient of correlation (r) of 99mTc-DTPA and Cockcroft formula, $r = 0.919$ (nearly perfect correlation).

**Figure 4: Scatterplots of glomerular filtration rate values of 99mTc diethylenetriaminepentaacetic acid (Gates' method) versus Cockcroft-Gault, 99mTc diethylenetriaminepentaacetic acid (Gates' method) versus 24 h urine creatinine clearance, and Cockcroft-Gault versus 24 h urine creatinine clearance**

There are many studies available in the literature comparing these three methods, each study having different opinion about the correlation among them and the relative superiority of each method.^{4,5,16,17} Many studies have revealed that Gates method overestimates the GFR.^{13,14} Itoh in his study of 133 patients with a wide range of renal function, compared Tc-99m-DTPA renography (Gates method) and CG method using plasma sample clearance method as reference. He concluded that Gates method tended to overestimate the GFR and contrarily CG tended to underestimate the GFR. He concluded that Tc-99m-DTPA renography is not suitable for GFR estimation.¹⁶ Our study has shown similar trend.

Prasad *et al.* in their study involving 897 patients with a wide range of renal function concluded that Gates method correlates better with plasma sampling method than formula based MDRD method, although overall both the methods showed poor correlation with the reference method making them suboptimal for clinical use. Both these methods overestimated GFR at lower levels of renal function and underestimated it at higher levels of renal function.¹⁷

There are many formula based methods described to calculate and predict the GFR by incorporating serum creatinine level and various biometrical variables.¹⁹ MDRD and C-G formulae are most commonly used. We studied the CG method in our study. However, it has been debated whether the equations correctly depict the GFR.^{16,19,20,21} Virga *et al.* evaluated the performance of 12 different creatinine-based equations in predicting the CrCl in patients on peritoneal dialysis and found that Gates, Virga, and 4-MDRD showed best results while the CG formula revealed a rather poor reliability.²² Actually, there are so many variables involved in calculating the GFR by the formula based methods, starting from the accurate measurement of serum creatinine itself and the various biometric parameters that the accuracy will always be doubtful.

In Tc-99m-DTPA renography, the method introduced by Gates is most commonly used, because of greater ease of administration, simplicity, accuracy, and precision of measurement.⁶ The GFR is calculated without blood or urine sampling. It has the added advantage of greater reproducibility and assessment of individual kidney function. It also detects additional renal abnormalities like obstructive uropathy. However, even in this, there are so many variables involved such as background correction, ROI drawn, state of hydration of patient, and calibration of camera. A simple change in the ROI drawn leads to a huge difference in GFR value.

Hence, the search for an ideal and simple way to measure GFR which can be close to inulin clearance and

radioisotope plasma sampling methods still continues. Our study had a few limitations as we did not use the reference gold standard method and the sample size was limited to the duration of the study.

However, this study clearly shows that there is a good correlation in the three methods of measuring GFR (99mTc-DTPA, 24 h urine CrCl and Cockcroft-Gault formula) and a significant fall in mean GFR obtained with age and with an increase in disease duration. This indicates that irrespective of the method used, the same method should be used for subsequent follow-up to accurately detect fall in GFR.

CONCLUSION

There is a wide variation in the absolute values of GFR obtained by the three methods (24 h CrCl, CG method of eGFR calculation, and Tc-99m-DTPA renography). Hence, it still remains questionable as to which is the most accurate method and it is also clear that these methods cannot be used interchangeably in the same patient for follow-up. However, one finding is evident that if the same method is used for follow-up, it is highly reliable in detecting the deterioration of renal function from the baseline value. The study also shows the steady decline in GFR with age and duration of diabetes and reiterates the importance to follow-up the patients of DM with GFR value for early detection of deterioration in kidney function.

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Prevalence, Clinical Presentation, and Management of Incisional Hernia in the Indian Population: A Cross-sectional Study

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Abstract

Introduction: Incisional hernia is a type of hernia caused by an incompletely healed surgical wound, and the abdomen is the most common site of its occurrence. The aim of the present study is to analyze the incidence, etiopathogenesis, various modes of presentation, and different therapeutic modalities of incisional hernia in developing countries like India.

Materials and Methods: This is a prospective and observational study conducted on 100 patients. Demographic profile and data regarding the type of surgery, post-operative complication, and duration after which incisional hernia developed were recorded in pro formas. The data were tabulated and analyzed for statistical significance using univariate and multivariate analysis.

Result: Incisional hernia occurs most commonly in the age group of 41-50 years. Incidence is more common in females with female to male ratio of 1.6:1. Maximum cases (48%) of incisional hernia occurred between 6 months and 1 year after surgical intervention. Most common cause for incisional hernia was found to be post-operative infection (47%). Incisional hernias occur more commonly in lower abdominal and gynecological surgeries. Laparoscopic hernioplasty is the first line of treatment for uncomplicated incisional hernias.

Conclusion: In Incisional hernias, the choice of operative technique is crucial. Mesh repair is considered superior to anatomical repair alone, and we recommend laparoscopic hernioplasty as the first line of treatment.

Key words: Hernioplasty, Incidence, Incisional hernia, Recurrence

INTRODUCTION

Hernia is defined as the gap in the continuity of the fascia. Incisional hernia is the appearance of gap in the post-operative surgical site with or without bulging. Some authors explain incisional hernia as a diffuse evisceration of peritoneum and abdominal contents through a weak scar of an operation or accidental wound. It is a type of hernia caused by an incompletely healed surgical

wound, and the abdomen is the most common site of its occurrence.^{1,2}

The most common cause of incisional hernia is the presence of infection at the surgical site which leads to the development of excessive tension causing inadequate healing. The other factors which increase the incidence of such type of hernia are obesity, advanced age, malnutrition, ascites, pregnancy, and other conditions that increase intra-abdominal pressure. Some authors believe that besides infection, the other factors are formation of hematoma and seroma, all of which result in decreased wound healing. Like any other hernia, it can lead to pain, bowel obstruction, incarceration, and strangulation.³⁻⁵

The incidence of occurrence of surgical scar hernia is about 5-11% in developed countries. It is thought

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that this incidence might be very high in developing countries like India due to increased rate of infection and malnutrition.⁶

Almost half of the cases of incisional hernia occur within first 2 years after surgery. The mode of treatment is surgical which ranges from anatomical repair to laparoscopic intervention. In traditional open surgical repair, the weakened tissue of the abdominal wall is re-incised, and a repair is reinforced using a prosthetic mesh. A mesh infection later in this variety of hernia repair most often needs a complete removal of the mesh and eventually results in surgical failure. Furthermore, large incisions essential for open repair are commonly allied with significant post-operative pain. Reported recurrence rates after open repair are up to 20% and are predisposed by mesh size and fixation type.^{5,7}

On the other hand, the laparoscopic incisional hernia repair is a new technique of surgery for this ailment. The operation is executed with the help of surgical microscopes and specialized instruments. The surgical mesh is placed into the abdomen underneath the abdominal muscles through small incisions to the side of hernia. As a result, the weakened tissue of the original hernia is not re-incised to implement the repair, and thus potential for wound complications such as infections is minimized. Second, performance of the operation through smaller incisions can make the operation less painful and speed recovery. Laparoscopic repair has been validated to be safe and a more irrepressible repair than open incisional hernia repair.^{3,8}

In case of strangulation, emergency surgical intervention is done. However, this treatment is associated with high incidence of recurrence and complications.^{9,10} Still, there are lots of controversy among surgeons regarding the ideal time and method of treatment. In this study, we have analyzed the various factors responsible for developing incisional hernia and the most effective treatment modalities in the Indian population.

The aim of the present study is to analyze the incidence, etiopathogenesis, various modes of presentation, and different therapeutic modalities of incisional hernia in developing countries like India.

MATERIALS AND METHODS

This is a prospective and observational study done in Teerthanker Mahaveer Medical College for duration of 1 year. The study was conducted on 100 patients fulfilling certain criteria.

Inclusion Criteria

The inclusion criteria were as follows: (a) Patient belongs to Indian race, (b) had positive history of single abdominal surgery, (c) age group between 21 and 60 years, and (d) developed hernia at the site of surgical incision.

Exclusion Criteria

The exclusion criteria were as follows: (a) Age < 21 or > 60 years, (b) had positive history of multiple abdominal surgeries, and (c) patients with chronic cough, respiratory diseases, and other debilitating medical illness.

Detailed history of the patients was recorded, and clinical examination was done. Patients underwent routine blood and radiology (ultrasound, chest X-ray) investigations. Demographic profile and data regarding the type of surgery, post-operative complication, and duration after which incisional hernia developed were recorded in pro formas. The data were tabulated and analyzed for statistical significance using univariate and multivariate analysis.

Various parameters which were studied are:

1. Age distribution
2. Sex distribution
3. Mode of presentation
4. Time of onset of herniation
5. Post-operative complication which predisposed to incisional hernia
6. Frequency of herniation in type of incision
7. Type of treatment done to patient for incisional hernia
8. Recurrence rate in different methods of treatment.

RESULTS

The 100 cases of incisional hernia admitted in our institute in 1 year were included in the study. Various parameters were recorded, tabulated, and analyzed statistically. The patients were treated by two different methods (laparoscopic hernioplasty and preperitoneal mesh repair), and post-operative recurrence rate and duration of hospital stay were recorded.

The age distribution of the 100 cases of incisional hernia ranged from 21 to 60 years and had maximum number of patients in the 41-45 years age group (42%), followed by 51-60 years (30%), 31-40 years (17%), and 21-30 years (11%) (Table 1).

This study included 62 female and 38 male patients with female to male ratio being 1.6:1. The difference was found to be significantly significant (<0.05) which proves that the incidence of disease is high in females as compared to males (Figure 1).

On clinical examination, 86 patients out of 100 had reducible bulging through surgical site. Only three patients presented with severe pain and had strangulated hernia, and thus emergency surgical intervention was done (Table 2).

21 patients had an early onset of herniation within 6 months following primary surgery, 48 cases between 6 months and 1 year, 20 cases from 1 to 5 years, and 11 cases had herniation by the end of 5 years (Figure 2). Hence, maximum cases (48%) of incisional hernia occurred between 6 months and 1 year after surgical intervention.

After taking detailed history out of 100 cases, in only 59 cases, proper reason for the development of incisional hernia could be determined. Most common cause for incisional hernia was found to be post-operative infection (47%), followed by cough (10%) and early return to work (2%) (Figure 3).

68% patients had previous surgeries through lower abdominal incisions, 18% patients with upper midline incision, 10% patients with right paramedian incision, and 4% with left paramedian incision (Table 3).

After the correction of anemia and blood pressure, all the patients underwent surgical correction of hernia. In 52 patients, laparoscopic hernioplasty was done, whereas in 39 patients, mesh repair was done. In only 9 cases, anatomical repair was preferred (Table 4). A total of 2 cases (one of anatomical repair and other of mesh repair) showed

the recurrence of hernia out of 100 patients. Both these cases showed the recurrence within 6 months after the repair of hernia.

DISCUSSION

This prospective and observational study was conducted on 100 patients with the aim of studying the incidence, etiopathogenesis, modes of presentation, and different

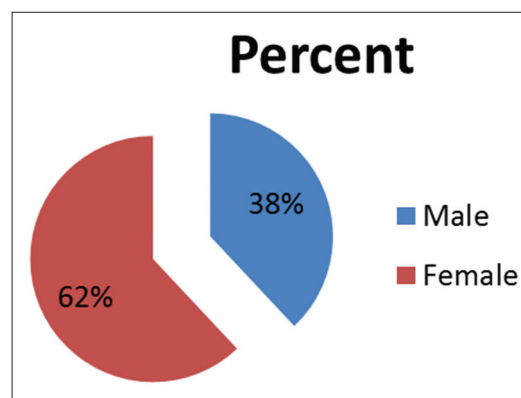


Figure 1: Sex distribution of the patients

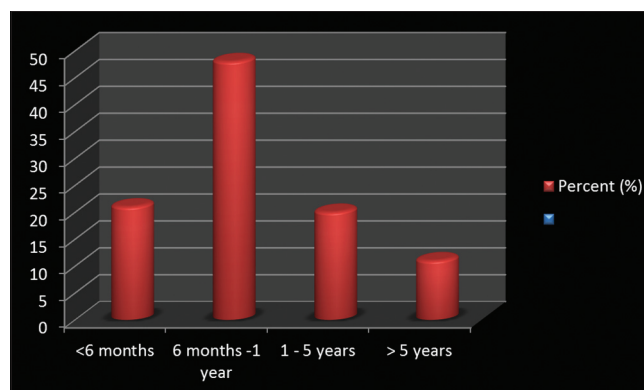


Figure 2: Time of onset of herniation

Table 1: Age distribution of the patients (years)

Age group of patients (years)	Percentage of patients
21-30	11
31-40	17
41-50	42
51-60	30

Table 2: Mode of presentation of the patient

Mode of presentation	Percentage
Reducible	86
Obstructed	11
Strangulated	3

Table 3: The frequency of incisional herniation in different type of incisions

Type of incision	Percentage
Lower abdominal vertical	21
Lower abdominal transverse	47
Upper midline	18
Right paramedian	10
Left paramedian	4

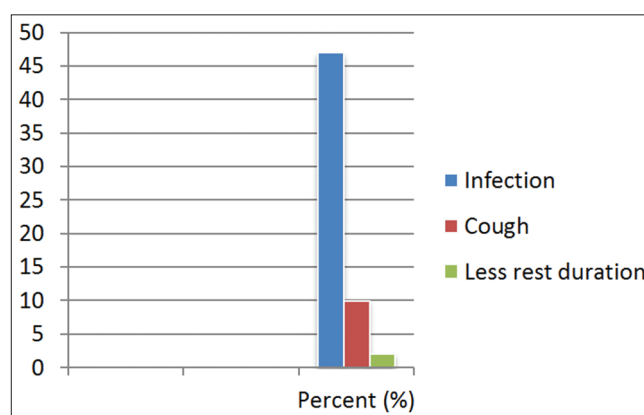


Figure 3: The post-operative complication which predisposed to incisional hernia

Table 4: Type of treatment done to patient for incisional hernia

Type of treatment	Percentage
Laparoscopic hernioplasty	52
Preperitoneal mesh repair	39
Anatomical repair	9

therapeutic modalities of incisional hernia in developing countries like India.

In our study, the most common age group involved is 41-50 years while female to male ratio was found to be 1.6:1. In a similar study done by Ellis *et al.*,⁶ 48% patients developing incisional hernia belonged to the age group of 31-40 years. Female to male ratio was found to be 4.8:1. In both the studies, the incidence of hernia development at the surgical site is more common in females. Millbourn *et al.*¹⁰ reported an incidence of 64.6% female population in their study of 383 patients. The reason behind this could be laxity of the abdominal muscles due to multiple pregnancies and increased number of lower abdominal incisions in females.

In various studies,¹¹⁻¹³ wound infection following the surgery was the main factor for the development of incisional hernia. The other common factors were burst abdomen following infection and chronic cough during post-operative period. All these findings are similar to our study.

In our study, the maximum cases (48%) of incisional hernia occurred between 6 months and 1 year after surgical intervention. In a research done by Bucknell *et al.*,⁸ 42% cases presented with hernia 1-5 years after primary surgery. 68% patients who had lower abdominal incisions developed incisional hernia followed by 18% patients with upper midline incision, 10% patients with right paramedian incision, and 4% with left paramedian incision. Similarly, Millbourn *et al.*¹⁰ and Carlson¹¹ also found that this type of hernia is common in females undergoing gynecological surgeries in which lower abdominal incisions are made. Some authors believe that incisional hernia rates do not differ by type of incision, and incision should be driven by surgeon's preference with respect to the patient's disease and anatomy.

In our study, three different methods were used for treating the patients. Only two patients who underwent mesh repair and anatomical repair showed the recurrence of disease. According to Bessa *et al.*,⁵ the mesh repair is a simple and

effective operation for incisional hernia. Jenkins¹³ in their study in 154 patients established the superiority of mesh repair over suture repair with regard to the recurrence of hernia.

CONCLUSION

- Incisional hernia occurs most commonly in the age group of 41-50 years
- Incidence is more common in females with female to male ratio of 1.6:1
- Maximum cases (48%) of incisional hernia occurred between 6 months and 1 year after surgical intervention
- Most common cause for incisional hernia was found to be post-operative infection (47%)
- Incisional hernias occur more commonly in lower abdominal surgeries and gynecological surgeries
- Laparoscopic hernioplasty is the first line of treatment for uncomplicated incisional hernias.

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Occurrence of Recurrent Breast Cancer after Multimodality Treatment

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Abstract

Background: Locally advanced breast cancer is common in developing countries. The advancement of the disease leads to decreased probability of radical cure and increase in treatment cost.

Aims: To study about the rate of occurrence of recurrent breast cancer after multimodality treatment and to compare the efficiency of treatment modality by way of incidence of recurrence.

Methods: A total of 60 patients underwent surgery, followed by chemotherapy and radiotherapy was studied in detail as they presented for regular follow-up. The selection criteria of patients were based on TNM classification of breast cancer from Stage II B, Stage III A, and Stage III B. Definite prognostic indicators could not be assessed as the period of study was of order of 2 years only.

Result: About 22 patients were treated with surgery and chemotherapy, 16 patients were treated with neoadjuvant, surgery, chemotherapy, and radiotherapy. Others were treated with surgery, chemotherapy, and radiotherapy. Recurrence rate was found to be 18% in the arm of surgery followed by chemotherapy; 16% in the arm of neoadjuvant followed by surgery; 9% in the arm of neoadjuvant followed by surgery, chemotherapy, and radiotherapy; 16% in the arm of surgery followed by chemotherapy and radiotherapy. This study showed re-recurrence rate is low in the treatment of locally advanced breast cancer (LABC) with neoadjuvant chemotherapy followed by surgery followed by chemotherapy and radiotherapy. The longest disease-free survival of 10 months was noted in this group.

Conclusion: The LABC is one of the most common forms of carcinoma breast in this institute. Tumor size, nodal metastasis remains the most important predictor lokoregional recurrence (LRR) in LABC. Multimodality therapy administered with meticulous follow-up provided acceptable rate of LRR. The disease-free interval is 10-month.

Key words: Breast cancer, Multi modality treatment, Recurrence

INTRODUCTION

Breast cancer in women is associated with a more aggressive disease and worst clinical outcomes. The present article aims to provide an overview of literature using the keyword indexed search strategy focused on recurrence and survival rates in women with an early stage breast cancer. The treatment of locally advanced breast cancer

(LABC) has changed dramatically over the last few decades. The introduction of neoadjuvant chemotherapy in LABC offered advantages like initiation of early systemic therapy and downstaging of tumors, which makes inoperable tumors operable and renders tumors suitable for breast conserving therapy.^{1,2} LABC refers to a term that includes a heterogeneous group of diseases. A subset of Stage IIB (T3N0), Stage III disease, and inflammatory breast cancer are included here. Data from the National Cancer Institute's Surveillance, epidemiology and end results program indicated that approximately 7% of breast cancer patients have Stage III disease at diagnosis. Median survival time is 4.9 years while the 5 years relative survival rate for this group of women is 55% when treated with multimodality treatment not including biologics.³ Tumor size and lymph

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node involvement are the main prognostic factors while the prognostic value of tumor grade, estrogen receptor/progesterone recep, and human epidermal growth factor receptor 2/neu status is not fully clarified.^{4,5} In the selected group of patients improving overall and disease-free survival (DFS) are major goals. The conversion of an initially inoperable breast cancer to an operable one or even more to conservatively operable is also of crucial importance. Both the lokoregional and systemic control represent major clinical problems in LABC. Neoadjuvant chemotherapy integrated into a multimodality program is the established treatment in LABC.^{6,7}

Aim

To study about the rate of occurrence of recurrent breast cancer after multimodality treatment and to compare the efficiency of treatment modality by way of incidence of recurrence.

METHODS

Observational case series study is based on the follow-up of patients with locally advanced breast cancer who were studied during the period between July 2008 and July 2010. A total of 60 patients underwent surgery, followed by chemotherapy and radiotherapy was studied in detail as they presented for regular follow-up. The selection criteria of patients were based on TNM classification of breast cancer from Stage II B, Stage III A and Stage III B. The modality of diagnosis and treatment of breast cancer was followed in institution. Meticulous history followed by thorough clinical examination and routine biochemical and radiological examination, invasive procedures for a diagnosis like FNAC. The patients were followed up as they underwent various modalities of treatment in the form of surgery, neoadjuvant, and adjuvant chemotherapy and radiotherapy supplemented by hormonal therapy. The period of follow-up ranged from a minimum of 3 months to a maximum of 18 months. The recurrence was observed by the reoccurrence of breast cancer on chest wall which was treated with radiotherapy and adjuvant chemotherapy. The result was observed using rate of recurrence which was compared with international result.

RESULTS

A total of 60 patients with disease profile of LABC were analyzed for this study during the period of 2009-2011. The patients belong to various socioeconomic and geographical backgrounds. Predominant age group of new patients was in the age group of 40-50 years. Majority of the case 36/60 was postmenopausal, 24/60 was premenopausal.

The study of recurrence of carcinoma was found to be as follows. The recurrence rate of 20% was observed in the end of the study with 8 cases of chest wall recurrence, 2 nodal recurrence, and 2 cases of distant metastases. Shortest recurrence interval was 3-month and longest was 10 months - leads to mean recurrence interval of 6.05 months. Recurrences were treated with radiotherapy and chemotherapy.

DISCUSSION

Use of neoadjuvant systemic chemotherapy and postmastectomy radiotherapy has become standard for patients with LABC because this treatment course improves prognosis substantially and enhances the possibility of surgery.⁸⁻¹⁰ Advances in neoadjuvant chemotherapy for LABC include not only earlier treatment of subclinical distant micrometastases and primary tumor downstaging but also the possibility of *in vivo* assessment of response to specific systemic agents.

The lokoregional recurrence was taken as an index of failure of multimodality treatment. The standardized results were envisioned as 20% which were comparable to the international data following multimodality treatment.

The recurrence rate was found to be 58% in the arm of surgery followed by chemotherapy; 16% in the arm of neoadjuvant chemotherapy followed by surgery; 9% in the arm of neoadjuvant followed by surgery, chemotherapy and radiotherapy; 16% in the arm of surgery followed by chemo and radiotherapy. This study showed recurrence rate is low in the treatment of LABC with neoadjuvant chemotherapy followed by surgery followed by chemotherapy and radiotherapy. The longest DFS of 10 months was noticed in this group.^{11,12}

CONCLUSION

Neoadjuvant chemotherapy integrated into a multimodality program is the established treatment in LABC. It has the potential to further improve the long-term control of LABC. Identifying which tumors are most likely to response to specific agents and regimens could significantly improve the prognosis. This study demonstrates clinicopathological variables such as nodal status, response to chemotherapy; pathological tumor size had a significant impact on disease free survival.

Dose-intensive and time-intensive multimodality neoadjuvant therapy was successfully administered to a mixed racial group over shortened times. Patients, who required mastectomy, are at a higher risk of relapse. Over

the last decade, the use of neoadjuvant chemotherapy has emerged as the standard of care for patients with large primary tumors or matted axillary nodal metastases.

Standard dose pre- and post-operative fluorouracil, epirubicin, and cyclophosphamide therapy combined with surgery and radiotherapy in the era of mammography screening seem to yield results comparable to those achieved with other conventional strategies in the treatment of unscreened populations.

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Placenta in Normal and Pregnancy Induced Hypertension in Relation to its Clinical Significance: A Gross Study

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Abstract

Introduction: Placenta is the most important and vital organ of intrauterine life. It plays important respiratory, nutritive, and excretory function during fetus development. Pregnancy induced hypertension (PIH) is one of the common problems in pregnancy and having adverse effect on placenta and leads so adverse fetus outcomes.

Purpose of Study: This study was conducted to study gross changes of placenta in PIH mothers and comparison with normal blood pressure group mothers and to derive conclusion for preventing adverse outcomes.

Methods of Study: This study was conducted in 50 normal (control group) and 50 PIH cases with their placenta after delivery collected and grossly examined for various variables and comparison was made using EpiInfo 7 software.

Results: As compare to control group, in PIH group mothers mean placental weight, volume, diameter, thickness, mean umbilical cord length, and mean cotyledon number were less. In PIH umbilical cord attachment was eccentric to marginal more rather than a central attachment. PIH group shows altered shape significantly like oval or irregular as compare to control and also a significant proportion of calcification, hemorrhage, and infarcted area ($P < 0.05\%$).

Conclusion: PIH affects placenta adversely and leads significant gross changes as compared to control group. This study concludes that fetus, placenta, and PIH interlinked and this study provides useful adjunct in planning and management of future pregnancy in hypertensive women.

Key words: Calcification, Eclampsia, Fetus, Infarction, Pregnancy Induced Hypertension, Placenta, Preeclampsia, Umbilical cord

INTRODUCTION

During fetal development, until the organs become functional, the placenta does most nutritive and respiratory supportive function to fetus. These include maintenance of homeostasis, provision of oxygen and gaseous exchange, waste removal, hormonal secretion and hemopoiesis, etc.¹

Hence, fetus proper growth and development depend on balance between fetus, placenta, and maternal unit.²

Placenta examination that's why reflects what had happened with it, when it was in mother's womb and what is going to happen with fetus in future and so in future pregnancy, fetus adverse outcome can be prevented. It has been observed that in pregnancy induced hypertension (PIH) maternal uteroplacental blood flow is decreased (by maternal vasospasm) and so leads fetal stem artery constriction leads adverse changes in placenta and adverse fetus outcome.³

MATERIALS AND METHODS

The study was conducted in 100 placentas. Among them, 50 mothers with uncomplicated pregnancy and 50 with PIH were selected randomly from in patients of the Obstetrics and Gynecology Department at tertiary care hospital.

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These two groups considered as control normal group and PIH group. Control group pregnant women having normal blood pressure, no proteinuria, and no edema. PIH group was having blood pressure at or above 140/90 mm hg on at least two occasions with 6 h interval for measurement after 20 weeks of the present pregnancy with or without proteinuria, edema, convulsion, or coma.

Clinical data with history and complaints obtained from case records along with hematological and biochemical laboratory investigations were also recorded.

After delivery placenta along with attached membrane and umbilical cord collected immediately, washed in tap water, blood clots were removed and mopped with cotton and was left for fixation in 10% formal saline for 24-48 h. Placenta than examined grossly along with palpation for various parameters such as shape of placenta, site of insertion of umbilical cord, mean umbilical cord length in cm, mean number of cotyledons, calcification, infarction of >5% area, weight of placenta in grams, thickness of placenta in cm, mean placental diameter, placenta volume, hemorrhage and hematoma.

Membranes were trimmed, and the umbilical cord was cut at distance of 5 cm from site of insertion. Placenta weight was measured in gram using weighing machine.

The diameter was calculated as mean of two maximum diameters that were measured at right angles to each other.⁴ The placental thickness was measured in cm by inserting needle in central, middle and peripheral zone, and mean thickness calculated from that.⁵

The volume of placenta was measured using water displacement method.⁵ After keeping placenta in formalin for about week, cotyledons were separated from the maternal surface of decidual septa by gentle pressure and then counted.⁶ The data were analyzed in both groups by Chi-square test using EpiInfo 7 software. The $P < 0.05$ was taken as statistically significant.

RESULTS

In our study, among the PIH group, 40 cases were of preeclampsia, seven cases of gestational hypertension and three cases were of eclampsia. In both groups' mothers, majority belongs to age group between 20 and 30 years.

Of the 50 control group, 20 (40%) were primigravida and 30 (60%) were multigravida, and of 50 PIH group, 35 (70%) were primigravida and 15 (30%) were multigravida. This shows that in this study, PIH was more

common in primigravida. Mean systolic blood pressure in control group was 122 and in PIH it was 152. Mean diastolic blood pressure in control group was 80 and in PIH it was 98 mm hg.

Placental weight, volume, diameter, and thickness value reported in tabulated form in both groups (Table 1).

The umbilical cord findings reported as tabulated form in both groups (Table 2).

After reporting above findings finally placenta shape, calcification, infarction, hemorrhage, and mean cotyledon number reported in Table 3.

DISCUSSION

Jain *et al.* and Manjunatha *et al.* found that 45.91% of control and 54.09% of PIH mothers were primigravida. In our study, 40% of control and 70% of PIH group

Table 1: Placenta weight, volume, diameter, and thickness

Parameter	Control group (50 patient)	PIH group (50 patient)	P
Mean placenta weight	512 g	410 g	Significant
Mean placenta volume	520 ml	418 ml	Significant
Mean placenta diameter	17.5 cm	14.5 cm	Significant
Mean placenta thickness	2.60 cm	2.20 cm	Significant

PIH: Pregnancy induced hypertension

Table 2: Umbilical cord findings

Parameter	Control group (50 patient)	PIH group (50 patient)	P
Central umbilical cord insertion	41	20	Significant
Marginal umbilical cord insertion	01	08	Significant
Eccentric umbilical cord insertion	08	22	Significant
Mean umbilical cord length in cm	26.5 cm	22.5 cm	Significant

PIH: Pregnancy induced hypertension

Table 3: Placenta shape, calcification, infarction, hemorrhage, cotyledon number findings

Parameter	Control group (50 patient)	PIH group (50 patient)	P
Circular shape placenta	32	20	Significant
Oval shape placenta	18	08	Significant
Irregular shape placenta	00	22	Significant
Infarction>5% area	00	10	Significant
Calcification	08	18	Significant
Mean cotyledon number	19	15	Significant
Hemorrhage	06	12	Significant

PIH: Pregnancy induced hypertension



Figure 1: Gross image of placenta of severe pregnancy induced hypertension. The figure showing irregular shape placenta with reduced weight and areas of hemorrhage

were primigravida which is comparable and it can be stated that primigravida most commonly affected with PIH (Figure 1).^{7,8}

In our study, PIH group showing oval and irregular shape placenta more as compared to circular shape. Whereas control group showing circular shape in majority which is comparable with Dadhich *et al.* study.⁹

The incidence of marginal and eccentric cord insertion more in PIH group as compare to control group which correlates with Pretorius *et al.* study.¹⁰ In our study, mean umbilical cord length is 4 cm less in PIH group as compare to control group that is similar to study by Jain *et al.*⁷

As compare to control group, PIH group showing mean cotyledon number less that is similar to study by Baloch *et al.*¹¹ The calcification was present in both groups but PIH showing more in number similar to Manjunatha *et al.* study.⁸

Mean placental weight was less in PIH group as compared to control group. This is similar finding to that of Udainia and Jain *et al.* and Majumdar *et al.* study.^{12,13} In our study, low placental weight were associated with low weight babies and also with intrauterine fetal death because of decreased uteroplacental blood flow in PIH.

The mean placental volume less in PIH as compare to control group which was similar finding to that of Aherne and Dunnill *et al.* study.¹⁴ This finding is because of placental insufficiency and so affected growth.

The mean placental diameter was less in PIH group as compare to control group which was similar finding to that of Rath *et al.*¹⁵

CONCLUSION AND SUMMARY

Primigravida females were among most commonly affected group.

Uteroplacental vascular thrombosis leading placental ischemic change and accelerated placental maturation leads to most of the gross changes placenta PIH. Hence, affected uteroplacental blood flow leads to adverse outcome in mother as well as fetus.

Hence, adverse outcome in hypertensive pregnancy can be improved if proper antenatal care, proper health facility, regular follow-up provided along with health education.

These studies conclude that fetus, placenta, and PIH interlinked and this study provides useful adjunct in planning and management of future pregnancy in hypertensive women.

We can come to the interference that such type of study on placenta is strongly indicated in PIH mother for preventing adverse outcome of fetus.

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Iron Status in ST- and Non-ST-elevated Myocardial Infarction

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Abstract

Background: Myocardial infarction (MI) is the most common cause of death worldwide. The major risk factors for MI are family history, diabetes mellitus, smoking, hypertension, and lipid. Excess serum ferritin as a risk factor for MI is a relatively newer concept. High serum ferritin may increase the risk of MI in the presence of other risk factors that increase the formation of free radicals, thus accelerating atherogenesis through stimulation of low-density lipoprotein oxidation.

Aim: The aim of this study is to evaluate iron status in cases of acute MI (AMI) (ST-elevated MI [STEMI] and non-STEMI [NSTEMI]).

Materials and Methods: The study was conducted in Department of Biochemistry, Mamata Medical College, Khammam. The participants attending OP and IP Departments of General Medicine and Cardiology in Mamata General and Superspeciality Hospital were recruited for the study. Study group comprises 64 cases of AMI and was subdivided based on ST-segment elevation in electrocardiogram as STEMI and NSTEMI (33 and 31). 34 sex- and age-matched healthy participants were selected as controls. Serum ferritin was measured by ELISA. Serum iron was measured by FERROZINE method.

Results: Mean serum ferritin and iron levels were significantly increased in case of AMI when compared with healthy participants.

Conclusion: Serum ferritin and iron levels were increased in AMI and the increase was more pronounced in patients with STEMI.

Key words: Atherosclerosis, Ferritin, Iron, Myocardial infarction

INTRODUCTION

Myocardial infarction (MI) is the most common cause of death worldwide. The major risk factors for MI are family history, diabetes mellitus, smoking, hypertension, and lipids.¹ Excess serum ferritin as a risk factor for MI is a relatively newer concept.² Ferritin is a large protein shell having molecular weight 450 KDa comprised 24 subunits, covering an iron core containing up to 4000 atoms of iron. Ferritin acts as the soluble storage form of iron in tissue.³ High serum ferritin may increase the

risk of MI in the presence of other risk factors that increase the formation of free radicals, thus accelerating atherogenesis through stimulation of low-density lipoprotein (LDL) oxidation.⁴ A possible association between body iron status and the risk of coronary heart disease was bolstered from a 3-year Finnish study relating increased levels of both serum levels of ferritin and dietary iron to an increased risk of MI.⁵ The association of high iron stores and coronary heart disease was first suggested by Sullivan.⁶ Results of some studies have been in favor of ferritin being a risk factor for acute MI (AMI).⁷

A harmful biological effect of excessive iron loading in the human body has been recently suggested. In this regard, iron overloading especially in myocardial tissue has been proposed to be a potent risk factor for ischemic heart disease and occurring AMI.^{5,6,8,9} The cardiac iron deposition

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results in a decrease of heart function on a certain genetic background.¹⁰ Iron can also directly injure the myocardium. Iron can be accumulated in cells as hemosiderin, ferritin, and free iron named labile cellular iron that is the most toxic form stimulating the formation of free radicals.^{11,12} Since serum ferritin concentrations are directly proportional to intracellular ferritin concentration, it is considered the best clinical measure of body iron stores.¹³ Recently, some evidences have been provided linking the increased incidence of coronary artery disease and elevated level of stored iron concentration.⁵ In these, increased estimated body iron stores have been associated with increased risk of AMI in some,¹⁴⁻¹⁶ but some observations could not reveal this relationship.¹⁷⁻²²

MATERIALS AND METHODS

The study was conducted in Department of Biochemistry, Mamata Medical College, Khammam. The participants attending OP and IP Departments of General Medicine and Cardiology in Mamata General and Superspeciality Hospital were recruited for the study. The cases were diagnosed based on (a) typical chest pain, (b) electrocardiogram (c) creatine kinase (MB) levels d) troponin i levels. Study group comprises 64 cases of AMI, and 34 sex- and age-matched healthy participants were selected as control. The study group was subdivided based on ECG (33 and 31).

Informed consent and clearance from the Ethical Committee was taken. Under aseptic precautions, 5 ml fasting blood sample was collected, and serum was separated after clot retraction. Serum ferritin was measured by ELISA. Serum iron was measured by FERROZINE method.

Study Design

This was a cross-sectional comparative study.

Inclusive Criteria

All the patients in the age group of 30-50 were included in the study.

Exclusive Criteria

1. Patients above 50 years
2. Patients on iron and antioxidant supplements.

Statistical Analysis

Mean \pm standard deviation values of all biochemical parameters were calculated in the study and control groups, and the mean difference was compared using *t*-test.

RESULTS

Mean serum ferritin and iron levels are increased in cases of MI compared to controls (Table 1). Among the cases,

there is a significant increase in the levels of mean serum ferritin and iron in cases of STEMI when compared to NSTEMI (Table 2).

DISCUSSION

In our study, serum ferritin and iron are significantly increased in MI, and the rise was more pronounced in STEMI. Serum ferritin more than 200 $\mu\text{g/L}$ has been introduced as a major predictor for occurrence of AMI and the higher rate of this marker led to 5-fold increased risk of MI.²³ Our findings are consistent with previous studies by Klipstein-Grobusch *et al.*²⁴ and Dominguez-Rodriguez *et al.*²⁵ Another evidence of an association between increased risk of MI and elevated serum ferritin concentrations came from the prospective Monica AMI project in middle-aged eastern Finnish men.¹⁰ Frey and Krider did not support the hypothesis that high serum ferritin levels could be associated with myocardial infarct.²⁶

A variety of the underlying reasons has been proposed to explain association between increased ferritin level and occurrence of AMI. First considering the key role of stress on triggering AMI, it was shown that peripheral blood monocytes derived from healthy individuals incubated with hydrocortisone showed a significant enhancement of their ferritin content, a finding suggesting that these cells activated by steroids during stress could be a source of the increased serum ferritin level leading to MI.²⁷ Basic research has provided strong evidence that LDL oxidation plays an important role in the pathogenesis of atherosclerosis and cardiovascular disease.²⁸ LDL oxidation can be enhanced by metal-catalyzed reaction, resulting in highly reactive hydroxyl radicals. Superoxide anions produced by oxidative stress and reducing agents have been found to be capable of mobilizing iron from ferritin. We observed that the elevated serum ferritin concentrations to be associated with increased risk of MI in the Indian population, and ferritin

Table 1: Normal cases and controls

Parameters	Cases mean \pm SD (n=64)	Controls mean \pm SD (n=34)	P
Ferritin ($\mu\text{g/L}$)	213.94 \pm 40.2	92.24 \pm 19.21	<0.001*
Iron ($\mu\text{g/dL}$)	110.01 \pm 27.18	81.11 \pm 17.33	<0.001*

*Statistically significant

Table 2: STEMI and NSTEMI

Parameters	STEMI mean \pm SD (n=33)	NSTEMI mean \pm SD (n=31)	P
Ferritin ($\mu\text{g/L}$)	238.52 \pm 43.6	187.81 \pm 36.22	<0.01*
Iron ($\mu\text{g/dL}$)	118.26 \pm 28.7	101.24 \pm 26.31	<0.01*

*Statistically significant. STEMI: ST-elevated myocardial infarction, NSTEMI: Non-ST-elevated myocardial infarction

may adversely affect MI risk in the presence of other risk factors. It may be possible that these factors in interaction with elevated body iron stores may accelerate atherogenesis by stimulating oxidation of LDL.²⁹

CONCLUSION

Increased serum ferritin and iron levels are seen in MI. The increase is more pronounced in STEMI. Although there are some pathophysiological mechanisms for the role of serum iron and ferritin levels to predict occurrence of AMI, the underlying mechanism remained to be elucidated in further studies. Therefore, screening for iron status and supplementation of antioxidants may be beneficial in the management of MI.

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Comparative Study between Interrupted and Continuous Suture Techniques in Ventricular Septal Defect Patch Closure: A Retrospective Study

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Abstract

Introduction: Ventricular septal defect (VSD) is the most common congenital cardiac anomaly that may occur as an isolated anomaly or as a part of complex of anomaly such as tetralogy of Fallot. Small defects may close spontaneously and may cause no significant disability in lifetime.

Materials and Methods: This is a comparison study of interrupted and continuous suture technique for closure of VSDs done with the objective to study the experience regarding the effectiveness, post-operative complication rates, and the total outcome done in the Department of Cardiothoracic Surgery, Government Rajaji Hospital from October 2012 to December 2015.

Results: A total of 43 total s were recruited for the study. Of these, 18 had VSD repair using glutaraldehyde-treated autologous pericardial patch and 25 had VSD repair using Gore-Tex patch. The majority of patients were in the age group of 6-10 years comprising 44% of the total study. Children under 5 years of age comprised <10% of the study group. The most common associated anomaly was congenital mitral valve abnormality, mainly cleft mitral valve and chordal prolapsed leading to significant mitral regurgitation requiring mitral valve repair. Right ventricular outflow tract obstruction was due to hypertrophied RV muscle bundle which required the division of the muscle bundle to relieve the obstruction. Two patients had significant aortic regurgitation due to aortic valve prolapse.

Conclusion: Continuous and interrupted suture techniques are equally effective in closure of VSD. Even though residual shunt is common with continuous suture technique VSD closure, 7% cases of residual shunt occurred in interrupted suture techniques in our institutions which is statistically insignificant.

Key words: Continuous suturing technique, Gore-Tex, Interrupted suturing technique, Pericardial patch closure, Polypropylene sutures, Ventricular septal defect

INTRODUCTION

Ventricular septal defect (VSD) is the most common congenital cardiac anomaly that may occur as an isolated anomaly or as a part of complex of anomaly such as tetralogy of Fallot.¹⁻⁴ Small defects may close spontaneously and may cause no significant disability in lifetime. Patients with cardiomegaly and large left to right shunts

are unquestionable candidates for the operation.⁵⁻⁹ By operating electively, the tendency to develop pulmonary hypertension, valvulitis, and bacterial endocarditis is virtually eliminated.^{10,11}

MATERIALS AND METHODS

All the patients for VSD closure were done by a single experienced surgeon. All patients undergoing repair for VSD in the Department of Cardiothoracic Surgery, Government Rajaji Hospital during October 2012-December 2015 were included in the study. Patients with VSD associated with complex anomalies and muscular typeth atiwere excluded from this study. One group used continuous suture for VSD closure and the other group used interrupted techniques for VSD closure.

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After median sternotomy, the thymus was dissected from the pericardium. Pericardium harvested as a free graft taking care to avoid injury to the phrenic nerves. It was treated with 0.6% glutaraldehyde solution for 20 min and rinsed 3 times in 0.9% saline solution for 5 min.

Cardiopulmonary bypass was started after aorta, superior vena cava, inferior vena cava cannulation. Under moderate hypothermia, cross clamp applied, antegrade cold blood cardioplegia given. Heart arrested in diastole right atrium was opened, and the VSD was inspected. The pericardial/Gore-Tex patch was trimmed to match the size of the VSD. The defect was closed with the pericardial patch using 4/0 or 5/0 polypropylene continuous suture, starting from the inferior margin and proceeding toward the anterosuperior margin and superiorly toward the aortic valve, avoiding injury to the aortic cusps. With the second arm of the suture, the postero-inferior margin was closed up to the septal leaflet of the tricuspid valve.

The tricuspid margin of the defect was closed with a reinforcing strip of pericardium. When using interrupted sutures pledget supported interrupted mattress sutures are placed around all margins of the defect and then passed through an appropriately tailored patch, which is lowered down and tied in.

Patients with an uneventful recovery were discharged after ten days. Echocardiography was done before discharge and documented.

Data Collection

The information collected regarding all the selected cases were recorded on a master chart. Data analysis was done with the help of computer using epidemiological information package developed by center for disease control, Atlanta.

Using this software range, frequencies, percentages, mean standard deviations, Chi-square, and “P” values were calculated. Kruskal-Wallis Chi-square test was used to test the significance of the difference between quantitative variables. A $P < 0.05$ is taken to denote significant relationship.

RESULTS

A total of 43 patients were recruited for the study. Of these, 18 had VSD repair using glutaraldehyde-treated autologous pericardial patch and 25 had VSD repair using Gore-Tex patch.

The majority of patients were in the age group of 6-10 years comprising 44% of the total study. Children

under 5 years of age comprised <10% of the study group (Tables 1-3).

Most of the VSD operated were restrictive physiology. The nonrestrictive type included the VSD of outlet type (Table 4).

The most common associated anomaly was congenital mitral valve abnormality, mainly cleft mitral valve, and chordal prolapsed leading to significant mitral regurgitation requiring mitral valve repair. Right ventricular outflow tract (RVOT) obstruction was due to hypertrophied RV muscle bundle which required the division of the muscle bundle to relieve the obstruction. Two patients had significant aortic regurgitation due to aortic valve prolapse (Tables 5-10 and Graph 1).

Table 1: Age distribution

Age (in years)	Cases n (%)
Up to 5	3 (6.9)
6-10	19 (44.2)
11-15	14 (32.6)
16-20	6 (13.9)
>20	1 (2.4)
Total	43 (100)
Range	5-29 years
Mean	11.3 years
SD	5.21 years

SD: Standard deviation

Table 2: Sex distribution

Sex	Cases n (%)
Male	20 (46.4)
Female	23 (53.6)
Total	43 (100)

Table 3: Type of VSD

Diagnosis	Cases n (%)
Subpulmonic	8 (18.6)
Subaortic	14 (32.6)
Perimembranous	20 (46.5)
Inlet	1 (2.3)
Total	43 (100)

VSD: Ventricular septal defect

Table 4: Hemodynamics

Type of hemodynamics	Cases n (%)
Restrictive VSD	37 (86.1)
Nonrestrictive VSD	6 (13.9)
Total	43 (100)

VSD: Ventricular septal defect

Table 5: Associated anomalies

Associated anomalies	Cases n (%)
Present	13 (30.2)
Absent	30 (69.8)
Total	43 (100)

Table 6: Suturing technique

Suturing technique	Cases n (%)
Continuous	17 (39.5)
Interrupted	26 (60.5)
Total	43 (100)

Table 7: Patch material used

Patch material used	Cases n (%)
Pericardium	18 (42)
Gore-Tex	25 (58)
Total	43 (100)

Table 8: Complications

Complication	Cases n (%)
Block	1 (2.3)
Stroke	2 (4.7)
IE	2 (4.7)
Renal failure	1 (2.3)
Residual shunt	3 (7)
Other complications	14 (32.5)
Death	3 (6.9)
Total cases with complications	24 (55.8)
Total cases without complications	19 (44.2)
Total	43 (100)

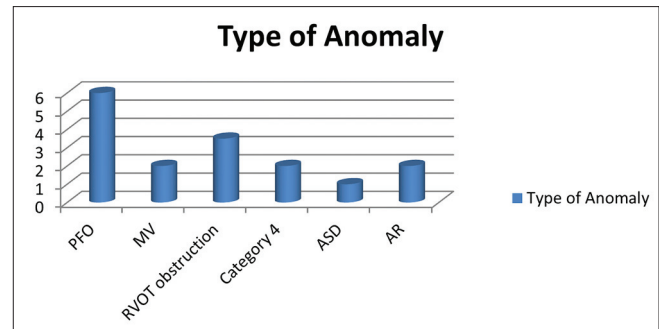
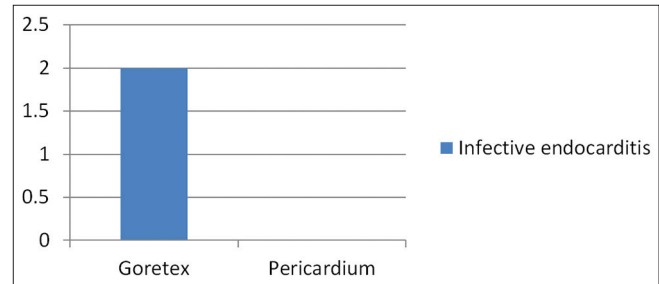
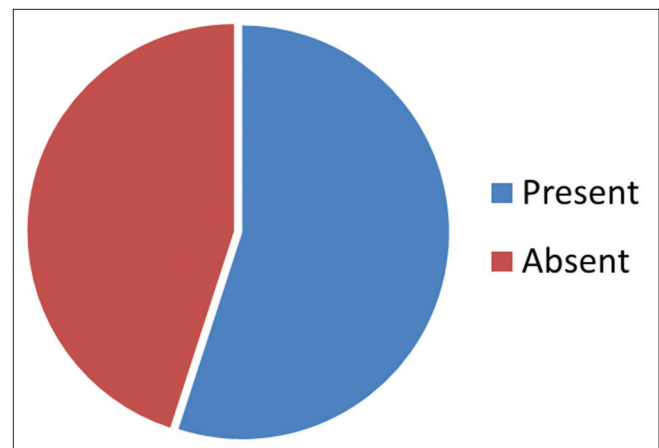
IE: Infective endocarditis

Two patients had infective endocarditis (IE) in Gore-Tex patch group. The residual shunt was present in three patients, none of them were significant enough to warrant re-exploration and closure. One patient had nodal rhythm in Gore-Tex patch group and received temporary pacing, recovered after 1 week (Graphs 2 and 3, Tables 11-21).

DISCUSSION

A total of 43 patients were recruited for the study, out of these, 17 had VSD repair using continuous and 26 had repair using interrupted suture techniques.

Continuous suture technique was employed in 40% of the study group. For most of the patients in this group, pericardial patch was applied. The glutaraldehyde-treated

**Graph 1: Associated anomalies****Graph 2: Infective endocarditis****Graph 3: Complications**

patch was more flexible and had better handling properties when compared to Gore-Tex patch, for ease of surgery. For the remaining patients, interrupted suture technique was used and most of them were from Gore-Tex group. They were mainly operated on by me during the study.

25 patients had VSD using Gore-Tex patch and 18 patch had VSD using Goreoperatglutaraldehyde-treated autologous pericardial patch.

Congenital mitral valve abnormalities were the most common associated anomaly, mainly chordal prolapsed and cleft mitral valve with significant mitral regurgitation requiring repair. AML cleft was closed with 5-0 prolene sutures, and chordal shortening was done.¹²⁻¹⁷

Table 9: Residual shunt

Residual shunt	Cases n (%)
Yes	3 (7)
No	40 (93)
Total	43 (100)

Table 10: Outcome

Outcome	Cases n (%)
Recovered	40 (93)
Death	3 (7)
Total	43 (100)

Table 11: Age and outcome

Age group (years)	Outcome, n (%)	
	Recovered	Death
Up to 5 (3)	2 (67)	1 (33)
6-10 (19)	18 (94.7)	1 (5.3)
11-15 (14)	13 (92.9)	1 (7.1)
16-20 (6)	6 (100)	-
>20 (1)	1 (100)	-
Mean age	11.48	9.0
SD	5.29	4.0
"P"	0.434	
	Not significant	

SD: Standard deviation

Table 12: Sex and outcome

Sex	Outcome, n (%)	
	Recovered	Death
Male (20)	19 (95.0)	1 (5.0)
Female (23)	21 (91.3)	2 (8.7)
"P"	0.897	
	Not significant	

Table 13: Diagnosis and outcome

Diagnosis	Outcome, n (%)	
	Recovered	Death
Subpulmonic (8)	7 (87.5)	1 (12.5)
Subaortic (14)	13 (92.9)	1 (7.1)
PM (20)	19 (95)	1 (5)
Inlet	1 (40)	-
Total	100	3

The most common VSD was outlet type which comprises 51% of the study population. Perimembranous type comprises 49% in the study population.

The transarterial approach was used for most of the patients. Two patients requiring aortic valve repair were

Table 14: Other variables and outcome

Variable	Outcome	
	Recovered n (%)	Death n (%)
Type of VSD		
Outlet (22)	20 (91)	2 (9)
PM (21)	20 (95)	1 (5)
Patch material used		
Pericardium (18)	17 (94.4)	1 (5.6)
Gore-Tex (25)	23 (92)	2 (8)

VSD: Ventricular septal defect

Table 15: Outcomes and other variables

Variable	Outcome		"P"
	Recovered	Death	
	n (%)	n (%)	
Type of hemodynamics			
Restrictive VSD (37)	35 (94.6)	2 (5.4)	0.898
Nonrestrictive VSD (6)	5 (83.3)	1 (16.7)	Not significant
Anomalies			
Present (13)	12 (92.3)	1 (7.7)	0.829
Absent (30)	28 (93.3)	2 (6.7)	Not significant
Suturing technique			
Continuous (17)	16 (94.1)	1 (5.9)	0.856
Interrupted (26)	24 (92.3)	2 (7.7)	Not significant
Residual shunt			
Yes (3)	3 (100)	-	0.989
No (40)	37 (92.5)	3 (7.5)	Not significant

VSD: Ventricular septal defect

Table 16: Complications and other variables

Variable	Complications				“P”
	Present		Absent		
	Yes	No	Yes	No	
Type of hemodynamics					
Restrictive VSD (37)	20	54.1	17	45.9	0.756
Nonrestrictive VSD (6)	5	83.3	1	16.7	Not significant
Anomalies					
Present (13)	10	76.9	3	23.1	0.499
Absent (30)	14	46.7	16	53.3	Not significant
Suturing technique					
Continuous (17)	6	35.3	11	64.7	0.351
Interrupted (26)	18	69.2	8	30.8	Not significant

VSD: Ventricular septal defect

approached through aortic exposure; mitral valve repair was done through interatrial septal approach.^{5,7,18-20}

One patient had nodal rhythm in Gore-Tex patch group with interrupted suture technique and temporary pacing was done but recovered after 6 days. Residual shunt was present in 3 patients, but none of them were significant for reexploration.

Table 17: Complications and other variables

Variables	Complications	
	Present	Absent
	n (%)	n (%)
Type of VSD		
Outlet (22)	12 (54.5)	10 (45.5)
PM (21)	12 (57.1)	9 (42.9)
Patch material		
Pericardium (18)	10 (46.7)	8 (44.4)
Gore-Tex (25)	14 (56)	11 (44)

VSD: Ventricular septal defect

Table 18: Patch material and residual shunt

Patch material used	Residual shunt	
	Yes	No
	n (%)	n (%)
Pericardium (18)	1 (5.6)	17 (94.4)
Gore-Tex (25)	2 (8)	23 (92)
Total	3	40

Table 19: Type of VSD and residual shunt

Type of VSD	Residual shunt	
	Yes	No
	n (%)	n (%)
Outlet (22)	2 (9)	20 (91)
PM (21)	1 (4.8)	20 (95.2)

VSD: Ventricular septal defect

Table 20: Type of hemodynamic and residual shunt

Type of hemodynamics	Residual shunt	
	Yes	No
	n (%)	n (%)
Restrictive (37)	1 (2.7)	36 (97.3)
Nonrestrictive (6)	2 (33.3)	4 (66.7)
P	0.747	
	Not significant	

Table 21: Patch material and suture techniques

Patch material used	Suture techniques	
	Continuous	Interrupted
	n (%)	n (%)
Pericardium (18)	10 (55.6)	8 (44.4)
Gore-Tex (25)	7 (28)	18 (72)

IE was noticed in 2 patients in Gore-Tex patch group with interrupted sutures.

Aortic valve prolapsed with aortic regurgitation was noted in 2 patients. Through transaortic route, they were approached

and modified Trussler's repair was done to correct the prolapsed right coronary cusp. RVOT obstruction was commonly due to RV muscle bundle hypertrophy; the obstruction was relieved by dividing the muscle bundle. Two patients had anomalous muscle bundle in RV which was excised. Patent foramen ovale was closed.^{5,21,22}

One patient suffered neurological deficit in the immediate post-operative period. Definite areas of infarct were noted in the computed tomography scan of the brain, but the patient recovered successfully. The patient regained full functional recovery after a period of 2-month.

Two patients had prerenal failure in the post-operative period and conservatively managed. In the 3-day period, his renal parameters returned to normal baseline.

Two patients from the interrupted suture technique group with Gore-Tex patch had IE were successfully treated for 3 week with antibiotics based on culture reports.

Three patients died in the immediate post-operative period, of which two died of post-operative cardiac failure, and one died due to pulmonary hypertensive crisis.

Residual shunt was noted in three patients. No patients warranted reexploration. Two patients were from the continuous suture technique group with Gore-Tex patch, irrespective of the type of VSD.

Limitations

This study is limited by its nonrandomized nature and the inherent limitations of the nonrandomized studies. Only those patients who were referred for surgery and underwent surgical repair were reviewed. Indications for surgery were based on the retrospective review of the referring cardiologist clinical notes and the surgical pre-operative notes. Although the study did not address long-term follow-up of these patients, long-term survival and clinical outcomes for patients after surgical closure of isolated VSD or consistently excellent, and we would anticipate the same for this study population. In addition, we intentionally excluded patients with multiple VSDs. We recognized that patients with multiple VSDs can be a challenging group for surgical repair. However, the focus of the study was patient with isolated, single VSD.

CONCLUSION

Continuous and interrupted suture techniques are equally effective in closure of VSD. Even though residual shunt is common with continuous suture techniques VSD closure, 7% cases of residual shunt occurred in interrupted

suture techniques in our institutions, which is statistically insignificant.

Incidence of IE is slightly higher in interrupted when compared to continuous suture techniques in our institution, could be explained by more number of pledgets used in interrupted technique which is also statistically insignificant.

Because of small number of groups included in our study, we are unable to come to conclusion and suggesting large randomized controlled study to ascertain this.

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Minimally Invasive Dynamic Hip Screw Fixation in Stable and Unstable Intertrochanteric Fractures

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Abstract

Introduction: In minimally invasive dynamic hip screw (DHS) fixation procedure, we have found a lesser amount of blood loss compared to the conventional DHS fixation. It is probably due to less soft tissue dissection and less exposure of the fracture fragments.

Objectives: To evaluate peroperative blood loss, duration of operation, duration of hospital stay in patients with stable and unstable intertrochanteric fractures.

Materials and Methods: Of 29 patients, 20 stable and nine unstable intertrochanteric fracture treated by minimally invasive DHS fixation. Peroperative average blood loss, post-operative hemoglobin (Hb) reductions, duration of surgery, and duration of hospital stay were studied.

Results: Average blood loss was 64 ml and post-operative Hb reduction was 1.1 g. Average wound size 3.5 cm. A mean duration of surgery 52 min and average duration of post-operative hospital stay was 6 days.

Conclusion: Minimally invasive DHS fixation is technically demanding with advantages of less blood loss, minimum soft tissue dissection, and shorter duration of hospital stay in stable and unstable intertrochanteric fractures.

Key words: Dynamic hip screw, Intertrochanteric, Minimally invasive

INTRODUCTION

The use of dynamic hip screw (DHS) still considered as a common mode of fixation in cases of intertrochanteric fractures of femur in patients resulting in stable fixation and early mobilization. Several studies are available showing, the minimally invasive DHS technique produces better outcome regarding the operating time, length of hospital stay, and blood loss compared to the conventional approach.¹⁻⁷ There is also rapid post-operative rehabilitation time in the minimally invasive DHS technique. This study is to confirm the same in cases of unstable fractures also.

MATERIALS AND METHODS

This is a prospective study conducted in RKMS in July 2012 to June 2015 in the Department of Orthopedics. 29 patients underwent minimally invasive DHS, and they are followed up for at least 6 months.

About 19 fractures of them were stable and 10 fractures were unstable (Tables 1 and 2). All closed stable intertrochanteric fractures (A.O. Type A1.1-A2.1) and few unstable fractures (A.O. Type A2.2, A2.3, and A3.2) were included in this study (Figure 1). Furthermore, the fractures which were to closed reduction were also included.¹

A.O. Type A3.1 and A3.3 and the compound fractures were excluded from this study.

Procedure

All surgeries were done under spinal anesthesia in fracture table. Closed reduction was possible in 18 patients. Open reduction required in rest 11 patients. Incision was placed

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1 cm distal to the trochanteric flare under fluoroscopic guidance. Diathermy was used in every case. Tensor fascia lata and vastus lateralis were split proximally and distally in line (Figure 2). After placement of the guidewire, position checked in anteroposterior (AP) and lateral views under image intensifier. Reaming was carried out through this incision. Fractures which failed closed reduction, we had gone for open reduction. Incision was increased and gently, the soft tissues were removed from fracture site. Proximal fragment's rotational deformity was corrected by direct thumb pressure over the anterior aspect of the neck, and one free handed guide wire placed to hold the fragment in position followed by reaming through the finally placed guide wire. Desired length of head screw was placed under fluoroscopic guidance. Over the guide wire, the plate was placed and rotated along the line of skin incision. Now, the guide wire was removed and the plate was inserted within soft tissue by retracting skin, fascia, and muscle (Figure 3). Side plate was fixed to the femur shaft with four cortical screws. Distal 4th cortical screw drill hole was placed first through drill sleeve and screw applied. Compression screw was applied (Figures 4 and 5). The drain was not used. Soft tissues were closed in layers (Figure 6).

Peroperative blood loss was measured weighting the blood-soaked gauge pieces and mops (Figure 7). We used vertical

drapes for the operation in 10 patients where the blood loss was measured directly.

Post-operative intravenous paracetamol 1 g injection was given 8 hourly for 2 days for the pain management followed by tablet paracetamol 1 g thrice daily given for another 3 days. Post-operative X-rays of hip in AP views were obtained within 24 h.

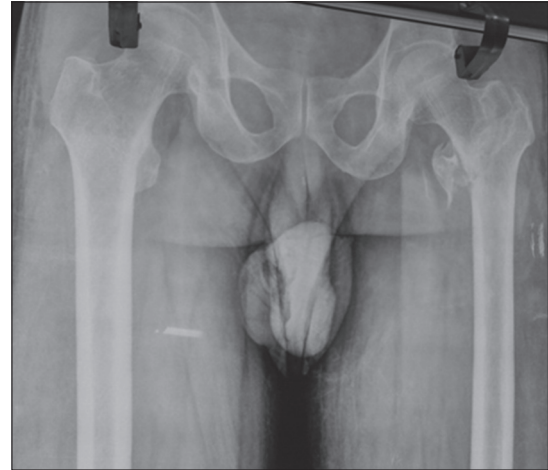


Figure 1: Pre-operative X-ray

Table 1: Master chart showing distribution of the study population

Age	Sex	AO type	Pre-operative Hb	Post-operative Hb	Duration of hospital stay	Amount of blood loss	Length of incision	Duration of surgery
78	Male	1.2	10.1	9.4	6	67	3.5	48
67	Male	2.2	10.5	9.3	6	75	4	50
89	Female	1.1	10.2	9.4	6	55	3.2	45
84	Male	1.3	10.8	9.8	7	75	3.4	50
78	Female	2.3	10.9	9.8	6	78	4.5	60
73	Female	1.3	10.2	9.2	6	65	3.3	48
67	Female	2.1	10.1	9.1	6	67	3.8	54
69	Male	2.1	10.4	9.5	6	67	3.9	50
81	Female	3.2	10.6	9.1	7	70	4.4	64
80	Male	1.2	10.9	9.8	5	60	3.6	52
82	Male	1.1	10.7	9.9	6	75	3.2	45
95	Female	3.2	10.6	9	6	73	4.4	63
64	Female	1.2	11	10.1	6	65	3.2	45
66	Female	2.1	10.8	9.7	6	60	3.3	57
73	Female	2.2	10.7	9.6	7	65	3.9	46
77	Male	1.3	10.5	9.2	6	72	3.4	54
69	Male	1.1	10.1	9	6	56	3.3	60
77	Female	2.3	10.9	9.6	5	75	3.7	51
70	Male	1.2	10.3	9.4	6	78	3.2	55
73	Male	2.2	10.1	9	6	68	3.6	57
74	Male	1.3	10.2	9.3	6	67	3.7	44
91	Male	3.2	10.5	9.2	7	67	4.2	58
80	Female	1.1	10.6	9.4	6	75	3	54
75	Male	2.2	10.5	9.4	6	50	3.9	51
76	Male	2.1	10.4	9.2	5	65	3.5	56
77	Male	2.3	10.3	9.1	6	77	3.7	58
78	Female	1.2	10.2	9.2	6	65	3.9	48
79	Male	2.1	10.1	9	7	64	3.8	54
81	Male	2.1	10.3	9.1	6	65	3.4	53

Hb: Hemoglobin

Post-operative Rehabilitation

Bedside knee bending and chest physiotherapies are started on day 2.

Partial weight bearing walking with walker was allowed after 48 h on day 3.

Full weight bearing walking started at average after 2 $\frac{1}{2}$ months.

Stitches removed after 14 days.

AP and lateral view X-rays are obtained at 1 month, 2 $\frac{1}{2}$ months, and 6 months.

RESULTS

All patients were regularly followed up for at least 6 months. Of 29 patients, 19 was having stable and other 10 was having unstable fracture patterns. The average age of the patients was 76 years (ranging from 64 to 96 years of age). There were 17 male and 12 were female with 15 right sided and 14 left sided fractures. 18 fractures were closely reduced and 11 required open reduction. The average

duration of operation was 52.7 minutes (ranging from 44 to 64 min). Perioperative blood loss was measured to be 67.62 ml (ranging from 50 to 78 ml). Post-operative average hemoglobin loss was 1.1 g/dl (Table 3).

The duration of hospital stay was 6.06 days on average (ranging from 5 to 7 days). Average wound size measured to be 3.65 cm (ranging from 3 to 4.5 cm) (Table 4). Except for 1 patient, all others having healthy and uncomplicated wound. That one diabetic patient showed persistent discharge for three consecutive weeks and improved later. All fractures had united at 2 and $\frac{1}{2}$ months.

DISCUSSION

Here, in this study, all fractures had united without complications. Several studies are there showing good results using minimally invasive approach for DHS fixation in stable intertrochanteric fractures of femur. But here, we have fixed both stable as well as several varieties of unstable fractures using minimally invasive techniques.

In minimally invasive DHS fixation procedure, we have found a lesser amount of blood loss compared to the conventional DHS fixation. It is probably due to less soft tissue dissection and less exposure of the fracture



Figure 2: Visualisation through the small incision



Figure 4: *In situ* plate and screws



Figure 3: Plate insertion

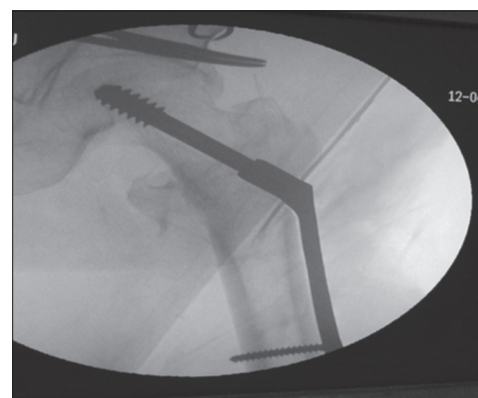


Figure 5: Intra-operative fluoroscopic image

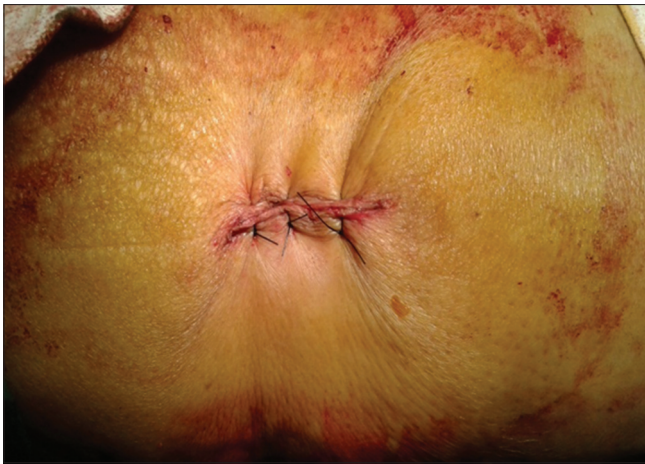


Figure 6: After closure



Figure 7: Amount of blood loss

Table 2: Demographic data distribution

Mean age	76 years
Gender	
Male	17
Female	12
AO fracture classification	
31A1.1	4
31A1.2	5
31A1.3	4
31A2.1	6
31A2.2	4
31A2.3	3
31A3.2	3

fragments. Table 3 shows the comparative analysis of the blood loss in different studies. Risks of blood transfusion and its cardiovascular and immunological complications are reduced due to the relatively less blood loss.

Table 3: Comparison of reduction of post-operative Hb in various studies

Study	n	Hb reduction (g/dl)	
		MIDHS	CDHS
Wong <i>et al.</i> (2009) ²	66	1.4	2.6
Ho <i>et al.</i> (2009) ³	88	1.18	2.4
Wang <i>et al.</i> (2010) ⁴	97	1.3	3.4
Pandey <i>et al.</i> (2013) ⁷	25	0.9	
Ours	29	1.1	

MIDHS: Minimally invasive dynamic hip screw, CDHS: Conventional dynamic hip screw, Hb: Hemoglobin

Table 4: Comparison of wound size in various studies

Study	n	Wound size (cm)	Barrel plate used
		MIDHS	(holes)
Wong <i>et al.</i> (2009) ²	66	2.5	4
Ho <i>et al.</i> (2009) ³	88	5	4
Alobaid <i>et al.</i> (2004) ⁵	48	3	2
Walia <i>et al.</i> (2010) ⁶	25	3	2
Pandey <i>et al.</i> (2013) ⁷	25	5	4
Ours	29	3.65	4

CONCLUSION

Minimally invasive DHS fixation is technically demanding with advantages of less blood loss, minimum soft tissue dissection, and shorter duration of hospital stay in stable and unstable intertrochanteric fractures.

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Ocular Side Effects of Sildenafil: A Prospective Study

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Abstract

Background: Sildenafil citrate (Viagra) is a drug commonly used for the treatment of impotence and pulmonary hypertension. There have been reports of adverse ocular side effects on the administration of these drugs. However, the reports are not consistent, and also very few studies have been done in India and practically none from Eastern India.

Materials and Methods: Standard equipment for visual acuity, visual field, tonometry, Vitreal study, retina and fundus, ocular computerized tomography, electroretinogram, visually evoked potential, fundus fluorescent angiography was used. 100 patients to be put on sildenafil for their medical problem were studied for ocular status and then again after 6 months' sildenafil therapy. 100 healthy persons were also studied before and after giving placebo. The results of the two groups were compared, analyzed, and inference drawn.

Results: About 7 out of test subjects receiving sildenafil had errors in refraction, compared to 5 in controls. Obviously, this was not clinically significant. Only two of those receiving sildenafil reported bluish visual flash that also only those receiving sildenafil in high doses, that is, 100 mg or above. Only one in the test population reported diplopia. 7 of the test subjects showed conjunctival redness. Cataract was noted in none, either in controls or test subjects. Vitreal pathology in the form of vitreal detachment or traction was observed in 3 test subjects. In 4 of the test subjects, intraocular pressure was raised. Paramacular edema was found in two test subjects. Retinal ischemic features were detected in 11 test subjects who received sildenafil for more than 6 months in any dose. Our findings tallied well with studies from abroad, and the main side effects we encountered were conjunctival injection and ischemic ocular retinopathy.

Conclusion: Mentionable acute side effect of sildenafil is bluish visual flash. Some clinically significant patterns of effects, following long-term administration, are also recognized, of which retinal ischemic blockade is the most prominent one.

Key words: Ischemic optic neuropathy, Ocular side effects of sildenafil, Sildenafil

INTRODUCTION

Trobe, MD, the noted neuro-ophthalmologist of the University of Michigan, aptly commented: "Patients who take erectile dysfunction drugs also have other reasons to get ischemic optic neuropathy. But patients who use these drugs-especially those who have vision in only one eye-are entitled to know that they may be at risk for this

condition."¹ Two commonly used drugs prescribed for the treatment of men with erectile dysfunction are: Sildenafil citrate (Viagra) and tadalafil. Having diverted blood flow from the head these two drugs cause two problems, *viz.*, blue vision by interfering with neurotransmission within the retina which is by the way just a temporary side effect and the second one is ischemic optic neuropathy which is of course a permanent one. However, it is difficult to establish a cause-effect relationship in this case because like as we find in case of amiodarone therapy, patients who take this drug might also get ischemic optic neuropathy due to other reasons. However, patients who use these drugs are definitely at risk for ocular side effects.²

According to Dr. Fraunfelder, in addition to vision having a blue hue, patients can also see shimmering around objects.³

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These drugs can cause central serous retinopathy, which is a collection of fluid in the macular and paramacular areas of the retina, and can also cause subconjunctival hemorrhages.⁴ However, a recent study found that there is “lack of conclusive evidence to indicate a direct cause-effect relationship between phosphodiesterase enzyme type 5 (PDE5) inhibitor use and vision-threatening ocular events. Men who use PDE5 inhibitors appear to suffer vision-threatening complications at the same frequency as the general population.”⁵ The study found that minor visual adverse effects occur in 3-11% of users and that they are reversible.

At present, there are several drugs available for oral treatment of erectile dysfunction, but Viagra (sildenafil citrate) is the very first of this kind. Its main function is to inhibit cGMP-specific PDE5. This enzyme is found in high concentrations in the vascular smooth muscle cell as well as in the smooth muscle cells of corpus cavernosum. Other than the latter, it is also found, though in lesser concentrations in blood vessels of the systemic circulation.⁶ In as much as sildenafil acts as a mild vasodilator, it was at one time envisaged as could have been a potential antianginal agent but that study totally fell flat.⁷ Sildenafil is also a weak inhibitor of PDE6.⁷ PDE6 is an enzyme present in high concentrations in the retina, particularly in the light receptor cells cones and rods.⁸ The plasma half-life of sildenafil is about 4 h and reaches a peak plasma concentration in about 1 h.⁸ In flexible-dose studies, visual abnormality in the form of a blue vision or flush was found to occur in 3% of patients treated with sildenafil where subjects received a high but fixed dose of sildenafil from the beginning of the study in the range 100-200 mg.⁹ It is assumed that the effects of sildenafil on vision are probably due to concomitant inhibition of the retinal PDE6 enzyme by sildenafil.¹⁰

Under the above-noted background, we ventured to study the morbidity pattern of side effects of sildenafil on the ocular system in our medical college in Kishanganj, Bihar, India.

MATERIALS AND METHODS

Case Selection

A total of 100 persons, between 18 and 70 years of age, all males, attending the Medicine OPD of MGM Medical College and LSK Hospital, Kishanganj, Bihar, and were getting sildenafil for the treatment of impotence, pulmonary hypertension, or for any other reason were randomly selected as subjects in the present study. They were thoroughly checked for ocular health before the commencement of sildenafil therapy. In our study, only

errors of refraction were allowed, but persons with other initial ocular defects were rejected from the study. The same was also applied for controls. 100 male healthy persons were selected as controls, and they were given a placebo instead of sildenafil for 6 months. Thus, necessary data from 200 eyes were obtained.

Exclusion Criteria

- A. All females of any age to keep uniformity of study
- B. Males of <18 years age and more than 70 years were excluded from the study
- C. Persons suffering from systemic illnesses such as diabetes mellitus, essential hypertension which themselves can have adverse effects on eyes
- D. Persons getting drugs other than sildenafil, which can affect eyes
- E. Persons already suffering from diseases of the eye before starting sildenafil, except minor errors of refraction
- F. Individuals with history or signs of surgical and/or laser interference upon eye
- G. Subjects who did not agree to give written consent.

Before commencement of the study permission of the college authorities, IEC, and written consent from participants were obtained.

Equipment Used

1. Snellen's chart
2. Jaeger's chart
3. Humphrey's visual field analyzer
4. Streak retinoscope
5. Ophthalmoscope: Direct and indirect
6. Fundus lens
7. Fundus fluorescent angiography (FFA) instruments
8. Ocular computerized tomography (OCT) apparatus
9. Visual evoked potential recorder
10. Ocular tonometer.

Clinical Study

All subjects and controls were first subjected to standard clinical examination in the MOPD preceded by usual history-taking, and followed by common laboratory tests. Being assured that these were within normal limits they were then officially registered as either subjects or controls.

These registered persons were then brought to ophthalmology OPD for ocular examinations. After a simple naked eye examination with torch and eye loop, they were then tested for acuity of vision regarding both near and distant vision with Snellen's and Jaeger's chart. Now, they were examined by direct and indirect ophthalmoscopy before and after pupillary dilatation. A streak retinoscopy was also done as also ocular tonometry.

The retina was then examined with fundus lens, FFA, and electroretinography. Subsequently, visual evoked potentials and OCT were also performed.

Data obtained from each eye by the above methods were corroborated.

Data Analysis

Data obtained from the clinical study were analyzed using Microsoft Excel. The findings of the controls were compared with those of the subjects receiving sildenafil.

RESULTS

The results of this study are given in Table 1 and Figure 1.

DISCUSSION

Our results show that 7 out of test subjects receiving sildenafil had errors in refraction, compared to 5 in controls. Obviously, this was not clinically significant. Only two of those receiving sildenafil reported bluish visual flush that also only those receiving sildenafil in high doses, that is, 100 mg or above. Only one in the test population reported diplopia. 7 out of 60 test subjects showed conjunctival redness. Cataract was noted in none, neither in controls nor test subjects. Vitreal pathology in the form of Vitreal detachment or traction was observed in 3 test subjects. In 4 of the test subjects, intraocular pressure (IOP) was raised. Paramacular edema was found in two test subjects. Retinal ischemic features were detected

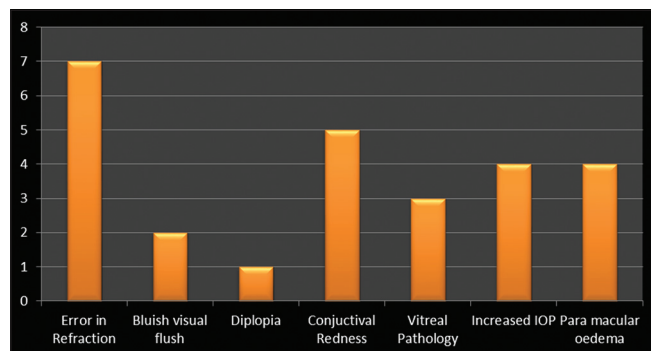


Figure 1: The ocular effects of sildenafil in column diagram

in 11 test subjects who received sildenafil for more than 6 months in any dose.

Studies done by previous workers showed that sildenafil did not have any noticeable ocular effect during short-term use except bluish visual flashes that also when suddenly put on a high dose (>100 mg).¹¹ However, when given for a long period, sildenafil does produce ocular side effects. These are discussed hereunder.

- According to reports by Pfizer¹² ocular side effects occur in:
 - About 3% of men taking doses of 25-50 mg
 - About 11% taking 100 mg doses
 - About 50% of men taking 200 mg
 - Nearly all men taking 600-800 mg.

In one report of the FDA Office of Post marketing drug risk assessment, it is mentioned that there have been a few cases of signs and symptoms suggesting conjunctival vasodilatation following sildenafil therapy.¹³ The commonly occurring presentations of this type are: Conjunctival injection, ocular redness, bloodshot appearance, and ocular burning. Two instances of extraocular muscle paresis have also been documented. One case reported that in the American Journal of Ophthalmology¹⁴ mentioned that an oculomotor nerve paresis but not affecting pupil was found to occur in a 56-year-old man with the pre-existing microvascular disease 36 h after he took a 50 mg dose of sildenafil. Again an abducent nerve palsy in a 76-year-old man with diabetes was found in another case. Other commonly reported complaints within the eye observed with sildenafil therapy are: Posterior vitreous detachment, retinal hemorrhage, and vascular occlusion. However, they were more common in individuals with preexisting diabetes mellitus, and these reports were not very frequent either.¹⁵

In early animal studies with sildenafil, it was found that sildenafil inhibits retinal PDE6 enzymes with an IC₅₀ of 27-58 nM.¹⁶ This was substantially less than its effect on the intended target, PDE5 (IC₅₀ 3.9 nM), and therefore, from this it could be presumed that sildenafil is safe for eye in its standard dose therapy. Yet, the evaluation of the safety of high doses of sildenafil on retinal histopathology was undertaken in rats and dogs as also on electroretinograms (ERGs) in the dog.¹⁷ As the plasma

Table 1: Comparison of ocular abnormalities between healthy controls and persons getting sildenafil

Population type	Error in refraction	Bluish visual flush	Diplopia	Conjunctival redness	Cataract	Vitreal pathology (detachment/traction)	Increased IOP	Paramacular edema	Retinal hemorrhage
Healthy controls	05	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Subjects getting sildenafil for 6 months	07	02	01	05	Nil	03	04	04	Nil

IOP: Intraocular pressure

levels of sildenafil decreases, the ocular side effects also decrease *pari passu*.¹⁷

Subsequent to the animal studies, studies were done to investigate the visual effects of sildenafil in human clinical studies also. These studies were done in three phases, *viz.*, Phase I, Phase II, and Phase III studies, that is, short-term, intermediate-term, and long-term studies.

In both Phase I and Phase II studies, sildenafil did not produce clinically significant changes in visual acuity, ERGs, IOP, contrast sensitivity, or pupillometry measurements compared with placebo. If however, a single oral dose of 100 and 200 mg was applied, a transient impairment of color discrimination in the blue/green range was detected using the Farnsworth-Munsell Hue test. However, these effects were fully reversible, dose related. Further study also failed to demonstrate any side effect on visual performance in any of the subjects.¹⁸ Overall, sildenafil was generally well tolerated in this limited sample of patients.¹⁹ In more than 50 countries, extensive use of sildenafil almost confirms well-tolerance of the drug in general population.²⁰

Another point that we need to distinguish actual drug effect for attribution of vascular events to sildenafil is from too much exertion during sexual arousal which obviously happens after sildenafil therapy.

CONCLUSIONS

Overall, current clinical data suggest that treatment with sildenafil can cause short-term, transient, reversible effects on color discrimination in the blue-green range with few if any clinically significant effects on other acute visual function tests. Some clinically significant patterns of effects, following long-term administration, are presently recognized. Of these, the retinal ischemic blockade is the most prominent one.

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Etiology and Risk Factors of Stroke in Young: A Prospective Study

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Abstract

Introduction: Stroke is one of the most important causes of high morbidity and mortality worldwide. Stroke was defined by World Health Organization criteria as rapidly developing clinical signs of focal, at times, global disturbance of cerebral function lasting for more than 24 h or leading to death with no apparent cause other than vascular origin.

Materials and Methods: This study was prospective descriptive and clinical study. Patients diagnosed to have stroke in young admitted in MGM Hospital in the Department of Medicine from January 2012 to August 2013.

Results: Sex ratio in our study was 1.7:1 (male:female). The mean age in the study population was 31.3 years. Male and female patients were 31.88 and 30.5 years, respectively. The majority of strokes occurred between the ages of 36 and 40 years at 40% and 43.75% of male patients were also in the same age group; whereas in females, it was only 28%. 36% of the all the patients were smokers, and among ischemic and hemorrhagic strokes 33.3% and 50% were smokers, respectively. Alcohol consumption was seen in 42% of patients and among ischemic strokes 39.1% and hemorrhagic strokes 75%. Diabetes mellitus (DM) was seen in 4% of patients, and they have ischemic stroke. Hypertension (HTN) was seen in 14% of the study group. Among ischemic strokes, 8.6% were hypertensive. Whereas HTN was seen in 75% of intracerebral hemorrhage cases. Transient ischemic attacks and previous family history of stroke were both seen in 24% of the patients. 21.7% of ischemic strokes also had the same, 50% of the hemorrhagic strokes had this history.

Conclusion: Smoking and alcohol consumption were important acquired risk factors for stroke among young. HTN and DM were nonmodifiable risk factors commonly seen, especially HTN in cases of intracerebral hemorrhage. Rarer risk factors like homocysteinemia should be considered during evaluation. Diagnostic challenges are to be expected when evaluating these patients.

Key words: Risk Factors, Stroke, Young

INTRODUCTION

Stroke is one of the most important causes of high morbidity and mortality worldwide. Stroke was defined by World Health Organization criteria as rapidly developing clinical signs of focal, at times, global disturbance of cerebral function lasting for more than 24 h or leading to death with no apparent cause other than vascular origin.¹ The diseases of cerebral blood vessels and the related

infarcts and hemorrhages, though principally occur in the elderly, the young are not spared. Community-based surveys from the West and Japan indicate average annual incidence of stroke as 111-180/100,000 general population and 9-28/100,000 in young people below the age of 45 years. Data from major Indian hospitals show 5-15% of stroke in young of all neurological admissions.²

Although various studies on stroke in young included subjects from second to fourth or fifth decade, in general, stroke in young includes subjects falling under the age group of 40 years.^{3,4} The etiology may vary with different age groups, but most of the risk factors are common to all age groups. Still, certain factors are confined to the young.

Stroke affecting the young has potentially devastating consequences on the individual, his family and the society

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in general. Several studies have analyzed the risk factors of stroke in young, but considering its impact on younger generation, it needs more studies for identification and modification of risk factors.⁵⁻¹⁰

MATERIALS AND METHODS

Study Design

A prospective descriptive and clinical study.

Source of Data

Patients diagnosed to have stroke in young admitted in MGM Hospital in the Department of Medicine from January 2012 to August 2013 and fulfilled the inclusion and exclusion criteria. The sample size was restricted to 50 cases.

Inclusion criteria: (1) Age <40 years, (2) patients with abrupt onset of focal or global neurological deficit attributable to vascular cause and persist for more than 24 h.

Exclusion criteria: Head injury.

Method of Collection of Data

All patients who fulfilled the inclusion and exclusion criteria were included in this study. A pro forma was prepared which included detailed history, clinical examination and requisite investigations available in our hospital. History includes all symptoms pertaining to stroke in detail with emphasis on all the risk factors attributable to the stroke in young. A detailed clinical examination was done, and neurological deficits were identified. Relevant investigations such as hemoglobin, total white cell count, erythrocyte sedimentation rate, routine urine analysis, blood glucose, blood urea, serum creatinine, serum lipid profile, chest X-ray, computed tomography scan, electrocardiography, bleeding time, clotting time, test for HIV, echocardiogram, activated partial thromboplastin time, and thrombin time were done for all patients. Other 53 investigations such as protein C, protein S, antithrombin 3, serum homocysteine, serum fibrinogen, antinuclear antibody, antiphospholipid antibodies, magnetic resonance angiography, and magnetic resonance venography if required and sickling test (if required) were done.

RESULTS

In this study, it has shown that stroke in young is more common in age group between 31 and 40 (60%) than in age <30 years. Youngest recorded was 15-year-old female with internal carotid artery (ICA) dissection.

Stroke in young also more common in males (64%) than in females (36%).

Overall smoking is present in 18 patients, in that only 4 patients (8%) are under the age 30, remaining 14 patients (28%) are between the age group 31 and 40. Smoking is only seen in male patients.

Alcohol intake is seen in 21 (42%) patients, in which 6 (12%) are under the age 30 and 15 patients are in between the age group 31-40. Alcohol intake also presents only in males. Hypertension (HTN) is relatively less common in young stroke patients seen only in 7 (14%).

It is also relatively common in the age group between 31 and 40, i.e., 6 patients (12%). It is seen only in one patient under the 30 years age group.

Diabetes is rare in young stroke patients seen only in 2 (4%) patients; those are also in the age group between 31 and 40 years.

Family history of stroke is present in 24% (12) of patients. In that 8% (4) are under the age 30 and 16% (8) are between the age 31 and 40.

Dyslipidemias are present in 34% of patients in this 30% of patients are in the age group 31-40 years. Only 4% of patients are under 30 years.

In the young also ischemic stroke is more common constitutes 84% of cases, venous infarcts 8% and hemorrhage 8%.

Hemorrhagic stroke seen only in male patients and venous stroke is more commonly seen in female patients (female: male - 3:1).

All the common risk factors are compared for the outcome of stroke whether ischemic or hemorrhagic.

Except the risk factor HTN for the hemorrhagic stroke ($P < 0.0067$) all other risk factors are not significant for the type of stroke.

In 23 patients (42%) only etiology is established. Out of total 50 cases, 26% of cases are preventable as they are due to infectious in etiology. Atherosclerosis is more common as age advances. It is seen in 19 patients (38%), out of which 17 (34%) are in the age group 31-40.

Atherosclerosis is more commonly seen, i.e., 34% in the patients in whom the etiology is not known.

On the contrary, it is seen only in 4% of patients with known etiology for this P value is 0.03 which shows the association is statistically significant (Tables 1-15).

DISCUSSION

Our study was based in south India comprising mainly a rural population. It should prove useful, then, for the diagnosis, management and prognosis of young stroke patients in similar areas. Sex ratio in our study was 1.7:1 (male:female). Mehndiratta *et al.*² showed a ratio of 1:08 in North India. The mean age of all the patients in our study was 31.38 years; a study in north India by Mehndiratta *et al.*² showed a similar mean age of 31.97 years. The mean ages of males and females were 30.66 and 33.28 years.² Our study had a higher mean age group among men at 31.88 years; whereas among women, it was much lower at 30.5 years probably because there were more number of females in this study who presented with cerebral venous thrombosis (CVT) in the early age.

Nagaraj *et al.*⁵ had showed an incidence of smoking associated with stroke to be 15% Dalal⁶ 40%, Bogousslavsky and Pierce⁷ 36.6% and Alvarez *et al.*⁸ 56.7%. In meta-analysis of 32 separate studies of relation between smoking and

stroke analyzed by Shinton and Beevers,⁹ there was a strong association between smoking and incidence of stroke. Our study showed 36%.

In the study of Nagaraj *et al.*, the frequency of alcohol consumption was 15%, Alvarez *et al.*⁷ 37.8% and Dalal⁶ 40%, the present study had 42%. In study by Nagaraj *et al.*,⁵ the incidence of diabetes was 11%, Dalal⁶ 20%, Grindal *et al.*¹⁰ 5.2%, Zunni *et al.*¹¹ 14.8% and Alvarez *et al.*⁸ 10.9%, whereas in our study it was 4%. In this study, 7 patients (14%) had HTN Dalal⁶ showed an incidence of 46.7%, Alvarez *et al.*⁸ 23%, Nagaraj *et al.*⁸ 22.6% and Grindal *et al.*¹⁰ 17.2%.

In the study of Mehndiratta *et al.*,² the incidence of homocysteinemia was 0.9%. This study showed 12% which did not concur with the above study probably because the levels of homocysteine can elevate temporarily after stroke, so it should be measured again after 8 weeks. In this study, homocysteine was measured during presentation of stroke.

Tubercular meningitis comprised 12% of cases which is higher in comparison to Mehndiratta *et al.*² But in a study by Grau *et al.*¹¹ showed an incidence of 19.2% which concurred with the present study. Rheumatic heart disease (RHD) leading to cardioembolic stroke comprised 10% of the cases. In a study by Mehndiratta *et al.*² showed 30%. Bansal *et al.*¹² showed an incidence of 16%. This study had less number of cases of RHD in comparison to other Indian studies probably because of small study group and incidence of RHD is decreasing now.

Diagnosis in other determined etiology includes hypercoagulable states 12%, viral encephalitis 4%,

Table 1: Clinical and laboratory parameters of the patients

Parameters	N (%)
Total number of cases	50
Male:Female ratio	32:18 (64%:36%)
Number of patients <30 years	20 (40)
Number of patients between 31 and 40 years	30 (60)
Smoking+	18 (36)
Alcohol intake+	21 (42)
HTN+	7 (14)
DM+	2 (4)
Dyslipidemia+	8 (16)
Ischemic stroke	42 (84)
Venous stroke	4 (8)
Hemorrhagic stroke	4 (8)
Homocysteine levels elevated	6 (12)
Etiology known	23 (46)
Carotid artery atherosclerosis+	19 (38)

DM: Diabetes mellitus, HTN: Hypertension

Table 2: Age and sex distribution

Age (years)	Female	Male	Total
<30	8	12	20
31-40	10	20	30
Total	18	32	50

Table 3: Smoking

Age (years)	Present	Absent	Total
<30	4	16	20
31-40	14	16	30
Total	18	32	50

Table 4: Alcohol

Age (years)	Yes	No	Total
<30	6	14	20
31-40	15	15	30
Total	21	29	50

Table 5: HTN

Age (years)	Present	Absent	Total
<30	1	19	20
31-40	6	24	30
Total	7	43	50

HTN: Hypertension

Table 6: Diabetes

Age (years)	Present	Absent	Total
<30	0	20	20
31-40	2	28	30
Total	2	48	50

Table 7: Family history of stroke

Age (years)	Present	Absent	Total
<31	4	16	20
31-40	8	22	30
Total	12	38	50

Table 8: Dyslipidaemia

Age (years)	Present	Absent	Total
<30	2	18	20
31-40	6	24	30
Total	8	32	50

Table 9: Type of stroke

Sex	Ischemic	Venous	Hemorrhagic	Total
Female	15	3	0	18
Male	27	1	4	32
Total	42	4	4	50

Table 10: Risk factor – Type of stroke

Risk factor	Infarct	Haemorrhage	P value
Age			
<30 years	20	0	0.14
31-40 years	26	4	
Sex			
Female	18	0	0.28
Male	28	4	
Smoking			
Present	16	2	0.6
Absent	32	2	
Alcohol			
Present	18	3	0.3
Absent	28	1	
HTN			
Present	4	3	0.0067
Absent	42	1	
DM			
Present	2	0	1.0
Absent	44	4	
Family h/o stroke			
Present	10	2	0.23
Absent	36	2	
Hypercoagulable states			
Present	6	0	1.0
Absent	40	4	

DM: Diabetes mellitus, HTN: Hypertension

ICA dissection 2%, sickle cell anemia 2%, gestational trophoblastic disease 2%, and middle cerebral artery stenosis in HIV 2% CVT was seen in 4 patients (8%). This does not concur with the study by Venkataraman *et al.*¹³ where incidence was 4.3%, but Towbin¹⁴ found CVT in 9% of 182 consecutive autopsies. Boussier and Barnett¹⁵ trial suggests that the true incidence is higher than that thought from autopsy series. Atherosclerosis had emerged

Table 11: Etiology of stroke

Etiology	Type of stroke	Number of patients
TB meningitis	Ischemic stroke	6
RHD	Ischemic stroke	5
Hypercoagulable states	Ischemic stroke	2
	Venous stroke	4
Viral encephalitis	Ischemic stroke	2
Other determined etiology	Ischemic stroke	4
Undetermined etiology	Ischemic stroke	27
Total		50

TB: Tuberculosis, RHD: Rheumatic heart disease

Table 12: Atherosclerosis with age

Carotid atherosclerosis	Present	Absent	Total
<30 years	2	18	20
31-40 years	17	13	30
Total	19	31	50

Table 13: Atherosclerosis with etiology

Carotid atherosclerosis	Known etiology	Unknown etiology	Total
Present	2	17	19
Absent	21	10	31
Total	23	27	50

as the main etiological factor responsible for 38% of the patients in our study. It is more seen as the age advances and seen more commonly in patients in whom etiology was not determined. So that it appears to be the major factor responsible for stroke in young also atherosclerosis was considered based on the criteria similar to Adams and Victor¹⁶ when the patient had 2 or more risk factors for atherosclerosis in the absence of identifiable causes. Bevan *et al.*¹⁷ showed 31%. In a case-control study at NIMHANS by Dakshinamurthy,¹⁸ it was found that 50% of stroke in young could be attributed to atherosclerosis.

Evaluations of various risk factors of stroke in young are important as they may play a major role in predisposing an individual to a disease which has terrible impact on the family and society. Stroke in young deserves an extensive evaluation that includes hematological, biochemical and angiographic studies. By these approaches, a large number of potential causes can be detected, and the treatment of these patients can be tailored according to the outcome.

Limitations of the Study

This study was conducted in only 50 patients. Studies with more number of patients are required to apply the results for the community. Rare causes cannot be found as there is no possibility to do genetic analysis and further investigations. Bias may occur as some patients may die even before reaching hospital or before complete testing.

Table 14: Comparison of risk factors

Risk factors	Present study	Dalal ⁶	Nagaraj <i>et al.</i> ⁵	Grindal <i>et al.</i> ¹⁰	Bogousslavsky and Pierce ⁷	Alvarez <i>et al.</i> ⁸
Smoking	36	40	15		36.6	56.7
Alcohol	42	40	15			37.8
DM	4	20	11	5.2		10.9
HTN	14	40	22.6	17.2	7.3	23.3
Family H/O stroke	24				17.1	

DM: Diabetes mellitus, HTN: Hypertension,

Table 15: Comparison of various etiology

Authors	Year	Common etiology
Srinivasan <i>et al.</i>	1984	Meningovascular syphilis, CVT
Adams <i>et al.</i> ¹⁶	1995	Cardioembolic, atherosclerosis
Bogousslavsky and Pierce	2000	Cardioembolic, atherosclerosis
Alvarez <i>et al.</i> ⁸	1989	Cardioembolic, atherosclerosis
Dalal <i>et al.</i> ⁶	1997	Atherosclerosis
Bevan <i>et al.</i>	1990	Cardioembolic, atherosclerosis
Nagaraj <i>et al.</i> ⁵	1997	APLA
Present study	2013	TB meningitis, cardioembolic, atherosclerosis

APLA: Antiphospholipid antibodies

CONCLUSION

This was one of the few studies done about strokes in young in rural populations in our country. The majority of the age distribution of stroke in this study was between the ages of 36 and 40 years, and it was the same among males. However, it was lower in females at 25-35 years. Smoking and alcohol consumption were important acquired risk factors for stroke among young. HTN and diabetes mellitus were nonmodifiable risk factors commonly seen, especially HTN in cases of intracerebral hemorrhage. Rarer risk factors like homocysteinemia should be considered during evaluation. Dyslipidemia in the form of elevated low-density lipoprotein and decreased high-density lipoprotein were also common. Atherosclerosis was the most common etiology for stroke in young. Cortical venous thrombosis should be kept in mind in young females. Diagnostic challenges are to be expected when evaluating these patients.

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Role of Systemic Antibiotics in Phacoemulsification Cataract Surgery

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Abstract

Introduction: Phacoemulsification under topical anesthesia is a preferred mode of cataract extraction. In recent years, the trend has changed toward using topical drops and intracameral antibiotics instead of systemic antibiotics in phacoemulsification cataract surgery.

Objective: To analyze the role of systemic antibiotics in phacoemulsification cataract surgery.

Materials and Methods: The present study is randomized controlled trial study which was conducted at Tertiary Eye Care Centre. A total of 100 subjects underwent cataract surgeries with phacoemulsification technique during one-quarter (April-June 2016). Surgeries were done by phaco technique.

Outcome Measures: The post-operative best-corrected visual acuity (BCVA) along with grades of congestion and discharge was compared among various groups. In addition to this, A/C reaction cells and flare along with corneal edema and vitritis were noted in two groups. Endophthalmitis was an important criterion, which was not seen in either group in any case.

Results: BCVA in the two groups was comparable after 1 month. In no case, endophthalmitis was seen. Cells and flare on the first post-operative day were seen in both groups but was insignificant.

Conclusion: It can be very well concluded that even with no antibiotic coverage the BCVA and rate of complications are nearly same if done by phacoemulsification technique but to be on safer side always use intracameral antibiotic in all cases where no systemic antibiotics are given

Key words: Antibiotics, Cataract, Phaco, Systemic, Topical

INTRODUCTION

Phacoemulsification has become the preferred method of cataract extraction worldwide because the complication rate in the expert's hands is minimal and the technique provides an almost quiet eye early postoperatively and an early visual rehabilitation.¹ However, for the masses especially in developing countries, the manual small incision cataract surgery (SICS) offers the advantage of sutureless cataract surgery at a low cost.² The smaller

incision of phacoemulsification compared to extracapsular cataract extraction (ECCE) renders the operation safer since decompression of eye is avoided. In addition, the procedure is associated with little induced post-operative astigmatism and early stabilization of refraction (usually 3 weeks for 3 mm incision). Post-operative wound-related problems such as iris prolapse are almost eliminated. One disadvantage of phaco is that it requires complex machinery to break up the lens nucleus and remove it through a small incision.³ In the recent years, trend has changed toward using topical drops for anesthesia.⁴⁻⁷ Furthermore, the majority of doctors use systemic antibiotics in developing countries. Many studies have been done on phacoemulsification, but this study focuses on the need of systemic antibiotics in the pre- and post-operative period of phacoemulsification. To the best of my knowledge, it is the first study to evaluate the need of systemic antibiotics in phacoemulsification.

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MATERIALS AND METHODS

Study Place

Rohilkhand Medical College and Hospital (Tertiary Eye Care Center).

Study Period

It is 3 months from April to June 2016.

Inclusion Criteria

Randomly 100 patients who came in OPD were included in the study.

Exclusion Criteria

Complicated cases having high blood pressure, diabetes, and severe asthma and non-cooperative patients.

METHODOLOGY

A total of 100 consecutive patients undergoing phacoemulsification were included in this study during 3 months. Certificate from the Ethical Review Committee was taken before conducting this study.

All confirmed cases were grouped into two categories on a randomized basis. A total of 45-50 cases were taken in each group.

Group A: It was a control group receiving a standard protocol of systemic antibiotics ciprofloxacin (500 mg) twice daily for 5 days. Along with this, anti-inflammatory drugs were also started.

Group B: This group received no systemic antibiotics only anti-inflammatory were given, and phacoemulsification was done under local anesthesia.

Following post-operative parameters were used for testing efficacy:

- Grades of congestion
- Discharge
- A/c reaction (cells and flare)
- Corneal edema
- Vitreous cells and vitritis
- Membrane formation
- Endophthalmitis.

Pre-operative data collection for each eye included the patient's age and gender, pre-operative acuity (UCVA and BCVA, i.e., uncorrected and best-corrected visual acuity, respectively) details of slit lamp examination of the anterior segment and preexisting ocular conditions likely to influence either the operative course or the final visual acuity. The intraocular pressure (IOP) was recorded

in all the cases by schiotz tonometry. The posterior pole was examined with slit lamp biomicroscopy using +90D or +78D lens. Indirect ophthalmoscopy was done to evaluate the retinal periphery. The status of another eye was similarly documented. In the case of nonvisibility of the posterior segment, B-scan was performed for the eye. Axial length measurement and keratometry were done and the SRK-2 formula was used to calculate the intraocular lens (IOL) power required. The systemic status of the patient was evaluated to ensure fitness for surgery under local anesthesia. Operative data included the name of the consultant, date of surgery, technique of surgery employed including the details of each step and the details of IOL implanted. The occurrence of any intraoperative complications was documented with details of subsequent management. All surgeries were phacoemulsification surgeries.

Steps of Surgery

All the prophylactic measures such as pre-operative lash trimming irrigation of lacrimal drainage system with antibiotic, antiseptic preparation of the operative site using povidone iodine were used in both the groups.

After cleaning and draping the eye, a wire speculum was applied. A paracentesis was made at 10'0 clock position with microvitrectomy blade. Trypan blue was used viscoelastic was injected into the anterior chamber. Whenever the capsulorhexis threatened to extend to the periphery, it was converted to a can opener capsulotomy. 7-10 cases were converted to the SICS technique where capsulotomy was done. Phaco was performed using peristaltic Chakshu machine. Standard divide and conquer technique was used. A clear corneal incision with 3.2 mm keratome blade was made. A second paracentesis was made at 2'0 clock position hydro dissection, and hydro delineation was performed after confirming the free rotation of the nucleus. A four-quadrant technique was used during trenching each quadrant was then emulsified and aspirated; cortical matter was cleaned using automated irrigation and aspiration. Anon-foldable poly methyl metha acrylate posterior chamber IOL with 5.25 mm optic was implanted into the capsular bag under viscoelastic. Viscoelastic was removed using automated irrigation and aspiration. The wound was checked for absence of leak and if present was sutured. Conjunctival flap repositioned over the incision. Intracameral antibiotic cefuroxime 0.25 ml was given in all patients at the end of surgery. Speculum was removed and eye was patched after instilling a drop of antibiotic.

Post-operative data were documented on the 1st day after the 1st week and finally at 4-week visit. Prednisolone acetate 1% eye drops with antibiotic combination were given 1 h for initial 2 days and then 6 times daily for 1st week. From

the 2nd week onward, antibiotic steroid combination was tapered over the next 4 weeks. On each of the visits UCVA and pinhole, improvements were noted along with slit lamp examination of the anterior segment along with fundus examination.

RESULTS

A total of 100 cataract surgeries were done by phacoemulsification cataract extraction. Patients were divided into two groups: Group A consisted of patients who underwent phaco with antibiotic coverage and Group B consisted of patients who underwent phaco without antibiotic coverage. Patients were followed up postoperatively on day 1 at 1st week and finally at 4th-week visit. BCVA and pinhole visual acuity were noted in all the visits, and final BCVA is shown in Table 1 and Figure 1. Grading of cells was performed with 2 mm long and 1 mm wide slit beam with maximal light intensity and magnification. The findings are recorded in Table 2. Cells and flare decreased subsequently in week's period of time. Cells and flare were seen in 12 eyes in Group A (6%) and 13 cases in Group B (6.5%). Vitreous cells were seen in 2 cases (1%) in Group A and 3 cases in Group B.

Table 1: BCVA (after 1 month)

Groups	6/60-6/36	6/36-6/18	6/18-6/12	6/12-6/6
Group A	2	10	15	18
Group B	1	13	17	15

BCVA: Best-corrected visual acuity

Table 2: Grading of anterior chamber cells in Groups A and B

Grade	Number of patients			
	Parameters			
	AC cells		Flare	
	Group A	Group B	Group A	Group B
0.5+	2 cases	3 cases	Nil	Nil
1+	1 case	2 cases	2 case	2 case
2+	2 cases	2 cases	1 case	2 case
3+	0	0	3 case	2 case
4+	Nil	Nil	1 case	0

Table 3: Parameters in cataract surgery in two groups

Parameters	Group A	Group B
Congestion	10	12
Discharge (watery)	2	1
Corneal edema	7	10
Cells (anterior chamber)	5	7
Flare (anterior chamber)	7	6
Vitreous cell and vitritis	2	2
Endophthalmitis	0	0

The mean age of the patients in both the groups was comparable.

There was no statistically significant difference in the age distribution or gender distribution in the two groups. Grades of congestion were noted in two groups. 10 patients in Group A and 12 patients in Group B had slight to moderate congestion (grading according to the BRIEN HALDEN VISION INSTITUTE). The discharge was watery in 2 patients in Group A and 3 patients in Group B; 1 patient had mucopurulent discharge which was well managed with higher antibiotics postoperatively. This patient was from Group B. Corneal edema (striate keratitis) was seen in 7 patients in Group A and 10 patients in Group B. Cells in the anterior chamber were seen in 5 cases in Group A and 7 cases in Group B. Flare was seen in 7 cases in Group A and 6 cases in Group B.

One case had membrane formation in the post-operative period, which was well managed by dilator anti-inflammatory and antibiotic coverage. Vitritis was seen in 2 cases in both the groups, which was controlled by steroids. In no case, endophthalmitis was seen in either group. Table 1 illustrates the post-operative visual acuity in the two groups. IOL was implanted successfully in all the cases. 8-10 cases were converted to SICS due to the extension of capsulorhexis. Better visual acuity was seen in group A due to younger age group pts. 5 cases in group A and 4 cases in group B converted to SICS are not included in BCVA.

DISCUSSION

Age-related cataract is a leading cause of reduced vision in both developed and developing countries (FRIEDMAN 2004, AND ESNIKOFF 2004). Surgery for cataract involves removal of opaque lens and replacement with IOL. To date, a number of techniques have been used for cataract surgery, however, phacoemulsification is most common method. Many surgeons have also used other methods such as intra and ECCE phaco section and sandwich and phaconit. Over the year, the techniques of cataract surgery have evolved into a safe and successful procedure for visual rehabilitation.

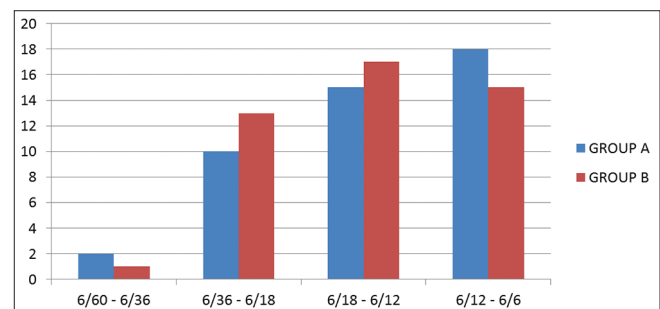


Figure 1: Best corrected visual acuity in two groups

Corneal Edema

Post-operative corneal edema can localize or diffuse. Post-operative edema in upper half of cornea near the main section indicates intraoperative trauma. Factors that predispose are mechanical endothelial trauma, prior endothelial disease or cell loss, excessive post-operative inflammation, and elevation of IOP (Reddy).

Aqueous Cells

Aqueous cells indicate disease activity and their number reflects disease severity. Grading of cells is performed with a 2 mm long and 1 mm wide slit beam with maximal light intensity and magnification. Improvement of inflammation is defined as either a two-step decrease in the level of activity or a decrease to inactive and worsening is defined as a two-step increase in a level of activity or an increase to a maximum grade.³ In our study, the improvement was seen in a week's period in 12 cases of edema.

Aqueous Flare

Aqueous flare reflects the presence of protein due to a breakdown of blood-aqueous barrier. Flare may be graded by laser interferometry using a flare meter or clinically by observing the degree of interference in the visualization of iris using the same settings as for cells. In our study, flare improved in 12 cases except in 1 case where membrane formation occurred³ which was improved in 15-day period.

Endophthalmitis

Endophthalmitis is a potentially vision-threatening complication of cataract surgery but may also occur following ocular procedure, trauma to the eye, metastatic systemic infection, and systemic inflammatory disorder.⁸⁻⁹ Typically, post-operative endophthalmitis is caused by the perioperative introduction of microorganism into the eye.¹⁰ The primary source of this intraocular infection considered to be bacteria from the patient ocular cornea, conjunctiva, lacrimal gland, blepharitis, and extraocular muscles.¹¹ However, contamination of sterilize instrument disposable supplies, prepared solution, the surgical field, or intraocular lens have been reported. Epidemic cluster of endophthalmitis has resulted from these types of external contamination.^{12,13}

With the advent of intracameral antibiotics and proper betadine painting of eye at least for 4-5 min, the rate of incidence of endophthalmitis has decline a lot. Most series report on an incidence rate ranging 5-4% in different studies worldwide.^{14,15}

In our study, none of the patients had endophthalmitis.

As number of patients were not large, so certain clinical signs and outcome cannot be generalized. Post cataract

surgery endophthalmitis is very uncommon but very serious complication of cataract surgery. There are several series on the epidemiological study of endophthalmitis from the India.

The rare nature of endophthalmitis makes randomized controlled trails difficult to conduct because of the very large sample sizes needed to make statistically valid comparisons. Thus, few trials have been conducted, and all that we are aware of are included here.

The antibiotic of choice has varied across studies of intracameral injections, with moxifloxacin, vancomycin, and cefuroxime all showing a reduction compared to no antibiotic injection (Table 3).¹⁶

CONCLUSION

Many studies have been done on phacoemulsification, but this study focuses on the role of antibiotics in pre- and post-operative period of phacoemulsification. There is no significant difference in BCVA and rate of complications in the two groups. Only limitation being the small size of the study group and short period of the study.

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Acute Retention of Urine: A Case Series to Establish Cause and Various Treatment Modalities

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Abstract

Introduction: Urinary retention is the inability to voluntarily urinate. Acute urinary retention (AUR) is the sudden and often painful inability to void despite having a full bladder. Chronic urinary retention is painless retention associated with an increased volume of residual urine. Patients with urinary retention can present with complete lack of voiding, incomplete bladder emptying, or overflow incontinence.

Materials and Methods: A prospective study of 18 months duration consists of patients. The patients were selected consecutively as and when they were presented during the study period considering the inclusion and exclusion criteria. Moreover, the outcome of results was assessed on cases of AUR in male patients aged >5 years in Era's Lucknow Medical College and Hospital.

Results: Mostly 69 (69%) patients in spontaneous retention were major AUR type. This may be due to mainly as the result of locoregional/general anesthesia and excessive alcohol intake of studied patients. Associated symptoms of studied patients in which 76 patients had fever followed by 70 patients had obstructive lower urinary tract symptoms (LUTS), 36 patients had hematuria, 30 patients had irritating LUTS, and 10 had discharge complaint, respectively. In the causes of AUR, 43 (43%) patients had found prostate enlargement.

Conclusion: Older age, severe LUTS, large drained volume at catheterization, and AUR of spontaneous origin favor Trial without catheter (TWOC) failure. As these variables also predict the risk of recurrent AUR/surgery after a successful TWOC, they could be used to identify the subgroup of patients that cannot be managed by medical therapy alone and should rapidly undergo surgery.

Key words: Acute retention, Treatment, Urine

INTRODUCTION

Urinary retention is the inability to voluntarily urinate. Acute urinary retention (AUR) is the sudden and often painful inability to void despite having a full bladder. Chronic urinary retention is painless retention associated with an increased volume of residual urine. Patients with urinary retention can present with complete lack of voiding, incomplete bladder emptying, or overflow incontinence.¹⁻³

In two large cohort studies of US men 40-83 years of age, the overall incidence was 4.5-6.8/1,000 men/year. The incidence dramatically increases with age so that a man in his 70s has a 10% chance and a man in his 80 s has more than 30% chance of having an episode of AUR. The prevalence of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) increases with increasing age. Similar data from Indian population is not available.^{4,6}

Acute Retention

AUR is usually characterized by the sudden, painful inability to void; painless AUR is rare and is often associated with central nervous system pathology. AUR may be further subdivided into precipitated or spontaneous retention. Precipitated AUR may be triggered by such events as surgical procedures with general or locoregional anesthesia, excessive fluid intake, bladder overdistension, urinary tract

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infections, prostatic inflammation, excessive alcohol intake, or use of drugs with sympathomimetic or anticholinergic drugs. In most cases, no triggering event is identified and AUR is called spontaneous. Spontaneous AUR is most commonly associated with BPH and is regarded as a sign of progression. The difference between precipitated and spontaneous retention has clinical relevance because BPH surgery is less common in cases of precipitated AUR. AUR occurs in an obstructed or decompensated lower urinary tract. The exact cause of AUR is unclear; however, several mechanisms have been suggested.⁷⁻⁹

Causes of Urinary Retention

Although classification systems vary, causes of urinary retention can be categorized as obstructive, infectious and inflammatory, pharmacologic, neurologic, or other. Other causes of lower urinary retention in both males and females include neoplasms, trauma, strictures, valves, and acute inflammation of the lower urinary tract.

Management of AUR

Because of the painful nature of acute retention, and the complications that may result from any form of retention, and the impact on the patient's quality of life; the initial management is usually an emergency. Urethral catheterization is the quickest and most frequently employed method. Other methods include suprapubic cystostomy, urethral bouginage with or without catheterization, and rarely bladder aspiration. Most of these methods are associated with complications such as pain, urethral trauma, hemorrhage, pericatheter urethritis, septic shock, and catheter retention.

Our objectives were to assess the causes of urinary retention in male patients aged >5 years, methods of relief of individual causes, associated complications, and the problems encountered in the process of management, in our setting of limited resources in Era's medical college, Lucknow.

MATERIALS AND METHODS

A prospective study of 18 months duration consists of patients. The patients were selected consecutively as and when they were presented during the study period considering the inclusion and exclusion criteria. Moreover, the outcome of results was assessed on cases of AUR in male patients aged >5 years in Era's Lucknow Medical College and Hospital.

Selection of Patients

A predesigned pro forma was used to record the relevant information (patients data, clinical findings, investigation

reports) from the individual patient selected with inclusion and exclusion criteria.

The study group consists total of patients from Emergency and General surgery OPD of Era's Lucknow Medical College:

1. Group A: 5-25 years
2. Group B: 25-45 years
3. Group C: 46-65 years
4. Group D: >65 years.

All male patients admitted in emergency with complaint of AUR and age <5 years were included in our study.

Patients with age ≤5 years and post-operative cases due to effect of anesthesia were excluded from the study.

Statistical Analysis

The results obtained in the study were presented in a tabulated manner as mean±standard deviation and were analyzed using Statistical Package for Social Sciences 20.0. Chi-square test was used for the analysis of the dichotomous data. $P < 0.05$ was considered statistically significant.

RESULTS

1. In the present study, the overall mean age was 42.27 ± 19.1 (range 6-79). Age is an important risk factor for developing AUR.
2. Mostly 69 (69%) patients in spontaneous retention were major AUR type. This may be due to mainly as the result of locoregional/general anesthesia and excessive alcohol intake of studied patients.
3. 94% were come with pain as symptom.
4. Associated symptoms of studied patients in which 76 patients had fever followed by 70 patients had obstructive LUTS, 36 patients had hematuria, 30 patients had irritating LUTS, and 10 had discharge complaint, respectively.
5. In the causes of AUR, 43 (43%) patients had found prostate enlargement.
6. The difference between age categories and causes was statistically significant ($P < 0.05$).
7. We have done immediate management of studied patients in which mostly 35 (35%) patients were urethral catheterization, 23 (23%) patients were suprapubic catheterization, 25 (25%) patients were alpha blocker + Trial without catheter (TWOC), 10 (10%) patients were TWOC, and 7 (7%) patients were circumcision, meatal dilatation.
8. The mean drained urine was 710.25 ± 150.7 (range 210-950).

DISCUSSION

AUR is usually characterized by the sudden, painful inability to void; painless AUR is rare and is often associated with central nervous system pathology. AUR may be further subdivided into precipitated or spontaneous retention.¹⁰

Because of the painful nature of acute retention and the complications that may result from any form of retention and the impact on the patient's quality of life; the initial management is usually an emergency. Urethral catheterization is the quickest and most frequently employed method. Other methods include suprapubic cystostomy, urethral bouginage with or without catheterization, and rarely bladder aspiration.¹¹

Although classification systems vary, causes of urinary retention can be categorized as obstructive, infectious and inflammatory, pharmacologic, neurologic, or other. Other causes of lower urinary retention in both males and females include neoplasms, trauma, strictures, valves, and acute inflammation of the lower urinary tract.¹²

Final management of AUR where mostly 57 (57%) patients was prolonged catheter and elective surgery group, 13 (13%) patients were immediate surgery and 30 (30%) patients were an indwelling catheter.

CONCLUSION

Older age, severe LUTS, large drained volume at catheterization, and AUR of spontaneous origin favor

TWOC failure. As these variables also predict the risk of recurrent AUR/surgery after a successful TWOC, they could be used to identify the subgroup of patients that cannot be managed by medical therapy alone and should rapidly undergo surgery.

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Comparative Study of Two Different Doses of Rocuronium Bromide with Suxamethonium Chloride for Endotracheal Intubation

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Abstract

Introduction: Suxamethonium chloride was a time-tested depolarizing muscle relaxant with quick onset of action and produced excellent intubating conditions but it is contraindicated and hazardous in certain situations. Rocuronium bromide had the most rapid onset, intermediate duration of action, minimal cardiovascular side effects, and no histamine release emerged as a good alternative.

Purpose of the Study: To evaluate the efficacy of two different doses of rocuronium bromide in comparison to suxamethonium chloride on the intubating conditions, with emphasis on the duration of action, hemodynamic changes after intubation, and occurrence of any untoward side effects with either drug.

Methods: This was a randomized clinical study conducted at a tertiary care center. 90 patients posted for elective surgeries were divided into groups of 30 each. Depending on the dose of the muscle relaxant Group S received succinylcholine 1.5 mg/kg, Group R6 and R8 received rocuronium bromide 0.6 mg/kg and 0.8 mg/kg, respectively. Laryngoscopy and intubation were done with an appropriate size oral endotracheal tube at 60 s. Relaxation of jaw, vocal cords, and response to intubation were assessed at 60 s and scored using a standard intubation scoring system after injection of the study drug. Results were tabulated and analyzed using mean, standard deviation, and Chi-square test.

Results: We observed excellent intubating conditions in 100% of Group S, 86.66% and 93.33% in Group R6 and R8, respectively. The duration of action of rocuronium 0.6 mg/kg was shorter than 0.8 mg/kg. Thus, increasing the dose led to a longer duration of action. Hemodynamic changes returned to preinduction baseline values by the end of 10 min in all three groups.

Conclusion: Rocuronium at both doses of 0.6 mg/kg and 0.8 mg/kg produced clinically acceptable intubating conditions and can be used as a safer alternative to succinylcholine in situations where it is contraindicated.

Key words: Endotracheal intubation, Intubating conditions, Intubation scoring system, Rocuronium bromide, Suxamethonium chloride

INTRODUCTION

The introduction of muscle relaxant (d-tubocurarine) into clinical practice in 1942 by Griffith HR and Johnson

GE) has refined and improved the anesthetic practice and was an important milestone in the history of anesthesia.¹ Before the introduction of muscle relaxants, inhalational agents had to be used for endotracheal (ET) intubation which was associated with inadequate depth of anesthesia. Further to achieve adequate intubating conditions, higher concentrations were needed to be used and were associated with hemodynamic disturbances.²

Succinylcholine (also known as suxamethonium chloride – introduced by Thesleff and Foldes in 1952) with its ultrarapid onset and short duration of action has been

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the drug of choice to obtain excellent intubating conditions in less than 60 s for both elective and emergency surgeries. However, the undesired side effects of succinylcholine led to a search for ideal neuromuscular blocking agent among the nondepolarizing type. Rocuronium bromide introduced into clinical practice by Dr. Sleight and late Dr. Savage in 1990, was the first drug to challenge the onset time of succinylcholine facilitating rapid and safe ET intubation devoid of its side effects.

In this context, the present study was undertaken to compare the intubating conditions of rocuronium bromide with that of succinylcholine along with the clinical duration of action, the hemodynamic changes, and the occurrence of any untoward side effects with either drug.

METHODS

This was a randomized clinical study conducted in the Department of Anesthesiology in the operating rooms of Rajah Muthiah Medical College and Hospital, Chidambaram, during 2014-2016. After getting approval from the Institutional Ethical Committee, the study was conducted on a total of 90 adult patients of either sex, aged between 18 and 60 years, belonging to either ASA Class I or II, posted for elective surgery. Patients were excluded from this study when they refused or if they were on medication that might interact with the study drugs. Those with potential airway problems and suspected difficult intubations were also excluded. Furthermore, those with hyperkalemia, neuromuscular, renal, hepatic, and allergic disorders were excluded. A detailed preanesthetic checkup was done for all patients, and informed consent was taken and procedure of the study was explained to them.

Patients were randomly assigned to any one of the following three groups with 30 patients in each group. Group S patients received intravenous (IV) succinylcholine 1.5 mg/kg, Group R6 and Group R8 patients received IV rocuronium 0.6 mg/kg and 0.8 mg/kg, respectively.

In the operation theater, an IV line was secured with appropriate size IV cannula and IV fluid connected. Monitors including noninvasive blood pressure (BP), electrocardiogram, pulse oximeter, and end-tidal carbon dioxide were connected, and pre-operative data such as baseline heart rate, oxygen saturation, and systolic and diastolic BPs were recorded. Patients were premedicated with injection glycopyrrolate 0.2 mg IV, injection ranitidine 50 mg IV, injection midazolam 0.05 mg/kg IV, and injection fentanyl 1.5 µg/kg IV 5-10 min before surgery.

All patients were preoxygenated with 100% oxygen for 3 min through Bain's circuit followed by standard anesthetic induction with injection thiopentone sodium 5 mg/kg body weight till there was loss of eyelash reflex. The IV line was flushed with running IV fluid, and a bolus dose of the study drug was given. Atraumatic laryngoscopy was done with Macintosh blade, and intubation with oral cuffed ET tube of appropriate size was done at 60 s. The anesthetist who performed laryngoscopy and intubation was blinded by covering the patient with a drape sheet while another anesthetist loaded the muscle relaxant and administered it. The time taken for laryngoscopy was kept within 15 s relaxation of jaw, vocal cords, and response to intubation was assessed and scored by the grading criteria given by Cooper *et al.* 1992³ (Table 1).

Vital parameters were recorded and monitored immediately after the study drug administration, immediately after intubation, and at 3, 5, 10, and 30 min intervals. If laryngoscopy and intubation failed at 60 s, it was repeated at 90 s and intubating conditions were assessed again. Any side effects such as electrocardiography (ECG) changes, muscle fasciculations, or any untoward effects due to histamine release such as skin flushing and erythema were also recorded if they occurred.

Bilateral air entry was confirmed and ET tube was firmly secured. After connecting the ET tube to Bain's circuit, controlled ventilation was started. Anesthesia was maintained with 33% oxygen, 66% nitrous oxide and sevoflurane. The clinical duration of action of initial bolus doses (from the time of administration of the study drug to the first respiratory attempt) was noted, and subsequently, all groups were maintained with injection vecuronium bromide 0.04 mg/kg till the end of the surgery.

At the end of the surgery, all patients were reversed with after adequate reversal with injection neostigmine 0.05 mg/kg IV and injection glycopyrrolate 0.01 mg/kg IV and were extubated after ascertaining the adequacy of reversal of neuromuscular blockade.

Table 1: Cooper *et al.* Scale (1992)

Score	Jaw relaxation	Vocal cords	Response to intubation
0	Poor (impossible)	Closed	Severe coughing bucking
1	Minimal (difficult)	Closing	Mild coughing
2	Moderate (fair)	Moving	Slight diaphragmatic movement
3	Good (easy)	Open	None
Total score	Excellent 8-9, Good 6-7, Fair 3-5, Poor 0-2		

RESULTS

The results were analyzed using SPSS software version 16 and Epi Info 6th version was used for trend analysis. The mean and standard deviation were calculated and used for calculating the significance of the difference. Qualitative data were analyzed using Chi-square test. $P > 0.05$, $P < 0.05$, and $P < 0.001$ were considered statistically nonsignificant, significant, and highly significant, respectively.

All the three groups did not differ with respect to age weight or gender distribution and were comparable with each other (Table 2). In Group S, all the 30 patients who received had excellent intubating conditions. In Group R6, 26 (86.66%) patients out of 30 had excellent intubating conditions with 4 (13.33%) patients showing good intubating conditions. In Group R8, 28 (93.33%) patients out of 30 had excellent intubating conditions with 2 (6.67%) patients showing good intubating conditions. None of the patients in all three groups had fair or poor intubating conditions. There were no cases of failed intubation at 60 s in any of the groups. Thus, the intubating conditions were comparable and statistically nonsignificant ($P = 0.389$) (Table 3 and Figure 1).

The jaw relaxation in Group S was good compared with Groups R6 and R8 and was statistically significant ($P = 0.0526$) (Table 4). There was no significant difference in the state of vocal cords at intubation between S, R6, and R8 groups ($P = 0.338$) (Table 5). Diaphragmatic movements were seen more in number in Group R6 (33.3%) and were statistically highly significant ($P = 0.0016$) (Table 6).

The duration of action of rocuronium 0.6 mg/kg was shorter than rocuronium 0.8 mg/kg. Thus, increasing the dose led to a longer duration of action. Succinylcholine

had the shortest duration of action among the drugs (Figure 2).

There was no significant rise in the mean heart rate after intubation ($P = 0.390$) which declined to the baseline preinduction values by the end of 10 min (Figure 3). The mean systolic BP was found to be more in Group S when compared to Groups R6 and R8, immediately after intubation up to 3 min which was statistically significant ($P = 0.074$). This returned to baseline values by the end of 5 min and became statistically nonsignificant ($P = 0.682$) (Figure 4). It was found that mean diastolic BP was higher in Group S when compared with R6 and R8, immediately after intubation up to 5 min which was statistically significant ($P = 0.097$) (Figure 5). This returned to baseline values by the end of 10 min and became statistically nonsignificant ($P = 0.129$). The rise in mean arterial pressure was more with succinylcholine than with rocuronium and declined to preinduction baseline values by the end of 10 min (Figure 6).

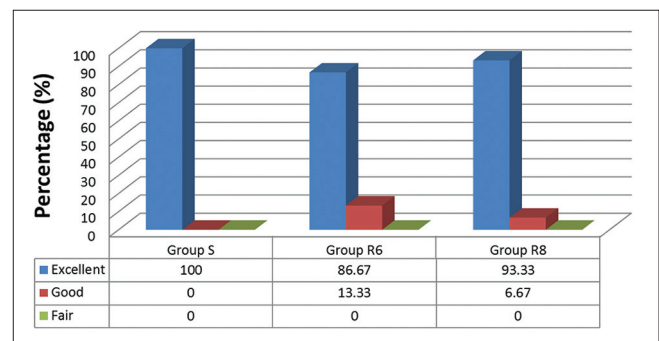


Figure 1: Comparison of the overall intubating conditions

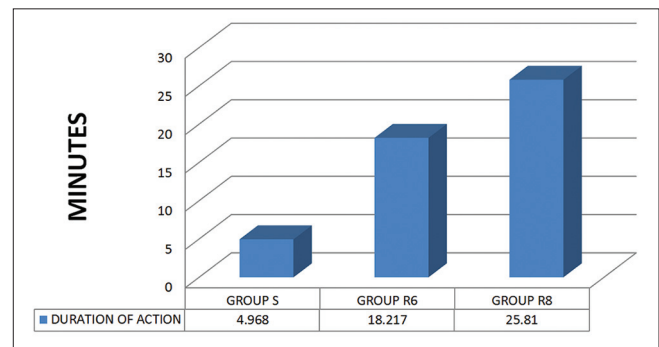


Figure 2: Duration of action

Table 2: Demographic data

Group	Group S	Group R6	Group R8	P value with significance
Mean age (years)	32±12 (SD)	29±10 (SD)	32±11 (SD)	0.101 (NS)
Mean weight (kg)	58±11 (SD)	54±9 (SD)	54±9 (SD)	0.667 (NS)
Gender ratio (male/female)	16/14	16/14	14/16	(NS)

SD: Standard deviation, NS: Nonsignificant

Table 3: Comparison of the overall intubating conditions

Intubating conditions and scores	n (%)			Chi-square value	P value and significance
	Group S	Group R6	Group R8		
Excellent (8-9)	30 (100)	26 (86.66)	28 (93.33)	0.74	0.389 Not significant
Good (6-7)	0 (0)	4 (13.33)	2 (6.67)		
Fair (3-5)	0 (0)	0 (0)	0 (0)		
Poor (0-2)	0 (0)	0 (0)	0 (0)		
Total	30 (100)	30 (100)	30 (100)		

DISCUSSION

Succinylcholine is the most commonly used muscle relaxant for intubation in both elective and emergency settings but with some adverse effects such as bradycardia, rise in

intraocular and intracranial pressures, muscle fasciculations, and post-operative myalgia. It is also not suitable in certain circumstances such as hyperkalemia, musculoskeletal disorders, burns, and central nervous system disorders.

Rocuronium bromide is a low potency, intermediate-acting derivative of vecuronium devoid of cardiovascular side effects⁴ and also devoid of histamine release.⁵ It was found to have a shorter onset time compared to vecuronium,⁶ cisatracurium,⁷ and mivacurium.⁸ Hence, this study was intended to test the efficacy of rocuronium bromide as a safer alternative to suxamethonium chloride for rapid ET intubation.

Selection of Drug Dose^{9,10}

The dosage of the neuromuscular blocking drug is usually selected based on the ED95 value. The dose required for ET intubation is employed in multiples of ED95 dose. The ED95 dose of succinylcholine is 0.3 mg/kg body weight. Three times the ED95 that is 1 mg/kg administration results in complete suppression of neuromuscular stimulation in approximately 60 s. Furthermore, there were no advantages when succinylcholine was used in doses larger than 1.5 mg/kg even in a rapid sequence intubation.

Rocuronium has been used in doses two to three times the ED95 dose to obtain clinically acceptable intubating

Table 4: Comparison of jaw relaxation during intubation

State	n (%)			Chi-square value	P value with significance
	Group S	Group R6	Group R8		
Good	30 (100)	25 (83.33)	28 (93.33)	5.89	P=0.0526 significant
Moderate	0 (0)	5 (16.67)	2 (6.67)		
Poor	0 (0)	0 (0)	0 (0)		
Minimal	0 (0)	0 (0)	0 (0)		
Total	30 (100)	30 (100)	30 (100)		

Table 5: Comparison of vocal cords at intubation

State	n (%)			Chi-square value	P value with significance
	Group S	Group R6	Group R8		
Open	29 (96.67)	26 (86.67)	28 (93.33)	2.17	P=0.338 Not significant
Moving	1 (3.33)	4 (13.33)	2 (6.67)		
Closing	0 (0)	0 (0)	0 (0)		
Closed	0 (0)	0 (0)	0 (0)		
Total	30 (100)	30 (100)	30 (100)		

Table 6: Comparison of response to intubation

State	n (%)			Chi-square value	P value with significance
	Group S	Group R6	Group R8		
None	30 (100)	20 (66.67)	26 (86.67)	12.86	P=0.0016 highly significant
Slight diaphragmatic movement	0 (0)	10 (33.33)	4 (13.33)		
Mild coughing	0 (0)	0 (0)	0 (0)		
Severe coughing/bucking	0 (0)	0 (0)	0 (0)		
Total	30 (100)	30 (100)	30 (100)		

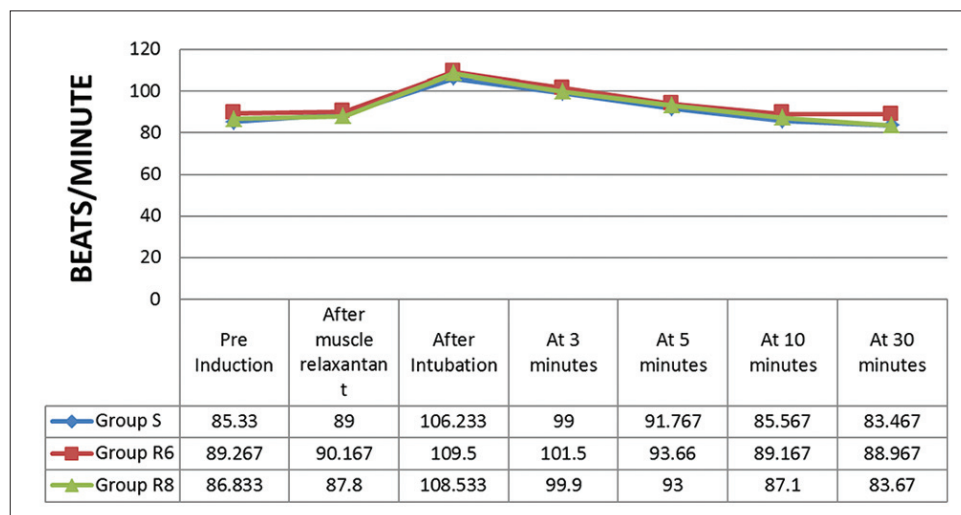


Figure 3: Comparison of heart rate variation

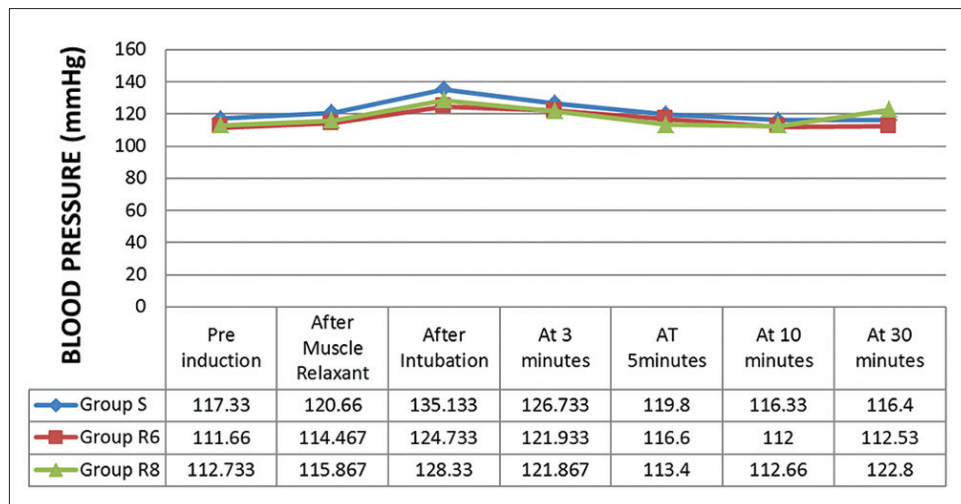


Figure 4: Comparison of mean systolic blood pressures

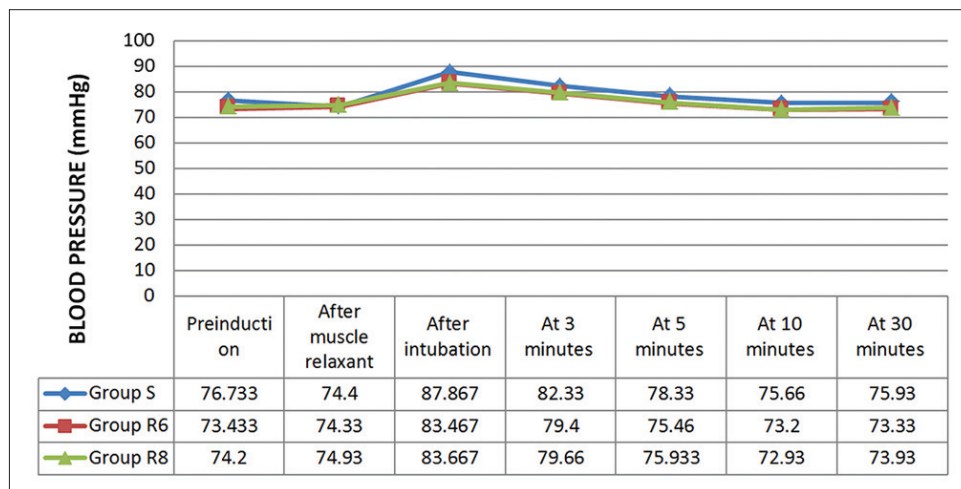


Figure 5: Comparison of mean diastolic blood pressures

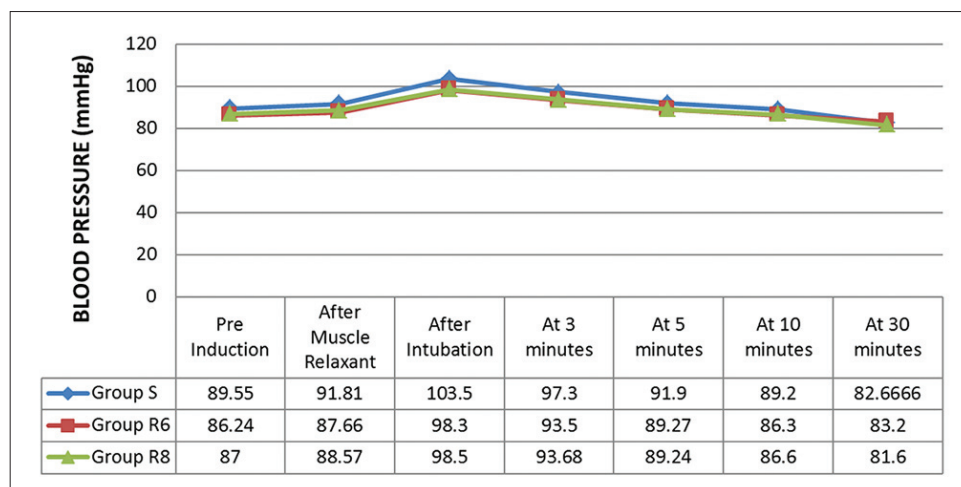


Figure 6: Comparison of mean arterial pressure variation

conditions. The ED95 dose of rocuronium bromide is 0.305 mg/kg body weight. Two times the ED95 dose of rocuronium bromide is 0.6 mg/kg body weight.

Three times the ED95 dose of rocuronium bromide is 0.9 mg/kg body weight has also been shown to provide excellent intubating conditions comparable to

succinylcholine. However, the duration of action was longer.

In our study, succinylcholine and rocuronium bromide has been employed at a dose of 1.5, 0.6 and 0.8 mg/kg body weight to assess the intubating conditions at 60 s.

Selection of Intubation Criteria¹¹

In most studies, the appropriate timing of ET intubation has been determined by 3 ways.

1. Clinical criteria such as jaw relaxation, vocal cord movement, and response to intubation were assessed according to a scale or a scoring system
2. Neuromuscular monitoring by twitch suppression (maximum blockade) or train of four (TOF) ratio
3. Predetermined time after administration of neuromuscular blockers, e.g., 60 s, 90 s, and 120 s.

In our study, we have relied on two of the parameters, namely, predetermined time after muscle relaxant administration at 60 s and the clinical criteria given by Cooper *et al.*, which most of the authors followed. We did not use neuromuscular monitoring at adductor pollicis because it was found that the onset of paralysis at the vocal cords and laryngeal muscles were rapid and preceded that of adductor pollicis. Hence, the TOF may give an incorrect picture of the intubating conditions with neuromuscular monitoring as there was significant difference in the onset times and the rate at which the neuromuscular block occurred between the two groups of muscles.¹²

Assessment of Intubating Conditions

In the present study, succinylcholine 1.5 mg/kg produced excellent intubating conditions in 100% of patients. The results were comparable to those studies conducted by Bhati and Parmar (2008),¹³ Gupta and Kirbahar (2010),¹⁴ Feroz *et al.* (2011),¹⁵ Bhale *et al.* (2013),¹⁶ and Parikh *et al.* (2014).¹⁷

Rocuronium 0.6 mg/kg produced excellent intubating conditions in 86.67% of patients and good intubating conditions in 13.33% of patients. The results were comparable to those studies conducted by Bhati and Parmar (2008),¹³ Gupta and Kirbahar (2010),¹⁴ and Belekar and Khamankar (2013).¹⁸

Rocuronium 0.8 mg/kg produced excellent intubating conditions in 96.67% of patients and good intubating conditions in 3.33% of patients. The results were comparable to the study conducted by Kurshid *et al.* (2015).¹⁹

Thus, increasing the dose of rocuronium bromide from 0.6 mg/kg to 0.8 mg/kg body weight not only increased

the incidence of excellent intubating conditions but also increased the duration of action.

The reason for the rapid onset time for a neuromuscular block with rocuronium was suggested to be the relative low potency of the drug. This ensured the presence of more relaxant molecular load in the blood stream and neuromuscular junction resulting in the larger concentration gradient toward the biophase. Another explanation could be the earlier occurrence of the block at the adductor muscle of the larynx and intubation can be performed before complete block is obtained at the adductor pollicis muscle.²⁰

Although the jaw relaxation was best with succinylcholine (100%), rocuronium was able to provide relatively good relaxation (83.33-93.33%) required for easy atraumatic laryngoscopy which is useful in emergent situations. There was no significant difference in the state of the vocal cords at intubation between the three groups. Open vocal cords without any movement were seen with succinylcholine in 96.66% and rocuronium bromide 86.66-93.33%. Diaphragmatic movements were seen more in those patients who received rocuronium bromide 0.6 mg/kg (33.33%) which was highly significant and may not be acceptable in the patients with a full stomach who are at increased risk of pulmonary aspiration of gastric contents as in emergency.

Clinical Duration of Action

In the present study, the time between the administration of the neuromuscular blocking drug and the first attempt at respiration clinically was taken as the clinical duration of action.

With succinylcholine 1.5 mg/kg, the clinical duration of action in this study was found to be a mean duration of 4.968 min. The minimum duration was 3.33 min, and the maximum was 7.00 min. The results were comparable with the following studies: Shukla *et al.* (2004),¹¹ Parikh *et al.* (2014),¹⁷ and Kurshid *et al.* (2015).¹⁹

The clinical duration of action of rocuronium 0.6 mg/kg in the present study was found to be with a minimum duration of 14.03 min and a maximum duration of 25.16 min. The mean duration of action was 18.21 min. This concurred with those studies by Verma *et al.* (2006)²¹ and Kurshid *et al.* (2015).¹⁹

In the present study, we used rocuronium at a dose of 0.8 mg/kg. The minimum duration of action was observed as 16.10 min, and the maximum duration of action was 33.80 min. The mean duration of action was 25.81 min. This was comparable to the study done by Kurshid *et al.* (2015).¹⁹

Hemodynamic Changes

In our the study, there was an increase in heart rate from baseline values by 24.49%, 12.26%, and 24.99% with succinylcholine 1.5 mg/kg, rocuronium 0.6 mg/kg, and 0.8 mg/kg, respectively, immediately after intubation. This gradually decreased to 7.5%, 4.92%, and 7.10% at the end of 5 min and returned to preinduction values by the end of 10 min.

The rise in systolic BP was 15.17%, 11.70%, and 13.83% in Group S, R6, and R8, respectively immediately after intubation. This declined to 2.13%, 4.42%, and 0.59%, respectively, among the three groups by the end of 5 min and was statistically nonsignificant. Furthermore, there was increase in diastolic BP from preinduction values by 14.50%, 13.65%, and 12.74% in group S, R6, and R8, respectively, postintubation. The diastolic pressures dropped to 2.08%, 2.76%, and 2.33%, respectively, by the end of 5 min.

The increase in mean arterial pressures after intubation was 15.57%, 13.98%, and 13.21% in Group S, R6, and R8, respectively. This gradually declined to 2.62%, 3.51%, and 2.57%, respectively, among the three groups and the return to preinduction values was seen by the end of 10 min in all groups.

These changes concurred with the studies by Bhale *et al.* (2013),¹⁶ Parikh *et al.* (2014),¹⁷ and Kurshid *et al.* (2015).¹⁹ Thus, greater hemodynamic stability was seen with rocuronium than with succinylcholine. The rise in heart rate and mean arterial pressure could be due to the sympathetic stimulation and stress produced by laryngoscopy and intubation. However, succinylcholine caused a greater stimulation of autonomic ganglion than rocuronium which explained the more significant hemodynamic variability in this group.

In our study, no adverse changes in ECG and oxygen saturation were observed. No other untoward side effects such as bradycardia, tachycardia, hypotension, hypertension, bronchospasm, cutaneous flushing, erythema, urticaria, or rashes. Only muscle fasciculations after the administration of suxamethonium chloride were noticed as predicted.

CONCLUSION

Rocuronium bromide at both doses of 0.6 mg/kg and 0.8 mg/kg produced clinically acceptable intubating conditions and can be used as a safer alternative to suxamethonium chloride in situations where suxamethonium chloride is contraindicated.

However, increasing the dose of rocuronium to 0.8 mg/kg produced excellent intubating conditions at 60 s itself, which was comparable with suxamethonium chloride and with lesser diaphragmatic movements that were found to be more useful in emergency situations, although it resulted in a longer duration of action.

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Effectiveness of Topical Proparacaine 0.5% to Augment the Mydriatic Effect of Tropicamide: Phenylephrine Combination Eye Drops

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Abstract

Introduction: Comprehensive intraocular examination requires pupillary dilation with the help of pharmacological agents to cause mydriasis. Dilation of the pupil is controlled by the sphincter and dilator muscle which are, in turn, innervated by the parasympathetic and sympathetic group of nerves, respectively. Pupillary response to mydriatic agents often depends on factors such as iris pigmentation, diabetes mellitus, and any local pathology.

Materials and Methods: The patients were divided into 2 groups for pupillary dilation. The study group was given a drop of 0.5% Proparacaine before giving a drop of Tropicamide and Phenylephrine while the control group was given the mydriatic combination alone. The pupillary size was measured and recorded before instillation of the mydriatic agent at the baseline (0 min), at 10 min, 20 min, 40 min and 60 min. The end point was taken as 8 mm pupillary size or the pupillary size at the end of 60 min.

Results: There was a statistically significant difference in pupil diameter between study eyes and control eyes at 10 and 20 min ($P < 0.021$ for 10 min, $P < 0.001$ for 20 min). The dilation of the pupil at the end of 60 min in the study eye was 8.00 mm, whereas it was 7.99 in the control eye. In our study, 75 out of 100 patients developed mean dilation of 7.75 ± 0.45 mm in the study eye while 46 of 100 patients developed mean dilation of 7.28 ± 0.75 mm in the control eye. There was no statistically significant difference in the augmentary effect of proparacaine among different age groups of study subjects.

Conclusion: It was found that pre-application of proparacaine followed by a commercially available 0.8% tropicamide - 5% phenylephrine showed a more mydriatic effect compared to commercially available 0.8% tropicamide - 5% phenylephrine alone.

Key words: Mydriasis, Phenylephrine, Proparacaine 0.5%, Tropicamide

INTRODUCTION

Comprehensive intraocular examination requires pupillary dilation with the help of pharmacological agents to cause mydriasis.¹ Dilation of the pupil is controlled by the sphincter and dilator muscle which are, in turn, innervated by the parasympathetic and sympathetic group of nerves, respectively. Pupillary response to mydriatic agents often

depends on factors such as iris pigmentation, diabetes mellitus, and any local pathology.

Tropicamide is non-selective muscarinic agent with no vasopressor effect which produces mydriasis but minimal cycloplegia, due to its parasympatholytic action.²

Phenylephrine^{2,3} is sympathomimetic drug acts on alpha-1 receptors to cause pupillary dilation, by stimulating the dilator pupillae. Because of its effect on alpha-1 receptors, it causes vasoconstriction of systemic, pulmonary and coronary arteries which leads to a reduction in cardiac output. Increase in blood pressure, tachycardia, and reflex bradycardia are the known side effects.^{2,3}

An ideal mydriatic drug should provide quick and adequate dilatation with minimal side effects. The commercially

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available ready mixture of 0.8% tropicamide with 5% Phenylephrine along with preservative is a popular mydriatic agent, often used multiple times to achieve mydriasis.

Proparacaine^{4,5} is a topical anesthetic agent which has membrane stabilizing effect and is used for a variety of tests and outpatient procedures.⁶

The aim of this study is to compare the mydriatic efficacy of preapplication of proparacaine.

Aim

To analyze if preinstillation of topical proparacaine 0.5% can potentiate the mydriatic efficacy of 0.8% tropicamide - 5% phenylephrine combination eye drops.

Objectives

This study aims to compare the mydriatic efficacy of 0.8% tropicamide - 5% phenylephrine combination eye drops with or without preinstillation of 0.5% proparacaine in patients attending ophthalmology outpatient department (OPD) at Sri Siddhartha Medical College and Hospital, Tumkur.

The right eye is the test eye/study eye - to receive 0.5% proparacaine followed by commercially available 0.8% tropicamide - 5% phenylephrine and left eye is the control eye - to receive only the combination eye drops - 0.8% tropicamide - 5% phenylephrine. Serial measurements of pupillary size are done to (i) compare the time taken for onset of action - mydriasis, and (ii) compare the time taken to achieve peak mydriasis.

MATERIALS AND METHODS

The study was conducted in the Department of Ophthalmology Sri Siddhartha Medical College, Tumkur, from October 2015 to February 2016. 200 consecutive eyes of 100 patients attending ophthalmic outpatient department were taken for the study. All patients who required pupillary dilation (mydriasis) as a part of their routine ophthalmic evaluation were included in the study. The study was approved by the Institutional Ethics Committee and a waiver of consent was given as the procedure is a routine ophthalmic outpatient procedure.

The subjects underwent routine ophthalmic evaluation - history, visual acuity testing, slit lamp examination, and retinoscopy. The patients were explained about the need for mydriasis and the expected side effects like transient stinging and lacrimation.

The patients were seated comfortably with their head resting. Baseline pupillary diameter was measured in both

eyes with the patient looking at distance, it was measured in the ambient light along the vertical meridian using a transparent scale, by resting the scale on the supraorbital margin and holding the scale in the mid pupillary line. All the measurements were made by the same observer, seated opposite to the patient and recorded in millimeters.

The study/test eye -RE ($n = 100$) received 1 drop of 0.5% of proparacaine eye drops in the inferior fornix. After 2 min, both the test eye and the control eye received 1 drop of the mydriatic eye drop - commercially available 0.8% tropicamide - 5% phenylephrine. The control eye- LE ($n = 100$) was the control eye wherein tropicamide and phenylephrine eye drops were given. All patients had preliminary anterior segment examination including slit lamp examination after visual acuity recording. A drop of topical proparacaine 0.5% eye drops was instilled in the lower fornix of the right eye of all the patients after explaining the procedure. The subjects were told to expect transient stinging and lacrimation immediately following the instillation. After a gap of 2 min mydriatic eye drops were instilled in the control eye and the test eyes, successively. The same was repeated at 10 min and 20 min. After any drop instillation, punctual occlusion was done for 1 min, patients were instructed to keep their eyes gently closed and avoid any globe movement. All these manoeuvres were intended to maximize the available time of the drug in the cul-de-sac.

The pupillary size was recorded before instillation of the mydriatic agent, 5 times in all -at the baseline (0 min), at 10 min, 20 min, 40 min and 60 min. The end point was taken as 8 mm pupillary size or the pupillary size at the end of 60 min.

Inclusion Criteria

A total of 200 eyes of 100 consecutive patients attending ophthalmology OPD, above the age of 18 years, who were able to understand and assent to the pupillary dilation procedure were included in the study.

Exclusion Criteria

History of diabetes,⁷ hypertension, use of any topical medication, presence of pupillary abnormalities, history of or signs of intraocular inflammation, any intraocular procedure/surgery like cataract surgery,⁸ formed the exclusion criteria.

OBSERVATION AND RESULTS

A total of 200 eyes were studied, belonging to 100 consecutive patients, of which 52 were men and 48 were women (Table 1, Figure 1). Their age ranged from 20 to 80 years, (Table 2, Figure 2) with a mean of

41.59 ± 14.41 years (men) and 43.85 ± 14.67 years (women) (Table 3).

There was a statistically significant difference in pupil diameter between study eyes and control eyes at 10 and 20 min ($P < 0.021$ for 10 min, $P < 0.001$ for 20 min)

Table 1: Frequency distribution of patients according to gender

Gender	Female	Male	Total
Observations (%)	48 (48.00)	52 (52.00)	100 (100.00)

Table 2: Distribution of patients according to Age group

Age group	Female	Male	Total (%)
20-39	21	29	50 (50)
40-59	19	12	31 (31)
60-79	8	11	19 (19)
Total	48 (48)	52 (52)	100 (100)

Table 3: Mean age of patients under study

Gender	Observations	Mean age±SD
Female	48	43.85±14.67
Male	52	41.59±14.41

SD: Standard deviation

(Table 4, Figure 3). The dilation of the pupil at the end of 60 min in the study eye was 8.00 mm whereas it was 7.99 in the control eye.

In our study, 75 out of 100 patients developed mean dilation of 7.75 ± 0.45 mm in the study eye while 46 of 100 patients developed mean dilation of 7.28 ± 0.75 mm in the control eye.

There was no statistically significant difference in the augmentary effect of proparacaine among different age groups of study subjects (Table 5).

DICUSSION

An adequate mydriasis allows for a complete intraocular examination which is achieved with the help of a suitable pharmacological mydriatic with little or no side effects.

In current ophthalmic practice, commercially available drops containing a combination of drugs are used to achieve pupillary dilation.^{9,10} Tropicamide acts by relaxing the iris sphincter muscle. It acts by non-selectively inhibiting the muscarinic action of acetylcholine, thereby blocking the cholinergic nerves supplying the smooth muscles of iris. The end effect is mydriasis and paralysis of ciliary muscle with the loss of accommodation for near objects.

Table 4: Mydriatic effect of proparacaine+tropicamide and phenylphrine - study eye (RE) and tropicamide and phenylephrine control eye (LE)

Mydriatic effect at different min	Right eye test/study	Left eye control	P	Association
	0.5% paracaine+0.8% tropicamide and 5% phenyl ephrine (mean±SD)	0.8% tropicamide and 5% phenyl ephrine (mean±SD)		
0 min	2.61±0.49	2.61±0.49	0.417	Not significant
10 min	4.23±0.73	3.67±0.88	0.021	Significant
20 min	6.19±0.61	5.52±0.89	0.001	Highly significant
40 min	7.75±0.45	7.28±0.76	0.381	Not significant
60 min	8.00±0.00	7.99±0.01	0.533	Not significant

SD: Standard deviation

Table 5: Mydriatic effect of tropicamide and phenyl ephrine + paracaine in right eye and tropicamide and phenyl ephrine alone among young and old age group

Mydriatic effect of right eye at different min	(mean±SD)		P	Association
	Age group<40	Age group>40		
	Study eye	Control eye		
	Tropicamide and phenyl ephrine+ paracaine	Tropicamide and phenyl ephrine		
0 min	2.58±0.49	2.64±0.48	0.236	Not significant
10 min	4.20±0.60	4.26±0.85	0.432	Not significant
20 min	6.22±0.61	6.16±0.61	0.317	Not significant
40 min	7.80±0.45	7.70±0.46	0.173	Not significant
60 min	8.00±0.00	8.00±0.00	0	Not significant

SD: Standard deviation

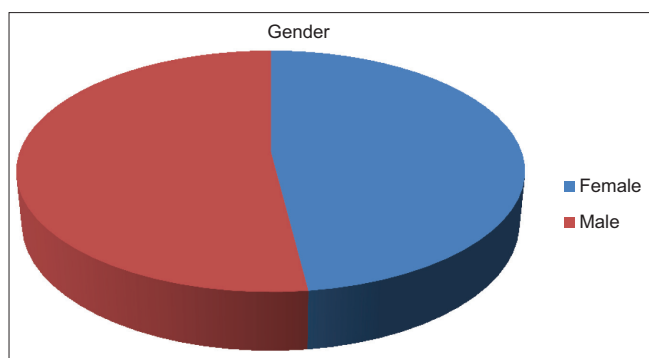


Figure 1: Frequency distribution of patients according to gender

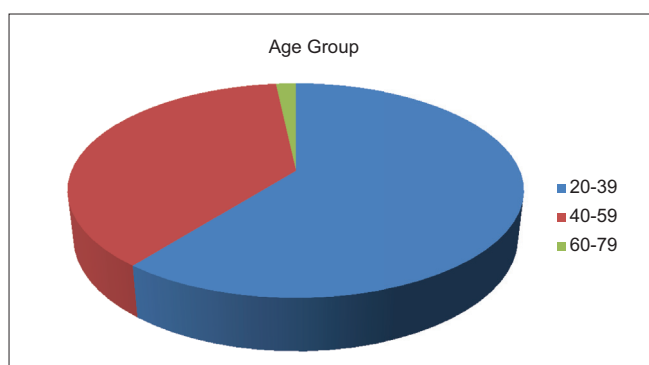


Figure 2: Distribution of patients according to age group

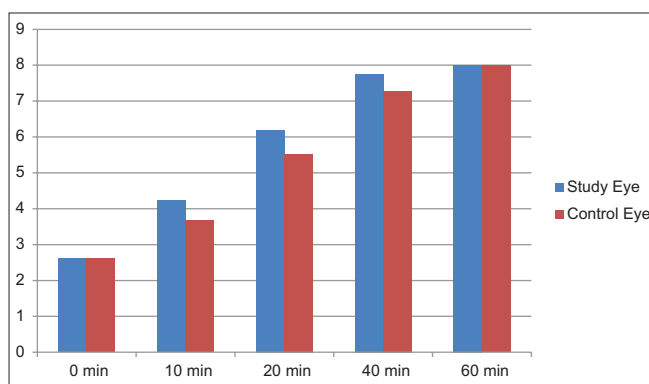


Figure 3: Mydriatic effect of proparacaine + tropicamide and phenylephrine - study eye (RE) and tropicamide and phenylephrine control eye (LE)

Phenylephrine^{11,12} acts on alpha-1 adrenergic receptors of sympathetic nerves supplying the dilator muscle. However, it has the potential to cause undesirable systemic effects like tachycardia and elevated blood pressure.

Proparacaine^{13,14} is a general purpose topical anesthetic in ophthalmological clinics. It is accepted by most patients as it causes minimal, transient discomfort, or irritation on instillation. It acts on the cell membrane and blocks the transient increase in membrane permeability to sodium ions that normally occurs with depolarization of the membrane.

In addition, local anesthetics causes lowering of the tear break-up-time, along with increase of corneal thickness, both point to subclinical micro epithelial changes, and this minimal damage to the corneal epithelial barrier facilitates increased transcorneal permeability of the drug thereby reducing dilation time, increasing the amplitude of maximum dilation and increasing the duration of dilation.^{14,15}

Our study mainly focused on the effectiveness of proparacaine to augment mydriatic effectiveness using tropicamide and phenylephrine eye drops. Baseline pupillary size was recorded in millimeters using a transparent scale. The end point was taken as 8 mm or the pupillary size at 60 min.

In our study, it was found that mydriasis was achieved comparatively quicker with the use of proparacaine in the study eye compared to the control eye with a *P* value of 0.001

A study by Ghose *et al.* found that pupillary diameters in the study eyes increased by 3.62 ± 0.75 mm, significantly more than in the placebo (control) group (*P* = 0.000). 90% of study eyes attained the clinically significant 6-mm size with preinstillation of lignocaine-many more than the 67% of control eyes (*P* = 0.016). The median time to achieve this critical 6 mm size was significantly faster in the study group (*P* = 0.005).¹⁶

In our study, we also compared the mydriatic effectiveness of proparacaine among different age groups as pupillary dilation in older age groups is generally more tedious and found that there was no statistical significance.

The limitations of this study included the lack of randomization and the method of pupillary size measurement.

CONCLUSION

It was found that preapplication proparacaine followed by a commercially available 0.8% tropicamide - 5% phenylephrine showed a more mydriatic effect compared to commercially available 0.8% tropicamide - 5% phenylephrine alone. Furthermore, the quicker onset of action increased patient comfort level by reducing stinging effect of commercially available 0.8% tropicamide - 5% phenylephrine, were an added advantage. This, in turn, helps in reducing patient waiting time and allowing quicker examination of patient, apart from increasing the compliance.

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Causes of Maternal Mortality and Changing Trends: A Retrospective Analysis

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Abstract

Background: Reduction in maternal mortality is a key international development goal. Data for causes of maternal mortality can help formulate policies to improve maternal health. We undertook this study to review the causes of maternal deaths at our center with an aim to reduce maternal deaths.

Materials and Method: A retrospective analysis of 294 maternal deaths over a period of 6 years was done in the Department of Obstetrics and Gynaecology, S.P. medical college, Bikaner, Rajasthan, in two phases, i.e., Phase I from 1st April 2008 to 31st March 2011 and Phase II from 1st April 2012 to 31st March 2015. Causes of death were analyzed along with the study of preventable causes and changing trends.

Result: The triad of hemorrhage, hypertensive disorders and sepsis was responsible for most of the maternal deaths in the study. Hemorrhage was the most important cause in both phases (24.73% and 37.96%). There was a decline in the percentage of deaths due to sepsis from 22.58% in Phase I to 10.19% in Phase II and a slight increase in hypertensive cases from 11.29% to 15.74%. Anemia was the most important indirect cause leading to 6.99% maternal deaths in Phase I and 7.41% in Phase II. Poor, illiterate, unbooked women from rural areas were at higher risk.

Conclusion: There has been an improvement in statistics, but it is still a long way to go. Strengthening the health-care system along with an attack on cultural and sociodemographic factors which cause underutilization of available services is required.

Key words: Changing trends, Maternal deaths, Maternal mortality

INTRODUCTION

Maternal mortality is unacceptably high worldwide.¹⁻⁵ There are about 880 maternal deaths every day.¹ Most of these occur in low-resource settings and can be prevented.¹⁻⁵ Seeing this, countries have united to reduce the global maternal mortality ratio to <70/100,000 live births between 2016 and 2030 as a part of the Sustainable Development Agenda.¹ No country should have a maternal mortality rate more than twice the global average.¹ The high maternal mortality rate is an indicator of inadequate health services as well as the low standard of living and low socioeconomic status of

the community.² Low status of the women in the society coupled with low literacy rates also leads to underutilization of available health services.^{1,2} A good number of maternal deaths can be averted by skilled care before, during, and after childbirth.¹⁻⁴ This study was conducted at the Department of Obstetrics and Gynaecology, P.B.M. Hospital, Bikaner, Rajasthan, with an aim to analyze the causes and risk factors associated with maternal mortality with a motive to guide measures to reduce maternal deaths and improve maternal and fetal outcomes. 186 cases of maternal deaths were studied in Phase I (1st April 2008 to 31st March 2011) and 108 cases were studied in Phase II (1st April 2012 to 31st March 2015). The cases were systemically analyzed and changing trends were also studied.

MATERIALS AND METHODS

This was a retrospective study of 294 cases of maternal deaths over a period of 6 years. The study period was

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divided into two phases of 3 years each. 186 cases were studied in Phase I from 1st April 2008-31st March 2011 and 108 cases in Phase II from 1st April 2012-31st March 2015. Each case was studied with respect to age, parity, residence, literacy, socioeconomic status, antenatal booking, mode of delivery, admission to mortality interval, etc. Causes of death were analyzed and other contributory factors were studied. Changing trends from Phase I to Phase II were observed.

Observations

The observations of our study are shown in Tables 1-3.

DISCUSSION

About 66.87% of maternal deaths in Phase I and 72.22% in Phase II were attributed to direct causes. The triad of hemorrhage, sepsis, and hypertensive disorders including eclampsia was the major cause in both phases, similar to various other studies.³⁻⁶ A significant number of maternal deaths resulting from this triad are preventable with early and appropriate intervention. Obstetric hemorrhage, mostly postpartum, was the single most important cause leading to a maximum number of maternal deaths in both phases, similar to other studies.⁶ PPH also needs a special mention because of the shortest episode-to-death interval in the absence of proper life-saving care. Number of maternal deaths attributable to PPH vary considerably between developed and developing countries, suggesting that deaths from PPH are preventable.⁷ Africa and Asia have the highest prevalence. Supervision of delivery by a skilled health-care provider and promotion of active management of the third stage of labor need to be emphasized. The high prevalence of anemia in women of developing countries further complicates PPH and needs to be targeted.⁷ Hypertensive disorders of pregnancy, particularly eclampsia, were responsible for 11.29% of maternal deaths in Phase I and 15.74% in Phase II. Good antenatal, intranatal, and postnatal care, early diagnosis of preeclampsia and impending eclampsia, early referral, quick and well-equipped transport facilities with immediate management at referral centers can reduce maternal and fetal morbidity and mortality.⁸ 10.19% of cases in Phase II were due to sepsis as compared to 22.58% in Phase I. The reduction may be related to promotion of clean deliveries, antibiotic coverage, and early surgical intervention.⁹ 3 cases of obstructed labor were reported in Phase I but none in Phase II. Improving nutrition in childhood for healthy bone and pelvic development, early diagnosis and referral of labor dystocia and operative intervention can help reduce maternal mortality and morbidity. Deaths due to unsafe abortions can be prevented by increasing access to family planning and contraceptive measures and safe abortion services.

Table 1: Distribution of cases according to demographic variables

Demographic variables	n (%)		
	Phase I	Phase II	Total
Age (in years)			
<21	40 (21.56)	24 (22.22)	64 (21.77)
21-25	79 (42.47)	48 (44.44)	127 (43.20)
26-30	43 (23.12)	22 (20.37)	65 (22.11)
31-35	14 (07.53)	10 (09.26)	24 (08.16)
36-40	4 (02.15)	2 (1.85)	6 (2.04)
>40	6 (03.23)	2 (1.85)	8 (2.72)
Residence			
Rural	119 (63.98)	76 (70.37)	195 (66.33)
Urban	67 (36.02)	32 (29.63)	99 (33.67)
Socioeconomic status			
Lower	143 (76.88)	68 (62.96)	211 (71.77)
Middle/upper	43 (23.12)	40 (37.04)	83 (28.23)
Education			
Literate	63 (33.87)	29 (26.85)	92 (31.29)
Illiterate	123 (66.13)	79 (73.15)	202 (68.71)

Table 2: Distribution of cases according to obstetric variables

Obstetric factors	n (%)		
	Phase I	Phase II	Total
Parity			
Primigravida	79 (42.47)	38 (35.19)	117 (39.80)
Multigravida	96 (51.61)	59 (54.63)	155 (52.72)
Grand multigravida	11 (05.91)	11 (10.19)	22 (07.48)
Antenatal booking			
Booked	166 (89.25)	98 (90.74)	264 (89.80)
Unbooked	20 (10.75)	10 (09.26)	30 (10.20)
Delivery			
Undelivered	56 (30.11)	30 (26.85)	86 (29.25)
Home delivery	74 (39.79)	09 (08.33)	83 (28.23)
Other hospitals	10 (05.38)	16 (13.89)	26 (08.84)
Our hospital	46 (24.73)	51 (49.07)	97 (32.99)
Abortion	00 (00)	02 (01.85)	02 (0.68)
Admission to mortality interval			
<1 h	28 (15.05)	06 (05.56)	34 (11.56)
1-6 h	44 (23.66)	20 (18.52)	64 (21.77)
6-12 h	36 (19.35)	22 (20.37)	58 (19.73)
12-18 h	10 (05.38)	16 (14.81)	26 (08.84)
18-24 h	13 (06.99)	06 (05.56)	19 (06.46)
1-7 days	43 (23.12)	33 (30.56)	76 (25.85)
>7 days	12 (06.45)	05 (04.63)	17 (05.78)

About 33.33% of maternal deaths in Phase I and 27.78% in Phase II were caused by indirect causes. Anemia was the leading cause followed by heart disease. Liver and respiratory diseases were other important indirect causes. Current prevention efforts for anaemia focus on universal iron supplementation during pregnancy.¹⁰ Additional factors which are often neglected include nutritional deficiencies of folic acid and vitamin B12, etc., infections such as HIV, parasitic infestations such as hookworm and schistosomiasis, and inherited anemias such as thalassemias.¹⁰ Preconceptional counseling and appropriate management during pregnancy are of vital

Table 3: Distribution of cases according to cause of death

Causes of maternal death	n (%)		
	Phase I	Phase II	Total
Direct causes			
Total	124 (66.67)	78 (72.22)	202 (68.71)
Hemorrhage	46 (24.73)	41 (37.96)	87 (29.59)
Sepsis	42 (22.58)	11 (10.19)	53 (18.03)
Hypertension/eclampsia	21 (11.29)	17 (15.74)	38 (12.93)
Obstructed labor	03 (01.61)	00 (00)	03 (01.02)
Unsafe abortion	03 (01.61)	02 (01.85)	05 (01.70)
Others	09 (04.84)	07 (06.48)	16 (05.44)
Indirect causes			
Total	62 (33.33)	30 (27.78)	92 (31.29)
Anemia	13 (06.99)	08 (07.41)	21 (07.14)
Heart disease	08 (04.30)	06 (05.56)	14 (04.76)
Hepatitis/liver disorders	08 (04.30)	03 (02.78)	11 (03.74)
Swine flu	06 (03.23)	02 (01.85)	08 (02.72)
Other respiratory diseases	05 (03.76)	01 (00.93)	06 (02.04)
Malaria	07 (02.69)	01 (00.93)	08 (02.72)
Epilepsy	00 (03.76)	01 (00.93)	01 (00.34)
Others	08 (04.30)	08 (07.41)	16 (05.44)

importance in medical disorders related to cardiovascular, liver or respiratory system. The complexity of pregnancy and these diseases requires a multidisciplinary approach involving obstetrician, anesthetist, cardiologist, or concerned system expert and trained nursing and paramedical staff.

A number of sociodemographic factors also affect maternal mortality. It was observed that poor, illiterate, unbooked women coming from remote rural areas were more vulnerable to morbidity and mortality. High parity is contributory, especially in cases with short birth intervals. The WHO also states that maternal mortality is higher in women coming from rural areas, poor communities, and in low-resource settings.¹ Poverty, distance, lack of information, inadequate services, and cultural practices prevent women from receiving or seeking care during pregnancy and childbirth.¹ Barriers that limit access to quality health services need to be identified and addressed at all levels of the health system.

About 38.71% cases in Phase I and 24.08% in Phase II died within 6 h of admission. 70.43% and 64.81% died

within 24 h. 15.05% of cases in Phase I succumbed within 1 h of admission as compared to 5.56% in Phase II. These figures could be related to improved transportation facilities after programs such as JSSY, leading to referred patients reaching the hospital before terminal stage, but many later succumbed to their complicated condition. There is still scope for betterment. Furthermore, there is also poor utilization of antenatal and intranatal facilities provided by the government at peripheral centers.

CONCLUSION

Hemorrhage is the leading direct cause of maternal deaths, followed by hypertensive disorders and sepsis. Anemia continues to be the most common indirect cause. Various sociodemographic factors are also related. Regional estimates vary and there is a slight improvement in statistics, but still, a large number of maternal deaths are preventable. Strengthening our health-care system as well as targeting sociodemographic factors that limit access to quality maternal health services is essential.

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Significance of Skill Reinforcement in Undergraduate Teaching: A Medical College Experience

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Abstract

Background: In pathology, peripheral blood smear (PBS) interpretation is one of the essential hematological investigations and so is the skill of smear preparation. Among students, this skill seemed to decline with time. Although as syllabus mandatory they had learned to do smear preparation in first year Bachelor of Medicine and Bachelor of Surgery (MBBS), in second year pathology practical assessments their performance for the same was found ineffective. Therefore, the study was taken up to know if there would be skill improvement of their previously acquired ability when reinforced.

Aim: The study was taken up to assess if there was skill improvement after a lecture-demonstration sessions using objective structured practical examination (OSPE) as an assessment tool.

Materials and Methods: A total of 36 randomly selected second year MBBS students from the Department of Pathology, Mandya Institute of Medical Sciences consented to be study participants. A pre-study assessment followed by post-lecture and post-demonstration sessions in gaps of each week was conducted and assessed, respectively. OSPE was the assessment method for a total score of 10 at each time. Statistical analysis for mean, standard deviation, and inferential statistics *t*-test was performed using EpiData software. Feedback from the students and faculty was taken.

Results: A considerable improvement between prestudy with postlecture and prestudy with postdemonstration was noted with $P = 0.001$. Furthermore, postlecture with post-demonstration analysis showed improvement with $P = 0.002$.

Conclusion: Lecture-demonstration of PBS preparation reinforced previously acquired knowledge of this essential skill required for a competent undergraduate student.

Key words: Objective structured practical examination, Peripheral blood smear, Practical demonstration, Reinforcement, Undergraduate student

INTRODUCTION

Pathology bridges the gap between basic sciences and clinical medicine. Peripheral blood smear (PBS) interpretation is one of the basic investigations in laboratory practice.¹ It is a mirror of ill health ranging

from infections to malignancy. Thereby assists clinicians in patient screening, diagnosis, monitoring disease progression, and therapeutic response in the evaluation of hematologic disease.¹ Although automation and molecular techniques in hematology are in use, still for many diseases the data from these analyzers would show a normal blood count but may miss on abnormal cellular morphology.² The automated techniques developed for smear preparation are reported to be inferior to the ones prepared by an experienced professional.² Hence, the diagnostic relevance of manual PBS reporting is still a worth. Therefore, it becomes important to have a well-prepared blood smear. This warrants careful attention toward the technique of good quality smear preparation.²

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In pathology practicals, we observed during the formative and summative assessments that students' performance on smear preparation was inefficient. As per university syllabus, the students in first-year Bachelor of Medicine and Bachelor of Surgery (MBBS) course mandatorily learn the skill of smear preparation. However, this skill seemed to decline with time. Therefore, the study was taken up to reinforce this essential skill.

Objective structured practical examination (OSPE) is a structured practical assessment system designed for pre- and para-clinical subjects.³ Here, the students' competency for various skilled tasks is tested at series of set stations. Assessment is done as per the predetermined checklist in each station by an individual examiner. Studies on OSPE have reported it to be objective, valid, and reliable with wide discrimination index compared to the conventional practical method.⁴ The examiner bias is eliminated. OSPE tests different desired components of competence better. It helps assess the domains of education involved in integrating knowledge and practical skills required for competent learning. This would influence student learning and provide an opportunity for improving the teaching and learning process through feedback.³

Aim

The study was taken up to assess if there was an improvement in PBS preparation skill after a lecture-demonstration sessions using OSPE as an assessment tool.

MATERIALS AND METHODS

We conducted a before and after quantitative study in the Department of Pathology, Mandya Institute of Medical Sciences, Mandya, in the months of January and February 2016. The study was started after obtaining clearance by the Institutional Ethical Committee. The study subjects included 36 randomly selected second year MBBS pathology students. OSPE was set up with five stations. These included two procedural stations, a questionnaire, an interpretative, and a rest station. Complete procedure time was kept at 25 min. The assessment was done for total of 10 marks using standard checklist. A pre-study OSPE was done to assess the already acquired skill ability of smear preparation. In the next week, didactic lecture was taken and with gap of a week post-lecture OSPE was conducted. In the consecutive week, 36 students were divided into small batches of six each. The assigned faculty for each batch did practical demonstration of the skill. Then, each student was allowed to practice under supervision. After a gap of 2 weeks, the post-demonstration (postdemo)

assessment was performed. The scores of three OSPEs were statistically analyzed. Feedback from the students and faculty was taken.

Plan of Statistical Analysis

Mean, standard deviation (SD) and inferential statistics *t*-test using EpiData software was done. $P < 0.05$ was considered as statistical improvement.

RESULTS

The study highlighted the need to reinforce the skill of PBS preparation in the second year during pathology practical. On evaluation of the OSPEs at three different points of time in the study, a remarkable improvement in the mean score and SD of the students was noted. The mean \pm SD score was analyzed among the 36 students. In the prestudy, it was found to be 2.25 ± 1.402 , postlecture 6.28 ± 1.684 , and after postdemonstration 7.19 ± 1.849 . The comparison of total scores obtained in prestudy, postlecture, and postdemo displayed a statistical considerable improvement in the student learning ($P = 0.001$). A considerable difference between pre-study and post-lecture scores was observed and it was statistically measurable ($P = 0.001$). Similarly, pre-study and post-demo ($P = 0.001$) and post-lecture and post-demo scores showed improvement ($P = 0.002$) (Tables 1 and 2, Graph 1).

DISCUSSION

Practical skills play a central role toward delivering successful patient health care. The success of the performance is dependent on the competency of the performer.⁵ Reinforcement skill is meant for increasing the

Table 1: Mean and SD in the study subjects related scores

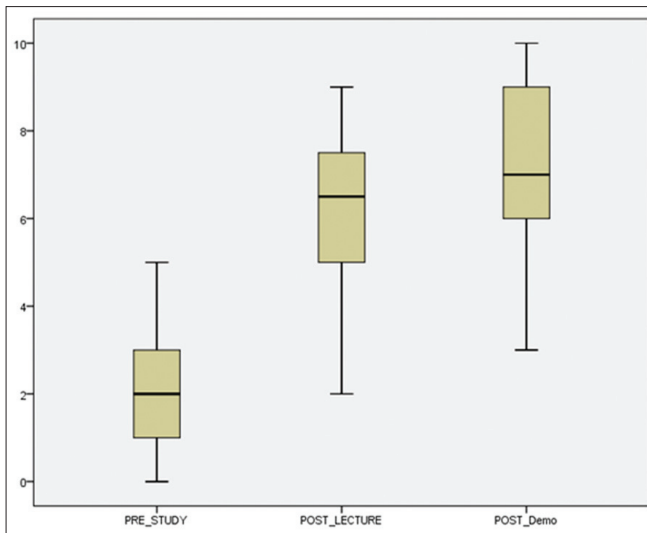
	Number of subjects	Mean \pm SD	Range
Prestudy	36	2.25 \pm 1.402	0-5
Postlecture	36	6.28 \pm 1.684	2-9
Poststudy	36	7.19 \pm 1.849	3-10

SD: Standard deviation

Table 2: Paired *t*-test was used to know a significance difference before and after intervention

	Mean \pm SD	<i>t</i> -test	<i>P</i>
Prestudy and postlecture	4.028 \pm 2.490	9.706	0.001
Prestudy and postdemo	4.944 \pm 2.460	12.057	0.001
Postlecture and postdemo	0.917 \pm 1.645	3.345	0.002

SD: Standard deviation



Graph 1: Boxplots show the median, interquartile range, outliers, and extreme cases of individual variables according to scores

participation of learners in the development of teaching process. The use of positive verbal and non-verbal cues would be the key component for this skill.⁶

This study highlighted that demonstration and practice under supervision improved PBS preparation skill considerably. In a cross-sectional descriptive study analysis by N. Upadhyay *et al.*, of 63 MBBS students and 24 basic medical sciences teachers, it was observed and also suggested that for the effective skill development practical demonstrations was very helpful. The authors also stressed that students should practice under supervision so that should any doubts arise during learning, the teachers could solve them at that moment.⁷

The observational analysis in this study showed good impact on students' learning behavior by forming small groups and practice under our supervision. Wader *et al.* in their study on new practical teaching methodology - "active learning" with emphasis on clinicopathological correlation for the second year MBBS 120 students, and 8 pathology postgraduate residents has also opined that in any study forming smaller student groups and making them practice under supervision is to be appreciated for easy, interactive, and clinically relevant learning.⁸

We had observed that although students learned this skill in the first year as a mandatory in the syllabus, but their performance in second year pathology assessments was found to be unsatisfactory. Hence, an attempt was performed toward reinforcement of the same. Reinforcement-learning mechanism model for skill learning recommended by Fu and Anderson was used in this study. The author's impression was that this learning

model for recurrent choices could be accounted for skill learning. The student tasks performance is dependent on learning which element to select in the presence of each object. Hence, the main component of this skill learning style is to know when to apply the right action given particular cues in the environment. Thereby in skill acquisition, this action may be considered as one of the core learning component.⁹

Another comparable study was done by the author Codagen using George and Doto's five-stage approach abbreviated as "SETT UP." Its expansion meant setting the scene to establish prior experience, to talk through the procedure, tips and tricks (provided by the instructor), undertake procedure (with direct supervision) and post-procedure feedback. This learning approach would lead to immediate correction of errors. A positive reinforcement hopefully would help the learner to develop skill mastery.¹⁰ Our study set up coincides with this approach.

In this study, OSPE scores statistically showed improvement in students' performance (Tables 1 and 2, Graph 1). The method tested both domains of knowledge and practical skill. Comparison of the pre-test, post-lecture, and post-demo scores showed statistical considerable improvement in the skill acquisition. Studies using OSPE as assessment have reported the methodology to be an effective method of evaluation with reliability and validity. Authors M Feroze and Jacob conducted pathology practical assessment for a batch of 64 students who were divided equally into two groups. One group took OSPE and the other conventional system of assessment. OSPE had six stations and included three categories of clinical pathology, spotters, and interpretative exercises. In the clinical pathology, one of the exercise kept for assessment, was on peripheral smear staining. The authors noted that OSPE measured practical skills better, as it was an objective, valid and reliable method without examiner bias. Interpretative exercises were the most relevant part and deserved the lion's share of total marks.⁴

In the study by Patil and Saini, OSPE was conducted in the formative assessment for 25 second-year MBBS students in pathology. Total of 20 marks were allotted for 10 stations. The authors concluded that assessment by OSPE could be considered as an effective tool for students' deep learning which would involve understanding and interpretation. Suggested that it could be used for formative and as a part of summative assessments. It would also definitely meet the specific criteria for judging and grading successful performance. Among students, the assessment system was opined to be fair, uniform with no bias. The authors also observed that OSPE created a comfortable, nonthreatening atmosphere. Accordingly, this assessment

method was found to have objectivity, reliability, validity, and was feasible.¹¹

Munjal *et al.* in their study used OSPE during the second pathology internal assessment examination for a total of 24 students. They were divided into batches and groups. OSPE had six stations for 10 min each. The six stations were divided into three categories. Peripheral smear staining was one of the exercise included in the clinical pathology category. Spotters and interpretative exercises formed the other two categories. The students feedback revealed that more than 90% of them agreed that OSPE was less stressful to perform and more comfortable. The authors concluded that OSPE tested different desired components (practical and correlative skills) of competence better.¹²

In one more study by Jaswal *et al.*, OSPE as a tool was introduced at the stage of formative assessment for biochemistry practical skills. The study group was 94 first-year MBBS students. The student feedback reflected that OSPE improved their practical skills. They expressed satisfaction with the method of assessment and were confident in performing the skills. Faculty felt that OSPE provided satisfaction and motivation to adopt it as an assessment tool.³

From our students' feedback, we noted that skill learning of PBS preparation by reinforcement was well accepted and appreciated by them. Faculty also opined that reinforcement satisfactorily improved the student's skill performance and OSPE assessment was uniform. Similar observations have been made in other studies. The authors have suggested that feedback should become the central component of the effective assessment.^{3,7,11,12} This would help pull through drawbacks in the conventional teaching-learning method and provide further improvement and standardization.⁷

CONCLUSION

In pathology ideal, PBS is a prerequisite for its proper interpretation. In this study, lecture-demonstration of PBS preparation reinforced previously acquired knowledge of this essential skill among the students. Skill reinforcement for undergraduates would become essential in moving toward the vision of competency-based medical education. Need for undergraduate curriculum to stress for reinforcement of teaching-learning aimed at skill competency across all medical colleges.

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Evaluation the Sonographic Appearance of Spectrum of Anterior Abdominal Wall Lesions and to Compare the Sonological Features with Pathological and Operative Diagnosis: A Cross-sectional Study

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Abstract

Background: Based on physical examination alone, it is often difficult to diagnose the specific anterior abdominal wall pathologies. The aims of the study were to evaluate the accuracy of the high-resolution sonography in the diagnosis of anterior abdominal wall pathologies.

Materials and Methods: All patients with the clinical manifestations of various anterior abdominal lesions in a period of 2-year were included in the study. All patients included in the study underwent anterior abdominal wall ultrasonography using 7.0-12.0 MHz high-frequency linear array transducer coupled with Color Doppler equipment, followed by pelvic scan using 3.5-5.0 MHz transducer whenever required. Findings during surgery and histopathology reports were noted and compared with the sonographic features.

Results: Our study showed a high prevalence of anterior abdominal lesions in patients in the age group of 20-40 years which constituted 60% of all cases. Females were affected more (66%). Incisional hernia was the predominant anterior abdominal wall lesions followed by ventral hernias, lipomas, and hematomas cases. Least common was anterior abdominal wall sarcoma. In total diagnostic accuracy of high-resolution sonography was 97.6% in our study.

Conclusion: High-resolution sonography is an accurate diagnostic imaging modality in anterior abdominal wall lesions. The advantages of high-resolution sonography include noninvasiveness, high accuracy, lack of ionizing radiation, simplicity, wide availability, cost-effectiveness, and repeatability.

Key words: Anterior abdominal wall, Desmoids tumor, High resolution, Incisional hernia, Ultrasonography, Ventral hernia

INTRODUCTION

Abdominal wall lesions often mimic intra-abdominal conditions and frequently present as palpable masses. Pathologic processes that may involve the abdominal wall

occasionally raise diagnostic challenges because of the low specificity of physical findings. Sometimes a clinically suspected intra-abdominal mass proves to be in the wall, and sometimes an abdominal wall lesion is seen as an incidental finding on abdominal sonography performed for some other reason. Often patients with chronic abdominal pain need an examination of the abdominal wall, especially, when a positive Carnett's sign suggests the cause of pain to be in the abdominal wall.^{1,2}

The abdominal wall is a laminated structure. The different layers are skin, superficial fascia, subcutaneous fat, muscle layer, the transversalis fascia, and a layer of extraperitoneal

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fat. The skin is echogenic (Figure 1). The subcutaneous fat layer is variable in thickness and is usually hypoechoic. The muscles reveal medium-level echoes. A typical lamellar pattern of the muscle fibers usually can be recognized.³ A wide range of imaging modalities is available for the evaluation of abdominal wall pathology ranging from plain X-ray abdomen to high-resolution ultrasonography (USG), computed tomography scan, and magnetic resonance imaging.

With the introduction of high-frequency, high-resolution probes, detailed examination, and recognition of different layers of the abdominal wall are now possible on USG examinations. A high-resolution examination is capable of deciding whether an abnormality is in the abdominal wall or inside the abdominal cavity.⁴

There is wide range of pathology effecting the anterior abdominal wall which ranges from simple fluid collection to hernias to complex neoplasms of the abdominal wall, hence early detection of this pathology with use of high-resolution USG and another cross-sectional imaging has revolutionized the treatment options for the surgeons.²

There are very few studies in India regarding the diagnostic accuracy of ultrasound in diagnosing abdominal wall lesions. Hence, the study was taken up to find the diagnostic accuracy of high-resolution ultrasound.

Objectives

1. To evaluate the sonographic appearance of spectrum of anterior abdominal wall lesions
2. To compare the sonological features with pathological and operative diagnosis
3. To assess the accuracy of high-resolution sonography and Color Doppler in the diagnosis of anterior abdominal wall lesions.

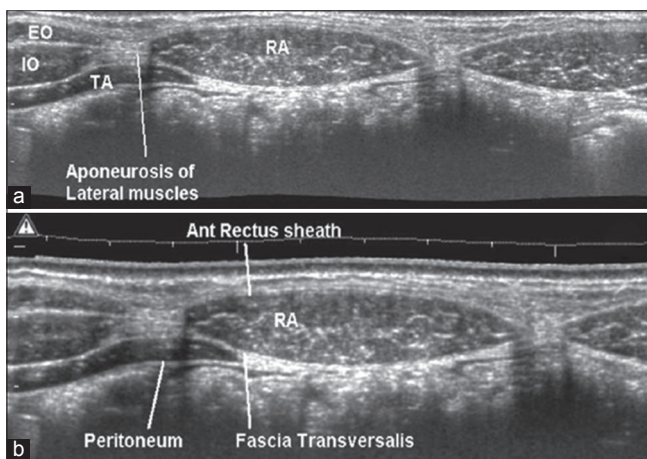


Figure 1: (a and b) Transverse sonography of the anterior abdominal wall. RA: Rectus abdominis, TA: Transverse abdominis, EO: External oblique, IO: Internal oblique

MATERIALS AND METHODS

This study is a study of 50 cases of anterior abdominal wall lesions that were seen consecutively in the Department of Radiology during a 2-year study period from September 2008 to September 2010, referred from two hospitals attached to J. J. M. Medical College, Davangere. Various patients with suspected anterior abdominal wall lesions and those anterior abdominal wall lesions which were picked up incidentally during routine sonography for some other cause were included in the study. These cases were evaluated using high-resolution USG with high-frequency linear array probe (7-12 MHz). All cases with clinical manifestations of anterior abdominal wall lesions of all age groups were included in the study. All cases with acute abdominal wall trauma were excluded from the study. All patients included in the study underwent anterior abdominal wall USG using 7.0-12.0 MHz high-frequency linear array transducer coupled with Color Doppler equipment (Philips Envisor CHD) followed by surgical or pathological confirmation whenever needed. This was followed by pelvic scan using 3.5-5.0 MHz transducer whenever required. Findings during surgery and histopathology reports were noted and compared with the sonographic features for assessing accuracy of high-resolution sonography. The purpose of the study was explained in local language (Kannada) or English, and the patients, who were willing to participate, were included in the study and a written consent was obtained. Ethical clearance was obtained from the Ethical Committee, J. J. M. Medical College, Davangere. Diagnostic accuracy of anterior abdominal wall lesion using high-resolution USG and Color Doppler was determined by comparing with operative and histopathological findings, by performing diagnostic validity tests such as sensitivity, specificity, and predictive values. Statistical analysis was performed using validity. The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were determined.

RESULTS

Among 50 clinical suspected anterior abdominal wall lesions, the most common indication for high-resolution sonography was incisional hernia, followed by anterior abdominal wall lump which is relatively a nonspecific clinical diagnosis, which later turned out be different lesions on high-resolution sonography as well as histopathology.

Among 50 various clinically suspected anterior abdominal wall lesions which were subjected for high-resolution sonography most commonly and accurately detected lesions of anterior abdominal wall was incisional hernia, i.e., as many as 22 cases out of 50 cases (44%) followed by

ventral hernias, i.e., 7 case out of 50 cases (14%). We would like to emphasize another anterior abdominal wall lesions other than hernias which was common in our study was anterior abdominal wall lipomas, i.e., as many as 4 cases out of 50 cases (8%) were in all 4 cases correlated with histopathological findings (Tables 1 and 2).

Histopathological/post-operative findings were correlated in the majority of the cases, i.e., in 42 cases out of 50 cases whenever required. Cases diagnosed on USG which were subjected for histopathology/post-operative findings accurately with our sonographic diagnosis in all cases with 97.6% accuracy (Table 3).

- Sensitivity = 100%
- Specificity = 75%
- Positive predictive value (efficacy) = 97.4%
- Negative predictive value = 100%
- Diagnostic accuracy 97.6%.

DISCUSSION

Anterior abdominal wall lesions often mimic intra-abdominal conditions and frequently presents as

Table 1: Various high resolution sonographies of anterior abdominal wall lesions

Ultrasound diagnosis	n (%)
Incisional hernias	22 (44)
Ventral hernias	7 (14)
Anterior abdominal wall lipoma	4 (8)
Anterior abdominal wall haematoma	4 (8)
Desmoidtumour	2 (4)
Dermoid cyst	2 (4)
Postoperativeseroma	1 (2)
External oblique pyomyositis	1 (2)
Neurofibroma	1 (2)
Metastatic melanoma	1 (2)
Resolving abscess	1 (2)
Abdominal wall sarcoma	1 (2)
Others	3 (6)

Table 2: Various histopathological/post-operative diagnosis of anterior abdominal wall lesions

Histopathology/post-operative findings	n (%)
Bowel loops	20 (40)
Not done	8 (16)
Dermoid cyst	2 (4)
Desmoidfibromatosis	2 (4)
Linea alba defect	2 (4)
Lipoma	4 (8)
Metatatic melanoma	1 (2)
Neurofibroma	1 (2)
Omental fat/bowel loops noted	5 (10)
Abscess	1 (2)
Others	4 (8)
Total	50 (100)

a palpable mass. This is a more common with patients who have thick anterior abdominal wall with a large layer of fat. Because of the introduction of newer scanning techniques with higher frequency probes and newer software like THI, it has lead to the better characterization and diagnosis of the lesion. Literature on this type of study is sparse in Indian literature and such studies have not been highlighted on incidence and the prevalence of anterior abdominal wall lesions.

Age

The time of onset of anterior abdominal wall lesions is well-known entity in congenital anterior abdominal wall lesions such as omphalocele, gastroschisis, cloacal exstrophy, and prune belly syndrome which can all be picked up during the second trimester antenatal sonography done during 18-24 weeks, hence age plays paramount importance in the diagnosis of anterior abdominal wall lesions. We categorized the age group of patients broadly into three groups (Table 4). Our study showed a high prevalence of anterior abdominal wall lesions in the age group of 20-40 years (60%), wherein the majority of cases were various types of incisional and ventral hernias. The higher prevalence of anterior abdominal wall lesions in the age group of 20-40 years probably explains the patients seeking medical/surgical attention more frequently than another age group due to various reasons.

Sex

Although there is no much significance of sex wise prevalence of anterior abdominal wall lesions, vast majority of studies in the literature have shown higher incidence of anterior abdominal wall lesions in females, majority being various kinds of incisional hernias, which probably explains the higher incidence of surgeries in females, e.g., Cesarean section which is the most commonly performed surgical procedure in the world literature (Table 5).

Table 3: Diagnostic validity of high resolution sonography

Test	Positive	Negative	Total
Positive	38	0	38
Negative	1	3	4
	39	3	42

Table 4: Age wise distribution of anterior abdominal wall lesions

Age group	Number of cases	Total %
<20 years	3	6
20-40 years	30	60
>40 years	17	34

Diagnostic Accuracy of Clinical Findings

Among 50 clinical suspected anterior abdominal wall lesions the most common indication for high resolution sonography was incisional hernia, i.e., 28 cases (56%) out of 50 cases, followed by anterior abdominal lump, i.e., 11 cases (22%) out of 50 cases which is relatively a nonspecific clinical diagnosis, which later turned out be different lesions on high resolution sonography as well as histopathology which necessitates high resolution sonography with high frequency probe which helps in characterization, nature of the lesion with a very high specificity than clinical findings and equal to or slightly less than that of histopathological and surgical findings.

Diagnostic Accuracy of Ultrasonographic Findings

Among 50 various clinical suspected anterior abdominal wall lesions which were subjected for high resolution sonography, most commonly and accurately detected lesions of anterior abdominal wall were various types of incisional hernias, i.e., as many as 28 cases out of 50 cases (56%) followed by ventral hernias, i.e., 7 cases out of 50 cases (14%). We would like to emphasize another anterior abdominal wall lesion other than hernias which were common in our study was anterior abdominal wall lipomas, i.e., as many as 4 cases out of 50 cases (8%) were in all 4 cases correlated with histopathological findings.

Diagnosis of incisional hernias and ventral hernias on sonography is relatively simple because sonography can readily detect the anterior abdominal wall defect, contents of the hernias, as well as the reducibility of hernias due to the real-time imaging, with the application of color Doppler sonography differentiation between strangulated and nonstrangulated hernias can be made out. Anterior abdominal wall lipomas was the next common lesions detected in our study (4 cases), all 4 cases were accurately detected on sonography with 100% accuracy, all 4 cases of anterior abdominal wall lipomas showed similar sonographic findings, i.e., well defined round to ovoid, isoechoic to slightly hyperechoic echotexture as compared to the adjacent muscles along with a thin echogenic capsule.

Another common lesion was desmoids tumor and dermoid cyst, i.e., 2 cases each (6.66%). Sonographic diagnosis of both desmoids tumor and dermoid cyst was 100% accurate, wherein desmoids tumor appeared

as well defined hypoechoic lesions with increased vascularity on color Doppler at the site of previous laparotomy scar.

Anterior abdominal wall lesions which were diagnosed on USG was subjected for histopathology/post-operative findings which correlated accurately with our sonographic diagnosis in all cases with 97.6% accuracy. We have shown that sonographic diagnostic accuracy paralleled to histopathological/post-operative findings.

Some Common and Interesting Anterior Abdominal Wall Lesions in Our Study

Hernias

Hernias are the most common abdominal wall lesions seen in sonographic practice. Depending on their location and cause, they are divided into different categories. With a high-frequency transducer, the fascial defect can be visualized underlying the hernia. Herniated bowel loops have a variable appearance depending on their air-fluid content and degree of obstruction. During the real-time examination, induction and reduction of a hernia can be observed. The patient is asked to cough or perform a valsalva maneuver while scanning over the suspected site is performed and with an increase in abdominal pressure, there will be better appreciation of hernia sac, site, and size of the defect and also contents of the hernia.

Ventral hernia

A ventral hernia occurs typically where there is no muscle support along the linea alba in the midline in the epigastrium (Figure 2) or periumbilical region (Figure 3). The defect can be easily made out in high-frequency probe, and the defect size can also be measured. The hernia very often contains only fatty tissue but at times may be large and contain bowel loops also.^{5,6}

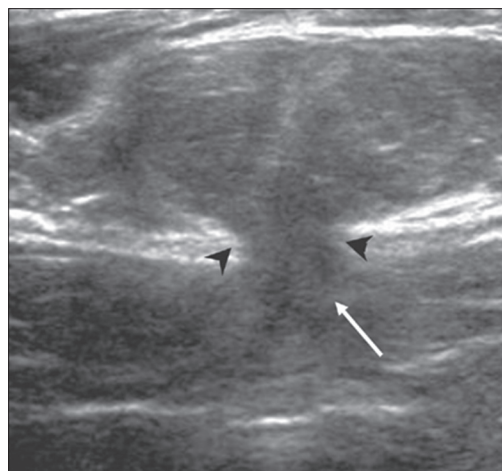


Figure 2: Ventral hernia. The omental fat is protruding through a defect in the rectus sheath

Table 5: Distribution of anterior abdominal wall lesions according to gender

Sex	Number of cases	Total number of cases	Total %
Male	17	50	34
Female	13	50	66

Incisional hernia

An incisional hernia develops as a late complication of abdominal surgery. It also has been seen after laparoscopic procedures. Most incisional hernias will present within the first year; however, some go unnoticed by the patient and are incidentally detected on sonography or computed tomography. Sonography is very useful in ruling out a hernia at surgical sites and in monitoring the integrity of wire mesh implants⁷⁻⁹ (Figure 4).

Spigelian hernia

A spigelian hernia occurs because of a defect in the aponeurosis of the transverse abdominis muscle and the rectus sheath. The most common site is the point where the linea semilunaris crosses the arcuate line.^{10,11} The hernias may sometimes extend laterally and present as a flank lump before the use of high-resolution sonography, the diagnosis of spigelian hernia was missed in 50% of cases as per literature (Figure 5).

Inguinal hernia

An indirect inguinal hernia occurs as a result of protrusion of the peritoneal sac and contents through the internal inguinal ring into the inguinal canal and sometimes into the scrotum.¹² The internal inguinal ring is a defect in the transversalis fascia anterior to the femoral vessels, lateral to the inferior epigastric artery, and inguinal ring is a defect in

the external oblique aponeurosis. Direct inguinal hernias protrude through a weakened inguinal canal floor, medial to the inferior epigastric artery. Depending on the content, namely, fluid, air-containing bowel, or fluid-containing bowel, inguinal hernias will have different appearances on sonography. Distended, adynamic bowel indicates obstructed loops. The inferior epigastric artery can be visualized on color Doppler sonography, and then, differentiation of a direct or an indirect inguinal hernia is possible^{3,13} (Figure 6).

Femoral hernia

A femoral hernia protrudes through the femoral canal (Figure 7). Sonographic differentiation depends on demonstration of the hernia medial to the femoral vein.¹⁴ Most patients are elderly and obese and have abdominal or groin pain with or without a palpable mass.

Neoplasms

Lipomas

Lipomas are the most common abdominal wall neoplasm. They are well defined, ovoid or pad like masses (Figure 8)

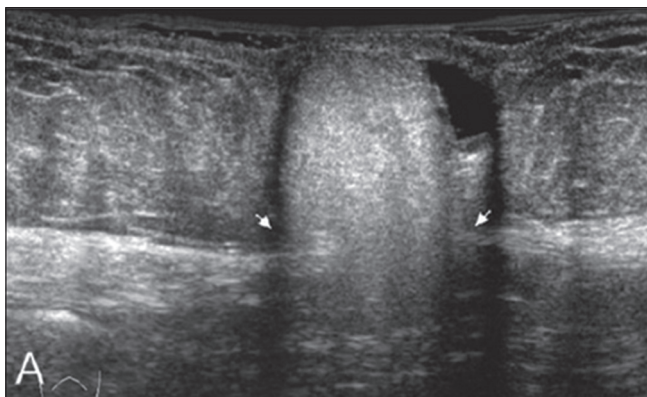


Figure 3: Peri-umbilical hernia. Fat is herniating through a defect in the rectus sheath

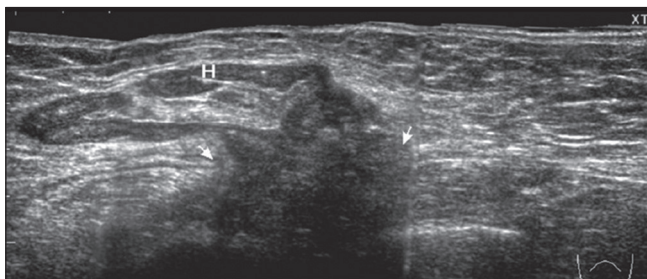


Figure 4: Incisional hernia. The image shows the hernial sac, protruding through a scar defect (H: Hernial sac)

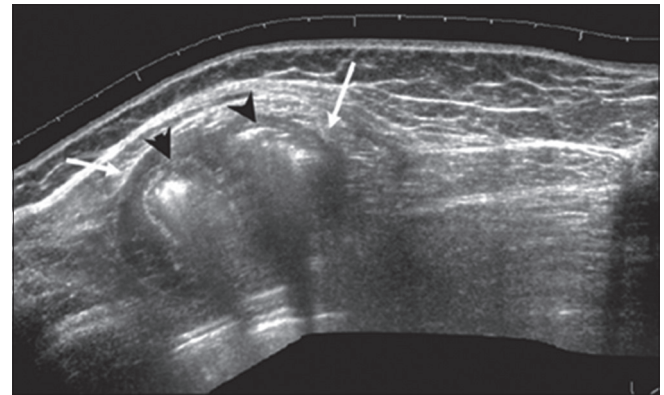


Figure 5: Spigelian hernia. The image shows the hernia containing bowel loops

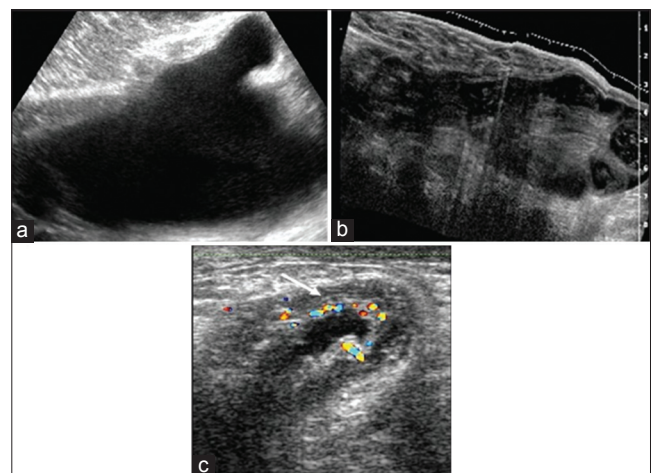


Figure 6: Inguinal herniae in different patients, (a) fluid containing and (b) non-obstructed, and (c) obstructed bowel loops

most of them reveal an iso to slightly hyperechoic texture as compared to the muscles, along with a thin echogenic capsule.²⁵

Desmoid tumor

Arises from the fascia or muscle aponeurosis. It often develops at the previous surgical scar and is more commonly in female patients than in male patients.^{6,7} Sonologically shows lobulated solid, well defined heterogeneous mass with moderate blood flow (Figure 9).

Metastatic melanoma

Is probably the most common metastatic malignant tumor to occur in the abdominal wall. Less commonly, metastases from lymphoma, lung, breast, ovary, and colon may be seen.

Fluid collections

Localized fluid collections in the abdominal wall may be due to seromas; abscesses or liquefying hematomas.

Seromas

These usually occur after surgical procedures. They usually appear as well-defined anechoic lesion with irregular

margins and internal echos with posterior acoustic enhancement on high-resolution sonography¹⁵ (Figure 10).

Abdominal wall abscess

May be due to various causes like - A cold abscess secondary to tuberculosis of the ribs may present as a lump. USG reveals pockets of fluid, along the costal margin, with internal echoes. Destruction of the corresponding rib may be seen.¹⁶⁻²⁰ Suture abscesses are seen as irregular collections within the layers of the abdominal wall, around infected sutures; fragments of suture material may sometimes be seen within this collection (Figure 11).

Hematomas

Hematomas commonly occur in the rectus sheath, in patients who are on anticoagulant therapy or in those who suffer from some coagulation disorder, especially following violent muscle contraction, e.g., after a bout of coughing or seizures. The shape of the hematomas depends on their location and follows the limits of the rectus sheath. Above the arcuate line, hematomas are usually ovoid in shape, with a superoinferior long axis, typically seen on one side. Below the arcuate line, they can extend across the midline, as there is no midline aponeurosis²¹⁻²³ (Figure 12). In neonates, an abdominal wall hematoma may be limited to the subcutaneous layer and

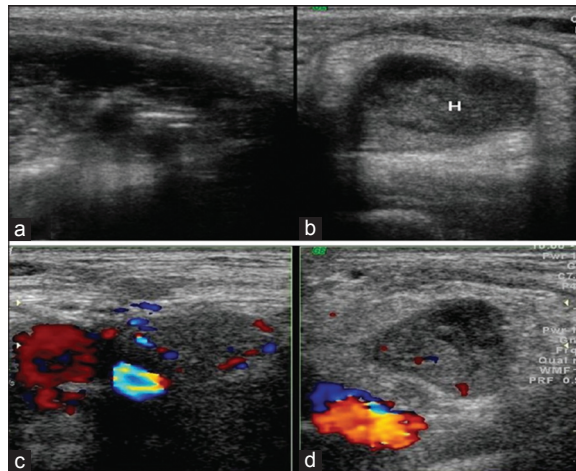


Figure 7: Femoral hernia - ultrasonography with color doppler.
(a) Grayscale images show a femoral hernial sac at two different levels. (b) The color Doppler images show the sac lying medial to the femoral vessels

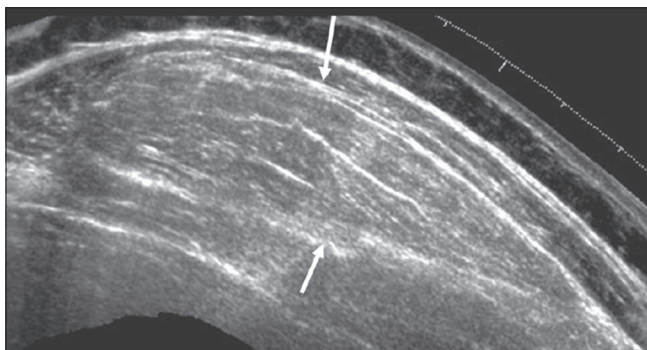


Figure 8: Lipoma. The image shows a well-defined mass with a capsule

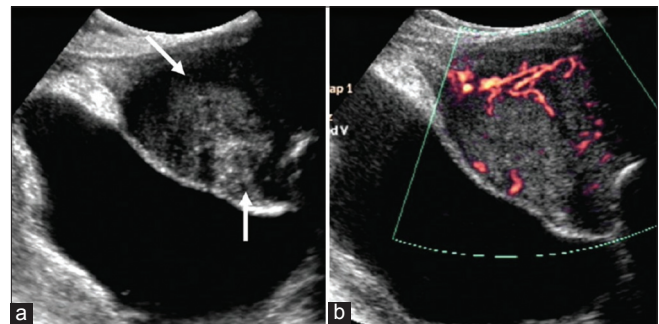


Figure 9: Desmoid. Grayscale (a) and color Doppler (b) images reveal a mass (arrows) at the site of a previous surgical scar, showing some vascularity within

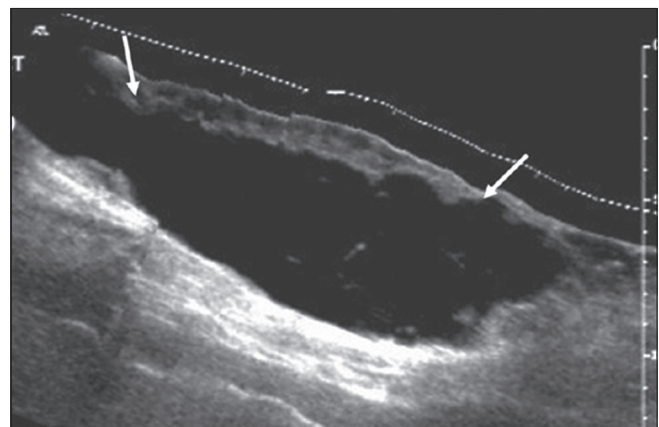


Figure 10: Seroma. Abdominal wall seroma, after splenectomy

may be spread transversely in the supraumbilical region. In post-operative patients, large hematomas may often be seen, in the vicinity of the surgical scar.

Miscellaneous

Urachal cyst

Aurachal cyst develops from urachal remnants. It is usually situated between the umbilicus and the urinary bladder. USG reveals fluid filled septated mass, with thickened wall and faintly echogenic fluid superior the bladder and attached to the lower mid anterior abdominal wall^{24,25} (Figure 13).

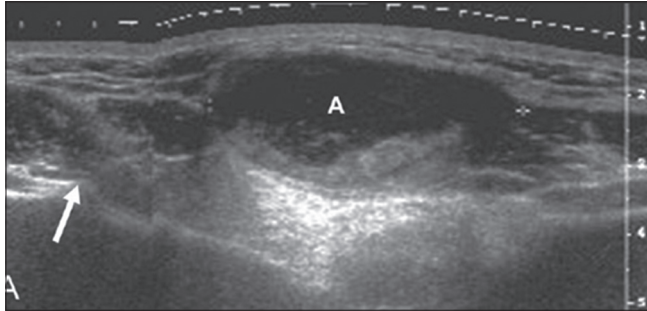


Figure 11: Complex abscess, inferior to the costal margin

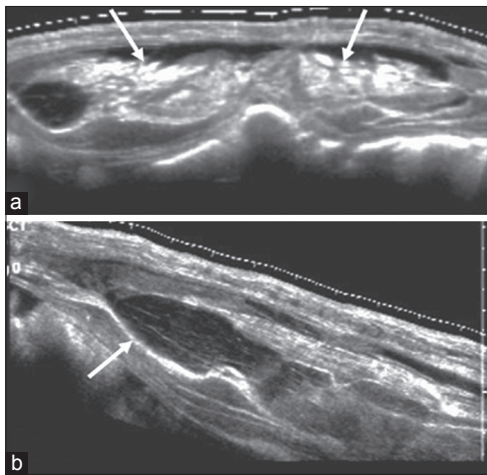


Figure 12: Rectus sheath hematoma. (a) Transverse and longitudinal (b) images show a hematoma following severe cough

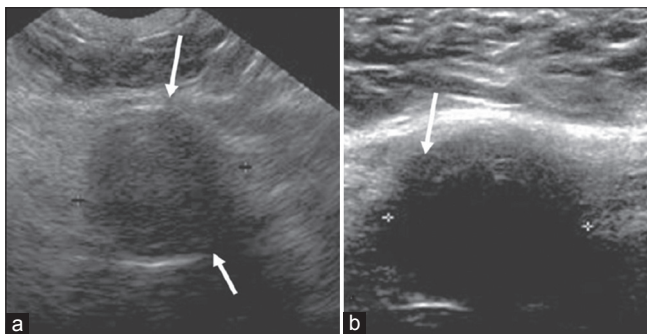


Figure 13: Urachal cyst. Transverse image shows an (a) infected urachal cyst (arrows), containing faintly echogenic fluid, the anterior wall of which produces (b) reverberation artifacts

Endometriosis

Endometriosis of the abdominal wall usually develops as complication of uterine surgery, due to seeding of endometrial tissue. Typically, it is seen as a focal mass at the scar of previous surgery. The size and the associated pain may vary cyclically.²⁶

CONCLUSION

The prevalence of anterior abdominal lesions was higher in the age group between 20 and 40 years. Ventral hernia was the most frequently encountered abdominal wall lesion. The most common indication for high-resolution sonography was palpable abdominal lump, which shows the low specificity of clinical examination in evaluation of anterior abdominal wall lesions. High-resolution sonography is an accurate tool in evaluation of various kinds of hernias (ventral, incisional, spigelian, and other types of hernias). We would like to emphasize on other anterior abdominal wall lesions other than hernias such as lipoma, desmoid, hematoma, dermoid cyst, metastatic melanoma, and resolving abscess, where sonography was an excellent complementary tool for the surgical management. Diagnostic accuracy of sonography was 97.6% in evaluation of hernias, lipomas, desmoid, dermoid, hematoma, and resolving abscess.

RECOMMENDATIONS

High-resolution USG is a very useful procedure which can be used for diagnosing the common abdominal wall lesions accurately.

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Comparative Assessment of Surgical Outcome Using Reduction Gear Handpiece and Conventional Handpiece While Removal of Impacted Mandibular Third Molars: A Prospective Study

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Abstract

Background: To find out the operating time and to investigate post-operative sequelae following impacted mandibular third molar surgery after using reduction gear and conventional handpiece for the osteotomy.

Materials and Methods: The study was conducted on 15 bilaterally symmetrical mandibular impacted third molars patients; one side of tooth was removed with reduction gear handpiece and another side with conventional handpiece with an average interval time of 3-4 weeks. Measurement of facial swelling, maximal interincisal distance was made preoperatively and on the 1st, 3rd, 5th, 8th, and 15th post-operative days. Pain was evaluated from patients response to numerical rating scale and operating time was also recorded in both groups.

Results: Reduction gear treated group showed a significant reduction in pain, swelling and trismus as compared with the control group at all intervals. There was statistically significant reduction in operating time in reduction gear handpiece treated group when compared to conventional handpiece treated group.

Conclusion: Reduction gear handpiece is an effective therapeutic tool for reducing operating time, and post-operative sequelae following surgical removal of impacted third molars. Moreover, further clinical trials with larger sample size should be done to get more affirmative and conclusive results.

Key words: Conventional handpiece, Reduction gear handpiece, Third molar surgery

INTRODUCTION

The chronological age of eruption of third molars is between 18 and 24 years with wide variation in the eruption time. The eruption failure being very common makes the removal of impacted third molars one of the most frequent surgical procedures in the maxillofacial region. Third molars are present in 90% of the population with 33% having at

least one impacted third molar.¹ In most of the situations, it results in recurrent pericoronitis, caries to adjacent tooth, cyst, etc. Removal of mandibular third molars is the eighth most common surgical event recorded in British National Health Service.² It is the most common and challenging surgery performed by the oral and maxillofacial surgeons and they are considered as the masters of it.³⁻⁵

One of the most critical steps in disimpaction is cutting the bone or osteotomy, for which many techniques are used, and if they are used injudiciously, they can be dangerous. However, rotary cutting instruments are potentially injurious because they produce excessively high temperatures during cutting of the bone, which can produce marginal osteonecrosis and impair regeneration

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and healing.⁶ Recently, after painstaking research and the application of advanced principles of physics, newer instruments have been introduced to reduce the difficulty and morbidity in third molar surgery. One such innovation is Reduction gear handpiece to make precise and safe osteotomies.

MATERIALS AND METHODS

The study was conducted on 30 randomly selected patients who required removal of impacted mandibular third molars, reporting to the Department of Oral and Maxillofacial Surgery, V. S. Dental College and Hospital, Bengaluru.

Patients with bilaterally impacted mandibular third molars who required removal, either for prophylactic reasons or because of pain, participated in this study and had given their consent.

RESULTS

In our study, patients reported lower values of pain on numerical rating scale in Reduction gear treated groups as compared to control group; Facial swelling showed a significant reduction in reduction gear treated groups on 1st and 3rd post-operative day as compared to controls. However, there was no significant difference between reduction gear handpiece treated groups and control group for this parameter on 3rd and 5th post-operative day. All values for facial swelling reached baseline in all the groups by the 8th post-operative day. Patients in the control group consistently had lower maximal interincisal opening on the 1st and 3rd post-operative day as compared with the reduction gear handpiece treated groups. However, there was no statically significant difference among the both groups; the interincisal mouth opening values reached baseline in both groups by the 8th post-operative day. The operating time was consistently lower in reduction gear handpiece treated group than conventional handpiece treated group; this parameter was statically significant (Figures 1-7).

DISCUSSION

The surgical removal of impacted teeth may range from relatively easy to extremely difficult depending on its location, depth, angulations, and the density of the bone. Regardless of the degree of difficulty, success depends primarily on correct preoperative planning, and on the careful execution that comes with extensive training and experience. One of the most critical steps in disimpaction is cutting the bone or osteotomy, for which many techniques

are used, and if they are used injudiciously they can be dangerous. However, rotary cutting instruments are



Figure 1: Pre-operative photographs - Profile pictures.
(a) Frontal view. (b) Right lateral view. (c) Left lateral view



Figure 2: Pre operative photograph. (a) Orthopantomograph. (b) Mouth opening. (c) Swelling measurement

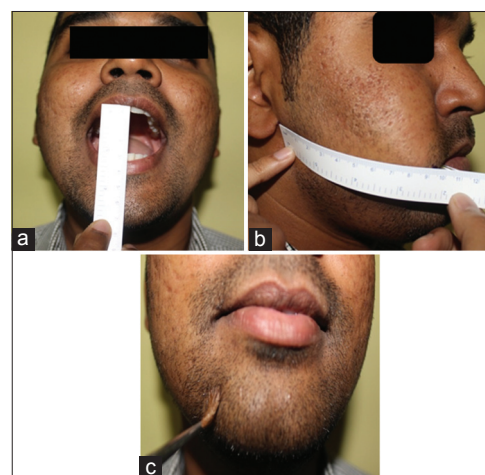


Figure 3: 1st Post-operative day after using conventional handpiece. (a) Mouth opening. (b) Swelling brush directional stroke test



Figure 4: 8th post-operative day using conventional handpiece. (a) Mouth opening. (b) Swelling



Figure 5: 1st Post-operative day after using reduction gear handpiece. (a) Mouth opening. (b) Swelling. (c) Brush directional stroke test

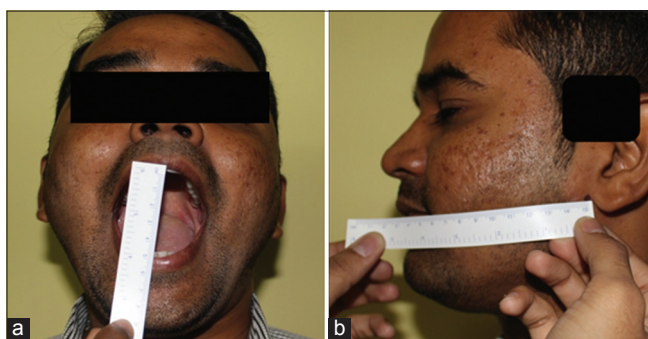


Figure 6: 8th Post-operative day after using reduction gear handpiece. (a) Mouth opening. (b) Swelling

potentially injurious because they produce excessively high temperatures during cutting of the bone, which can produce marginal osteonecrosis and impair regeneration and healing. Recently, after pains taking research and the application of advanced principles of physics, newer instruments have been introduced to reduce the difficulty and morbidity in third molar surgery.⁷

One such innovation is reduction gear handpiece to make precise and safe osteotomies. These handpieces are most

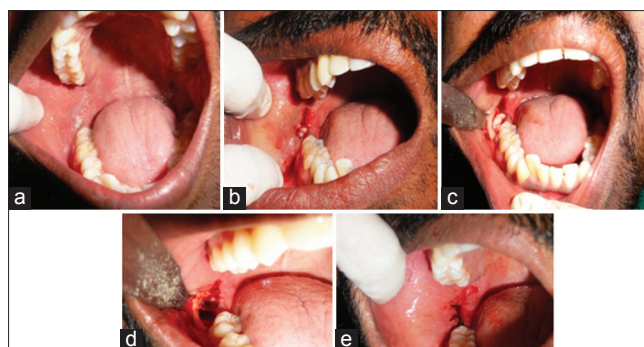


Figure 7: Surgical procedure of mandibular third molar. (a) Impacted tooth. (b) Ward's incision. (c) Mucoperiosteal reflection flap. (d) Gutting and elevation of tooth. (e) Closure with 3-0 mersilk

commonly used in implant surgeries and endodontics. Two important factors to understand reduction gear handpieces are speed and torque. Speed is expressed in revolutions per minute (rpm), whereas torque is expressed in watts and is an indication of the tool's cutting power. Torque is the ability to cut precisely and efficiently through a bone structure. Cutting efficiency is actually a balance between the speed and torque delivered to the bur. Reduction gear handpiece offers smooth, constant torque that does not vary as the bur meets resistance, the bur is connected through gears in the head of the handpiece to a central drive shaft that is physically turned by the motor. Reduction gear motors also offer accuracy by enabling the end user to set precise speeds for procedures, rather than the conventional "feathering" of the rheostat.⁸

In our study, we evaluated and compared five parameters, i.e., Mouth opening, pain, swelling, sensory disturbances with baseline values between two groups on 1st, 3rd, 5th, 8th, and 15th post-operative days and operating time, based on obtained result from statically analysis we can briefly conclude that there was consistently lower decrease in mouth opening in reduction handpiece group than conventional handpiece group on 1st, 3rd and 5th post-operative day, the mean of pain score (NRS), swelling were lower in reduction gear handpiece than conventional handpiece on 1st, 3rd and 5th post-operative days, facial swelling with a tape measure as two reference point from corner of mouth to just below the ear lobe, where most post-operative swelling is concentrated, however, all data were statistically insignificant. There was complete absence of sensory disturbances in both the groups.

The operating time was calculated to find out the efficacy of the operation, and statistical analysis showed that there was a significant difference between the two techniques. The mean duration of operation was longer in the conventional handpiece group than in the reduction gear handpiece group, The operating time was measured in minutes from placement

of incision to placement of last suture; there was consistently less operating time was required in reduction gear handpiece group than the conventional handpiece group; this parameter was statistically significant, so we can conclude that cutting efficiency of reduction gear handpiece was more and less of post-operative sequelae like swelling, pain, trismus were consistently less in reduction gear handpiece group when compared to conventional handpiece group.

Student's *t*-test (two-tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Intergroup analysis) on metric parameters. We, therefore, conclude from our study that cutting efficiency, operating time and post-operative outcomes were favorable in reduction gear handpiece group than the conventional handpiece group.

CONCLUSION

The results obtained suggested that reduction gear handpiece was effective in reducing. Post-operative pain, swelling, and trismus following removal of mandibular third molars. However, both reduction gear and conventional handpiece showed no statically significant difference in managing postoperative outcome. Moreover, it was found

that reduction gear handpiece had less operating time, which was statically significant, further clinical trials with larger sample size should be done to get more affirmative and conclusive results.

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Open Versus Closed Lateral Internal Sphincterotomy in Chronic Anal Fissures: A Prospective Study

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Abstract

Background: Fissure-in-ano is a very common anal disorder which predominantly presents with severe pain. Lateral internal sphincterotomy remains the main treatment modality. This may be performed using open or closed method, each with their attendant complications.

Objective: This prospective study compared the results and complications of open versus closed technique of lateral sphincterotomy in patients with chronic anal fissure.

Materials and Methods: A total of 64 patients with chronic anal fissure were enrolled in this study. Of these, 34 patients underwent open lateral sphincterotomy, and 30 underwent closed sphincterotomy. They were followed up for 6 months postsurgery. The results and complications of the two groups were compared and statistically analyzed.

Results: Post-operative complications such as pain, bleeding, infection, incontinence, and recurrence were compared between the two groups. Pain, bleeding, and incontinence to flatus were significantly lesser in the closed group ($P < 0.05$), while there was no difference in the incidence of infection and recurrence between the two groups.

Conclusion: Closed lateral internal sphincterotomy is a better alternative compared to open sphincterotomy in the treatment of chronic anal fissures.

Key words: Chronic fissure, Closed method, Lateral sphincterotomy, Open method

INTRODUCTION

A longitudinal ulcer in the anal canal is called as fissure in ano. It can be an acute anal fissure or chronic anal fissure. It is one of the benign painful conditions of anoderm, which is caused by raising internal sphincter spasm with impaired tissue perfusion. The classical vicious cycle formed by pain, and consequently, internal sphincter spasm that leads to fissure formation causes pain in anoderm.^{1,2} Hence, the aim of the treatment is to break this vicious cycle. Chronic

fissures are characterized by sentinel tag, hypertrophic anal papillae, anal sphincter spasm, and fibrosis. In recumbent position, the chronic fissure is commonly seen posteriorly at 6 o' clock position and sometimes in 12 o' clock position. Chronic fissures are more difficult to treat conservatively.³ There are many methods to relax the hypertonic internal anal sphincter such as topical glyceryltrinitrate (0.2%), topical diltiazem, botulinum toxin injection, and surgical internal sphincterotomy. Among these methods, surgical sphincterotomy has the highest healing rate with low recurrence.⁴⁻⁶ There are various surgical methods of treatment of anal fissure such as anal dilatation, fissure excision, fissure excision with sphincterotomy, open lateral anal internal sphincterotomy and closed anal internal sphincterotomy. This study was designed to compare the results of the open and closed technique of lateral internal sphincterotomy with reference to post-operative complications and outcomes.

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MATERIALS AND METHODS

This is a prospective study conducted from 2013 to 2014 in our hospital, which is a tertiary care center. In total, 64 patients were included in our study. These patients were evaluated and diagnosed as chronic anal fissure by detailed history and physical examination. These patients were randomly divided into two groups. In Group A 34 patients were treated with open lateral sphincterotomy (OLS) and in Group B 30 patients were treated with closed lateral sphincterotomy (CLS). In all patients, parameters such as age, sex, pain, bleeding, perianal swelling, constipation, and pruritus ani were collected before surgery. Site of anal fissure was documented for all patients. Both the groups of the patients were evaluated before surgery for anesthetic fitness. Patients with hemorrhoids, fistula and any other anorectal diseases were excluded from the study.

In Group A, with the patient in lithotomy position clear identification of the internal sphincter was done after making an 1 cm incision in 3 o' clock position. Sphincter segment was hooked with curved artery forceps and divided with electrocautery or by scissors. Then, pressure was maintained for few minutes to ensure good hemostasis. Wound was kept open for healing through secondary intention.

In Group B, the anal canal was retracted using an anal retractor. The internal sphincter is felt like a tight band. Intersphincteric groove was identified by palpation. An 11 size scalpel was introduced through the perianal skin at 3 o' clock position to enter into the intersphincteric groove. Anal canal support was provided with the back of grasping forceps, and when the tip of the blade reached the dentate line, the blade was turned inward and forward to cut the internal anal sphincter. The pressure was applied for few minutes for hemostasis.

In both methods, about $\frac{1}{3}$ to $\frac{1}{2}$ of internal sphincter was divided. Patients were followed up for 6 months after surgery to assess the results and complications such as pain, bleeding, infection, incontinence, and recurrence.

Statistical analysis was performed using SPSS software version 17. The Chi-square test was used to analyze statistical significance of results. $P < 0.05$ is considered as statistically significant.

RESULTS

In our study group, the most common presentation of anal fissure was pain on defecation. Of the 64 patients, 41 were males and 23 were females with a ratio of nearly 2:1. The mean age was 34 ± 5 years. About 60% of the patients

had a posterior fissure and 36% had anterior fissure. Only 2 patients had both anterior and posterior fissures. This is similar to the observation made by Gupta *et al.*⁷ After surgery, almost 85% of the patients were symptom-free on post-operative day 2. Post-operative pain and other complications are enlisted in Table 1.

In OLS group 9 patients had significant day 2 post-operative pain but only 2 patients had it in CLS group, which is statistically significant ($P = 0.036$). Post-operative bleeding was present in 5 patients, with all the patients in the OLS group ($P = 0.028$). Wound infection was seen in 3 patients in the OLS group, and there was none in the CLS group, which is not statistically significant ($P = 0.095$). Incontinence to flatus was present in 3 patients in the CLS group and 11 patients in the OLS group with a P value of 0.031. At the end of 6 months, of the 48 patients who reviewed, 2 patients had recurrence in the OLS group and 3 patients in the CLS group ($P = 0.75$).

DISCUSSION

Chronic anal fissure can be easily managed by surgical treatment. OLS and CLS are the two effective methods commonly performed for fissure in ano. In our study, anal pain (69%) and bleeding (60%) are the most common modes of presentation. In the study by Hananel and Gordon,⁸ 90.8% presented with pain and 71.4% with bleeding. In our study, post-operative pain relief was present in 87.5% of patients in CLS group and 75% in OLS group, which is similar to Hiltunen and Matikainen.⁹ Regarding post-operative complications, pain, bleeding, and incontinence were significantly lesser in the CLS group, while infection and recurrence were similar in both the groups. Pernikoff *et al.* have reported that the complication rate is relatively higher in OLS.¹⁰ Kortbeek *et al.*¹¹ and Ullah and Nadeem¹² also observed that closed sphincterotomy is associated with lesser complications when compared to open method.

CONCLUSION

Closed lateral internal sphincterotomy can be used as a treatment of choice for chronic anal fissure. It is effective

Table 1: Comparative table of OLS versus CLS

Factors	Group A (OLS)	Group B (CLS)	P value
Number of patients	34	30	
Pain	9	2	0.036
Bleeding	5	0	0.028
Infection	3	0	0.095
Incontinence	11	3	0.031
Recurrence	2	3	0.75

OLS: Open lateral sphincterotomy, CLS: Closed lateral sphincterotomy

and safe with lower rates of complication than open sphincterotomy technique.

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Effect of Intrathecal Clonidine on Post-operative Analgesia in Pregnant Patients Undergoing Lower Segment Caesarian Section

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Abstract

Introduction: Neuraxial anesthesia is now the preferred technique for lower segment cesarean sections (LSCS). Although epidural, spinal, continuous spinal, and combined spinal-epidural techniques have all been advocated, the most cesarean sections are performed under single-shot spinal anesthesia.

Aim: To evaluate the efficacy of clonidine in prolonging the duration of post-operative analgesia when combined with bupivacaine and the property of clonidine to potentiate the analgesic effect of bupivacaine and to observe the safety of intrathecally administered clonidine.

Materials and Methods: Pregnant patients belonging to the American Society of Anesthesiologists Physical Status I and II from 18 to 28 years, weighing 45-70 kg were included in the study. The patients were randomly allocated into two groups, Group B and Group C. Group B administered with 0.5% hyperbaric bupivacaine 10 mg and Group C administered with 0.5% hyperbaric bupivacaine 10 mg with clonidine 75 µg.

Results: A mean duration of analgesia in Group B is 176.9 ± 69.5 and Group C is 288.6 ± 130.3 . Time to 2 segment regression in Group B is 126.8 ± 56.5 and Group C is 214.6 ± 103.5 .

Conclusion: An addition of 75 µg of clonidine to hyperbaric bupivacaine is safe and beneficial to pregnant patients posted for LSCS.

Key words: Analgesic, Bupivacaine, Clonidine, Lower segment caesarean sections

INTRODUCTION

Bupivacaine in orthopedic surgeries had proved that the combination of clonidine was effective in preventing the tourniquet pain and effectively prolonging the post-operative analgesia. Spinal anesthesia has increasingly become the technique of choice for lower segment cesarian section.¹ It has the advantages of simplicity of technique,^{2,3} rapid onset of action, and reliability in producing uniform sensory and motor blockade as compared to epidural anesthesia.⁴⁻⁶ Its main disadvantage relates to its limited

duration of action and hence the lack of long-lasting post-operative analgesia. Spinal anesthesia and post-operative analgesia can be prolonged using adjuvant to local anesthetic such as adrenaline,⁷ midazolam,⁸ opioids, neostigmine, and clonidine.⁹⁻¹⁴ Clinical studies have suggested that intrathecal clonidine prolongs sensory as well as a motor block of spinal anesthesia. It decreases local anesthetic requirements and provides prolonged post-operative analgesia.^{9,14-17} Other beneficial effects are anti-emesis, reduced post spinal shivering, anxiolysis, and sedation.¹⁸ Increased sedation caused by it may also be unwanted at times. The necessity to find out the lower effective dose of clonidine to avoid its known side effects like hypotension and bradycardia and sedation prompted us to design this study.

Aim

To evaluate the efficacy of clonidine in prolonging the duration of post-operative analgesia when combined with

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bupivacaine and the property of clonidine to potentiate the analgesic effect of Bupivacaine and to observe the safety of intrathecally administered clonidine.

MATERIALS AND METHODS

Open-labeled, randomized controlled study was conducted in Department of Anesthesiology, Tirunelveli Medical College in Pregnant patients belonging to American Society of Anesthesiologists Physical Status I and II. Patients from 18 to 28 years, weighing 45-70 kg were included in the study. Patients with systemic illness, patients with partial block or failed block, height <145 cm, procedures ending with hysterectomy or requiring blood transfusion, anemia, bleeding disorders, contraindication to clonidine, patients with psychiatric problems, and patients having spinal deformities were excluded from the study. After getting, informed consent, the patients were randomly allocated into two groups. Group "B" was administered with bupivacaine and Group "C" was administered with clonidine group. 0.5% hyperbaric bupivacaine 10 mg was injected in Group B and 0.5% hyperbaric bupivacaine 10 mg with clonidine 75 µg was injected in Group C.

RESULTS

The study was conducted on 70 patients randomly allotted into 2 groups as given below and the visual analog pain scale assessed.

After 2 h postoperatively, both Groups B and C patients exhibited a pain score of 0-1 and were comfortable, manifesting no signs of pain (Table 1). After 3 h, 8 patients in Group B manifested mild to moderate levels of pain requiring systemic analgesic supplementation. In Group C, only 5 patients manifested pain which required analgesic supplementation (Table 2). After 4 h, 31 patients in Group B manifested pain requiring systemic analgesic supplementation. In Group C, only 8 patients manifested pain which required analgesic supplementation (Table 3). After 6 h, 34 patients in Group B manifested pain, with almost 97% requiring systemic analgesic supplementation (Table 4).

In Group C, only 23 patients manifested pain, with an average only 66% required analgesic supplementation. 12 of the patients did not show any sign of pain, which is 34% of the study group had a good analgesic effect even after 6 h duration.

The mean "duration of analgesia" and mean "time to 2 segment regression" between the two groups were

Table 1: VAP score (2nd h)

Pain score	Number of patients (%)	
	Group B	Group C
0-1	35 (100)	35 (100)
2-4	0 (0)	0 (0)
5-6	0 (0)	0 (0)
>7	0 (0)	0 (0)

VAP: Visual analog pain scale

Table 2: VAP score (3rd h)

Pain score	Number of patients (%)	
	Group B	Group C
0-1	7 (20)	21 (60)
2-4	20 (57)	9 (26)
5-6	6 (17)	5 (14)
>7	2 (6)	0 (0)

VAP: Visual analog pain scale

Table 3: VAP score (4th h)

Pain score	Number of patients (%)	
	Group B	Group C
0-1	3 (8)	20 (57)
2-4	1 (3)	7 (20)
5-6	6 (17)	6 (17)
>7	25 (72)	2 (6)

VAP: Visual analog pain scale

Table 4: VAP score (6th h)

Pain score	Number of patients (%)	
	Group B	Group C
0-1	0 (0)	6 (17)
2-4	1 (3)	6 (17)
5-6	4 (12)	10 (30)
>7	30 (85)	13 (36)

VAP: Visual analog pain scale

statistically significant ($P < 0.0001$) (Table 5). The hemodynamic variables such as mean arterial pressure (MAP), pulse rate did not significantly differ at all the time periods of monitoring (5, 10, 15, 20, 30, 60, 90, 120). The SPO₂ of Group B was lesser than Group C at 5th min only. In all other time periods, the SPO₂ of the Group C was lesser than Group B which is statistically significant, though it is not clinically significant.

DISCUSSION

Clonidine added to bupivacaine for spinal anesthesia in caesarean section improves the immediate post-operative analgesia effect. The effective dose range of intrathecal clonidine for post-op analgesia is not known till date. Actually, all effects of clonidine including

Table 5: Comparison of duration of analgesia

Category	n	Mean±SD		Mean difference	t	Diff	Significance
		Group B	Group C				
Duration of analgesia	35	176.9±69.5	288.6±130.3	111.7	4.475	68	P<0.0001
Time to 2 segment regression	35	126.8±56.5	214.6±103.5	87.8	3.955	68	P<0.0001

SD: Standard deviation

analgesia are dose dependent. This study suggests that compared to bupivacaine alone, the addition of 75 µg clonidine to bupivacaine produced a strong analgesia with a mean duration of 288 minutes. Furthermore, our patients were not administered any additional opioids or tranquilizers perioperatively that may have potentiated the analgesic action of clonidine. Van Essen *et al.*¹⁹ studied the effect of addition of intrathecal clonidine to hyperbaric bupivacaine on post-operative pain and morphine requirements after caesarean section. He demonstrated that addition of 75 µg clonidine to hyperbaric bupivacaine prolongs spinal analgesia and the motor block after caesarean section and improves early analgesia. In this study using clonidine 75 µg alone the analgesia lasted for a mean of 288 min. The dose is lesser than that used by Coombs *et al.*, but the duration of analgesia is closer to that study even without opioid. Mendez *et al.*¹³ used epidural clonidine in doses of 400 and 800 µg for cesarean section, and they found that 800 µg group had 5 h of median duration of analgesia and this is closer to this study. This study shows that the intrathecal route required lesser dose than epidural route but with the same duration of analgesia and is safer with no side effects. Filos *et al.*²⁰ 150, 300, 450 µg intrathecal clonidine for its hemodynamic effects. They found the 300 and 450 µg group had hemodynamic stability, but the 150 µg group presented with immediate fall in MAP but with no delayed fall in this group. There was no incidence of significant bradycardia in all the three groups. This study with 75 µg clonidine also showed no significant hemodynamic changes. Moreover, it had no measurable deleterious side-effects in mother. Although MAP was lower in the Group C, this apparently was not considered clinically important, as the fall in MAP was manageable with intravenous fluids and the occurrence of bradycardia was not significantly different between the two groups. Furthermore, the average MAP did not decrease >20% from baseline.

CONCLUSION

This study has demonstrated that addition of 75 µg clonidine to hyperbaric bupivacaine prolongs post-operative analgesia and the two segment regression after caesarean section, without clinically significant

hemodynamic derangements or any adverse effects. Hence, intrathecal clonidine along with bupivacaine proves to be a safer alternative to intrathecal opioids and with a dose of 75 µg, the hemodynamic profile is also very acceptable. Thus, intrathecal clonidine 75 µg not only potentiates and prolongs the analgesic effect of bupivacaine but also has a good safety profile for intrathecal use.

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Pattern of Medical, Surgical and Orthopedic Disorders during Annual Pandharpur Wari Pilgrimage

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Abstract

Introduction: Pandharpur pilgrimage also called as Pandharpur wari is a holy pilgrimage existing over 800 years and consists of 200-250 km foot pilgrimage starting from Alandi (District: Pune), passing through district Satara and ending at Pandharpur (District: Solapur) (Western Maharashtra, India). The wari takes place during the month of Ashad (July) every year and lasts for 18-21 days.

Materials and Methods: The study enrolled all the pilgrims who sought medical help at our ambulance station, which travelled with the warkaris along the entire route. They were enrolled and given treatment. Their information was filled in a preset questionnaire, by medical personnel who were also delivering treatment. The data were entered into Microsoft excel sheet and were analyzed using statistical tests.

Results: A total number of pilgrims (who sought medical help) were 2365 (male - 1436, female - 929) (registered - 2079, non-registered - 286). 33% of pilgrims were undertaking pilgrimage for more than 10 years. The most common medical disorders observed were diarrhea, respiratory tract infections, knee pain, back pain, and foot pain. All these disorders showed an increasing pattern as the pilgrimage progressed with more cases reported in Solapur district (Malshiras, Wakhari). Orthopedic and Surgical disorders included fractures ($n = 4$), accidents, contused lacerated wounds, and gynecological problems. There was statistically significant increase in a number of patient disorders as the pilgrimage proceeded.

Conclusion: There is a need for coordinated, permanent effort in providing medical help to pilgrims, and the villages through which this pilgrimage travels. Furthermore, more research is needed in understanding this mega event so that coordinated efforts in terms of clean hygienic food and drinking water, toilet services, sewage disposal, and sanitary care can be provided during this mega event to prevent the disease burden in the pilgrims and the villagers.

Key words: Medical disorders, Orthopedic disorders, Pandharpur wari, Pilgrims, Surgical disorders

INTRODUCTION

Pandharpur Ashadhi Ekdashi wari is one of the most famous pilgrimages in India, which has been taking place for

more than 800 years. The annual pilgrimage to the famous Vitthal temple at Pandharpur in Maharashtra (Western India) is an unparalleled phenomenon that is undertaken by pilgrims of various castes, creed, rich, and poor. The pilgrims follow the tradition of carrying the paduka (footwear) of the saints in a palakhi (palanquin). This annual pilgrimage is a 21-day trek and over 250 km, which culminates on the Ekdashi (11th day after the full moon in the month Ashadh [June-July]) according to the Hindu lunar calendar. The warkaris (pilgrims) walk their way to Pandharpur and spend their nights in the camps set up in different villages en route. The local people from these villages make arrangements to

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lodge and feed the warkaris. The halts are, namely at Pune, Jejuri, Lonand, Malshiras, and Wakhari.

Although local people cooperate, the provisions for food, drinking water and sanitation always fall short of the demand. Open air defecation and toileting is very common, and thus, increasing the chances of food and water-borne diseases among the warkaris and also among the locals' days after the wari has left the place. July month is the peak for the monsoon season in India, thus increasing chances of respiratory infection, plus walking for a 200 km increases foot and footwear related problems. Pilgrims suffer from various common medical disorders and receive medical help and treatment from the number of private medical camps, ambulances and hospitals and government mobile dispensaries. Our study was aimed at studying the pattern of medical and surgical disorders during this holy pilgrimage.

Various studies describing medical diseases during Hajj pilgrimage¹⁻³ Amarnath pilgrimage^{4,5} have been reported, as far as our knowledge and literature search, no study till date assessing medical disorders during this Pandharpur pilgrimage exists.

MATERIALS AND METHODS

The study is a prospective study conducted during the pilgrimage period. The Ethics Committee approval was taken before undertaking this study. The study enrolled all the warkaris who sought medical help at one of our medical ambulances. Our ambulance travelled as the pilgrimage proceeded. The study was conducted at five different places along the route of pilgrimage; these places are as follows - Pune city (Hadapsar, Pimpri Chinchwad), Jejuri, Phaltan, Malshiras, and Wakhari.

The inclusion criteria were as follows - Pilgrims who have new medical problems during the pilgrimage seeking medical attention and aggravation of asthma. Data of the enrolled warkaris were collected by medical personnel by filling a set questionnaire. The data collected was entered into Microsoft excel sheet and was analyzed, and statistical tests were applied. Most of the disorders were addressed at the ambulance station with medicines and injections, dressing and primary medical treatment. Patients with accidents and fractures were referred to the nearest tertiary center for further management.

RESULTS

Total numbers of pilgrims (who sought medical help) were 2365 (male - 1436, female - 929). The most common age group was from 31 to 70 years ($n = 2014$)

(range - <10-90 years) (Table 1). Registered were 2079, nonregistered were 286 (Table 2). 67% of the pilgrims were undertaking pilgrimage for <10 years, 33% of pilgrims were undertaking pilgrimage for more than 10 years (Table 3). The most common medical disorders observed were diarrhoea, respiratory tract infections, knee pain, back pain, foot pain, orthopedic and surgical disorders included fractures ($n = 4$), accidents, contused lacerated wounds, gynecological problems (Table 4 and Figure 1). All these disorders showed an increasing pattern as the pilgrimage progressed with more cases reported in Solapur district (Malshiras, wakhari) (Figure 2a-c). There was statistically significant increase in a number of all patient disorders ($P < 0.0001$, $P < 0.005$) (except knee, whole body pain, ear and footwear problems) as the pilgrimage proceeded (Tables 5 and 6). However, the disorders occurring in unregistered patients did not show a significant correlation than those with registered patients as was hypothesized ($P > 0.05$) (Table 7). The statistical test applied was Chi-square test.

DISCUSSION

Pandharpur pilgrimage (wari) is a holy pilgrimage existing over 800 years and consists of a 200-250 km of barefoot

Table 1: Age and sex distribution in wari patients

Age (years)	Male	Female	Total
10-20	44	20	64
21-30	127	73	200
31-40	222	242	464
41-50	352	194	546
51-60	367	230	597
61-70	256	151	407
71-80	60	19	79
81-90	8	0	8
Total	1436	929	2365

Table 2: Registered/unregistered

Registered/unregistered	Number of cases (%)
Registered	2079 (87.9)
Unregistered	286 (12.1)
Total	2365 (100)

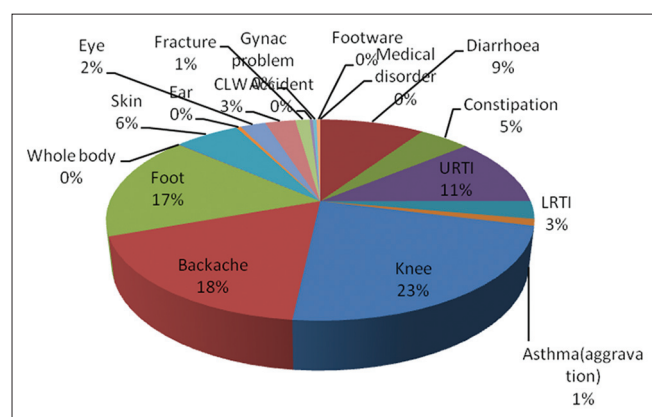
Table 3: Total number of years of wari

Total years of wari	Number of cases
1 st time	140
1-3	603
4-6	422
7-10	424
11-20	532
21-30	153
>30	91
Total	2365

Table 4: Medical disorder during wari

Medical disorder	Number of cases	Percentage (n=2365)
Diarrhea	397	16.8
Constipation	195	8.2
URTI	460	19.4
LRTI	121	5.1
Asthma (aggravation)	46	1.9
Knee	961	40.6
Backache	747	31.6
Foot	710	30
Whole body	3	0.1
Skin	249	10.5
Ear	16	0.7
Eye	99	4.1
CLW	116	4.9
Fracture	54	2.3
Accident	12	0.5
Gynac problem	14	0.6
Footware	14	0.6

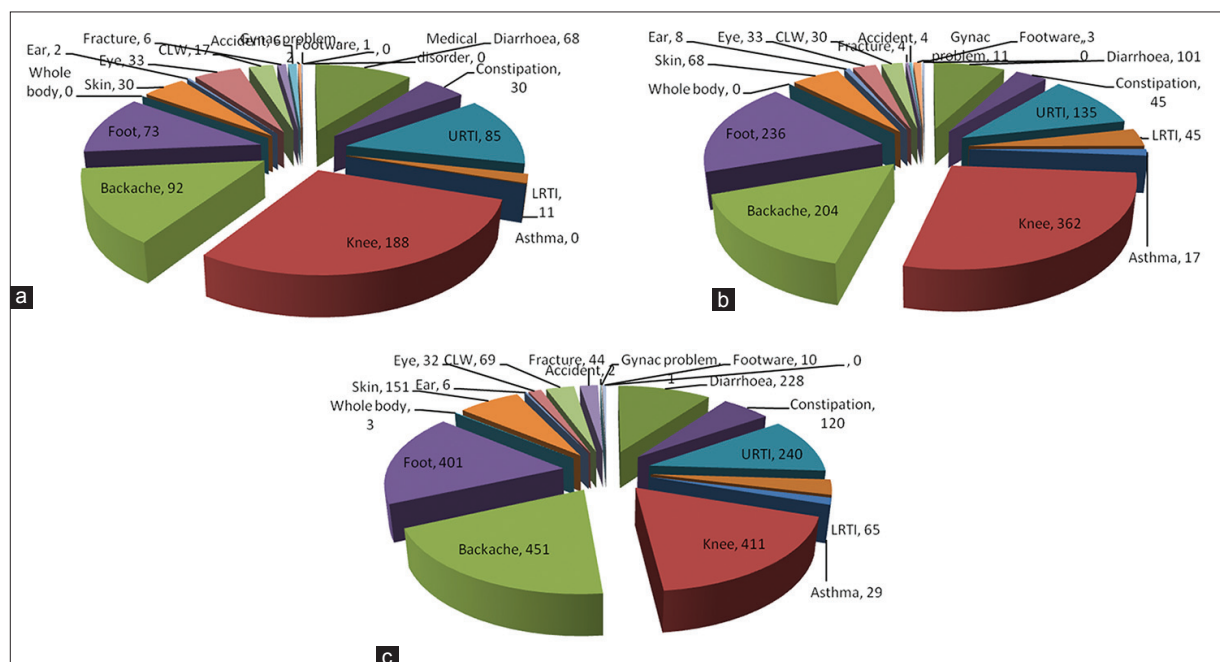
URTI: Upper respiratory tract infection, LRTI: Lower respiratory tract infection

**Figure 1: Disease burden percentage wise**

pilgrimage starting from Alandi (District: Pune) and ending at Pandharpur (District: Solapur) (Western Maharashtra, India). The wari takes place during the month of Ashad (July) and lasts for 18-21 days. There are two palaquein (palkhis), the Saint Dynaneshwar and Saint Tukaram Palkhi and the route is as follows - Saint Tukaram's Palkhi procession starts from Dehu and reaches Pandharpur via Aakurdi, Pune. Lonikalbhor, Yavat, Varvand, Baramati, Indapur, Akuj and Wakhri, respectively. Saint Dnyaneshwar's Palkhi goes through the cities of Alandi, Pune, Saswad, Jejuri, Lonand, Faltan, Natepute, Malshiras, Velapur, Shegaon and Wakhri to Pandharpur. Both the palkhis meet at Wakhri and proceed to Pandharpur (Figure 3).

The wari's unit of organization is the Dindi - A group of few dozen to a thousand men and women, often from the same village or community. Each Dindi has a truck with luggage and supplies, and staff who travel ahead in the morning to set up camp and cook at pre-appointed rest stops while the pilgrims walk in the day most of them barefoot.

The Saint Dnyaneshwar procession includes a pilot bullock-cart followed by two ceremonial horses, 27 Dindi, the chariot, and hundred more Dindis. During this 18-21 days March various rituals and events for entertainment are held at different places, all keeping to a tight schedule. The warkaris give up all the wordly pleasures and comforts, during their journey to Pandharpur. They uphold a strict vegetarian diet throughout and observe fasts during the pilgrimage. During this journey, the warkaris always address each other as "Mauli" (mother like) and never use their real names. These warkaris

**Figure 2: (a) Pune district disease burden, (b) Satara district disease burden, (c) Solapur district disease burden**

are undemanding and highly disciplined. Not a single mishap or major accident has occurred till date in the history of this pilgrimage. Political parties, other organizations and individuals stand by the road to hand out water and food to the pilgrims. The locals at each halt also help generously.

Such a pilgrimage requires clean water for drinking, ablution, and maintaining sanitation issues at the halts, housing tents and other facilities, considering the magnitude of the event and over 8 lakh devotees participate during this event, provisions in terms of clean food, drinking water provisions and sanitation facilities appear scarce. These lack of basic sanitation, create a major health risk and needs to be researched. Separate research is required

for understanding the requirements and providing these facilities and understanding the management of the wari. The social and economic impact of wari has been studied,⁶ however, health impact is not yet studied.

Baad in his study of employment generation during the wari period in Pandharpur concluded that the temporary employment (lodging, boarding services, and temporary services), generated by the wari is three and half times more than the permanent employment (production services).⁶

Pendharkar *et al.* in their social impact study of Pandharpur wari concludes with a discussion on the wari's contribution to social discourse, the ecological embeddedness of its performative traditions, the competing interests of a socially endowed temple complex, and the implications of new varieties of appropriation influencing the wari's spiritual commons.⁷

Hajj is the largest annual religious ritual in the world, and also an obligation to be carried out at least once in the lifetime of every physically, psychologically and financially Able Muslim, also it is one of the largely studied in terms of medical conditions and infectious disease outbreaks.¹⁻³ Al-Ghamdi *et al.* studied the pattern of admission to hospitals during Hajj pilgrimage, hospital admission during Hajj is related to old age and occurs in patients with associated comorbid conditions. During this mild weather lower respiratory tract infections and exacerbation of bronchial asthma and chronic obstructive pulmonary diseases are the most commonly encountered diseases during Hajj.¹

In India, Kumbh Mela is one of the biggest mass gatherings which have been studied and have been associated with

Table 5: Medical disorder according to registered/unregistered pilgrims

Medical disorder	Registered (n=2079)	Unregistered (n=286)	Total	Z value	P value
Diarrhoea	351	45	397	0.5	>0.05
Constipation	167	28	195	0.95	>0.05
URTI	404	56	460	0.06	>0.05
LRTI	109	12	121	0.81	>0.05
Asthma	41	5	46	0.26	>0.05
Knee	845	116	961	0.03	>0.05
Backache	661	86	747	0.59	>0.05
Foot	634	76	710	1.4	>0.05
Whole body	3	0	3	1.71	>0.05
Skin	210	39	249	1.66	>0.05
Ear	13	3	16	0.67	>0.05
Eye	78	21	99	2.25	>0.05
CLW	105	11	116	0.97	>0.05
Fracture	48	6	54	0.23	>0.05
Accident	12	0	12	3.48	<0.001
Gynac problem	10	4	14	1.29	>0.05
Footware	14	0	14	3.74	<0.001

URTI: Upper respiratory tract infection, LRTI: Lower respiratory tract infection

Table 6: Medical disorder during according to place

Medical disorder	Pune n=116	Jejuri n=360	Lonand n=548	Phaltan n=280	Natepute n=84	Bshegaon n=73	Velapue n=36	Malshiras n=318	Wakhri n=549	Total 2365
Diarrhea	14	54	73	28	21	17	9	87	94	397
Constipation	4	26	32	13	4	11	3	22	80	195
URTI	15	70	96	39	30	18	9	77	106	460
LRTI	2	9	10	35	13	0	6	26	20	121
Asthma	0	0	9	8	1	0	0	0	28	46
Knee	53	135	275	87	16	41	7	51	296	961
Backache	44	48	136	68	7	46	2	34	362	747
Foot	23	50	155	81	15	37	6	50	293	710
Whole body	0	0	0	0	0	0	0	1	2	3
Skin	6	24	44	24	6	20	4	41	80	249
Ear	0	2	5	3	0	2	0	0	4	16
Eye	13	20	24	9	2	3	0	10	17	99
CLW	0	17	16	14	2	1	3	19	44	116
Fracture	0	6	2	2	0	0	1	1	42	54
Accident	0	6	4	0	0	0	0	1	1	12
Gynac problem	1	1	6	5	0	0	0	0	1	14
Footware	1	0	3	0	0	0	0	10	0	14

URTI: Upper respiratory tract infection, LRTI: Lower respiratory tract infection

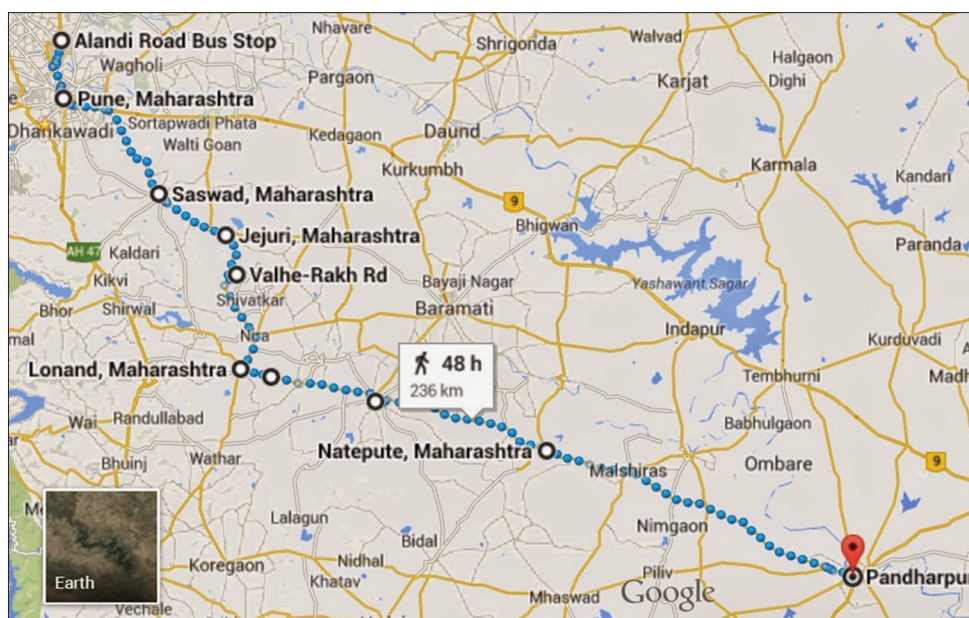


Figure 3: Route and map of Pandharpur wari (Maharashtra, India)

Table 7: Medical disorder during according to district

Medical disorder	District			Chi-square value	P value
	Pune (n=476)	Satara (n=828)	Solapur (n=1061)		
Diarrhoea	68	101	228	31.41	<0.0001
Constipation	30	45	120	24.19	<0.0001
URTI	85	135	240	12.81	<0.005
LRTI	11	45	65	10.12	<0.005
Asthma	0	17	29	12.95	<0.005
Knee	188	362	411	5.11	>0.05
Backache	92	204	451	110.16	<0.0001
Foot	73	236	401	80.29	<0.0001
Whole body	0	0	3	3.69	>0.05
Skin	30	68	151	29.19	<0.0001
Ear	2	8	6	1.69	>0.05
Eye	33	33	32	12.77	<0.005
CLW	17	30	69	10.54	<0.005
Fracture	6	4	44	30.78	<0.0001
Accident	6	4	2	7.49	<0.05
Gynac problem	2	11	1	12.34	<0.005
Footware	1	3	10	4.14	>0.05

CLW: URTI: Upper respiratory tract infection, LRTI: Lower respiratory tract infection

diasaters^{8,9} and Amaranth yatra^{4,5} is one of the most holy pilgrimage in northern Himalayas, associated with casualties due to difficult terrain and high altitude problems. Mir *et al.* studied the profile of nontraumatic surgical disorders found in the pilgrims/trekkers travelling to Shri Amarnathji Cave; they concluded that Pilgrims who intend taking up the yatra in future should seek medical advice before their departure.⁵

Of the 2365 pilgrims who were enrolled, the most common disorders were of diarrhea, respiratory tract infection, problems arising due to walking like knee pain, back pain, foot, and footwear related problems. As the pilgrimage

progressed, the disorders increased significantly. District wise and place wise patient number increased significantly as the pilgrimage reached its end point at Pandharpur. Although we hypothesized that unregistered pilgrims will have more health related disorders than registered pilgrims, this was not found in our study maybe due to a small number of unregistered pilgrims enrolled. The only drawback of our study could be the number of patients enrolled considering 8 lakh devotees in pilgrimage.

CONCLUSION

During Pandharpur wari, a lot of uncoordinated private and government medical support (Private ambulance, on road private hospitals, government public health centers) is provided; however, there has been no study until this date to assess the actual problems and effects of medical services delivery on the field. Our study aims to assess the pattern of medical, surgical and orthopedic disorders occurring during this event, which will not only document but also help to plan for organized and coordinated medical relief services during this event.

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Incidence of Types of Thyroid Carcinoma in an Iodine-rich Area: Thoothukudi Southern Coastal City

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Abstract

Introduction: Thyroid cancer is the most common malignancy in the human body. Thoothukudi being a coastal city in southern Tamil Nadu, an iodine-rich area, might have been expected to show a lower incidence of papillary carcinoma (PTC). Our study is to analyze the higher incidence of PTC and other types also.

Aim: To analyze the incidence of various types of thyroid malignancy in iodine-rich area like Thoothukudi.

Materials and Methods: A cross-sectional comparative study in patients with thyroid swelling whose fine needle aspiration cytology (FNAC) has revealed malignant results. FNAC and histopathological examination of biopsy was done.

Results: Out of the total 114 patients, 79.5% were females and 21.5% were males. The most common age group was 31-40 years 44.48%. The pathological classification with FNAC and biopsy revealed PTC the most common with 80 cases out of 114.

Conclusion: Among carcinoma thyroid PTC thyroid is the most common particularly even though in an iodine-rich area. Carcinoma thyroid has a higher prevalence among females rather than males. The highest number of the patients were seen in the age group of 30-40.

Key words: Thyroid, Carcinoma, Iodine rich area

INTRODUCTION

Thyroid cancer is the most common malignancy in the human body. It accounts for 1% of all cancers. It shows a geographic variation in incidence, tumor type, and natural history. The number of new cases of thyroid cancer was 13.9 per 100,000 men and women per year. The number of deaths was 0.5 per 100,000 men and women per year. These rates are age-adjusted and based on 2009-2013 cases and deaths. Approximately, 1.1% of men and women will be diagnosed with thyroid cancer at some point during their lifetime,¹ based on 2010-2012 data. Thyroid malignancy

commonly presents clinically as either solitary thyroid nodule or multinodular goiter. Pre-operative diagnosis with fine needle aspiration cytology (FNAC) is useful to decide the management. Histopathological study is also used to confirm the diagnosis. This study was conducted in a tertiary care hospital, Thoothukudi Government Medical College Hospital, Thoothukudi. Thoothukudi being a coastal city in southern Tamil Nadu, the people here with their high dietary iodide intake, low thyroid weight, and low serum thyroid stimulating hormone (TSH) levels might have been expected to show a lower incidence of papillary carcinoma (PTC). However, there have been consistent reports of higher incidence of PTC in our area. Our study is to analyze the higher incidence of PTC and other types also. In recent years previously accepted link between thyroid cancer and endemic goiter "has been much disputed. Pendergrast *et al.*² found no difference in incidence of thyroid cancer in goitrous and non-goitrous areas in the U.S.A. or any evidence of reduction in incidence in goitrous areas subsequent to the introduction of

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iodized salt. In further reviews, the evidence is regarded as inconclusive, but a link is upheld between endemic goiter and associated follicular and anaplastic histological types of thyroid carcinoma. According to Thorvaldsson *et al.*,³ the findings together with the known high relative frequency of follicular carcinoma and low frequency of PTC in areas of endemic goitre, lead to the suggestion that the incidence of PTC and follicular carcinoma are separately influenced by dietary iodide,⁴ PTC being high in areas of high iodide intake and 'low in areas with low dietary iodide.

Aim

To analyze the incidence of various types of thyroid malignancy in an iodide rich area like Thoothukudi.

MATERIALS AND METHODS

A cross-sectional observational study was conducted in Department of General Surgery in Thoothukudi Government Medical College Hospital, Thoothukudi, an iodine-rich southern coastal city in South India. Patients with thyroid swelling whose FNAC has revealed malignant results are included while Patients with thyroid swelling due to other causes like colloid goiter or inflammatory disease are excluded. A detailed history is obtained from all the patients, and complete clinical examination was done. The data collected from the patients documented in a proforma. Age and sex are noted on each patient. Informed consent is obtained from all the patients. Pathological methods used are FNAC and histopathological examination of biopsy.

RESULTS

A total of 114 samples of patients with thyroid swelling who's FNAC have revealed malignant results. Out of the total 114 patients, 79.5% of the patients (91) were females and 21.5% of patients (23) were males. The sex ratio between male and female cases was 1:3.6 in favor of the females (Figure 1).

The average age of presentation was 40 years. We had patients as young as 19 years presenting as carcinoma thyroid and 70 years was the oldest age of presentation. The most common age group was 31-40 years with 39 patients about 44.48% of the total cases, followed by the age group 41-50 with 34.2% (Table 1).

The pathological classification with FNAC and biopsy revealed PTC the most common with 80 cases out of 114, follicular carcinoma next with 23 out of 114, anaplastic carcinoma 1 out of 114, and medullary carcinoma 10 (Figure 2 and Table 2).

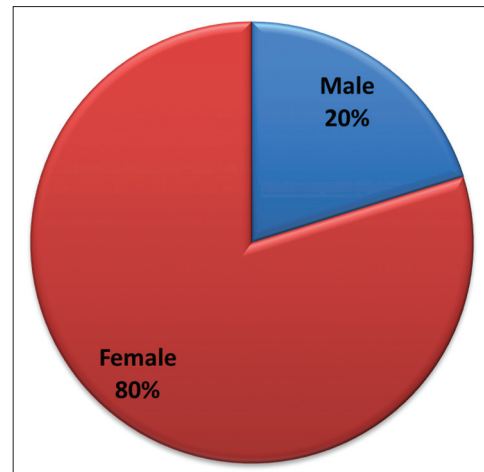


Figure 1: Incidence of thyroid carcinoma distributed in gender

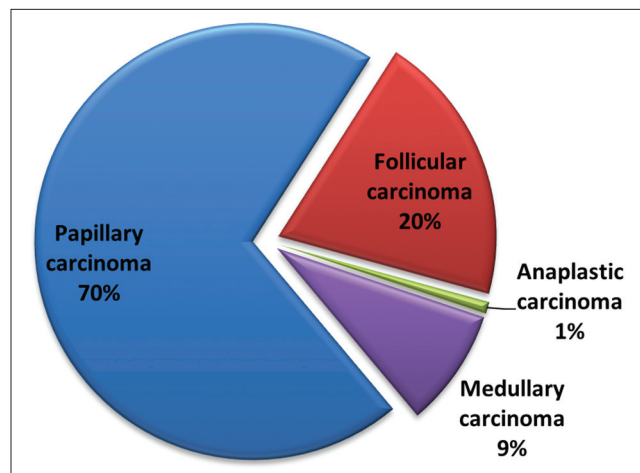


Figure 2: Pathological incidence of carcinoma thyroid

Table 1: Distribution of carcinoma thyroid patients in age groups

Age group	Number of patients	Male	Female
11-20	2	0	2
21-30	25	5	20
31-40	39	10	29
41-50	30	5	25
51-60	13	3	10
>61	5	0	5

Table 2: Pathological classification of carcinoma thyroid

Age	PTC	Follicular carcinoma	Anaplastic carcinoma	Medullary carcinoma
11-20	2	-	-	-
21-30	20	4	-	1
31-40	30	5	-	4
41-50	20	5	-	5
51-60	5	8	-	-
>61	3	1	1	-

PTC: Papillary carcinoma

DISCUSSION

PTC is the most common form of well-differentiated thyroid cancer, and the most common form of thyroid cancer to result from exposure to radiation. Fine-needle aspiration biopsy (FNAB)⁵⁻⁷ is considered the best first-line diagnostic procedure for a thyroid nodule. A comparison of the incidence of the different histological types of thyroid Carcinoma in an area of high dietary iodide and an area of normal iodide intake has been made. In our study, the percentage of PTC among all carcinomas is 70.4%, and this is consistent with thyroid cancer in an iodide rich area. A histopathological study Williams *et al.*¹ a study conducted in Iceland and Northern Scotland where Iceland was the more iodine rich area and their study showed a result of PTC 71% among all carcinomas in Iceland and only 54% in northern Scotland. These findings together with the known high relative frequency of follicular carcinoma and low frequency of PTC in areas of endemic goiter,^{8,9} lead to the suggestion that the incidence of PTC and follicular carcinoma are separately influenced by dietary iodide, PTC being high in areas of high iodide intake, and low in areas with low dietary iodide. According to Williams *et al.*,¹ the people of Iceland, with their high dietary iodide intake, low thyroid weight, and low serum TSH levels might have been expected to show a lower incidence of PTC. However, there are a number of observations which taken together with the observations reported here, support the suggestion that a high dietary intake of iodide may be associated with a high incidence of PTC of the thyroid.^{10,11} This has drawn parallels in our study and has also consolidated the same point of view.

CONCLUSION

Among carcinoma thyroid PTC thyroid is the most common which correlates with literature. On the basis of classification according to sex, carcinoma thyroid has a higher prevalence among females rather than males. PTC showed a higher incidence even though the area under study is an iodine-rich area.

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Assessment of C-reactive Protein in Cases of Acute Myocardial Infarction and Its Correlation with Risk Factors

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Abstract

Introduction: Acute myocardial infarction (AMI) is a significant cause of morbidity and mortality worldwide, which results from occlusion of coronary artery. C-reactive protein (CRP) is an acute phase protein, synthesized by hepatocytes in response to cytokines released into circulation by activated leukocytes. It is a sensitive marker of coronary inflammation as well as the extent of myocardial necrosis. CRP measurement has many advantages in detection and monitoring the acute phase response.

Aim: To assess serum CRP level in newly diagnosed cases of AMI and to assess correlation with risk factors.

Materials and Methods: A total of 90 patients presenting with AMI admitted to ICCU in the Department of Cardiology, Mamata General & Super Specialty Hospital, Khammam, were included in the study. All the patients were diagnosed based on clinical examination electrocardiogram, troponin-I, and cardiac enzymes. Serum CRP levels were measured by enzyme-linked immunosorbent assay method. Patients were divided into two subgroups based on the presence of major risk factors hypertension: Diabetes mellitus and smoking. All values are expressed as mean \pm standard deviation. The results obtained are analyzed statistically.

Results: This study showed that mean serum CRP levels were increased in the study group. Among two subgroups, mean CRP level increased significantly in the group with risk factors when compared with another group.

Conclusion: Patients with AMI cases shows the presence of major risk factors and higher CRP level who may require more stringent treatment and monitoring when compared with subjects without risk factors.

Key words: Acute myocardial infarction, C-reactive protein, Hypertension, Diabetes mellitus

INTRODUCTION

Acute myocardial infarction (AMI) is the significant cause of morbidity and mortality worldwide. In India, the majority of death occur due to MI.¹ MI results from the rupture of atherosclerotic plaque with thrombus formation and occlusion of coronary artery resulting in reduction of blood supply to the portion of myocardium. Inflammation has also

been studied extensively to play a major role in MI.² Since inflammation is believed to have a role in the pathogenesis of cardiovascular events, measurement of markers of inflammation has been proposed as a method to improve the prediction of the risk of these events.⁴ Inflammation plays a crucial role in intermediary pathogenesis linking diabetes with a commonly existing conditions thought to originate through inflammatory mechanisms interleukin 6 a major proinflammatory cytokine is produced in a variety of tissues including activated leukocytes, adipocytes and endothelial cells. c-rp is the principle downstream mediator of the acute phase response and is primarily derived via IL-6 hepatic biosynthesis.⁵ Ford examined the relationship between C-reactive protein and BMI and diabetes and showed elevated c-rp concentrations in patients with diabetes.⁶ It has been theorized that acute myocardial

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infarctions (AMIs) and other acute coronary events that are precipitated by atherosclerosis are due to arterial blockage from fat deposits. It is now known, however, that atherosclerosis involves more than just lipids. Inflammation has also been studied extensively to play a substantial role in myocardial infarction.⁷ Kannel and McGee found that this diabetes report extended prior Framingham study findings with more-robust 20-year data for estimating the relative risk of specified atherosclerotic cardiovascular events from prior diabetes.⁸

Chae CU *et al* suggest that increased blood pressure may be a stimulus for inflammation and that this is a possible mechanism underlying the well-established role of hypertension as a risk factor for atherosclerotic disease.¹⁰

In 1999, Russel Ross was the first, who published that atherosclerosis is an inflammatory disease.⁹ Inflammation is an important feature of atheroma and is associated with activation and proliferation of macrophages, endothelial cells, and smooth muscle cells. There have been studies in assessing C-reactive protein (CRP) values and biomarker of inflammation for prediction of cardiovascular events.³ Several studies showed that CRP is not only inflammatory marker but is also involved in pathogenesis of MI. Recent observations suggest that the atherosclerotic process is characterized by a low-grade inflammation altering the endothelium of the coronary arteries and is associated with an increased level in markers of inflammation such as acute phase proteins and cytokines. Cumulative evidence indicates that inflammation, at both focal and systemic levels, plays a key role in destabilization and rupture of atherosclerotic plaques, leading to acute cardiovascular events.^{11,12}

CRP is an acute phase protein synthesized by hepatocytes in response to cytokines released into circulation by activated leukocytes. CRP inhibits endothelial cell nitric oxide synthase production via destabilizing endothelial nitric oxide synthase.¹⁸ Decreased no release causes CRP-mediated inhibition of angiogenesis-stimulating endothelial cell apoptosis. CRP activates complement system which mediates monocyte and neutrophil recruitment in an injured myocardium, and therefore, leads to increase in infarct size.¹⁸ CRP measurement has many advantages in detection and monitoring the acute phase response.

MATERIALS AND METHODS

The total of 90 cases presenting with AMI admitted to ICCU in the Department of Cardiology Mamata General & Super Speciality Hospital, Khammam, were included in the study. All the patients were diagnosed based on clinical examination, electrocardiogram, troponin-I, and cardiac enzymes. 90 patients are selected as controls. Serum CRP

levels were measured by immunoturbidimetry (ERBA kit) method.

Cases were divided into two subgroups based on the presence of major risk factors hypertension: Diabetes mellitus and smoking. Among them, 54 cases with risk.

Study Design

Cross-sectional comparative study.

Exclusive Criteria

1. Patients below 30 and above 50 aties,
2. Patients on statin treatment.

Inclusive Criteria

Patients in the range of 30-50 years.

Statistical Analysis

Mean and standard deviation values of all biochemical parameters were calculated in study and control groups, and the mean difference was compared using *t*-test.

RESULTS

This study showed that mean serum CRP level was significantly increased in the study group when compared with controls. Among two subgroups, mean serum CRP level was increased significantly in the group with risk factors when compared with another group without risk factors (Tables 1 and 2; Figures 1 and 2).

DISCUSSION

CRP, an acute phase protein, is a marker of systemic inflammation that has been associated with increased risk of incident MI. Tissue necrosis is a potent acute phase stimulus following MI; there is a major CRP response, the magnitude of which reflects the extent of myocardial necrosis.¹⁵ In the early phase of MI, proinflammatory cytokines directly interfere with the myocardial contractility, the vascular endothelial function and recruitment of other inflammatory cells.¹⁴ Patients of AMI showed increased CRP level.

An association between sustained high values of CRP following AMI and its adverse outcomes was first reported in 1982.¹³ Recent observation suggests that the atherosclerotic process is characterized by a low-grade inflammation altering the endothelium of coronary arteries and is associated with an increase in the level of markers of inflammation. In an attempt, to improve global cardiovascular risk prediction considerable interest has focused on CRP. CRP is not only an excellent biomarker of inflammation but it is also a direct participant in

Table 1: Mean±SD, P value among cases and controls

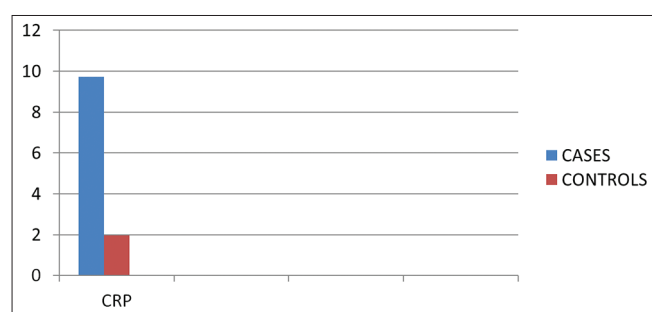
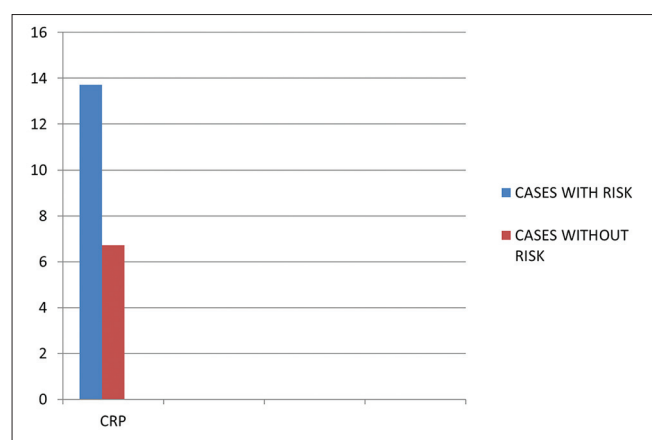
Parameter	Cases (mean±SD) n=90	Controls (mean±SD) n=90	P
CRP	9.72±2.74	1.97±0.86	<0.01

SD: Standard deviation, CRP: C-reactive protein

Table 2: Mean±SD, P value among subgroups (cases with risk factors and without risk factors)

Parameter	Subgroup-1 (n=54) Cases with risk factors	Subgroup-2 (n=36) Cases without risk factors	P
CRP	13.71±3.01	6.72±1.54	<0.02

SD: Standard deviation, CRP: C-reactive protein

**Figure 1: Mean±standard deviation, P value among cases and controls****Figure 2: Mean±standard deviation, P value among subgroups (cases with risk factors and without risk factors)**

atherogenesis. The mechanism of CRP pathogenicity is binding of abundant CRP to the ligands exposed in dead and damaged cells, triggering substantial complement activation with release of chemotactic factor and opsonization of cells in and around the lesion leading to enhanced infiltration by inflammatory cells and consequent damage.¹⁴ Elevated CRP has been associated with many diseases such as CHD, insulin resistance, hypertension, and metabolic syndrome. In addition to its role as a biomarker,

some studies found that CRP has a role in the development of endothelial dysfunction and elevated blood pressure.

Subclinical inflammation as indicated by elevated CRP levels may be one of the causal mechanisms contributing to the development of hypertension. There is evidence to indicate that systolic BP could promote oscillatory shear stress to stimulate the release of proinflammatory cytokines.²⁰ Inflammatory cytokines from obesity, insulin resistance could promote arterial inflammation.²¹ The inflammatory state itself may promote the release of free radicals and could increase NO degradation rate and lower its availability. CRP downregulates NO synthase and reduces NO release and bioactivity.²² Possible effect of systemic inflammation on BP may be mediated through alteration in the synthesis and degradation of vasodilating and vasoconstricting factors. Previous cross-sectional studies have been shown that CRP levels are positively associated with systolic blood pressure,^{23,24} pulse pressure,²⁵ and hypertension.²⁶

Insulin resistance (IR), a reduced physiological response of peripheral tissues to the action of insulin, is one of the major causes of Type 2 diabetes and plays a critical role in the pathogenesis of cardiovascular diseases (CVDs). Recent studies have shown that the worldwide prevalence of IR and its associated risk factors have increased markedly. IR is believed to be associated with chronic inflammatory response which is characterized by abnormal cytokine production and the activations of proinflammatory signaling pathways.²⁷⁻²⁹

The systemic inflammatory biomarker CRP when measured in the blood with high sensitivity assay has been reported to be a strong and independent predictor of MI, ischemic stroke, Type 2 diabetes, and hypertension. Several studies have provided strong evidence of association between CRP and CVD risk independent of traditional risk factors, such as cholesterol, blood pressure, alcohol consumption, and smoking habit.³⁰⁻³² This is in accordance with the study of Gelaye *et al.*

Components of the metabolic syndrome (i.e., central obesity, increased plasma triglyceride concentrations, low plasma concentrations of high-density lipoprotein-cholesterol, hypertension, and increased concentrations of blood glucose) correlate with increased plasma CRP concentrations, and CRP measurement contributes to risk prediction in individuals with the metabolic syndrome.¹⁹

Elevated CRP levels are a strong independent predictor of Type 2 diabetes and may mediate associations of TNF-αR2 and IL-6 with Type 2 diabetes.

This is in accordance with the study conducted by Sano *et al.*¹⁶ and Auer *et al.*¹⁷

Sanchis *et al.* found that CRP levels increase in patients with AMI with hypertension and diabetes mellitus.

Dibra *et al.* found that diabetes was positively related to CRP concentration.

In our study, the increased CRP level was more pronounced in the presence of major risk factors. As hypertension, diabetes mellitus and smoking are well-known independent risk factors for atherosclerosis. The patients with these risk factors may require more stringent treatment and should be monitored for future complications.

CONCLUSION

CRP levels are increased in AMI, and the increase was more pronounced in patients associated with risk factors. The patients with these risk factors may require more stringent treatment and should be monitored for future complications.

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Clinical, Biochemical and Hematological Profile in Dengue Fever

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Abstract

Introduction: Dengue is the most common mosquito borne endemo-epidemic arboviral infection in many of the tropical and subtropical regions of the world. In the last 50 years, an incidence has increased 30-fold with increasing geographic expansion to new countries and in the present decade from urban to rural settings. About 50 million dengue infections occur annually and approximately 2.5 billion people live in dengue endemic countries.

Objectives: To analyze the clinical, biochemical and hematological parameters of dengue fever.

Materials and Methods: A total of 100 patients collected from AMC/IMC/WARDS of Mahatma Gandhi Memorial Hospital Warangal, during the period November 2012-October 2013.

Results: A total of 100 patients admitted to our hospital with fever and immunoglobulin M dengue positive were studied. Out of 100 patients, 81 (81%) patients were diagnosed to have dengue fever.

Conclusion: To conclude, in this study classical dengue fever was the most common clinical presentation followed by complicated forms such as dengue hemorrhagic fever and dengue shock syndrome. Most of the patients presented with classical features such as fever myalgias, arthralgias, pain abdomen, vomiting, headache, rash, and bleeding manifestations. The treatment of dengue is mainly supportive. However, appropriate fluid management plays a major role in outcome of the disease.

Key words: Dengue, Dengue hemorrhagic fever, Dengue shock syndrome, Thrombocytopenia

INTRODUCTION

Dengue is the most common mosquito borne endemo-epidemic arboviral infection in many of the tropical and subtropical regions of the world. In the last 50 years, an incidence has increased 30-fold with increasing geographic expansion to new countries and in the present decade from urban to rural settings. About 50 million dengue infections occur annually and approximately 2.5 billion people live in dengue endemic countries.¹

In addition, the impact of dengue illness on the health sector leads to considerable global economic burden in

endemic countries, most of which are developing nation.^{2,3} Dengue is caused by dengue virus (DEN) and is transmitted to humans by the bite of *Aedes aegypti* mosquito.

DEN is a small single-stranded RNA virus comprising four distinct serotypes (DEN-1 to -4). These closely related serotypes of the DEN belong to the genus *Flavivirus* and family *Flaviviridae*. "Asian" genotypes of DEN-2 and DEN-3 are frequently associated with severe disease accompanying secondary dengue infections.⁴⁻⁶

Intrahost viral diversity (quasi species) has also been described in human hosts. Dengue has a wide spectrum of clinical presentations, often with unpredictable clinical evolution, and outcome. While the most patients recover following a self-limiting nonsevere clinical course, a small proportion progress to severe disease, mostly characterized by plasma leakage with or without hemorrhage. Intravenous rehydration is the therapy of choice; this intervention can reduce the case fatality rate to <1% of severe cases.

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The group progressing from nonsevere to severe disease is difficult to define, but this is an important concern since appropriate treatment may prevent these patients from developing more severe clinical conditions. Symptomatic DEN infections were grouped into three categories: Undifferentiated fever, dengue fever (DF), and dengue hemorrhagic fever (DHF). DHF was further classified into four severity grades, with Grades III and IV being defined as dengue shock syndrome (DSS).^{7,8}

Objectives

To analyze the clinical, biochemical and hematological parameters of dengue fever.

MATERIALS AND METHODS

A total of 100 patients collected from AMC/IMC/WARDS of Mahatma Gandhi Memorial Hospital Warangal, during the period November 2012-October 2013, presenting with acute febrile illness, who are immunoglobulin M (IgM) seropositive for dengue and satisfying inclusion and exclusion criteria.

Patients belonging to the age group of above 12 years, belonging to both sexes were selected and included in the study group.

Inclusion Criteria

- Any acute febrile illness with positive IgM to DF was included in the study.

Exclusion Criteria

- Patients with age group below 12 years of age
- Patient with identified bacterial focus (e.g., Typhoid fever with positive dengue IgM)
- Any other identified specific infections (e.g., malaria with positive dengue IgM and patients with inadequate data, lab parameters)
- Patients with only IgG but not IgM.

RESULTS

A total of 100 patients admitted to our hospital with fever and IgM dengue positive were studied. Out of 100 patients, 81 (81%) patients were diagnosed to have DF.

Ten (10%) patients were diagnosed to have DHF and 9 (9%) patients were diagnosed to have DSS based on WHO criteria (Table 1).

This study included 53 (53%) male patients and 47 (47%) female patients. Male to female ratio is 1.13:1 (Table 2).

Among males 43 were DF, 5 DHF and 5 DSS.

Among females 38 DF, 5 DHF and 4 DSS.

DF cases were more among males, i.e., 43 (53%) than in females, i.e., 38 (47%).

DHF cases among males were 5 (50%) and females 5 (50%).

DSS cases were more among males, i.e., 5 (55.5%) and females 4 (44.5%) (Table 3).

Age-wise Distribution of Dengue Cases

The majority of the cases of dengue fall in the age group between 13 and 40 years where in 21 cases (21%) belong to 13-20 years group, 24 cases (24%) belong to 21-30 years group, and 23 cases (23%) belong to the age group of 31-40 years. The mean age, in our study, was 36.6 ± 15.4 years. Youngest was 13 years and the eldest was 70 years.

Age Distribution According to Clinical Spectrum

In this study, the highest number of cases were found in the age group between 21 and 30 years with a total of 24 cases of with 20 (20%) cases of dengue fever, 2 (20%) cases of DHF, and 2 (22.22%) cases of DSS, followed by age group between 31 and 40 years with 23 cases of which 17 (17%) cases of DF, 2 (20%), and 4 (44.44%) cases of DSS. Fever is the most common presenting symptom observed in 100 cases (100%) followed by myalgias seen in

Table 1: Clinical spectrum of dengue cases

Diagnosis	n (%)
DF	81 (81)
DHF	10 (10)
DSS	9 (9)
Total	100 (100)

DF: Dengue fever, DHF: Dengue hemorrhagic fever, DSS: Dengue shock syndrome

Table 2: Gender wise distribution

Sex	n (%)
Male	53 (53)
Female	47 (47)
Total	100 (100)

Table 3: Sex distribution of dengue cases according to clinical spectrum

Sex	n (%)		
	DF	DHF	DSS
Male (53)	43 (81.13)	5 (9.43)	5 (9.43)
Female (47)	38 (80.85)	5 (10.64)	4 (8.51)
Total (100)	81 (81)	10 (10)	9 (9)

DF: Dengue fever, DHF: Dengue hemorrhagic fever, DSS: Dengue shock syndrome

71 cases (71%), headache in 61 cases (61%), joint pains in 65 cases (65%), vomiting in 48 cases (48%), pain abdomen in 56 cases (56%), and bleeding in 21 cases (21%).

- Bleeding manifestations were significantly high in patients with DHF, i.e., in 10 (100%) and DSS in 3 (33.3%) patients than in DF seen in 8 (9.8%) patients. The difference was statistically significant with $P = 0.00001$.
- SOB was significantly high in patients with DSS seen in 3 (33.3%) of patients and in 4 (4.94%) patients with DF. The difference is statistically significant with $P = 0.004$.
- Bleeding was noted in 21 (21%) patients.
- Malena was the most common manifestation seen in 15 (15%) cases followed by gum bleeding seen in 4 (4%) cases, epistaxis in 3 (3%) cases, skin bleeding in 3 (3%) cases, hematuria in 2 (2%) cases, and hematemesis in 1 (1%) case.

DISCUSSION

DF is the one of the most important arboviral infections. It has become a major global public health problem with more than 100 million infections worldwide annually, including 2,50,000-5,00,000 cases of DHF and 24,000 deaths annually. In the last 50 years, incidence has increased 30-fold with increasing geographic expansion to new countries.

Dengue inflicts a significant health, economic, and social burden on the population endemic for the disease. In India, epidemics are becoming more frequent. Involvement of younger age group and increasing in the frequency of epidemics are indicators of higher incidence of infection. The presentation of dengue infection varies from nonspecific febrile illness to more serious forms of the disease DHF or DSS.

Bleeding involvement in dengue infection is usually mild and all stages of the disease can copresent with bleeding manifestations, significant bleeding can occur in patients with DHF and DSS. Early recognition and meticulous management are very important to save precious lives from this disease.

A total of 100 patients admitted to our hospital with fever of $>101^{\circ}\text{F}$ and IgM dengue positive were studied.

Comparison of Clinical Spectrum with other Studies

In this study, DF was seen in 81% of the study population and the incidence of DHF and DSS was 10% and 9%, respectively. In a study done by Neeraja *et al.*,⁸ the prevalence of DF, DHF, DSS was 85%, 5% and 10%, respectively. In

a study done by Pancharoen *et al.*,⁸ there was high incidence of DHF, i.e., 60.4%. The results of this study corresponds to a study by Neeraja *et al.*⁸ (Table 4).

From these observations, we can conclude that the incidence of each clinical spectrum varies with geographical area.

Comparison of Sex Distribution with other Studies

This study included 53 (53%) male patients and 47 (47%) females, out of which 43 (43%) males and 38 (38%) females were diagnosed to have DF. Male to female ratio was 1.13:1. In studies done by Dash *et al.*¹¹ and Neeraja *et al.*,⁸ Male: Female ratio is 2.8:1, 2:1, respectively (Table 5).

In our study, DSS is a more common in males than females. 5 (5%) males and 5 (5%) females were diagnosed to have DHF. 5 (5%) males and 4 (5%) females were diagnosed to have DSS.

Fever was the presenting complaints in all the cases in our study. In the study conducted by Aggarwal *et al.*,¹² Dash *et al.*,¹¹ Neeraja *et al.*⁸ and Khan *et al.*² fever was present in 93%, 100%, 100% and 98.3%, respectively (Table 6).

Comparison of Various Symptoms with other Studies

Other symptoms

Myalgias and joint pains were seen in 71% and 65% cases in our study, respectively. In the study conducted by Dash *et al.*,¹¹ Neeraja *et al.*⁸ and Khan *et al.*,² myalgias was present in 70%, 53% and 23.8%, respectively. Joint pain was found in 55% and 15% of patients in study done by Dash *et al.*¹¹ and Neeraja *et al.*,⁸ respectively.

Table 4: Clinical profile of the disease

Author	Year	Place	Clinical profile
Pancharoen <i>et al.</i> ⁹	1995	Thailand	DF: 22.3% DHF: 60.4% DSS: 17.3%
Neeraja <i>et al.</i> ⁸	2004	Hyderabad	DF: 85% DHF: 5% DSS: 10%
Present study	2012-13	Warangal	DF: 81% DHF: 10% DSS: 9%

DF: Dengue fever, DHF: Dengue hemorrhagic fever, DSS: Dengue shock syndrome

Table 5: Sex distribution

Author	Year	Place	Male: Female ratio
Kamal <i>et al.</i> ¹⁰	2002	Warangal	0.72:1
Dash <i>et al.</i> ¹¹	2003	Gwalior	1.28:1
Neeraja <i>et al.</i> ⁸	2004	Hyderabad	2:1
Present study	2012-13	Warangal	1.13:1

Table 6: Analysis of various symptoms fever

Study	Year	Place	Fever (%)	Myalgia (%)	Joint pain (%)	Headache (%)	Rash (%)	Bleeding (%)
Dash <i>et al</i> ¹¹	2003	West Bengal	100	70	55	85	56	-
Neeraja <i>et al</i> ⁸	2004	Hyderabad	100	53	15	74	41	7
Khan <i>et al</i> ²	2006	Karachi	98.3	23.8	36	75	37.8	-
Aggarwal <i>et al</i> ¹²	1996	Chennai	93%	-	-	-	-	-
Present study	2012-13	Warangal	100	71	65	61	40	21

Headache was seen in 61% of patients in our study. Similar incidence was present in other studies too. In the study conducted by Dash *et al.*,¹¹ Neeraja *et al.*⁸ and Khan *et al.*,¹³ headache was present in 85%, 74% and 75%, respectively. Rash was one of the presenting complaint seen in 40 % of patients. In the study conducted by Dash *et al.*,¹¹ Neeraja *et al.*⁸ and Khan *et al.*,² rash was found to be present in 56%, 41% and 37.8%, respectively.

Bleeding was a presenting complaint in 21% of patients in our study. In study conducted by Neeraja *et al.*,⁸ bleeding was observed in 7% of the patients, the percentage of bleeding was found to be higher in our study.

Vomiting and pain abdomen was found in 48% and 56% of patients in our study, respectively. The incidence of this was not mentioned in other studies. The findings in this study correlated with studies done by Dash *et al.*,¹¹ Neeraja *et al.*,⁸ and Khan *et al.*²

Comparison of Shock with other Studies

This study has shown features of shock in 9 (9%) patients. The study conducted by Nimmanitya *et al.*⁴ showed the incidence of shock in 35% of patients (Table 7).

From these observations, we can conclude that incidence of each clinical complications varies with geographical area.

Clinical Examination

Out of 100 patients in our study all had fever, i.e., 100%.

Bleeding

In our study, bleeding manifestations were observed in 21 (21%) cases and the most common bleeding manifestation in our study was malena noted in 15 (15%) cases followed by gum bleeding in 4 (4%) cases, epistaxis in 3 (3%) cases, skin bleeding in 3 (3%) cases, hematuria in 2 (2%) cases, and hematemesis in 1 (1%) case.

Bleeding manifestations were significantly high in patients with DHF and DSS than in patients with DF with $P = 0.00001$.

Hematemesis was the most common bleeding manifestation reported in other Indian studies.

Table 7: Shock

Study	Place	Shock (%)
Nimmanitya <i>et al</i> ⁴	Sear	35%
Present study	Warangal	9%

Comparison of Bleeding with other Studies

Bleeding was observed in 21 (21%) cases in our study, studies done by Kumar *et al.*¹⁵ Anuradha *et al.*¹⁶ and Rahman *et al.*¹⁷ have noted bleeding in 31.2%, 52.6% and 46%, respectively (Table 8).

Comparison of Tourniquet Test with other Studies

Tourniquet test was positive in 26 (26%) cases in our study and is found in patients with platelet count <1 lakh.

None had positive Hess test with platelet count of >1 lakh. The association is statistically significant with $P = 2E-06$. Other studies have noted varying results (Table 9).

Systemic examination

The systemic examination revealed nonspecific findings like any other viral illness.

Hepatomegaly

This study showed hepatomegaly in 4% of patients. Study conducted by Aggarwal *et al.*¹² Neeraja *et al.*⁸ Halstead *et al.*²⁰ and Mohan *et al.*²¹ showed incidence of hepatomegaly in 90%, 74%, 71% and 72% patients, respectively (Table 10).

Comparison of Hepatomegaly with other Studies

Investigations

The mean hemoglobin and hematocrit in this study were of 13.1 g/dl and 38.8%, respectively.

The hematocrit ranged from 24.2% to 55%. In DHF and DSS, an increase in hematocrit levels was noted with mean hematocrit values of 41.4% and 40%, respectively.

Hemoglobin level ranges from 8.3% to 19.5%. In DHF and DSS mean hemoglobin levels noted was with 14.3 g/dl and 12.9 g/dl, respectively. Hemoglobin and hematocrit values are not significant in our study.

Table 8: Other studies have noted following pattern of bleeding

Study	Place	Year	Bleeding	Type
Kumar <i>et al</i> ¹⁵	Lucknow	2000	31.2%	Haemat-Emesis
Anuradha <i>et al</i> ¹⁶	New Delhi	1998	52.6%	Epistaxis
Rahman <i>et al</i> ¹⁷	Bangladesh	2002	46%	Malena
Present study	Warangal	2012-13	21%	Malena

Table 9: Tourniquet/Hess test

Study	Place	Test
Nimmanitya <i>et al</i> . ⁴	Sear	83.9%
Kabra <i>et al</i> ¹⁸	Delhi	40%
Gomber <i>et al</i> ¹⁹	Delhi	25%
Present study	Warangal	26%

Leukocyte count

The range of leukocyte count varied from 1600 to 20,000 cells/ml with a mean count of 6,978 cells/ml. Leukopenia was observed in 18 (18%) cases with 13 (16.05%) cases in DF, 3 (30%) cases in DHF, and 2 (22.22%) cases of DSS patients.

Leukocyte count is not significant in our study.

In Butt *et al.*, study of 104 patients 55 (52.8%) had leukopenia.²² The mean total leukocyte count was 5200 cells/cu mm, which almost correlates with this study.

Comparison of Thrombocytopenia with other Studies

In this study, 61 (61%) patients had thrombocytopenia meeting the WHO criteria, i.e., <1 lakh cells/cu mm. The mean platelet count in our study is 96,880 cells/cu mm.

The association of thrombocytopenia with DEN infection has been proved to be significant (0.002). Studies done by Cherian *et al.*,²³ Singh *et al.*²⁴ and Khan *et al.*² showed the incidence of thrombocytopenia in 94.7%, 61.39% and 81.4%, respectively. This correlated with the above mentioned studies.

In this study, a comparison was done between the platelet count and the presence of bleeding. Bleeding manifestations were seen more in patients with thrombocytopenia than with patients of normal platelet count. The association between thrombocytopenia and bleeding manifestations has been proved to be statistically significant ($P = 3.7E-05$) (Table 11).

Prothrombin Time and Activated Partial Thromboplastin Time

Few studies have documented utility of PT/PTT as a diagnostic indicator. PT is a sensitive indicator of synthetic function of liver. The prolonged APTT in the acute phase may be due to hepatic injury and a low grade disseminated intravascular coagulation.

Table 10: Hepatomegaly

Study	Year	Place	Hepatomegaly (%)
Mohan <i>et al.</i> ²¹	2000	Delhi	74%
Aggarwal <i>et al</i> ¹²	1996	Chennai	90%
Present study	2012-13	Warangal	4%

Table 11: Thrombocytopenia

Study	Year	Place	Thrombocytopenia (%)
Cherian <i>et al</i> ²³	1990	Hyderabad	94.7%
Singh <i>et al</i> ²⁴	2003	Delhi	61.39%
Khan <i>et al</i> ²	2006	Thailand	81.4%
Present study	2012-13	Warangal	61%

Mean PT in our study is 12.5 s and is 11.9 s in patients with DF, 15.3 s in patients with DHF and DSS. Mean PT is significantly high in patients with DHF and DSS with $P = 0.000$ (F value 9.15).

Elevated PT was observed in 8 (8%) cases in our study with 2 (2.47%) cases in DF, 3 (30%) cases in DHF and 3 (33.33%) cases of DSS.

Mean APTT in our study was 33.4 s and is 31.2 s in patients with DF, 39 s in patients with DHF and 47.2 s in patients with DSS.

Elevated APTT was observed in 7 cases in our study with 2 (2.47%) cases of DF, 2 (20%) cases of DHF and 3 (33.33%) cases of DSS.

Features of Fluid Leakage

Out of 100 patients in the study, 15 (15%) patients showed evidence of pleural effusion, 8 (8%) patients were found to have pedal edema, 15 (15%) patients were found to have ascites. This correlated with the studies done by Neeraja *et al.*⁸ and Dash *et al.*¹¹ As per WHO guidelines pedal edema, ascites and pleural effusion are the supporting evidence of plasma leakage, the distinguishing feature of DHF.

Final Diagnosis

This study had DF 81 (81%), DHF 10 (10%), and DSS 9(9%) cases among total of 100 cases.

CONCLUSION

To conclude, in this study, classical DF was the most common clinical presentation followed by complicated forms such as DHF and DSS. Most of the patients presented with classical features such as fever myalgias, arthralgias, pain abdomen, vomiting, headache, rash, and bleeding manifestations. Hypotension, hemorrhagic spots, jaundice, pedal edema, ascites, and pleural effusion

are the common findings on examination associated with complicated forms of the disease. Bleeding, shock, hepatitis, and polyserositis are the complications seen in severe forms. On investigation deranged liver function tests, renal function tests, ascites, hepatosplenomegaly on ultrasonography and pleural effusion on chest radiography are more commonly seen in patients with DHF and DSS. Platelet count does not correlate with the severity of the disease. Positive Hess test needs close observation and early hospital referral. Blood pressure should be monitored for evaluating the progress of the disease. Bleeding tendencies should be closely watched. The treatment of dengue is mainly supportive. However, appropriate fluid management plays a major role in outcome of the disease.

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Analysis of Subjective Well-being and Gratitude among Adolescents in Tirunelveli District

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Abstract

Introduction: One of the most important goals of human being in life is to be happy. Happiness is being evaluated with subjective well-being concept in psychology. Gratitude is an acknowledgment made by a person to others for receiving anything of value.

Aim and Objectives: (i) To assess the levels of subjective well-being and gratitude among adolescents by administering suitable questionnaires, (ii) to find whether the subjective well-being is related to the age or gender of the individual, and (iii) to find out the association between well-being and gratitude.

Materials and Methods: The study is done in adolescents of age 13-19 years from schools and colleges and data from them is collected by the questionnaire.

Results and Conclusion: The data collected from 392 adolescents were analyzed with SPSS and found to have decrease in subjective well-being with increasing age, and there is no difference in subjective well-being between males and females.

Key words: Adolescents, Gratitude, Subjective well-being

INTRODUCTION

All of us would like to spend our lives happily.¹ Individuals live with a happy future expectation.² Happiness is being evaluated with subjective well-being concept in psychology. Subjective well-being means evaluating own positive and negative affections and life satisfaction of individuals. Gratitude is an acknowledgment made by a person to others for receiving anything of value. Gratitude has been found to be associated with an increase in happiness, life satisfaction, hope, empathy, self-esteem, and positive emotions. Adolescence is a period in which various physical, cognitive, social, and ethical changes occur. To experience healthy adolescence, it is important to develop better mental health. It has been reviewed from many studies that individuals having a higher subjective well-being are more social and creative, have a better immune system,

live longer, earn more money are better citizens, are more productive in business life and cope with stress better. Hence, this study is undertaken.

Aims and Objectives

1. To assess the levels of subjective well-being and gratitude among adolescents by administering suitable questionnaires
2. To find whether the subjective well-being is related to the age or gender of the individual
3. To find out the association between well-being and gratitude.

MATERIALS AND METHODS

The study was conducted in various schools and colleges in Tirunelveli after Institutional Ethical Committee clearance. Around 392 students, both male and female in the age group of 13-19 years were selected. Personal information regarding their family members, their educational status, occupation, and H/O any chronic illness, etc., were obtained by a pro forma, and the subjective well-being is assessed by a WHO Well-Being Index and Gratitude by GQ-6 questionnaire by Michael E *et al.*

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Table 1: Age-sex distribution

Age (years)	Sex		Total
	Male	Female	
12-15	78	167	245
16-19	70	77	147
Total	148	244	392

Table 2: Comparing scores between different age groups

Score	Mean±SD		P value	Statistical significance
	Age			
	12-15 years	16-19 years		
Well-being	16.35±3.8	14.52±4.7	<0.05	Significant
Gratitude score	29.15±6.1	29.90±7.3	>0.05	Not significant

The above data show that there is significant decrease in subjective well-being among the adolescents of 16-19 years, and there is no difference in gratitude scores between two groups. SD: Standard deviation

Table 3: Comparing scores related to gender of the individual

Score	Mean±SD		P value	Statistical significance
	Sex			
	Boys	Girls		
Well-being	15.21±4.5	15.94±4.09	>0.05	Not significant
Gratitude score	28.86±7.4	29.78±6.01	>0.05	Not significant

The above data show that there is no significant difference in both subjective well-being and gratitude between boys and girls. SD: Standard deviation

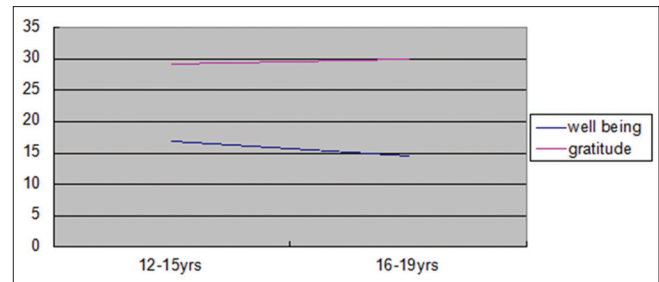
Table 4: Comparing well-being and gratitude scores

Well-being	Gratitude scores		Statistical inference
	Low N=193 (%)	High N=199 (%)	
Below 13	59 (30.6)	58 (29.1)	$\chi^2=0.095$, df=1,
Above 13	134 (69.4)	141 (70.9)	0.758>0.05
			Not significant

There is no correlation between well-being and gratitude scores

RESULTS

The data collected were analyzed by SPSS. Among 392 adolescents analyzed 148 were males and 244 were females. The data collected were analyzed for age wise and sex wise difference in scores (Figure 1 and Tables 1-4).

**Figure 1: Comparing scores between different age groups**

DISCUSSION

Results of our study show that there is a significant decrease in subjective well-being in adolescents of the age group between 16 and 19 years, as compared to the younger age group. This may be attributed to the stress on them, because of educational burden and fear about their future plans. There is no difference in the scores of subjective well-being and gratitude between boys and girls. These results correlate with the findings of Eryilmaz (2010)³ and Sood and Gupta.⁴ From these facts, we can find that there is no difference in the treatment of boys and girls at the family and the people whom they come across so much as to cause any difference in the scores related to gender of the individuals. Even though some studies⁵ show that feeling of gratitude increases the positive thoughts and improves well-being, in our study, there is no such correlation and is similar to study by Sood and Gupta.⁴

CONCLUSION

In the schools and colleges, adolescents of 16-19 years should be focused on improving the subjective well-being and causes of decrease in well-being should be further investigated in future studies.

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Vacuum-assisted Closure in Chronic Nonhealing Ulcers: A Randomized Control Study

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Abstract

Introduction: Vacuum-assisted closure (VAC) is a relatively new technology with applications in a variety of difficult to manage acute and chronic wounds. It involves the application of open cell foam to a suitable wound, adding a seal of adhesive drape and then the application of subatmospheric pressure to the wound in a controlled way.

Materials and Methods: A randomized control study was conducted at a tertiary care center in Madurai between the June 2013 and May 2014. Cases were those who underwent VAC and controls were those, who underwent conventional dressing total 25 cases and 25 controls, were selected from the same wards at different time periods.

Results: The study conducted among 50 participants divided into two groups cases and controls. The result showed that male and female distribution was almost equal in control and cases. 72% and 56% of the control and cases population, respectively, were males, whereas 44% of the cases were females grade of the ulcer distribution was almost equal in cases and control. Turning unsterile after VAC. However, 90% unsterile turns sterile after VAC. VAC dressing produces more split skin grafts before discharge and less rate of amputation, So, VAC dressing has better results in patients.

Conclusion: VAC dressing decreases hospital stay and improves pus culture sterility VAC dressing improves outcome by decreasing the number of amputations and increasing the number of patients undergoing skin grafting. Furthermore, VAC dressing has better result in patients with normal Doppler and has good result in patients with nonactive osteomyelitis.

Key words: Conventional dressing, Ulcer care, Vacuum-assisted closure

INTRODUCTION

Among the most common causes for admission, in general, surgical ward is chronic nonhealing ulcer of which diabetes is the most common etiology. In most of the cases, hospital stay of many weeks is required for management of the above. In many cases, they ultimately go for amputation. Wounds do not only lead to hospitalization of the patient but also lead to consequences like amputation of the limb and at times, even death. Vacuum-assisted closure (VAC) is a relatively new technology with applications in a variety of difficult to manage acute and chronic wounds.¹ It involves

the application of open cell foam to a suitable wound, adding a seal of adhesive drape and then the application of subatmospheric pressure to the wound in a controlled way.²

The application of negative pressure wound therapy (NPWT) to promote wound healing was first described in Russian medical literature for patients having infected breast wounds. These original reports actually described the application of a topical suction-cup-type apparatus to the surface of the wound to create negative pressures of around 80 mm Hg.^{2,3} Subsequent reports have described the successful management of enterocutaneous fistulae and open abdominal wounds using flat drains that delivered negative pressure under compliant plastic films.³⁻⁶ In these reports, surgical gauze was being used to create an interface between the surface of the wound and the vacuum source.

The purpose of this type of wound management is to decrease wound healing time and to facilitate wound care in situations that otherwise might be considered

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difficult or nonhealing; Of late, the NPWT has become a very commonly used method because of its lack of complications and effectiveness in complex situations. Still, in our hospital, the majority of dressings are conventional. The aim of the study is to show the advantage of VAC over conventional dressing in our hospital.

MATERIALS AND METHODS

A randomized control study was conducted at the Government Rajaji Hospital, Madurai, which is a tertiary care center between the June 2013 and May 2014. Patients are selected from general surgery wards. Patients were randomly allocated into two groups: Cases, and controls. Cases were those who underwent VAC and controls were those, who underwent conventional dressing total 25 cases and 25 controls, were selected from the same wards at different time periods. Patients included in the study are classified according to the grade of the ulcer (Wagner classification). All grades are included except grade 0 and 5, age between 13 and 70 years, diabetic ulcers, traumatic ulcers. We excluded those with fistulas to organs or body cavities, necrotic tissue in Eschar, osteomyelitis (untreated) exposed blood vessels and Gangrenous foot.

Method of Study⁷

During the period of study, cases and controls selected from the general surgery wards. After debridement of the wound, VAC dressing is applied after the bleeding gets stopped. Pre-VAC and post-VAC C and S are taken. Dressing is given for 72 h and intermittent suction is given for 10 min in an hour, daily for 12 h with a negative pressure ranging from 100 to 125 mm of mercury. Rest of the time drain of the VAC dressing connected to the Romo-VAC suction drain. Doppler study to assess the vascularity of the limb before the procedure and X-ray taken to rule out osteomyelitis. Control group patients are given with conventional dressings. The outcome variables that were assessed were the difference in the rate of healing, hospital stay, and us C and S before and after VAC.

Materials Used for Study

- Transparent, sterile material (OP-SITE)
- Transparent adhesive plaster
- Sponge (presterilized)
- Suction drain with suction apparatus.

Sequence of Procedure

1. Wound preparation
2. Placement of foam and drain
3. Sealing with drapes.

Procedure

The patient selected for VAC therapy undergoes wound debridement and homeostasis is achieved. Pre-VAC culture and X-ray to rule out active osteomyelitis is taken. A piece of presterilized foam (about one cm in thickness) is cut to the size of the wound and is placed on it. Then, a perforated drainage tube (Romo-VAC suction drain tube is used here) is put on it. Again a piece of foam is placed on the underlying foam and tube. The whole foam with tube is covered with a sterile transparent dressing (opposite). The tube is connected to a common suction apparatus with a pressure gradient. Suction is applied with a negative pressure of 100-125 mm of Hg for 10 min hourly for 12 consecutive hours. Rest of the time this drainage tube is connected to the Romo-VAC suction apparatus. Dressing changed after 72 h and post-VAC culture is taken. There cycles of dressings and vacuum are applied statistical assessment is done using outcome variables.

Statistical Analysis

Data were analyzed using computer software, statistical package for social sciences version 12. Data are expressed in its comparison between controls and cases; Chi-square (χ^2) test was used as nonparametric test. For all statistical evaluations, a 2-tailed $P < 0.05$ was considered significant.

RESULT

The study conducted among 50 participants divided into two groups: Cases and controls. The result showed that male and female distribution was almost equal in control and cases. 72% and 56% of the control and cases population, respectively, were males, whereas 44% of the cases were females. The gender difference between groups was not found to be statistically significant. Age distribution was almost equal in control and case groups. Chi-square test shows no statistical significance as $P > 0.05$. Duration of hospital stay in days was found to be statistically significant between groups. Control population stayed more days in hospital than cases. Majority (52%) of the cases left the hospital within 3 weeks time, whereas major chunk (88%) of control population stayed more than 3 weeks time (Table 1).

Grade of the ulcer distribution was almost equal in cases and control. Chi-square test shows $P > 0.05$, which is statistically not significant (Table 2). Chi-square test shows study is not significant as $P > 0.05$. Hence, VAC dressing has almost similar effect on normal Doppler study in case and control group. However, VAC dressing shows better results in patients with normal Doppler study (Table 2).

With regards to culture sensitivity, Chi-square test shows a significant statistical association as $P < 0.001$. Patients with

sterile pre-VAC culture are not turning unsterile after VAC. However, 90% unsterile turns sterile after VAC.

VAC dressing produces more split skin grafts before discharge and less rate of amputation. Chi-square test shows study is significant as $P < 0.001$. Hence, VAC dressing have better results in patients (Table 3).

DISCUSSION

The study conducted among 50 participants showed that age distribution was almost equal in control and case groups

Table 1: Distribution of age, gender, and hospital stay among study groups

Study variables	Group		Total (%)
	Control (%)	Cases (%)	
Gender			
Male	18 (72.00)	14 (56.00)	32 (64.00)
Female	7 (28.00)	11 (44.00)	18 (36.00)
Age (years)			
<40	1 (4.00)	2 (8.00)	3 (6.00)
40-49	4 (16.00)	5 (20.00)	9 (18.00)
50-59	11 (44.00)	8 (32.00)	19 (38.00)
Duration of hospital stay			
7-14	1 (4.00)	6 (24.00)	7 (14.00)
14-21	2 (8.00)	7 (28.00)	9 (18.00)
21-28	10 (40.00)	6 (24.00)	16 (32.00)
28-35	6 (24.00)	5 (20.00)	11 (22.00)
>35 days	6 (24.00)	1 (4.00)	7 (14.00)
Total	25	25	50

Table 2: Ulcer grading and Doppler report among study groups

Study variables	Group		Total (%)	Chi-square and P value
	Control (%)	Cases (%)		
Ulcer grading				
Grade 1	1 (4.00)	2 (8.00)	3 (6.00)	$\chi^2=0.603$; $P>0.05$
Grade 2	10 (40.00)	11 (44.00)	21 (42.00)	
Grade 3	10 (40.00)	8 (32.00)	18 (36.00)	
Grade 4	4 (16.00)	4 (16.00)	8 (16.00)	
Doppler findings				
Normal	19 (76.00)	18 (72.00)	37 (74.00)	$\chi^2=0.104$; $P>0.05$
Vascular impairment	6 (24.00)	7 (28.00)	13 (26.00)	
Total	25 (100)	25 (100)	100 (100)	

Table 3: Analysis of cases and control groups in outcome/plan

Outcome/plan	Group		Total	Chi-square and P value
	Control	Cases		
Discharge	19 (76.00)	11 (44.00)	30 (60.00)	$\chi^2=16.133$ $P<0.001$
Split skin graft	0	12 (48.00)	12 (24.00)	
Amputation	6 (24.00)	2 (8.00)	8 (16.00)	
Total	25	25	50	

duration of hospital stay in days was found to be statistically significant between groups. Control population stayed more days in hospital than cases a blinded, prospective, randomized controlled trial of topical negative pressure wound closure in India by Mody *et al.*⁸ also showed similar results faster healing rate and less hospital stay. On assessing the outcome of the study, it was found that 16% required amputation and also 60% of the study participant were discharged without any complications.

With regards to culture sensitivity report, it was found that Chi-square test shows a significant statistical association as $P < 0.001$. Patients with sterile pre-VAC culture are not turning unsterile after VAC.

Studies by Lone *et al.*⁹ and Morykwas *et al.*,² all showed the efficacy of VAC dressing over conventional dressing and its better outcome. More than this VAC dressing decreases hospital expenses, hospital waster, and nursing care required The bacteriological and cytological assessment of VAC on purulent wounds Davydov *et al.*¹⁰ has shown efficacy of VAC in turning pus C and S sterile.

CONCLUSION

VAC dressing decreases hospital stay and improves pus culture sterility VAC dressing improves outcome by decreasing the number of amputations and increasing the number of patients undergoing skin grafting. Furthermore, VAC dressing has better result in patients with Normal Doppler and has good result in patients with nonactive osteomyelitis NPWT aids in the recovery time and may reduce the need for more extensive operations.^{11,12} NPWT is a useful tool in transforming a wound to a point where more traditional dressings or simpler surgical methods for reconstruction can be used. Although a pragmatic addition at present, NPWT is a well-deserved addition to the armamentarium of wound healing and reconstruction.

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Analysis of Functional Outcome of Complex Tibial Plateau Fractures (Schatzker Type 5 and Type 6) Treated with Hybrid External Fixators

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Abstract

Introduction: Despite many advances in the case of intra-articular fractures, a survey of literature indicates that many authors report only slightly better than 50% satisfactory results, closed or operative methods of treatment. For over 3 decades, various modalities of treatment starting from traction, knee-spanning external fixator to total knee arthroplasty for tibial plateau fractures. Minimal intervention and hybrid external fixator can provide a fair outcome with fewer complications.

Aim: To evaluate functional outcome of tibial plateau fractures (Schatzker Type 5 and Type 6) treated with hybrid external fixator.

Materials and Methods: This is a prospective study of 20 cases of tibial plateau fractures (Schatzker Type 5 and Type 6) surgically fixed with hybrid external fixator system.

Results: All fractures united by 6-10 weeks. Compound fractures showed 15 Neer's rating score and closed fracture showed 17 score; in our study, 5 patients had pin site infections, 3 had wound infection, 4 had knee stiffness, 1 had varus malunion, and 1 with 0.5 cm shortening.

Conclusion: The choice of treatment with hybrid external fixator system can be considered for high-energy tibial plateau fractures, especially in compound fractures the advantage being early mobilization preserving fracture hematoma, avoids soft tissue disruption.

Key words: Compound fracture, Hybrid external fixator, Schatzker Type 5 and Type 6

INTRODUCTION

Despite many advances in the care of intra-articular fractures, tibial plateau fractures continue to be a difficult surgical problem. A survey of the literature indicates that many authors report only slightly better than 50% satisfactory results with either closed or operative methods of treatment.^{1,2} The failures of treatment are usually due to residual pain, stiffness, instability deformity, recurrent effusions, and giving way. Review of over 140 of these fractures treated by both closed and operative

methods has shed considerable light on the reason for the failures.^{3,4}

For over three decades, various modalities of treatment starting from (traction, knee-spanning external fixator to total knee arthroplasty) used for tibial plateau fractures. Traction and closed reduction followed by the pop application will not restore the articular surface and lead on to articular surface collapse and knee stiffness. Ordinary external fixators are not suitable for tibial condyle fractures because if it is applied we should span the knee joint lead on to stiffness of knee joint. Open reduction and fixation with plating even though will lead to good reduction of articular surface, it will not protect already damaged soft tissue will lead on to wound necrosis and complications. ORIF with dual plating has been an attractive treatment method for these types of injuries.⁵ Since the early 1990s, to reduce the incidence of devastating complications such as joint stiffness, malunion, skin loss, osteomyelitis, amputation,

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and even death can occur.⁶ Hybrid external fixator for high-energy tibial plateau fractures usually protect soft tissue envelope. It also allows access to soft tissue cover during the fracture treatment. If we add additionally cannulated screws and K-wires for articular surface reduction, it will give additional stability lead on to earl knee mobilization and also avoids knee stiffness.^{4,7} Minimal interventions and hybrid external fixation can provide a fair outcome with fewer complications compared to open reduction internal fixation with plating or other methods.

Aim

To evaluate functional outcome of tibial plateau fractures (Schatzker Type 5 and Type 6) treated with hybrid external fixator.

MATERIALS AND METHODS

This is a prospective study conducted in the Department of Orthopedics, Tirunelveli Medical College Hospital. The Institutional Ethics Committee approval and informed consent from the patients were obtained. After surgery, the patient symptom was subsided. The patient walked with walker with touch toe. After 2 weeks, the patient was started on partial weight bearing walking with walker and 6 weeks full weight bearing with walker support. After 6 weeks, the fracture was united radiographically. Fixator was removed and patella tendon bearing (PTB) cast applied with patient allowed to full weight bearing walking. After 2 weeks, the PTB cast was removed. And start to walk with walker and gradually discarded the walker.

Inclusion Criteria

1. Age above 20 years
2. Closed tibial plateau fractures (Schatzker Type 5 and Type 6)
3. Compound tibial plateau fractures (Grade I to Grade III B)

Exclusion Criteria

1. Age <20 years
2. Patients with co-morbid medical condition
3. Closed tibial plateau fractures (Schatzker Types 1-4)
4. Compound tibial plateau Grade III C fractures
5. Associated fractures such as floating knee and pilon fractures.

RESULTS

The analysis was done using Neer's rating system for knee, and the following results were obtained.

According to Neer's score rating system for knee, the 40% patients had excellent and 40% patients had good outcome. 13% of patients had fair outcome and only 5% had poor outcome (Table 1).

Out of 20 cases, 8 cases were Type 5 and 12 cases were Type 6 Schatzker, and the average Neer's scoring for them was 17.25 and 14, respectively (Table 2).

Out of 20 cases, our study had 7 cases of closed fracture and 13 cases of compound fracture which were treated by hybrid fixator showed average Neer's score of 17.28 and 14.78, respectively (Table 3).

Road traffic accident predominates assault in mode of injury perhaps fall injury stood last (Figure 1).

Among the high-energy fractures of tibial condyle, Type 6 showed more frequency. Type 5 almost equals the frequency (Figure 2).

Most common complication is pin site infection, overcame by regular dressing. Knee stiffness found in 20% of patients, managed by physiotherapy (Table 4).

Table 1: Distribution of study patients in grade

Grading	Number of cases (%)
Excellent	8 (40)
Good	8 (40)
Fair	3 (13)
Failure	1 (5)

Table 2: Results according to Schatzker's type

Schatzker's type	Number of cases	Average Neer's rating score
Type 5	8	17.25
Type 6	12	14

Table 3: Results based on type of fracture (closed/open)

Fracture	Number of cases	Average Neer's rating score
Closed fracture	7	17.28
Compound	13	14.78

Table 4: Complications

Complications	Number of cases (%)
Pin site infection	5 (25)
Knee stiffness	4 (20)
Malunion	1 (5)
Shortening	2 (10)
Wound infection	3 (15)

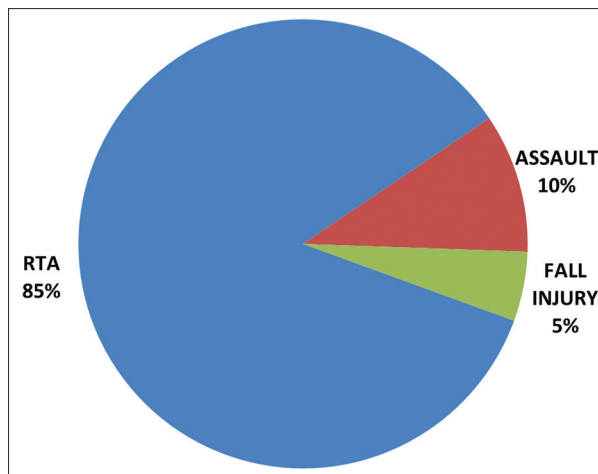


Figure 1: Mode of injury

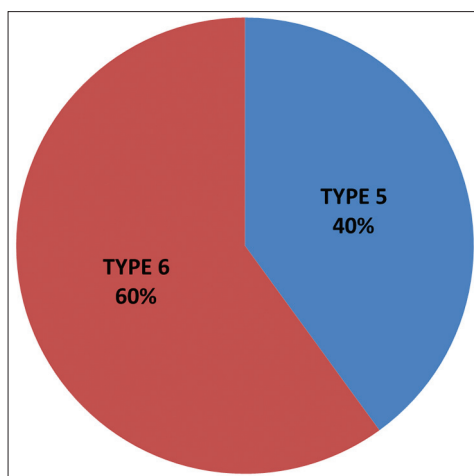


Figure 2: Classification of fractures

DISCUSSION

The average time for fracture healing was 8 weeks (ranging from 6 to 10 weeks). Fracture pattern, type of fracture (closed/open), and presence of infection significantly affected the fracture healing. Anatomical reduction and relatively stable fixation had early rehabilitation and reduced complications.^{8,9}

In recent years, use of hybrid fixator for tibial condyles fractures, especially for compound fractures has increased because of easy applicability, less blood loss compared to ORIF with plating. Preservation of the fracture hematoma aids in good healing potential and early union. Avoids skin necrosis which was potential problem in proximal tibia fractures and also allows room for skin/flap cover in cases of compound fractures with skin loss/bone exposed.^{5,10}

Pin site infection is the most common complication of our study. Even though it looks high, it was managed properly with early intervention by proper dressing and appropriate antibiotics. If not diagnosed early, it will cause spread of infection into the joint through pins in the 5/8th ring lead to septic arthritis which is most dreaded complication.

Knee stiffness was another notorious complication for proximal tibia fractures. In our study, it was 20% even though it looks high-study period was too short to commit these results.^{11,12} After a couple of years, the range of movements in these patients may improve and functional outcome may go up.

CONCLUSION

In general, hybrid external fixator is a promising alternative treatment for high-energy tibial plateau fractures. It allows anatomical reconstruction of the articular surface, stable fixation of fracture fragments, early rehabilitation of the joint, and care of associated soft tissue injuries, without a high rate of complications.

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Variations in Shape of Mandibular Coronoid Process in 200 South Indian Subjects

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Abstract

Introduction: Mandible being largest and strongest bone of skull, having various morphological features may show changes with reference to age, sex, and race. With this objectivity in mind, this study was conducted to furnish more information on variations in shape of coronoid process of the mandible.

Materials and Methods: This study was conducted in 200 dry human south Indian mandibles. The data pertaining to above was taken and subjected to statistical analysis.

Results: Overall triangular type of coronoid process (67%) more prevalent than hook shape (30%) and rounded (3%). Triangular type more prevalent in males (72.2%) than females (51.1%), whereas hook shape more prevalent in females (44.9%) than males (25.2%) and rounded more prevalent in females (4.1%) than males (2.6%).

Conclusion: Shape of coronoid process may be used for sexing of mandibles. Coronoid process is used to identify the site for injection of local anesthetic or for excision of nerve for facial neuralgia.

Key words: Facial neuralgia, Gender, Hook, Rounded, Triangular

INTRODUCTION

Mandible is an interesting bone since it depicts morphological changes in relation to age.¹ Morphological changes like alteration in shape of certain bony process of mandible like coronoid process. Moreover, these variations forms interesting line of investigation from clinical point of view. An extensive literature is available on the shape of coronoid process.² The coronoid process seems to be suitable for paranasal augmentation in the dry skull study. Its clinical application is also favorable because its size and morphology fits into the paranasal region, with the additional advantages of biocompatibility, availability, and reduced operation time for harvesting.³ Hence, an attempt is made in this study to provide more information on morphology of coronoid process.

MATERIALS AND METHODS

This study was conducted on 200 dry human mandibles available in the department of Anatomy, Subbiah Institute of Medical Sciences, Shimoga. Out of 200, 180 belong to adults and 20 belong to elderly individuals. Out of 180 adults, 135 were of males and 45 were of females. Moreover, out of 20 elderly, 16 were of males and 4 of females.

In this study, coronoid process of 200 mandibles was observed on both sides for its shape. Different shapes of coronoid process observed are triangular, rounded, and hook shaped (Figures 1-3).

Statistical analysis was performed by descriptive statistics and Chi-square test.

RESULTS

Overall triangular type of coronoid process (67%) more prevalent than hook shape (30%) and rounded (3%). Triangular type more prevalent in males (72.2%) than females (51.1%), whereas hook shape more prevalent in females (44.9%) than males (25.2%) and rounded more

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Figure 1: Triangular shaped



Figure 2: Hook shaped



Figure 3: Rounded shaped

prevalent in females (4.1%) than males (2.6%). The study was statistically significant with a $P < 0.1$ (Table 1).

Table 1: Variations in shapes of coronoid process

Sex	Triangular (%)	Hook shaped (%)	Rounded (%)
Male	109 (72.2)	38 (25.2)	4 (2.6)
Female	25 (51)	22 (44.9)	2 (4.1)
Total	134 (67)	60 (30)	6 (3)

DISCUSSION

Among the various morphological observation, shape of coronoid process depicted sexual dimorphism. Coronoid process was triangular in shape in 67% of male mandibles. This is almost similar to findings of study.⁴ The variations in the shapes of the coronoid process in the adult human mandible were studied. According to the study the shape of the coronoid processes of both sides of 157 dry adult human mandibles, 100 males and 57 females of Indian origin, were studied to classify the variations. Three types were evident (1) hook shaped, (2) triangular and rounded. Hook shaped coronoid processes were found in 86 (27.4%) sides, triangular in 154 (49%), and rounded in 74 (23.6%) sides. Hook shaped coronoid processes were found bilaterally in 35, triangular in 64 and rounded in 26 mandibles. Of the remaining 32 mandibles, the appearance was different on both the sides. The incidence of the rounded type was almost equal in male and female mandibles; in the triangular type, it was slightly more in the female mandibles while the hook-shaped type was slightly more in male mandibles.³ This could be considered as a more convincing male sex feature of mandible besides the other minor established differences.

CONCLUSION

In this study, certain differences could be observed in the morphology of the mandible. Male mandibles showed the triangular coronoid process and female mandibles in contrast less triangular coronoid process. The above findings are of immense forensic value in differentiating the sex of mandibles and in per serve as use full landmark for clinicians.

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Functional Outcome of Distal Radius Fracture Managed by Minimally Invasive Plate Osteosynthesis: A Prospective Study

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Abstract

Introduction: Fracture of distal radius is the most common fracture encountered by orthopedic surgeons. Many studies have associated even as little as 1 mm of incongruence of articular surface landed with worst outcome.

Aim: To evaluate functional outcome of distal radius fractures treated by minimally invasive plate osteosynthesis (MIPO).

Materials and Methods: This is a prospective study randomly selecting 23 cases of distal radius fractures treated with MIPO with age between 20 and 70 years, functional outcome was evaluated using MAYO wrist score.

Result: In our study all fracture united by 6-8 weeks. 2 patients had malunion and 2 patients had wrist stiffness and 1 patient had superficial infection.

Conclusion: MIPO can be utilized for extra-articular distal radius fracture and with minimal articular involvement, it avoids extensive soft tissue dissection, allows early mobilization, provides better functional outcome.

Key words: Distal radius fracture, Minimally invasive procedure, Plate and screws

INTRODUCTION

Fracture of the distal radius is the most common fracture encountered by orthopedic surgeons. The desire for anatomical restoration of the distal radius often is the rationale for operative treatment. Many studies have associated as little as 1 mm of incongruity of the articular surface with worse outcomes, whereas other reports have found no association between radiographic arthrosis and outcomes.¹ There are various treatment options for distal radius fractures including nonoperative, external fixation (percutaneous pinning, bridging external fixator) and internal fixation (dorsal and volar plating, fragment

specific fixation). The indications differ depending on the patient, their demands, and the type of fracture. As the prime goal of treatment is to maximize function in the hand and wrist, it is essential to consider the factors that may predict fracture instability or functional outcome, in planning treatment. In conventional plating, there is more soft tissue dissection including stripping of pronator quadratus which may lead to post-operative pain and scarring and impede the range of motion. The deep head of pronator quadratus is a dynamic stabilizer of distal radioulnar joint.² Further, the blood supply from the pronator quadratus is also disrupted which may lead to avascularity of articular fragments and delay fracture healing. In minimally invasive plate osteosynthesis (MIPO), the soft tissue dissection is limited and the implant is slid under intact pronator quadratus. The biomechanical advantages of soft tissue are left undamaged. Besides, the mini-incision provides better cosmetic results. Hence, the technique of MIPO can be utilized for extra-articular and simple type of intra-articular fractures of distal radius.³

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Aim

To evaluate functional outcome of distal radius fractures treated by MIPO.

MATERIALS AND METHODS

This is a prospective study conducted in the Department of Orthopedics, Tirunelveli Medical College Hospital. Institutional Ethics Committee approval and informed consent from the patients were obtained.

Inclusion Criteria

1. Age above 20 years
2. Closed distal radius fractures
3. Extra-articular and minimally comminuted intra-articular fractures.

Exclusion Criteria

1. Age <20 years
2. Compound fractures
3. Severely comminuted intra-articular fractures
4. Severe osteoporosis.

Procedure and Post-operative Protocol

Patient in supine position in conventional table with arm extended in arm table, under regional anesthesia, under tourniquet control, the affect limb is painted and draped. Closed reduction of fracture done under fluoroscopy guidance. If a satisfactory reduction is possible, the fracture is provisionally fixed with K-wires inserted from the styloid process to the proximal ulnar side or in reverse direction depending on the fracture pattern. In case of comminuted fractures, more than one K-wires may be needed to maintain the reduction and articular congruity. Two skin incisions of about 2 cm length were made. The position of the incision is dependent on the fracture pattern and length of the plate. In fractures within 1 cm of the articular surface, a transverse incision parallel to the proximal wrist crease was chosen. In fractures, more than 1 cm away from the articular surface, longitudinal incision parallel to the flexor carpi radialis was made. The flexor carpi radialis was retracted to the radial or ulnar side. Radial artery identified and retracted. Then, the flexor pollicis longus was identified and retracted to expose pronator quadratus. If reduction was satisfactory, plate was slid under the pronator quadratus through a small longitudinal incision. In case, where open reduction was needed, the distal part of the muscle is incised to aid visualization of fracture fragment and reduction. Under fluoroscopy guidance, 2 cm incision was made parallel to flexor carpi radialis according to the plate placement. The plate was provisionally fixed to radial shaft with a K-wire. After confirming the reduction in anteroposterior and lateral views, screws were applied in the transverse and longitudinal limbs of the plate. Stability

of the fixation was verified after removing the K-wires. In some cases, fixation was augmented with additional K-wires. Wound closed in layers.

Post-operative Protocol

After surgery, the limb was kept in elevated position. The timing of rehabilitation was based on:

1. Fracture pattern
2. Bone quality
3. Stability of the fixation
4. Patient compliance.

Second Post-operative Day

In comminuted fractures, the limb was immobilized in supportive splint for the first week. In the second post-operative day, wound inspection was done and dressing changed. Finger, elbow, and shoulder mobilization exercises were started. Exercises to maintain the tone of the finger flexors were started. After 1 week, the supportive splint was removed and wrist flexion and extension exercises were started according to patients pain tolerance. The patient was advised to review on 10th post-operative day for suture removal. On 10th day, patients understanding and compliance with exercises were evaluated and taught accordingly. The patient was reviewed on 4th post-operative week, during which rotational movements were started. Subsequent follow-ups were done on 10th week with radiological investigation to check for bony union.

RESULTS

The age group varied from 20 to 70 years with mean age of 41 years. Incidence of fracture was observed maximum between 40 and 50 years of age which accounted for approximately 39% in this study (Table 1).

This study revealed the increase in the fracture incidence in men when compared with the women, which is due to increase in longevity of men. The incidence decreased in women may be explained by the increased use of hormone replacement therapy (Table 2).

High energy injury is the cause of the majority of distal radius fractures with approximately 60% of fractures being related to the road traffic accidents in this study (Table 3).

The Frykman's classification of distal radius fracture is based on the articular surface involvement and intactness of distal ulna. This study revealed the intra-articular fractures are encountered frequently more when compared to others (Table 4).

Mayo wrist score-clinician rated outcome measure. It includes four measures of outcome: Pain intensity

(25 points), functional status (25), range of motion (25), and grip strength (25). A total of 100 points. In this study, the “Mayo wrist score” after the MIPO was found to be 80-90 which is considered as good according to the scoring system (Table 5).

DISCUSSION

The goal of surgery for unstable distal radius fracture is to obtain and maintain an anatomical reduction and to allow restoration of function.¹ Achieving fracture stability is a prerequisite for attaining a satisfactory outcome for distal radius fractures. Unstable fractures are at increased risk for loss of reduction and subsequent malunion.² Malunion

Table 1: Distribution of study patients in age group

Age group	Number of cases (%)
20-30	7 (31)
31-40	3 (13)
41-50	9 (39)
51-60	4 (17)

Table 2: Distribution of study patients in gender

Sex	Number of cases (%)
Male	17 (78)
Female	6 (22)

Table 3: Distribution of study patients in mode of injury

Mode of injury	Number of cases (%)
RTA	14 (61)
Accidental fall	9 (39)

RTA: Road traffic accidents

Table 4: Distribution of study patients in Frykman's classification

Frykman classification	Number of cases (%)
Type I	4 (17)
Type II	3 (13)
Type III	9 (40)
Type IV	4 (17)
Type V	3 (13)

Table 5: Distribution study patients in Mayo wrist score

Mayo wrist score	Number of cases (%)
90-100	4 (17.5)
80-90	12 (52)
70-80	4 (17.5)
60-70	3 (13)

can potentially lead to a poor functional outcome with residual pain, loss of motion, decreased endurance and grip strength, midcarpal instability, and post-traumatic arthritis. MIPO techniques are commonly utilized in the management of fractures of distal femur, proximal, and distal tibia.¹ In this study, we initiated MIPO technique for distal radius fracture presuming that the advantages of MIPO may improve the functional outcome. Numerous prospective studies to evaluate the functional outcome of various treatment options including plaster immobilization, external fixation, and open reduction with internal fixation. Good or excellent results were achieved in 43%, 80%, and 63% in each group. Recent studies show further improvement in functional outcome of ORIF owing to advances in implants and surgical techniques.⁴ Wright *et al.* reported retrospective study of 21 patients treated with plating and external fixation. In this study, there was no functional difference between the two groups.⁵ Egol *et al.* conducted a prospective randomized study involving 88 cases. Although the patients treated by plating had significant early improvement in the range of movement of wrist, in absolute terms the difference in range of movement was clinically unimportant.⁶ At one year radiological, clinical and functional outcomes were similar in two groups. These studies attribute soft tissue preservation in external fixation to the good functional outcome with the technique, even though the radiological outcome was better in ORIF than external fixation.⁷ However, external fixation is associated with high risk for infection and stiffness. Incidence of pin tract infection usually with *Staphylococcus aureus* and *Staphylococcus epidermidis* has been reported between 0.5% and 30%.⁸ With MIPO both advantages of articular reduction with ORIF and soft tissue preservation with external fixation can be obtained. In our study, the functional outcome with Mayo wrist score was comparable to the results reported with conventional plating and external fixation.¹ Further, in our study, only one patient developed mild infection which is much lower compared to the external fixator. Nerve injury,⁹ commonly median nerve injury, has been reported with incidence of 0-17% in conventional plating technique. In our study, no neurovascular injuries had occurred since the incision were made on safety zones considering the neurovascular anatomy.¹⁰ In our study, malunion was reported in 2 cases. Both patients had higher comminution (Frykman classification type 5) which indicates that MIPO is not suitable for all distal radius fractures. Proper selection of patients according to the fracture characteristics will certainly decrease this complication. Average flexion and extension arc have been found to be 102 and supination/pronation arc to be 154° (Rozental and Blazer 52° flexion, 53° extension, 71° supination and 73° pronation).¹¹ Operating time and radiation exposure are not significantly higher when compared to the conventional

plating technique. The limitation of this study includes small study group, short follow-up period, and absence of control group.

CONCLUSION

The results of MIPO are comparable to conventional plating technique. MIPO can be utilized for extra-articular distal radius fracture and with minimal articular involvement. It avoids extensive soft tissue dissection, provides rigid fixation, allows early mobilization, provides better functional and cosmetic outcome, and decreases the duration of hospital stay.

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Comparison of Efficacy of Oral Clonidine and Oral Midazolam as Premedication in Children

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Abstract

Background: Various drugs have been used as premedication in pediatric anesthesia practice. Clonidine, α -2 agonist has entered anesthesia practice and its efficacy as an oral premedication drug is to be evaluated.

Aim: The aim of this study is to evaluate and compare the clinical effects of oral midazolam and oral clonidine as premedication in children with regard to drug acceptance, pre-operative sedation, anxiolysis, acceptance of mask for induction of anesthesia, intravenous (IV) cannulation, and recovery profile.

Materials and Methods: A prospective randomized, double-blind comparative study in children, ASA physical Status I in the age group of 1-10 years, posted for elective lower abdominal surgeries (duration 30-45 min) was done. Patients were randomized into two groups, Group C and Group M of 50 each. Patients in Group C received powdered clonidine tablet (100 μ g) dissolved in 100 ml of water in the dose of 4 μ g/kg, 45 min before surgery. Patients in Group M received preservative free parenteral form of midazolam in the strength of 5 mg/ml in the dose of 0.5 mg/kg 45 min before surgery.

Results: All the children accepted the drugs very well without spitting (or) vomiting. 90% of patients in clonidine group have sedation scores of 2 and 3 when compared with midazolam group, 54% respectively. Anxiety level on separation from parents was high with midazolam group. Level of mask acceptance, response to IV cannulation was better with clonidine group. The post-operative agitation is higher with midazolam group compared to clonidine group.

Conclusion: Clonidine is a better oral premedicant drug in children producing higher sedation, decreased anxiety, improved mask acceptance and response to IV cannulation and diminished post-operative agitation.

Key words: Anesthesia, Clonidine, Lower abdominal surgery, Midazolam, Pediatrics

INTRODUCTION

Premedication plays a pivotal role in general anesthesia. Oral medication is well accepted by children than another route of administration. They are given to allay anxiety, to produce amnesia, sedation, analgesia, to facilitate smooth induction and to reduce secretion. They should be easily administered, should be safe for the patient, should not prolong the recovery from anesthesia, and should not

produce undue depression of cardiovascular, respiratory and central nervous systems.¹ Clonidine is a centrally acting α -2 agonist commonly known as an antihypertensive drug. Due to its sedative, hypnotic and analgesic properties it is used in anesthesia. Its main site of action is on the locus ceruleus in the upper brainstem in the floor of the fourth ventricle.² Midazolam in parenteral form, due to bitter taste is mixed with cola. It has anxiolytic, sedative, hypnotic, anticonvulsant, muscle relaxant, and anterograde amnesic effects. If the receptor occupancy of the midazolam is 20%, it causes anxiolysis, 30 to 50% it causes sedation, more than 60% it causes unconsciousness. It produces dose-related ventilatory depression, decreases arterial pressure by decreasing systemic vascular resistance.³ Oral clonidine premedication reduces the minimum alveolar concentration of sevoflurane in children.⁴

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MATERIALS AND METHODS

This prospective randomized double-blind comparative study was conducted in Department of Anesthesiology, Government Rajaji Hospital, Madurai, Tamil Nadu, India. After approved by the institutional ethics committee, this study was conducted in 100 ASA I patients in the age group 1-10 years. Undergoing elective surgeries such as inguinal herniorrhaphy, hydrocele repair, urethroplasty, and orchidopexy patient. Written informed consent was obtained from parents. Exclusion criteria: ASA III and IV, patients on other sedative narcoleptic drugs, A detailed preanesthetic check-up was done on all patients and relevant hematological, biochemical and radiological investigations were carried out for all patients as per surgical requirements. The patients were randomly allocated into two groups. Group C patients received. Clonidine premedication 4 µg/kg and Group M received midazolam 0.5 mg/kg orally 45 min before surgery. All the children were given general anesthesia and vital signs were monitored throughout the surgery. All the children were anesthetized in the sequence of preoxygenation, induction with thiopentone and atropine, intubation by using succinylcholine and maintenance with oxygen, nitrous oxide, Fentanyl, and atracurium. Neuromuscular blockade was reversed at the end of the surgery with neostigmine and atropine. The parameters observed were degree of sedation, level of anxiety for separation from mother, mask acceptance for preoxygenation, reaction to intravenous (IV)

cannulation, post-operative agitation, and any side effects associated with these drugs.

RESULTS

50 patients in each group in mean age of 5.040 in clonidine group and 4.72 in midazolam group. Mean weight of Group I is 16.3 kg and Group II is 17.16 kg (Table 1). Surgeries performed in both groups are comparable the $P = 0.692$ (Figure 1). The mean values for clonidine group in 2.0 ± 0.452 mean value for midazolam is 1.56 ± 0.541 . The Student's t -test is highly significant ($P = 0.000$). Thus, clonidine has better sedation score than midazolam group. The anxiety level on separation from mother was compared (Table 2). Mean value for clonidine group = 3.38 ± 0.69 for midazolam group = 2.04 ± 0.8 Student's t -test is highly significant ($P = 0.000$). Clonidine has better score. The mask acceptance was compared in both the groups (Table 2). The mean/standard deviation value for clonidine group = $2.5/1.015$ and for midazolam group = $1.52/0.646$. Clonidine group has better mask acceptance. Reaction to IV cannulation was compared between the two groups (Table 2). The mean value for clonidine group = 2.46 ± 0.61 and for midazolam group = 1.58 ± 0.609 Student's t -test is highly significant ($P = 0.000$). Hence, the clonidine has better score than midazolam group. Post-operative status was compared between the two groups (Table 2). The mean value for clonidine group = 2.5 ± 0.71 and for midazolam group = 1.8 ± 0.54 Student's t -test is highly significant ($P = 0.000$).

Table 1: Demographic comparison of study group

Criteria	Clonidine Group I	Midazolam Group II	P value
Age (Years)	5.040	4.72	0.580
Sex (M/F)	44/6	45/5	0.749
Weight (kg)	16.3	17.16	0.486

DISCUSSION

The efficacy of oral midazolam as premedication in children has been evaluated in previous studies that dose of 0.5 mg/kg is adequate for premedication in children.⁵

Table 2: Distribution variables in study groups

Variables	Score	Grade	Clonidine Group I	Midazolam Group II
Intensive of sedation	1	Awake	5	23
	2	Drowsy	40	26
	3	Asleep	5	1
Reaction to drug administration	1	Crying	0	14
	2	Anxious	5	21
	3	Calm, uncooperative	21	14
	4	Calm, co operative/asleep	24	1
Anxiety level on acceptance of mask	1	Combative/crying	9	28
	2	Moderate fear of mask	17	18
	3	Cooperative on assurance	14	4
	4	Calm/cooperative	10	0
Reaction to intravenous cannulation	1	Crying	3	24
	2	Withdrawal of hand	21	23
	3	Grimace	26	3
Post-operative status	1	Agitated/crying	6	13
	2	Crying, consolable	12	34
	3	Calm/asleep	32	3

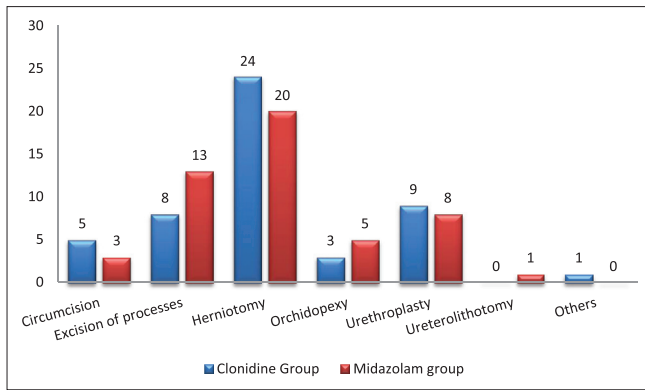


Figure 1: Distribution of surgeries in study group

Midazolam does not affect the recovery from anesthesia.⁶ Oral midazolam has been well accepted by children than rectal midazolam.⁷ The efficacy of oral clonidine in pediatric surgeries has been extensively studied. In our study, oral clonidine in the dose 4 µg/kg was given. Mikawa *et al.* compared the two doses of oral clonidine (2 and 4 µg) and concluded that 4 µg/kg is an effective dose. Hence, we decided to use 4 µg/kg of clonidine in our study.⁸ McMillan *et al.* Compared different dose of midazolam (0.5, 0.75 and 1 µg/kg) and used the parental form of midazolam and concluded that 0.5 µg/kg is safe and effective. Hence, we decided to use parenteral form of 0.5 µg/kg of midazolam.⁹ Nicole Almenrader *et al.* performed a prospective open study in 64 children who were randomly associated to receive either oral midazolam 0.5 µg/kg or oral clonidine 4 µg/kg as premedication. This study demonstrates the advantages of oral clonidine in both pre-operative period and during recovery compared with oral midazolam. Clonidine causes sedation similar to natural sleep where the patient can be easily aroused to perform the test. Clonidine acts by inhibition of spontaneous and evoked activity of central monoaminergic systems involved in modulation of sleep and cortical arousal.¹⁰ In our study, 90% of clonidine group had sedation scores of 2 and 3 compared to 54% in midazolam group. Regarding anxiety level on separation from parents, 48% in clonidine group was calm and cooperative compared to 2% in midazolam group.

Mask acceptance was 48% in clonidine group and only 8% in midazolam group. On comparing the response to IV cannulation, 48% of patients in midazolam group only 6% of patients in clonidine group are using. In our study, there was a trend towards an increased incidence of emergence agitation in midazolam group compared with clonidine group. In our study, the post-operative agitation is higher in midazolam group compared to clonidine group. 64% in clonidine group are calm/asleep while only 6% of patients in midazolam group are calm/asleep.

CONCLUSION

Oral clonidine can be used as a better premedicant drug to produce optimal sedation and emotional state than midazolam. The majority of the clonidine group children were calm and asleep during post-operative period compared to midazolam.

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Functional Outcome of Complete Acromioclavicular Joint Dislocation Repair Using Double Endobutton Technique: A Prospective Analysis

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Abstract

Introduction: Acromioclavicular (AC) joint injuries account for 9% of shoulder girdle injuries. Injury to the AC joint represents spectrum of soft tissue disruption that can lead to long-term disabilities of shoulder biomechanics. The management of AC joint injuries have a debate from the time of Hippocrates regarding operative management is necessary and which procedure produced a best functional outcome.

Aim: The aim of this study is to analyze the functional outcome of double Endobutton and Mersilene tape reconstructions done for complete AC joint disruptions, to assess the need for repairing the "AC capsule, ligaments and coracoclavicular ligament," reduction and AC joint stability, to identify complications related with this procedure, to assess the functional status using DASH Score, CONSTANT Score.

Materials and Methods: Our study introduces an operative technique for coracoclavicular ligament reconstruction using double Endobutton Mersilene tape and #5 Ethibond suture that provide anatomical reconstruction.

Results: We operated 20 cases of AC joint injuries. Out of 20 cases, 3 cases had mild complications. All other cases had excellent outcome according to the Quick DASH score. 0 means best outcome and 100 means poor outcome. Our result averages DASH score 5.3.

Conclusion: AC joint repair using double Endobutton had excellent functional outcome compared to traditional methods.

Key words: Endobutton, #5 Ethibond, Mersilene tape

INTRODUCTION

Acromioclavicular (AC) joint injuries account for approximately 9% of shoulder girdle.^{1,2} Injuries to the AC joint represent a spectrum of soft tissue disruptions that can result in mild, transient pain to significant displacement, chronic pain, and changes in shoulder biomechanics results in long-term disability.³ In AC injuries, males are

affected most commonly with a male-to-female ratio of approximately 5:1 and age group affected <30 years and are commonly occurs in athletes and contact sport persons, in which the mechanism of injury is direct blow to the lateral aspect of the shoulder.^{4,5} Management of AC joint injury has a debate from the time of Hippocrates and Galen, regarding when operative management is necessary and which procedure produces the best functional outcome with least morbidity.⁶ A classification based on the spectrum of injury in addition to nonsurgical and surgical treatment options. Our study mainly to analyze the functional outcome of complete AC injuries treated with double Endobutton and Mersilene tape, an anatomical reconstruction of coracoclavicular ligaments. We will be analyzing the results based on clinical outcomes and radiological assessment so as to ascertain the efficacy of this procedure.

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Aim

The aim of this study is to analyze the functional outcome of double Endobutton and Mersilene tape reconstructions done for complete AC joint disruptions, to assess the need for repairing the “AC capsule, ligaments and coracoclavicular ligament,” reduction and AC joint stability, to identify complications related with this procedure, to assess the functional status using DASH Score.

MATERIALS AND METHODS

This is a prospective study conducted in the Department of Orthopaedics, Tirunelveli Medical College Hospital. The Institutional Ethics Committee approval and informed consent from the patients were obtained. Complete AC joint disruptions (Rockwood and Young Type III-VI), acute injuries, closed injuries in age group of 18-60 years were included in the study. Exclusion criteria: Chronic injuries, elderly patients, and compound injuries. Specified post-operative protocol was followed for all patients. Outcome was measured based on DASH questionnaire. The time protocol extends from within 24 h of injury to 7 days of injury.

Procedure and Post-operative Protocol

General measures

All patients received in the emergency ward were evaluated for any associated major injuries such as chest injury and brachial plexus injury. Then, X-ray of involved shoulder anteroposterior (AP), Zanca view, and X-ray of both shoulders standing STRESS AP view was taken. The patient was immobilized with arm sling. All cases were taken up for surgery before the 7th day.

Surgical technique

The base of the coracoid tip is palpated and an incision 2" above it is made extending to the anterior edge of the distal clavicle. Flaps are raised medially and laterally. Along the fibers of deltoid it is split, and coracoid is identified and cleared up to the base. At the coracoid base, the medial and lateral edges are made out clearly. Articular disc of AC joint was debrided to allow for good reduction. Manual reduction of clavicle is done and the reduction is held while from the top of the clavicle about 3 cm medially to the AC joint and midway between the anterior border and posterior border of the clavicle, drill tip guide wire is introduced. The drill hole should be positioned directly over the base of the coracoid, and the drill should be directed a little anteriorly. When the guide wire is drilled through the clavicle, the guide wire is easily viewed in between the clavicle and coracoid. The tip of the guide wire is drilled throughout the base after the confirmation of its position in the center, between the medial and

lateral edges. The 4.5 mm “cannulated drill” is reamed over the drill tip guide wire the clavicle well reduced, the channel length is determined using “Endobutton depth gauge.” Another 2.5 mm drill hole is made 1 cm lateral to the Endobutton drill hole. Through first and fourth holes of the Endobutton “#5 Ethibond” inserted and Mersilene tape inserted into second and third holes of Endobutton.” Endobutton, with its sutures, is pushed to the top of the clavicle through holes drilled using a 3.2 mm “smooth cylindrical plunger.” The Endobutton is seen in the space between clavicle and coracoid which is pushed into the coracoid drill hole until it protrudes out of the underside of coracoid. One end of Mersilene tape is pulled up, to lock the Endobutton to the underside of the coracoid. Of the 2 pairs of Ethibond tails, one is pulled out the interval between coracoid and clavicle. This will leave 1 suture with 2 tails going through the coracoid Endobutton and exiting the top of the clavicle. Firm downward pressure is applied on the clavicle to maintain the best reduction. With very firm pull upward on Mersilene tape, in another Endobutton, free ends of Mersilene tape passed into 2nd and 3rd hole and Ethibond into 1st and 4th holes. The sutures are tied on top of the Endobutton. This locks the Endobutton in place and reconstruction of conoid of coracoclavicular ligament is complete. The sutures in the coracoclavicular space are retrieved and 1 tail is passed through the second (2.5 mm) drill hole. The suture is tied. Thus, the trapezoid portion of the coracoclavicular ligament is recreated. In all our cases, the coracoclavicular ligaments could not be repaired due to difficulty in identifying the ligament, friability of tissue.

Post-operative Protocol

Pendulum exercises were started on the 2nd post-operative date and passive mobilization started as patient tolerated. Within 3 weeks, active exercises were started and full range of movement was started after 3 weeks. We have used the DASH questionnaire, Quick DASH score and Constant score as they reflect the subjective and objective perspective of the shoulder function. The range of movement as required in the Constant score was measured with a goniometer.

RESULTS

These studies comprised 20 patients were admitted in the Department of Orthopaedics, Tirunelveli Medical College Hospital. The followings are the observations and the results compiled at the end of the study. AC joint injuries are most commonly encountered in age group of 20-30 years. Young adults are most commonly affected compared to children and elderly (Figure 1). Male patients are more in this study 90% (Figure 2).

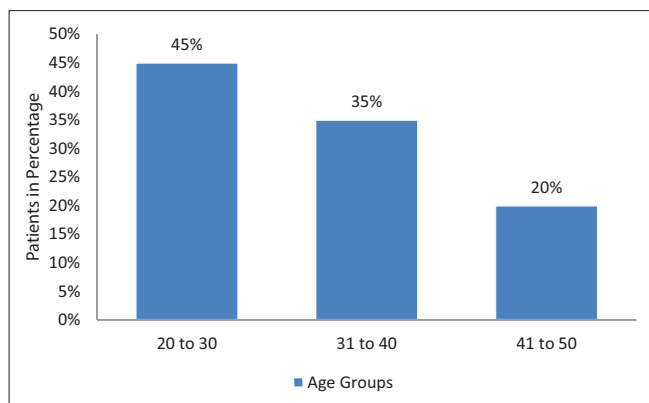


Figure 1: Age group distribution

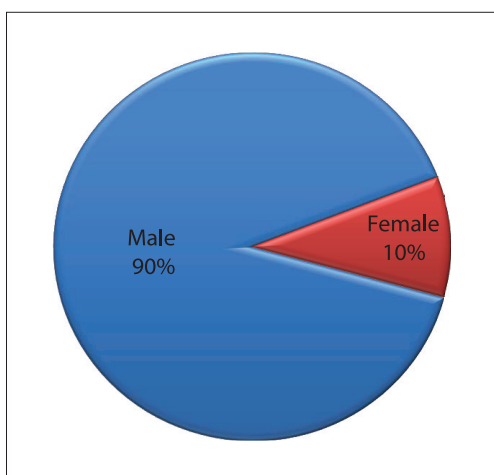


Figure 2: Gender distribution of study patients

There are 5 types of AC joint injuries. Even though types 1 and 2 more common patients have only mild symptoms which are usually treated conservatively. Surgical management is needed for types 3-5, among which, type 5 is more common (Figure 3).

Isolated AC joint injuries are most common, other fractures usually associated with AC joint injuries are rib fractures, scapula fractures, and tibial condyle fractures. Among which, rib fractures are more common accounts to around 50% followed by scapula fractures and tibial condyle fractures. If associated scapula # is the present functional outcome after AC joint repair with Endobutton is less (Figure 4).

AC joint repair with Endobutton is usually associated with very few complications such as stitch granuloma (1 patient), superficial infection (1 patient), and shoulder stiffness (1 patient). These complications are very less compared to other methods of management for AC joint injury. Hence, our treatment with Endobutton repair has a better functional outcome (Figure 5).

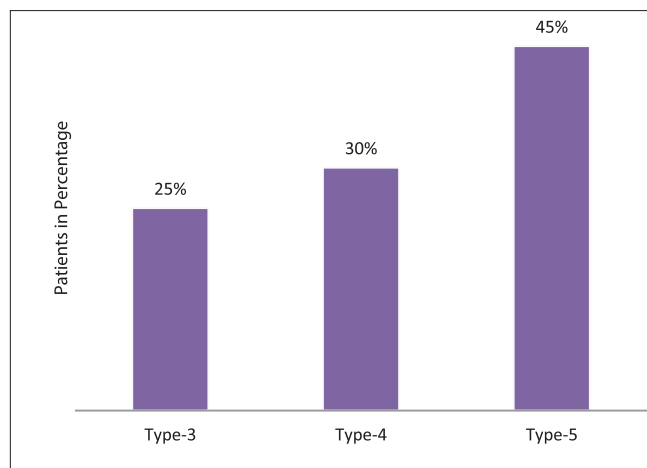


Figure 3: Distribution of type of injury in study patients

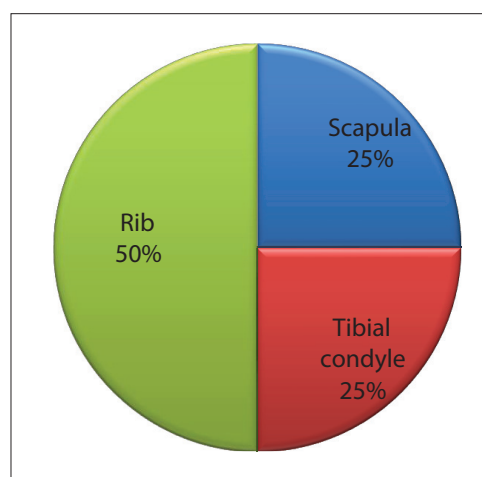


Figure 4: Distribution of associate injury in study patients

We have done DASH scoring for 20 patients who underwent surgery. In DASH score, 0 means no disability 100 means extreme difficulty; points are assigned from 1 to 5. The average DASH score is 5.3. All the patients have good functional outcome following Endobutton repair (Figure 6).

DISCUSSION

Surgical treatment for AC joint injuries has much higher success rates in recent studies.¹⁻³ Many studies have demonstrated successful outcome even with nonoperative treatment. There were problems with hardware failure like Bosworth screw, hook plate, and so there will be need for a second procedure to remove the hardware.⁷ There are various attempts to improve the original Weaver-Dunn technique to stabilize the AC joint using nonmetallic fixation. However, there was implant-related problems including infection, soft tissue reactivity, and fractures have been observed although many of these modifications have

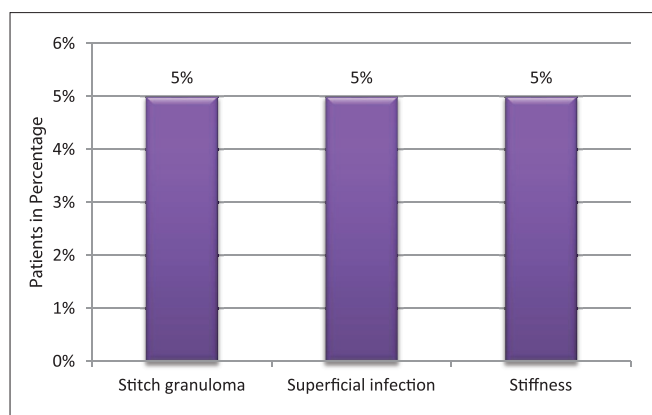


Figure 5: Complications in study patients

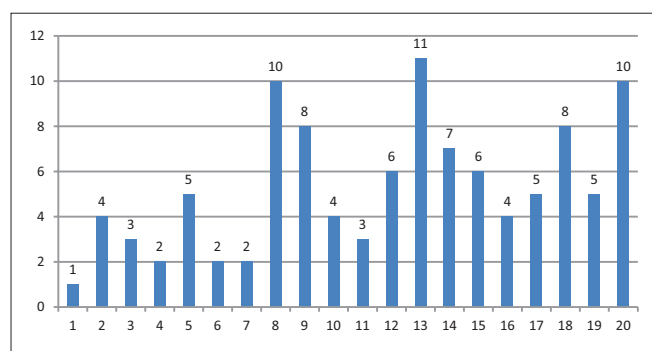


Figure 6: DASH score of study patients

shown excellent success.⁸ So, the development of purely biologic constructs with the use of allograft or autograft to reconstruct the coracoclavicular complex arises due to these implant-related problems. Biomechanical studies reveal that to recreate the native anatomy and finding materials that can tolerate the cyclic loading without deformation or failure the ultimate strength, stiffness, and load elongation curves of the native complex have been measured against various repair constructs. Testing has been done with both simple load to failure modes as well as response to cyclical loading to simulate post-operative conditions. Traditional procedures such as the Weaver-Dunn have been shown to be much weaker and much more compliant than the native ligament leading, thereby explaining the frequently observed high failure rate of this procedure. Numerous modifications of the original Weaver-Dunn procedure have been evaluated with biomechanical studies.⁸ The most common modification involves stabilizing the joint by placing a cerclage material around the base of the coracoid and through a hole in the clavicle. Thick, robust materials such as polydioxanone bands or large tendon grafts have indeed shown comparable strength relative to the native complex; however, their load-elongation curves indicate lower stiffness in most of the tested materials.⁹ More importantly, nonanatomical techniques such as cerclage fixation method drags the distal clavicle

anteriorly. A study by Baker *et al.* shows that “even when the drill hole is placed within 2 mm of the anterior edge of the clavicle,” the clavicle is dragged anteriorly. During the healing process, when the constant cyclical forces act on it, this malreduction likely lead to weakening of the construct and there is osteolysis of clavicle at the level of cerclage.¹⁰ Fixation placed in anatomically correct positions may improve implant stability and response to cyclical loads. Indeed, several newer techniques have been described that anatomically placed holes in the clavicle and coracoid followed by placing grafts or fixation devices to achieve stability. The Endobutton and Mersilene device reproduce the course of the conoid portion of the coracoclavicular ligament which is placed in an anatomically correct fashion. By approximately, 40% (internal testing by Smith and Nephew) the strength and stiffness of the device exceed the native ligament complex. Only surface of the 2 metal Endobutton bear the deforming forces of the weight of the arm, not the suture material itself, thereby suture material has less chance of soft tissue reaction. 5# Ethibond that passes through the Endobutton holes used to recreate the course of the trapezoid component of the coracoclavicular ligament, thereby additional horizontal plane stability. In addition, the drill holes which are made relatively small (4 mm), allowing the implant to be used either as conjunction with other biologic implants or a standalone device to improve long-term stability. With minimal soft tissue dissection, the technique uses a small incision and is technically straightforward.

CONCLUSION

AC joint reconstruction by Endobutton and Mersilene tape results in early functional recovery and full range of shoulder movements. Endobutton avoids the implant-related complications and further surgery to remove the implant. In our series, double Endobutton and Mersilene tape have good results of functional outcome and pain-free shoulder movements. Intraoperative and post-operative complications are minimal in our case series. Endobutton, Mersilene tape, and #5 Ethibond give both vertical and horizontal stability of AC joint.

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“Quadriceps angle”: An Important Indicator of Biomechanical Function of Lower Extremity and Its Relation with Anterior Knee Pain

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Abstract

Introduction: Quadriceps angle (Q-angle) is an important indicator of biomechanical function in the lower extremity and describes the lateral force applied to the patellofemoral joint by the contraction of the quadriceps muscle. It is a quantitative measurement of patellar position with respect to the lower extremity alignment. Nowadays, not only in sports world but also in general population, patellofemoral pain syndrome, and dislocations of knee joint have become very common problem.

Aim: To evaluate the relationship between the anterior knee pain and Q-angle and also to find bilateral differences in mean Q-angle.

Materials and Methods: A total of 240 adults (112 males and 128 females) as cases and controls of the age group 19-35 were studied. The measurement of Q-angle was carried out on both right and left lower limbs with the help of goniometer in both cases and controls, and data were statistically analyzed.

Results: Q-angle is significantly associated with anterior knee pain in both males and females having $P < 0.000$ with females having greater Q-angle, being more prone to anterior knee pain. This study also showed bilateral differences in Q-angle in both males and females.

Conclusion: This anatomical expression of Q-angle can be used as a tool for early prediction of anterior knee pain and hence substantiates the need for lifestyle modification to counteract this syndrome at its nascent stage.

Key words: Anterior knee pain, Patellofemoral syndrome, Quadriceps angle

INTRODUCTION

The knee joint is a complex synovial joint of body that gets involved in about 50% musculoskeletal injuries and dysfunctions of which patellofemoral joint is involved in majorities of injuries and dysfunctions related to knee joint. An important measure of alignment of patellofemoral joint is quadriceps angle or Q-angle.¹ Q-angle was first described by Brattstroem² as an angle formed between ligamentum patellae and the extension of the line formed

by the quadriceps femoris muscle resultant force with its apex at patella.

Q-angle is formed at the point of intersection of two imaginary lines.

1. First line is drawn from ASIS to the center of patella (CP)
2. Second line is drawn from tibial tuberosity (TT) to the CP.

Q-angle is an important indicator of biomechanical function in the lower extremity and describes the lateral force applied to the patellofemoral joint by the contraction of the quadriceps muscle.³ It is a quantitative measurement of patellar position with respect to the lower extremity alignment.^{4,5}

Q-angle is widely used as an important parameter to assess patellofemoral joint functions and prevention of knee

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alignment problems in sports medicine. Increase in Q-angle beyond normal range increases lateral pull of quadriceps muscle on patella causing extensor mechanism misalignment potentiating patellofemoral pain syndrome (PFPS) which is also known as anterior knee pain syndrome.⁶ It is a common condition encountered in orthopedic and sports medicine outpatient department. Persons with PFPS typically experience diffuse peripatellar or retropatellar pain. Pain is aggravated by squatting or climbing stairs or sitting with knees flexed for a prolonged period of time.⁷ PFPS is more common in females than males⁸ and in overweight persons.⁹ The normal Q-angle varies from 8° to 12° in males and 10°-20° in females, according to different studies. A Q-angle of 20°-22° is supposed to be the predisposing factor to patellar dislocation and anterior knee pain according to previous studies.¹⁰ A higher Q-angle increases the lateral pull of the quadriceps. Deviation from the normal range of values obtained from Q-angle measurement has been implicated in several knee disorders.¹ In Indian lifestyle, there is more risk of compressive forces on the patellofemoral joint while performing excessive flexion in sitting crossed legs and squatting position. Hence, patellofemoral joint problems and increased Q-angle seem to be more common among them.

Measurement of Q-angle clinically using a goniometer is a simple and most widely used method adopted in sports medicine. Measurement of Q-angle helps us in screening of abnormal Q-angle in persons who are more prone to wear and tear injuries of the knee joint. Moderate to substantial amounts of bilateral variability of Q-angle values have been demonstrated in individual¹¹ which is attributed to bilateral asymmetry in quadriceps muscle strength.^{11,12} This study focuses on relation of Q-angle with anterior knee pain and also to document bilateral variability in the mean value of Q-angle in both sexes.

MATERIALS AND METHODS

This study was conducted at the Department of Orthopaedics and Physiotherapy and at the Department of Anatomy, in M. G. M. Medical College, Indore, Madhya Pradesh, India.

Material

The study included subjects both males and females between 19 and 35 years of age having anterior knee pain as cases and controls with no history of anterior knee pain or any congenital or hereditary disorders.

Methodology

The measurement of Q-angle was carried out on both right and left lower limbs with the help of universal goniometer in both cases and controls.

A goniometric method as described by Jha and Raza was adopted.¹³ The measurement of the Q-angle was performed with the subject in supine with quadriceps relaxed and keeping the pelvis square. The legs were extended at the knee joint and the feet were placed in a position of neutral rotation, such that the toes were pointing directly upwards and the feet were perpendicular to the resting surface. It is the most commonly used method as it is easy to perform and is reliable.¹⁴ Prior informed consent was obtained from each subject. Measurements were taken twice for accuracy and to take out mean in a well-lighted room. The measurements for male subjects were taken in the presence of a male attendant.

After selection of cases and controls, following groups were made further:

SMU = Symptomatic males with unilateral anterior knee pain.

SMB = Symptomatic males with bilateral anterior knee pain.

SFU = Symptomatic females with unilateral anterior knee pain.

SFB = Symptomatic females with bilateral anterior knee pain.

CM = Control males.

CF = Control females.

Statistical Evaluation

Data thus were compiled, tabulated, and analyzed statistically on word excel and SSP software. Descriptive statistics (mean \pm standard deviation) of the Q-angle for the right and left lower extremity were tabulated for both males and females. Data obtained was analyzed using Student *t*-test and *P*-values were calculated.

RESULTS

Statistical calculations of cases and controls have been summarised in Tables 1 and 2.

In cases, mean Q angle of females is significantly higher than those of males when corresponding limbs of males and females are compared (Fig 1).

Mean RQA in symptomatic females with unilateral knee pain is $20.68 \pm 2.541^\circ$ and mean right Q-angle (RQA) in symptomatic males with unilateral knee pain is $15.17 \pm 2.11^\circ$. Similarly mean left Q-angle (LQA) in symptomatic females with unilateral knee pain is $17.31 \pm 2.496^\circ$ and mean LQA in symptomatic males with unilateral knee pain is $13.29 \pm 2.541^\circ$. Mean RQA in symptomatic females with bilateral knee pain is $20.73 \pm 2.832^\circ$ and mean RQA in symptomatic males with bilateral knee pain is $15.95 \pm 2.371^\circ$. Similarly mean LQA in symptomatic females with

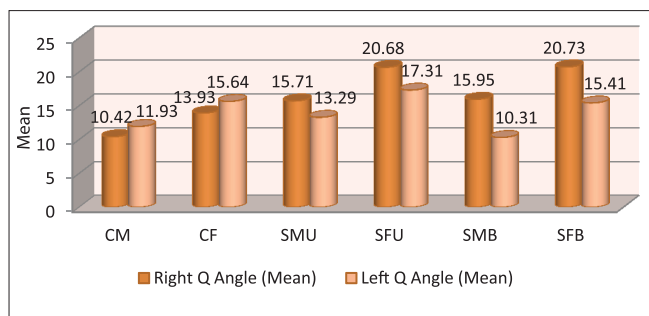


Figure 1: Means of right Q-angle and left Q-angle

bilateral knee pain is 15.41 ± 1.971 degrees and mean LQA in symptomatic males with bilateral knee pain is $10.31 \pm 0.215^\circ$. In controls, Mean RQA in females is $13.93 \pm 1.470^\circ$ and mean RQA in males is 10.42 ± 0.225 degrees. Similarly mean LQA in females is $15.64 \pm 2.11^\circ$ and mean LQA in males is $11.93 \pm 1.436^\circ$ (Table 1).

When Student *t*-test is applied for comparing the means of Q-angles of males and females separately on both sides and *P*-value calculated, the value is found to be highly significant ($P < 0.000$).

Mean of RQA and LQA is significantly higher in females with *t* value of 11.425 and 8.485 in right and left limbs respectively. Similarly, in controls, mean Q angle of females is significantly higher than those of males when corresponding limbs of males and females are compared with *t* value of 7.571 and 8.826 in right and left limbs respectively and *P* value calculated, the value is found to be highly significant ($P < 0.000$) (Table 2).

Table 3 shows comparison between right and left Q angle in controls to study the bilateral variability. The *P*-value is significant at or below 0.05. RQA of CM is 10.42 ± 0.225 , and LQA is 11.93 ± 1.436 . Mean difference (ΔQ) between the two sides is -1.51 . The *t*-test is applied to compare the two means; *t*-value found is -5.451 and *P*-value calculated is 0.001 which is highly significant.

RQA of CF is 13.93° and LQA of CF is 15.64° . The mean difference (ΔQ) between the Q-angles for two sides is -1.71 .

The *t*-test is applied to compare the two means; *t*-value is -7.826 and $P < 0.05$ which is highly significant. The results of this study show that bilateral asymmetry exists in males ($\Delta Q = -1.51$) and females ($\Delta Q = -1.71$), with greater asymmetry seen in females as compared to males.

DISCUSSION

Quadriceps femoris angle (“Q-angle”) can be considered as an index of knee function and patellofemoral kinetics.

Table 1: Mean and SD of RQA and LQA of controls and cases with anterior knee pain

Group	RQA		LQA	
	Mean \pm SD	SEE	Mean \pm SD	SEE
CM	10.42 \pm 0.225	1.74	11.93 \pm 1.436	0.185
CF	13.93 \pm 1.470	0.188	15.64 \pm 2.114	0.271
SMU	15.71 \pm 2.117	0.294	13.29 \pm 2.541	0.306
SFU	20.68 \pm 2.541	0.306	17.31 \pm 2.496	0.427
SMB	15.95 \pm 2.371	0.263	10.31 \pm 0.215	0.205
SFB	20.73 \pm 2.832	0.323	15.41 \pm 1.971	0.312

SD: Standard deviation, RQA: Right Q-angle, LQA: Left Q-angle, CM: Control males, CF: Control Females, SMU: Symptomatic males with unilateral anterior knee pain, SFU: Symptomatic females with unilateral anterior knee pain, SMB: Symptomatic males with bilateral anterior knee pain, SFB: Symptomatic females with bilateral anterior knee pain

Table 2: Significant “t-value” of Q-angle between comparison group of males and females in both cases and controls

Cases and controls	<i>n</i>	Mean	<i>t</i> -value	<i>P</i> -value	Significance
Cases					
RQA					
Males	52	15.17	11.425	0.000	Highly Significant
Females	68	20.68			
LQA					
Males	52	13.29	8.485	0.000	Highly Significant
Females	68	17.31			
Controls					
RQA					
Males	60	10.42	7.571	0.000	Highly Significant
Females	60	13.93			
LQA					
Males	60	11.93	8.826	0.000	Highly Significant
Females	60	15.64			

RQA: Right Q-angle, LQA: Left Q-angle

Table 3: Comparison between RQA and LQA to study bilateral variability in study population (controls)

Student t-test	Males (n=60)	Females (n=60)
RQA	10.42 \pm 0.225	13.93 \pm 1.470
LQA	11.93 \pm 1.436	15.64 \pm 2.114
t-value	-5.451	-7.826
P-value	0.001	0.000
Significance	Highly significant	Highly significant

RQA: Right Q-angle, LQA: Left Q-angle

The findings of this study suggest that larger Q-angle is significantly associated with anterior knee pain in both males and females. Females have greater Q-angle than males, so they are more prone to develop anterior knee pain. In SMU group, mean RQA was 15.71° and mean LQA was 13.29° . In SFU group, mean RQA was 20.68° and mean LQA was 17.31° . The mean RQA in SMB was 15.95° , and 20.73° in SFB. Mean LQA in SMB group was 10.31° , and 15.41° in SFB.

In CM group, mean RQA was 10.42° and mean LQA was 11.93° . In CF group, the mean RQA was 13.93° and mean LQA was 15.64° . In this study, mean of Q-angle of patients of anterior knee pain was significantly higher than those without knee pain (controls). This suggests that high Q-angle is significantly associated with anterior knee pain. The findings of this study suggest that there is bilateral asymmetry in Q-angle. The mean Q-angle on the left side is greater than on right side in asymptomatic (control) males and females. The reason for this may be the bilateral difference in the quadriceps strength. It was found that Q-angle varied inversely with the quadriceps strength.¹⁵ As in most of the controls right limb is the dominant limb, their RQA is smaller than LQA. It was observed that mean Q-angle of symptomatic subjects in the right limb was higher than that observed in left symptomatic subjects. This is quite opposite to what was obtained in asymptomatic subjects. There is little evidence in literature regarding this observation. It may be postulated that possibility is high that right limb of symptomatic subjects may have suffered greater trauma in addition to other intrinsic factors as compared to the left limb. As more number of cases of anterior knee pain is of the right side, the mean Q-angle value in the symptomatic group is greater on the right side than on left side. Bilateral variability in Q-angle does exist in both males and females. Therefore instead of taking mean, Q-angles must be measured separately by clinicians both on right and left side.

Emami *et al.*¹⁶ concluded a study on 100 anterior knee pain patients and 100 controls. They found mean Q-angle for men, women and all subjects in case group was 15.3° , 20.1° and 18.0° , respectively. Mean Q-angle for men, women and all subjects in control group was 12.1° , 16.7° and 14.4° , respectively. In this study, the mean Q-angle for men, women and all subjects in case group was 15.8° , 20.7° and 18.25° , respectively. Mean Q-angle of men, women and all subjects in control group was 11.12° , 14.78° , and 12.92° . The results of this study are in accordance with the results obtained in the above study.

Livingston and Mandigo¹¹ conducted a study to find out whether Q-angle were bilaterally symmetric in individuals; asymptomatic and symptomatic for knee pain. They found out that there were significant right versus left lower limb differences in Q-angles, both in symptomatic and asymptomatic group ($P < 0.001$) and between males and females ($P < 0.05$). They found Q-angles are not bilaterally symmetric, with the magnitude and direction of observed asymmetry varying according to whether an individual is asymptomatic, unilaterally symptomatic or bilaterally

symptomatic for anterior knee pain which is in accordance with the present study.

CONCLUSION

We concluded that larger Q-angle is significantly associated with anterior knee pain in both males and females. Moderate to substantial amount of bilateral variability of Q-angle has been demonstrated which is attributed to bilateral asymmetry in quadriceps muscle strength. Therefore, this anatomical expression of Q-angle can be used as a tool for early prediction of Anterior Knee Pain and hence substantiates the need for lifestyle modification to counteract this syndrome at its nascent stage.

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Sandwich Technique of Closure of Spigelian Hernia: A Novel Technique

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Abstract

Spigelian hernia is a rare interparietal hernia accounting for 0.12-2.4% of all abdominal wall hernia. Herniation occurs through a defect or weakness in the Spigelian fascia, which is the aponeurotic layer between the lateral edge of rectus abdominis muscle medially and the semilunar line laterally. All presented with gradually enlarging swelling in the right or left iliac fossa, which showed complete reducibility and positive impulsion on coughing. Abdominal ultrasonography suggested the presence of abdominal wall defect of size ranging from 1 to 2.5 cm in maximum diameter at linea semilunaris line. On dissection, the defect was through the musculoaponeurotic sheath of the internal oblique and transverse abdominis muscle. After reduction of the contents, an underlay meshplasty with nonabsorbable prolene mesh was done. After the closure of the external oblique aponeurosis, another prolene mesh was put over the defect (onlay) so that the defect was sandwiched between the two prolene meshes. The skin and subcutaneous tissue was closed with a negative suction drain in all cases. 10½ months of mean follow-up revealed no recurrence. Hence, sandwich technique of closure of Spigelian hernia is a safe, feasible, acceptable, and associated with no short-term recurrence rates. However, long-term follow-up is needed to prove the efficacy of this technique.

Key words: Sandwich technique, Spigelian fascia, Spigelian hernia, Ventral abdominal hernia

INTRODUCTION

Spigelian hernia is a rare variety of ventral abdominal wall hernia, in which there occurs protrusion of pre-peritoneal fat, a sac of peritoneum or an organ through a defect or weakness in the Spigelian fascia, which is the aponeurotic layer between the lateral edge of rectus abdominis muscle medially and the semilunar line laterally.^{1,2} The hernia was named after a Belgian anatomist Adriaan Van der Spieghel who was the first to describe the semilunar line or linea Spigeli in 1645 and it was first recognized by Josef Klinkosch in 1764.³ It is also known as “spontaneous lateral ventral hernia” or “hernia of linea semilunaris.”

CASE REPORT

Four patients, three female and one male, with age ranging from 34 to 52 years (mean age 41.5 years) presented with gradually enlarging swelling in the lower abdominal wall. Three had swelling on the left iliac fossa and one in the right iliac fossa. The swellings enlarged in size on coughing and straining and were reduced in supine position. Colicky abdominal pain was present in two cases, but none of them presented with features of intestinal obstruction. There was no associated comorbid illness in any of the cases (Table 1). On examination, impulsion on cough was present with complete reducibility in all patients. Normal bowel sounds heard in all cases. Abdominal ultrasonography suggested the presence of abdominal wall defect of size ranging from 1 to 2.5 cm in maximum diameter at linea semilunaris line.

During surgery, a transverse incision was given over the hernia. On dissection, the defect was found along the lateral border of rectus sheath with the external oblique aponeurosis intact over it. The defect was through the musculoaponeurotic sheath of the internal oblique and

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transverse abdominis muscle. There was herniation of sac containing preperitoneal fat in one case (Figure 1), omentum in three cases (Figure 2). After reduction of the contents, an underlay meshplasty with nonabsorbable prolene mesh was done (Figure 3). After the closure of the external oblique aponeurosis, another prolene mesh was put over the defect (onlay) (Figure 4) so that the defect was sandwiched between the two prolene meshes. The skin and subcutaneous tissue was closed with a negative suction drain. Postoperatively, the patient had an uneventful recovery. Mean hospital stay was 4½ days (range 3-6 days). Sandwich technique, which was used to provide strength to the hernia defect revealed no signs and symptoms of recurrence within a mean follow-up period of 10½ month (Table 1).

DISCUSSION

Spigelian hernia is a rare interparietal hernia accounting for 0.12-2.4% of all abdominal wall hernia, with a female preponderance and occurring between 4th and 7th decades

of life. “Spigelian hernia belt of Spangen” is a 6 cm transverse strip above the line joining both anterior superior iliac spines, where the Spigelian fascia is wider and weaker. About 90% of Spigelian hernias are found within this belt.² In most of the time, hernia sac passes through the transversus abdominis and the internal oblique aponeuroses and spreads out in the interstitial layer posterior to the external oblique aponeurosis, which is the most common type. The sac may spread in the interstitial layer between the transversus abdominis aponeurosis and the internal oblique muscle, which is comparatively less common and breach of external oblique aponeurosis so that the sac lies in the subcutaneous plane is the least common type.⁴ In its early stage, there is protrusion of preperitoneal fat through the Spigelian aponeurosis. In the later stage, the peritoneal sac may enter containing greater omentum, small intestine, or part of the colon. Although rare, Spigelian hernias may contain an acutely inflamed appendix, Crohn’s appendicitis, even an incarcerated Meckel’s diverticulum.⁵

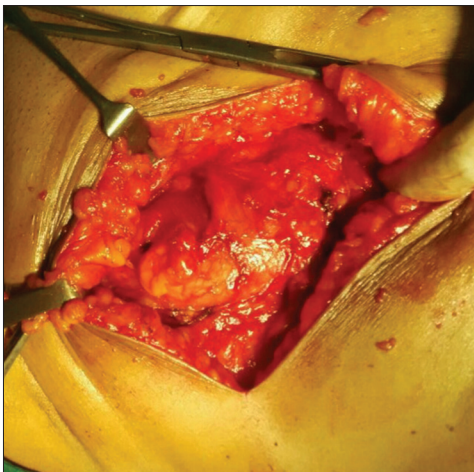


Figure 1: Hernial sac containing preperitoneal fat

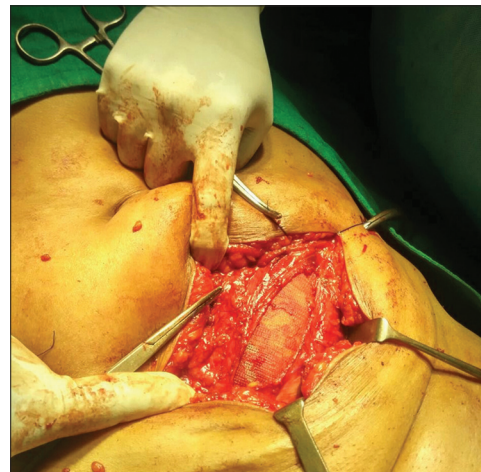


Figure 3: Underlay meshplasty with nonabsorbable prolene mesh



Figure 2: Hernial sac containing omentum

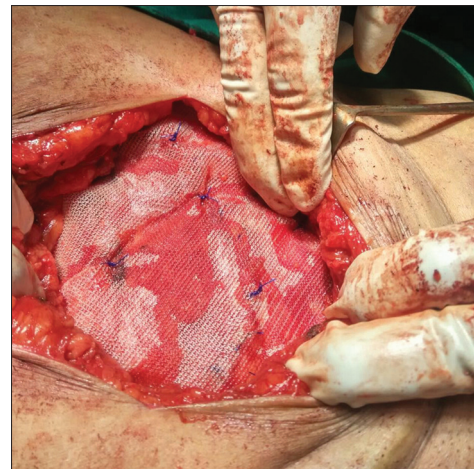


Figure 4: Onlay meshplasty with non absorbable prolene mesh

Table 1: Clinical characteristics of the patients

Patients	Age (years)	Gender	Side of defect	Co-morbidities	Contents of hernia sac	Post-operative complications	Hospital stay (days)	Follow up (months)
Patient 1	34	Female	Left	Nil	Pre-peritoneal fat	Nil	4	14
Patient 2	44	Female	Left	Nil	Omentum	Nil	5	12
Patient 3	36	Male	Right	Nil	Omentum	Nil	3	9
Patient 4	52	Female	Left	Nil	Omentum	Nil	6	7

The patients usually present with abdominal pain, a mass in the anterior abdominal wall or signs of incarceration with or without intestinal obstruction. Accordingly, the differential diagnosis includes rectus sheath hematoma, seroma, parietal abscess, lipoma, peritoneal tumor implants and pseudocyst at the end of the ventriculo-peritoneal shunts. Although operator dependent, ultrasonography is considered as the first line of investigation to detect the defect in the Spigelian fascia, due to its dynamic capability to perform a real-time examination in both supine and upright positions and while the patient performs a Valsalva maneuver.⁶ Computed tomography scan and magnetic resonance imaging are only required if there is doubt in making the diagnosis.

Surgical repair of Spigelian hernia is recommended because of high risk of intestinal obstruction and strangulation. Surgery can be performed either by open technique or laparoscopically. Simple closure of defect in the form of herniorrhaphy was recommended by Spangen.¹ According to Nozoe *et al.*, hernioplasty by suturing the internal oblique and transversus muscles to the rectus sheath is an ideal procedure.⁷ Nowadays in the era of tension free meshplasty, a nonabsorbable preperitoneal or onlay mesh repair is usually preferred for reconstruction. In 1992, Carter and Mizes reported the first laparoscopic repair for Spigelian hernia.⁸ Intraperitoneal, transabdominal pre-peritoneal and total extraperitoneal laparoscopic techniques with underlay mesh placement have been described with significantly lower morbidity, shorter hospital stay and low recurrences rates.^{2,9,10}

Regarding open approaches to surgery no procedure has been shown to have definitive advantages over others, especially in view of the rarity of these cases. Bleichrodt *et al.* used omentum-polypropylene sandwich technique for repair for abdominal wall defects.¹¹ Very less literature is available on using sandwich technique for repair of

Spigelian hernia. In our study, we used a novel technique of sandwiching two prolene meshes in between the layers of abdomen to strengthen the defect in the Spigelian fascia showed a good result.

CONCLUSION

Sandwich technique repair of Spigelian hernia is safe, easy and novel idea to strengthen the Spigelian fascia. It provides better results in short-term follow-up without recurrences; however, long-term follow-up is needed to provide its efficacy.

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Unusual Aggressive Large Radicular Cyst Invading Maxillary Sinus: A Case Report

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Abstract

Radicular cyst is a common odontogenic cystic lesion of the maxillofacial region and the most common odontogenic cystic lesion of inflammatory origin, it arises from the epithelial residues in periodontal ligament as a result of inflammation. We report a case of large radicular cyst of right posterior maxilla invading maxillary sinus, which was secondarily infected and was treated by surgical enucleation and curettage.

Key words: Diagnosis and prognosis, Maxillary sinus, Radicular cyst

INTRODUCTION

The radicular cyst is the most common cystic lesion in maxillofacial region. It is the most frequent among, and classified as, odontogenic inflammatory cysts. It usually grows slowly, rarely attains a large size and causes destruction of the surrounding structures. Mobility, displacement, and root resorption of the adjacent teeth are possible, especially in enlarging cysts. It has male predilection and occurs more often in the permanent dentition than the deciduous dentition. The majority of the radicular cysts (60%) are seen in maxilla, especially in the incisor-canine region. They are commonly asymptomatic unless infected, and discovered during routine radiographic examination.^{1,2}

Radicular cysts are seen as round or ovoid uni- or multilocular radiolucencies associated with the apex of a non-vital tooth. The radiolucencies have a radiopaque margin which extends from the lamina dura of the involved teeth. However, this margin disappears in the

case of inflammation and rapid extension, accompanied by commonly observed loss of lamina dura of the adjacent teeth.¹ In this article, we present a case of large, unusual aggressive radicular cyst invading the entire right maxillary sinus.

CASE REPORT

A 28-year-old man was referred to the maxillofacial outpatient clinic by a dentist owing to a swelling in the right posterior region of maxilla for past 2 weeks; there was a history of root canal treatment of molar in same region 12 years back, intraoral examination revealed a swelling in the area of the right maxillary canine extending to the second molar. The swelling was bonyhard, nontender, expansion of the buccal cortex, approximately 3.5 cm in size, and the overlying mucosa was taut. The adjacent teeth tested vital, and no evidence of periodontal disease or caries was detected. There was no tooth mobility; the occlusion remained unchanged. The patient was asymptomatic and was otherwise healthy, and reported a noncontributory medical history. No history of trauma was recorded. Extraoral head and neck examination was unremarkable. There was no evidence of lymphadenopathy or any abnormal masses or rashes.

The panoramic radiograph of the patient showed a well-defined, unilocular, and radiolucent lesion from canine

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to second molar involving sinus. Fine needle aspiration cytology was tried which was unyielding, then surgical enucleation and curettage was performed under general anesthesia, a crevicular incision from lateral incisor to last molar with anterior releasing mucosa was placed and a full mucoperiosteal flap was raised. A plane of cleavage was established between cystic epithelial lining and surrounding bone. The whole cystic lining was enucleated into and it was sent for histopathological examination and curettage was done to make sure all remnants were removed; lesion was found to be eroding the medial and posterior wall of sinus, with feature of secondary infection with discharge of brown cheesy material. Primary closure of cystic cavity done with vicryl 3-0 sling sutures placed through interdental papilla, and interrupted sutures over releasing incision. The patient was kept on regular follow-up. The wound healed uneventfully (Figures 1-5).

DISCUSSION

The radicular cyst is an inflammatory cyst associated with the root apex of a nonvital tooth. Because of the high incidence of pulpal pathology, it is the most common cyst of the oral and maxillofacial region. Radicular cysts can occur at any age, but curiously, they are seldom seen in children despite the high incidence of pulpal and periapical pathology in this group, which implies that there are few if any epithelial rests that result from the development of primary teeth.

Clinically, these cysts are associated with a tooth that is carious, has undergone previous restorative care, has sustained trauma, or is an apparent failure of root canal therapy. Radiographically, an apical radiolucency will be noted, but rarely, will there be bony expansion unless there is secondary infection.



Figure 1: Pre-operative intraoral photo depicting buccal and lingual cortical expansion

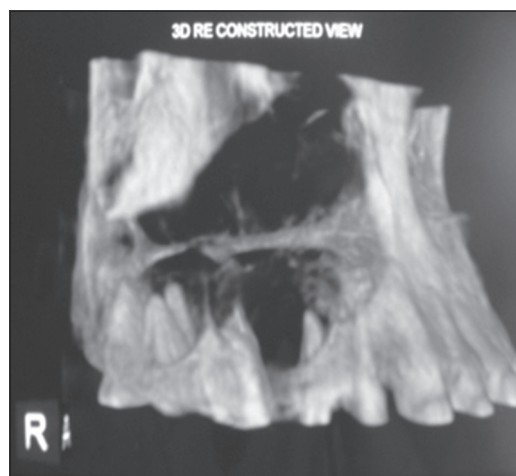


Figure 3: Three-dimensional view of computed tomography scan depicting invasion maxillary sinus

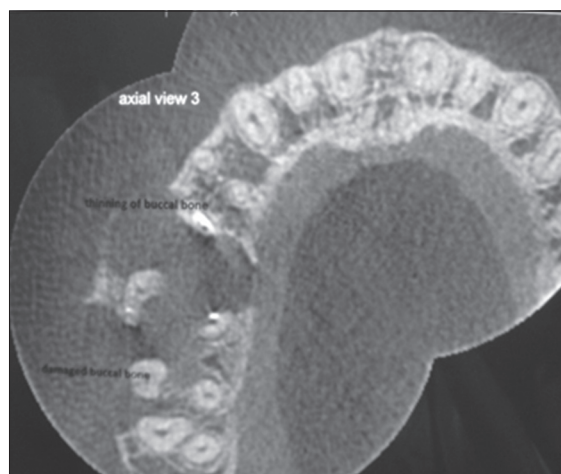


Figure 2: Axial view computed tomography scan depicting buccal and lingual cortical expansion with resorption

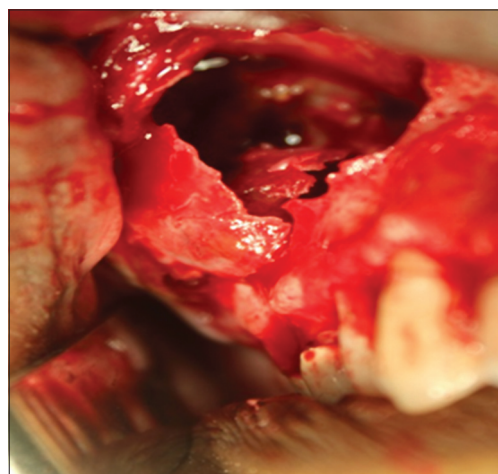


Figure 4: Intra-operative view depicting radicular cyst invasion into maxillary sinus

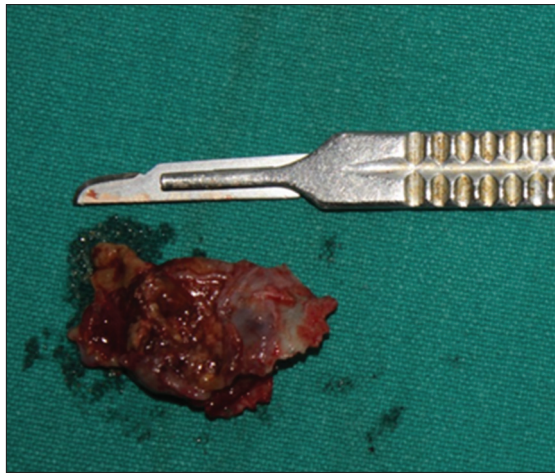


Figure 5: In toto removal of the radicular cyst

Much has been written about the radiographic distinction between periapical granulomas and radicular cysts, and yet there is no real distinction. The presence of a thin rim of sclerotic bone around the radiolucency is as indicative of a periapical granuloma as it is of a cyst.

Most radicular cysts are small, in the range of 0.5-1.5 cm, but they can exceed 5 cm. Some will also cause a regular smooth resorption of adjacent tooth roots, or they may have an irregular resorption of their roots of origin, presumably because of infection or osteoclastic factors elaborated by the cyst.

The radicular cyst is the model pathogenesis of an inflammation stimulated cyst and has been extensively studied. The origin of the cyst epithelium lies with rests of Malassez, which are epithelial remnants of Hertwig epithelial root sheath that lie dormant within the periodontal ligament. The products of pulpal infection and necrosis spill out into the periapical tissues, inciting an inflammatory response. The inflammatory cells secrete a host of lymphokines to neutralize, immobilize, and degrade bacteria. They also induce bone resorption through the elaboration of interleukin-1 and Osteoclast activating factors. These same cells are thought to elaborate many other factors.

Either directly or indirectly acts as epithelial growth factors, stimulating the proliferation of the rests of Malassez in the periapical granuloma. As the epithelial cell mass enlarges, the central cells become distant from their blood supply and break down, thereby forming a cyst. The cyst continues to enlarge by epithelial proliferation in the lining and by hydrostatic pressure generated in the cyst lumen from the hyperosmolarity created by cellular breakdown and sloughing of cells into the lumen. Therefore, the osmotic gradient favors transudation of fluid into the lumen,

which maintains its hydrostatic pressure and causes further resorption of the surrounding bone. This cycle can be broken and reversed in most situations if the inflammatory focus is removed (i.e., root canal therapy or tooth removal). However, if the tooth is removed, the apical lesion should be removed as well.³

Differential Diagnosis

A periapical granuloma is radiographically and clinically indistinguishable from a radicular cyst. In the anterior mandible, the early osteolytic phase of periapical cemento-osseous dysplasia is a consideration, as is the uncommon sublingual salivary gland depression. In the posterior mandible, a submandibular salivary gland depression is a possibility as are idiopathic bone cavities. If the cystic cavity is large, then it could be a challenge to diagnose it through clinically and radiographically.⁴⁻⁶

It is important to remember that throughout both jaws, a wide array of odontogenic cysts and tumors, plus central mucoepidermoid carcinoma and certain fibro-osseous diseases, can begin or develop radiolucencies that may appear periapically.³

Prognosis

Radicular cysts are definitively resolved if the tooth and the apical lesion are removed. If tooth is removed and the cyst is not, most cysts will involute because of the removal of the inflammatory focus. A few rare cases will retain their cystic stimulation independent of the tooth, probably by ongoing inflammation in the wall of the cyst. This is termed a residual cyst. Endodontically treated teeth will resolve radicular cysts as they do periapical granulomas as long as they have a successful pulp canal debridement and fill. In cases of endodontic failure due to incomplete fills or other pulpal leakage, the apical radiolucency will darken and enlarge, indicating a continuation of the granuloma-radicular cyst spectrum.⁷⁻¹⁰

In such cases, performing endodontic therapy again, often with assisted magnification techniques, will enable the treatment of accessory untreated canals. These accessory canals must be instrumented and filled and the previously treated canals retreated to larger sizes and filled. Apicoectomies with a retrofill of the apical area and curettage of the residual lesion or tooth removal is indicated if this retreatment fails.³

CONCLUSION

With this report of case, we emphasize on thorough clinical and advanced radiographic examination of cystic lesion of posterior of maxilla because this could be latent or masked due to shadow of maxillary sinus in normal radiographs.

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Fallopian Tube Herniation through the Drain Site: A Rare Case Report

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Abstract

Intra-abdominal drains have been used since long to prevent intra-abdominal collection, and detect any anastomotic leaks. Their use is not without complications. We report a case of a 24-year-old female, who presented with fallopian tube herniation through the drain site that was kept during cesarean section. The drain was kept in view of hemolysis, elevated liver enzyme levels, and low platelet levels syndrome. On 5th post-operative day, the patient presented with this herniation, and she was managed appropriately. By presenting this case report, we aim to reduce such complications in future. Drains are used to drain body fluids in certain circumstances but do not prevent infection or promote wound healing. Drainage tubes are not a substitute to a good surgical technique.

Key words: Drain site, Fallopian tube, Herniation

INTRODUCTION

Drains inserted after surgery to drain accumulated fluid content sometimes become the focus of infection such as blood and pus. They do not promote wound healing or prevent infection. However, they are also associated with complications such as hemorrhage, infection, tissue damage, pain, blockage, and herniation of viscera. However, in current practice, their use is restricted by good surgical techniques and confidence of surgeons, except for in unavoidable in certain clinical situations.¹⁻³

CASE REPORT

A 24-year-old, primi at 37 weeks gestational age was referred from nearby government headquarters as jaundice complicating pregnancy. She was admitted, evaluated, coagulation abnormalities corrected with blood products.

The patient was stable while the cause of jaundice was still investigated for the next day she had fetal distress. An emergency lower segment cesarean section was performed to deliver an alive preterm female baby of birth weight 2 kg and good APGAR. Postoperatively her renal parameters were in the rising trend with adequate I/O, ultrasonography revealed B/L hydronephrosis, and she was diagnosed as nonoliguric renal failure on conservative management.

On the 4th post-operative day, drain that was placed on the left side was removed and small pinkish viscera protruded through the drain site. The size of it increased as the patient coughed and increased intra-abdominal pressure. The viscera were identified as fallopian tube and as time passed it became edematous.

The next day, relaparotomy and resection of the herniated fallopian tube was performed. The other side fallopian tube and ovary were normal. Thorough peritoneal wash given. The patient was started on higher antibiotics.

Despite all this, the patient developed one episode of generalized tonic-clonic seizure the next day and was febrile. She was intubated and investigated with a provisional diagnosis of metabolic seizures. Computed tomography brain revealed multiple infarcts and she was started on

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octreotide and antiedema measures. Her general condition improved and was extubated 2 days later (Figures 1-3).

DISCUSSION

The use of intra-abdominal drain dates back to Hippocrates era with the first drain being used for a case of empyema gallbladder. The only definitive indication for the use of pelvic drain, after surgery, is following

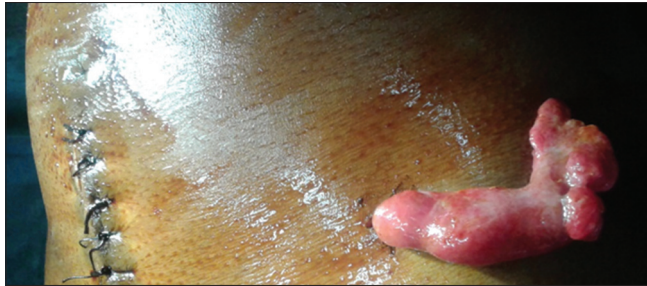


Figure 1: Hernated fallopian tube – Fimbrial end

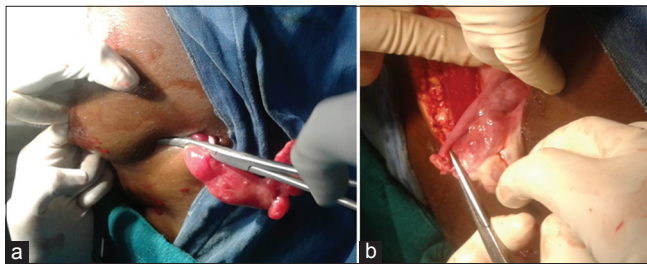


Figure 2: (a and b) Surgical correction of fallopian tube herniation



Figure 3: Resected end of fallopian tube

tubo-ovarian abscess or presence of infection. Although it is advisable to leave a pelvic drain when there is evidence of clotting defect, a drain is not a replacement for achieving hemostasis. There are proponents and opponents, but the type of drain and its use is largely a matter of personal preference. Different types of drains are used in the peritoneal cavity including passive, closed suction, and stump.

Studies regarding the use of prophylactic drains have come up with controversial results. However, it is associated with increased rate of infection, discomfort, and post-operative morbidity. It has been reported that herniation of viscera increases with increase in port size more than 10 mm. Factors which increase intra-abdominal pressure such as coughing, straining, prolonged surgery poor nutrition, infection, obesity, and steroid use may cause poor wound healing and herniation.

In our case, the patient had poor nutrition and respiratory infection that would have resulted in herniation of fallopian tube through the drain site.

As the laparotomy for the herniated fallopian tube was performed the next day, she had fever and developed infection. Hence, early repair would result in better outcome with low morbidity.

CONCLUSION

Drains are not a substitute for good surgical techniques. Surgical drains are associated with different complications and herniation of viscera is one among those. Herniation of fallopian tube is uncommon. Prevention of tubal prolapse can be achieved by suturing the adnexae high in the pelvis at abdominal hysterectomy and by the proper closure of the pelvic peritoneum. Correction of respiratory infections which increase the intra-abdominal pressure and predispose to herniation through drain site is very important.

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