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Case Series

Case Series of Acute Myocardial Infraction in Teenagers: Alarming Incidence

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Abstract

We may presume acute myocardial infarction (AMI) is not a likely cause of chest pain in teenagers, but although rare, young adults and even teenagers are also presenting with AMI. Increasing AMI in young age is partly explained conventional risk factors such as smoking dyslipidemia, unhealthy food habits, lack of exercise, but several non-atherosclerotic risk factors are described in adolescents. These are coronary artery ectasia (CAE), spasm, and drug abuse such as cocaine, coronary artery anomalies, coronary embolism, coronary artery dissection, hypercoagulable states, and use of oral contraceptive (OC) pills. Here, we report the two cases of a previously healthy 16-year-old boy and 16 years female of AMI without known risk factors. The possible mechanism for AMI in male is CAE and in female patient OC pills is probably linked with AMI. Our aim is to increase awareness of diagnosis AMI even in adolescents with chest pain so that mishap would not happen.

Key words: Coronary artery ectasia, Coronary heart disease in teenagers, Myocardial infarction, OC pills, Risk factors

INTRODUCTION

Coronary heart disease (CAD) is a major cause of morbidity and mortality with acute myocardial infarction (AMI) being one of the most common presentations of CAD. AMI is rare in teenagers and young adults and accounts for only 3% of all patient with coronary artery disease in individuals younger than 40 years of age. Younger age group has different risk profile as compared with older populations. Non-atherosclerotic causes are usually responsible for AMI in teenagers. Among the many described non-atherosclerotic causes are spontaneous coronary artery dissection, and coronary spasm related to drug use, coronary artery ectasia (CAE), embolism from aortic valve, thrombosis from hypercoagulable states, coronary anomalies, and antiposholipid syndrome are more prevalent in this age group.[1]

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Here, we present two cases of a previously healthy 16-year-old male and female who presented with myocardial infarction without known risk factors.

Here will want to emphasis required to consider diagnosis of AMI in teenagers presenting as chest pain and to discuss different risk profile for AMI in teenagers. Coronary artery disease is alarmly increasing younger population including teenagers too.

CASE REPORTS

Case 1

A 16-year-old male came to our hospital with a complain of chest pain since past 2 days. There was no significant previous medical history and non-addict. On examination, vitals were normal. Respiratory function was normal. Blood investigations revealed that troponin I was positive, but CBC, LFT, and RFT were normal. ECG showed ST elevations in leads V1-5 with consistent with acute ST elevation anterolateral infarction [Figure 1]. Echocardiography showed mild LV dysfunction with the left anterior descending (LAD) artery territory hypokinesia. Coronary angiogram (CAG) showed ecstatic proximal

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left anterior descending artery [Figure 2]. There was no presence of atherosclerotic lesion. Based on above findings, diagnosis of anterior wall myocardial infarction was made. However, no conventional risk factors for this could be elicited.

The patient was given conservative treatment only (dual antiplatelet therapy with Low-Molecular-Weight Heparin [LMWH] and statin). The patient was better after 1 month follow-up and was lost was further follow-ups.

Case 2

A 16-year-old female came to our hospital with a complain of chest pain for an hour. The patient was on oral hormonal medication (Cypoterone acetate 2 mg and E estradiol 0.03 mg in combination) since past 2 months for menorrhagia and had taken 1st dose of covaxin 1 month back. The patient was obese with 27.5 BMI. On examination, vitals were normal. Respiratory function was normal. ECG showed acute anterior wall myocardial infarction [Figure 3]. She was thrombolysed with streptokinase and treated with dual anitiplatelets, statin LMWH, beta-blockers, and antianginals. Echocardiography showed mild LV dysfunction with LAD artery territory hypokinesia. CAG showed normal coronary arteries [Figure 4]. There was no presence of atherosclerotic lesion. Her tests for Protein S, Protein C, antithrombin III, homocysteine, and factor V leiden were negative. The patient was given conservative treatment only (dual antiplatelet therapy with LMWH and statin). The patient was better after treatment and post-treatment echocardiography showed improved LV function with LV apical clot.

DISCUSSION

Earlier AMI was thought a disease of older population but affecting youngers and even teenagers too nowadays. Although it occurs at younger age in India compared to Western population but rare in teenagers. The clinical presentation, risk factors for myocardial infarction in young patient, differs from those in older patients. Coronary arteriography performed in young patients after myocardial infarction has identified a relatively high prevalence of angiographically normal coronary arteries.[2] Furthermore, risk factor analysis in young patients with AMI has shown a particularly high prevalence of smoking compared with that in older patients with higher prevalence for males as compared to females.[2]

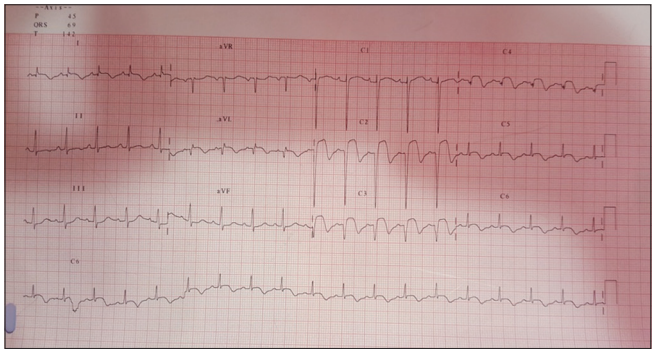

Figure 1: ECG findings

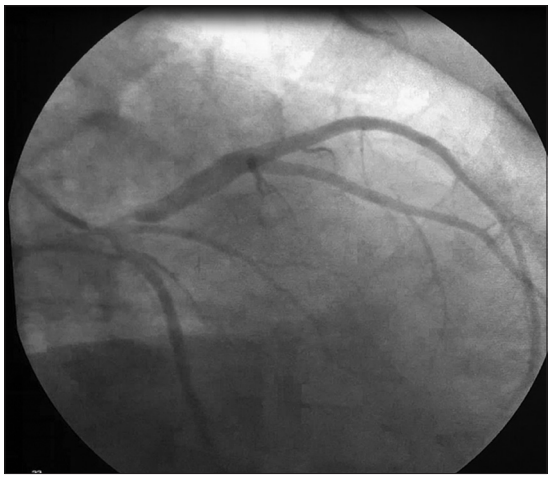

Figure 2: Coronary angiogram showed ecstatic proximal left anterior descending artery

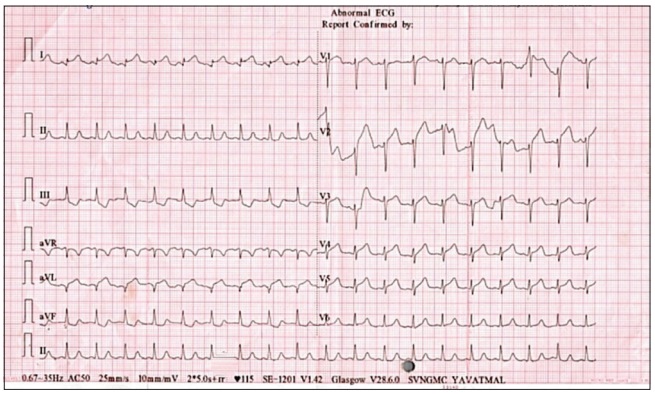

Figure 3: ECG on admission showing anterior wall MI

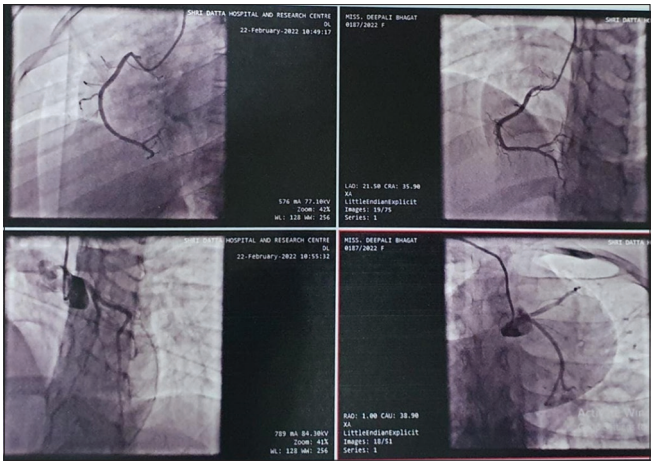

Figure 4: CAG showing normal coronaries

MI in young patients having normal coronary arteries can be due to arteritis, thrombosis, embolization, CAE or spasm, patients on oral contraceptive (OC) pills, coronary artery dissection, and anomalous coronary arteries. As is the case with venous thrombosis, coronary thrombosis can be seen in hypercoagulable states, such as protein C and protein S deficiency, antiphospholipid syndrome, or nephrotic syndrome.[2] Coronary artery spasm can cause MI in patients with cocaine abuse and also in association with alcohol binges. In some cases, the cause of MI in young patients can be the result of atherosclerotic process, which starts in early childhood.

In our male patient, CAG showed proximal LAD ectasia. The various studies by Befeler *et al.* and Alford *et al*., have defined CAE as an abnormal enlargement of one part of the coronary artery to 1.5–2 times more than the diameter of an adjacent normal segment is defined as CAE, and further, enlargement is defined as coronary artery aneurysm. CAE may be congenital or acquired. The associated diseases reported in its etiology are 50%atherosclerosis, 20–30% congenital diseases, and 10–20% inflammatory or connective tissue diseases.[3] The thinning of the vascular media layer is remarkable in the pathogenesis of atherosclerosis and ectasia. Thin vascular wall and an increased wall stress result in a vicious cycle, thus a diffuse ectasia or local aneurysm develops as a result of progressive dilatation in the coronary. CAE is mostly asymptomatic. Symptomatic cases usually emerge in the form of effort angina or rest angina. Some studies reported that ectasia caused slow blood flow, thrombus formation, and vasospasm in coronary arteries; and it could lead to an ischemic episodes without obstructive CAD.

The ischemic mechanism in patients with CAE though has not been fully understood, it is accepted that the leading cause of ischemia and angina is the impaired microvascular perfusion. It has been reported that a slow or turbulent flow in the dilated vessels resulted in thrombosis or ischemia at the ecstatic segment, leading to embolism in the distal coronary artery.[3] In our male patient, CAE is a possible mechanism for AMI.

Our second case (female patient) was taking OC pills since 1 month. Her CAG was normal, no detectable hypercoagulable state. Although lowering the dose of estrogen in combined hormonal contraceptives has reduced the risk of thrombosis, it has not eliminated it. With regard to arterial thromboembolism, Lidegaard *et al.* found relative risks of stroke of 1.60 (95% confidence interval [CI] 1.37–1.86; NNH 29 762), 1.75 (95% CI 1.61–1.92; NNH 23 810), and 1.97 (95% CI 1.45–2.66; NNH 18 409) among patients taking combined hormonal contraceptives containing EE at a dose of 20 μg, 30–40 μg and 50 μg, respectively, compared with non-users. The corresponding relative risks for myocardial infarction were found to be 1.40 (95% CI 1.07–1.81; NNH 357 143), 1.88 (95% CI 1.66– 2.13; NNH 162 338), and 3.73 (95% CI 2.78–5.00; NNH 52 329).[4]

It has been proposed that the observed difference in thrombosis risk between agents containing different progestogens is the total estrogenicity of the combined product. Estrogenicity is determined by both the dose of EE and the type of progestogen used. Sex hormone-binding globulin can be used as a marker of estrogenicity, because the hormone levels rise in states of high estrogen. Cyproterone acetate-ethinyl estradiol raises the levels of sex hormone-binding globulin by 300–400% compared with a 50% increase caused by levonorgestrel preparations, which are known to have the lowest risk of thrombosis.[4] This excessive rise in estrogenicity caused by CPA-EE likely increases the risk of thrombosis through various effects on the coagulation pathway, including reduction of the activity of various coagulation inhibitors (e.g., antithrombin, protein C, and tissue factor pathway inhibitor); increased levels of coagulation factors, including II, VII, VIII, and X; and increased platelet aggregation.[5]

Various studies of young AMI by Duvernoy *et al.* who described acute MI in two adolescents' males (14 years, 15 years) and studies by Miyayama *et al*., Maghaieth *et al*., Shahsavariet *et al*., Abid *et al*., Jaymali *et al*., Yildiz *et al*., and Chen *et al.* have described non atherosclerotic cases of AMI. All these patients are older than 20 years and only one female patient of 30 years by Abid *et al*.[2]

However, prognosis seemed to be also affected by angiographic picture and by the occurrence of revascularization. The absence of significant coronary stenosis and presence of healthy coronary arteries was associated with a better prognosis.

CONCLUSION

Although rare, considering diagnosis of AMI in teenagers presenting with chest pain can avoid catastrophe. Risk profile is different in young AMI. Our two cases have two different etiologies for AMI. One is with CAE and another with OC pills. Arterial thrombosis is less common than venous with OC pills. Our female case had suffered AMI possibly secondary to arterial (coronary) thrombosis with OC pills and to the best of our knowledge youngest female patient with AMI.

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Original Article

Corelation of Pre-operative Parameters with Conversion Rate and Duration of Post-operative Hospital Stay in Patients Undergoing Laparoscopic Cholecystectomy: A Prospective Observational Study

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Abstract

Introduction: Laparoscopic cholecystectomy (LC) continues to be the choice of treatment for cholelithiasis. Conversion to open surgery may be necessary to prevent injury (e.g. bile duct injury), treat an intraoperative complication (e.g., bleeding, bowel injury, bile duct injury), or due to failure to progress. Therefore, the aim of this study is to determine the rate of conversion to open cholecystectomy (OC) and identify the associated factors, and subsequently post-operative hospital stay.

Materials and Methods: Ethical clearance was obtained by the institute. The study was conducted in total of 311 patients, with complains of the upper abdominal discomfort and sonography diagnosis of cholelithiasis, or incidentally detected cholelithiasis on ultrasonography. A written informed consent was obtained from all the participants. The collected data was recorded in a predesigned pro forma. All $P < 0.05$ were considered to be statistically significant.

Result: The rate of conversion was 12.5% and the mean age was 48.0900 ± 14.8818 years. A higher incidence of conversion was seen among individuals in the age group of 31–60 years and 61–90 years. Women are twice as likely as men to develop gallstones. Out of 311 patients, 199 (63.98%) were female and 112 (36.01%) were male. Thirty-nine patients underwent conversion and 25 of them were female. Similarly, conversion to OC was seen to be high in patients with deranged liver function test.

Conclusion: Within the given limitations of study, we can conclude that the rate of conversion was 12.5% and the mean post-operative hospital stay in laparoscopic group was 1 day, whereas for the conversion group, it was 4 days.

Key words: Acute cholecystitis, Associations with various parameters, Conversion to open surgery

INTRODUCTION

Laparoscopic cholecystectomy (LC) continues to be the choice of treatment for cholelithiasis.[1] It has been the standard approach for symptomatic gallstones for more than two decades and is associated with improved recovery and lower morbidity.[2] It is preferred due to its safety, reliability, cost-effectiveness, negligible mortality, shorter duration of hospitalization (early return to work), better cosmesis, minimal wound complications, and temporary paralytic ileus. However, in certain situations, it might not be feasible and a surgeon may have to move to a safer choice: An open cholecystectomy (OC).[1]

LC today can be as straightforward operation, but may also be an operative approach faught with underlying complexities necessitating conversion, leading to longer operative time, longer hospital stay, and more post-operative morbidity and higher hospital costs.[3]

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Some studies have shown that certain factors are associated with an increased risk of conversion from laparoscopic to OC. These include pre-operative factors such as age, sex, body mass index >30, emergency admission, previous abdominal surgeries, history of diabetes, high white blood cell count, high alkaline phosphatase (ALP) level, high bilirubin level, and signs of acute cholecystitis on ultrasound, and intraoperative factors such as difficulty in defining the anatomy, adhesions, and increased gallbladder wall thickness.[4]

Some of these complications and several other factors can necessitate the conversion from LC to OC.[5]

Conversion to open surgery may be necessary to prevent injury (e.g., bile duct injury), treat an intraoperative complication (e.g., bleeding, bowel injury, and bile duct injury), or due to failure to progress. Several other pre-operative factors may also increase the risk of open conversion, prolonging operating time and hospital stay. Pre-operative identification would improve consent, scheduling and identify cases.[2]

Therefore, the aim of this study is to determine the rate of conversion to OC and identify the associated factors, and subsequently post-operative hospital stay.

MATERIALS AND METHODS

Study Area

General Surgery department of Apollo Multispecialty Hospitals Limited, Kolkata.

Study Population

1. Inclusion criteria – Complains of the upper abdominal discomfort and sonography diagnosis of cholelithiasis, or incidentally detected cholelithiasis on ultrasonography were included in the study.
2. Exclusion criteria – Patient voluntarily choosing to undergo OC or patient not willing to share their medical reports for evaluation purpose were excluded from the study.

Sample Size

Three hundred and eleven patients selected for the study.

Study Design

This study was prospective observational study

Study Duration

All the cases from July 2019 to June 2020.

Since the study intends to assess the corelation of pre-operative parameters with conversion rate and duration of post-operative hospital stay in patients undergoing LC. A prospective observational research design was adopted for the study.

A total of 311 patients presenting to the General Surgery department of Apollo Multispecialty Hospitals Limited, Kolkata with complains of the upper abdominal discomfort and sonography diagnosis of cholelithiasis, or incidentally detected cholelithiasis on ultrasonography were included in the study. Period of study was from July 2019 to July 2020. Before the commencement of the study, ethical clearance was obtained from the Institutional Ethical Committee. After explaining the purpose of the study, a written informed consent was obtained from all the participants. The collected data were recorded in a predesigned pro forma.

Statistical Analysis

For statistical analysis, data were entered into a Microsoft Excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables.

The significance will be calculated using mean, standard deviation, and calculated "*P*" value. The Chi-square will be used to find the correlation with selected demographic factors and the findings will be documented in tables, graphs, and diagrams and $P \leq 0.05$ was considered for statistically significant.

RESULTS AND DISCUSSION

The rate of conversion was 12.5% and the mean age was 48.0900 ± 14.8818 years. A higher incidence of conversion was seen among individuals in the age group of 31–60 years and 61–90 years as shown in Table 1. Women are twice as likely as men to develop gallstones which is highlighted in Table 2. Out of 311 patients, 199 (63.98%) were female and 112 (36.01%) were male. Thirty-nine patients underwent conversion and 25 of them were female.

Ultrasonography is the simplest, easiest, and an early tool for the evaluation of gallbladder diseases. Pre-operative USG can dictate the rate of conversion.[6] In this study, it was observed that 32 (82.1%) patients in the conversion group had a thick and edematous gallbladder wall with stone in conjunction with multiple gallbladder stones seen in 35 (89.7%) patients in the conversion group was an ideal predictor for conversion to OC as shown in Figure 1. Moreover, the presence of Common bile duct (CBD) stones seen in 21 3.85%) patients on Magnetic resonance

cholangiopancreatography (MRCP) in the conversion group as shown in Figure 2.

Among blood parameter, increased total blood count: 23 (59%) patients, along with increased neutrophil count in differentiated leukocyte count patients, were found to be significant factors contributing toward conversion of LC to OC as shown in Table 3.

Deranged pancreatic enzymes represented by Serum Amylase and Lipase did not contribute toward conversion of LC.

The following parameters were included in liver function test for this study: serum glutamic-oxaloacetic transaminase (SGOT) – 19 (48.7%) patients, ALP – 33(84.6%) patients as Respectively shown in Tables 4 and 5. Deranged

Table 1: Association between age and conversion

Age	Laparoscopic cholecystectomy	Percentage (%)	Conversion	Percentage	Total	Chi-square value	*P*-value
≤30	30	11.03	2	5.1	32	16.1655	0.0003
31–60	193	70.96	19	48.7	212		
61–90	49	18.01	18	46.2	67		
Total	272	100	39	100	311		

Table 2: Association between sex and conversion

Sex	Laparoscopic cholecystectomy	Percentage	Conversion	Percentage	Total	Chi-square value	Risk estimate	Confidence interval	*P*-value
Female	174	63.97	25	64.1	199	0.0003	0.9943	0.4940–2.0013	0.9871
Male	98	36.03	14	35.9	112				
Total	272	100	39	100	311				

Table 3: Association between TLC and conversion

TLC (/cumm)	Laparoscopic cholecystectomy	Percentage	Conversion	Percentage	Total	Chi-square value	Risk estimate	Confidence interval	*P*-value
4000–10,000	221	81.25	16	41.03	237	30.4363	6.2292	3.0718–12.6320	<0.0001
>10,000	51	18.75	23	58.97	74				
Total	272	100	39	100	311				

ALP: Alkaline phosphatase

Table 4: Association between SGOT and conversion

SGOT (U/L)	Laparoscopic cholecystectomy	Percentage	Conversion	Percentage	Total	Chi-square value	Risk estimate	Confidence interval	*P*-value
10–42 U	203	74.63	20	51.28	223	9.1662	2.7949	1.4093–5.5431	0.0024
>42	69	25.37	19	48.72	88				
Total	272	100	39	100	311				

SGOT: Serum glutamic-oxaloacetic transaminase

Table 5: Association between ALP and conversion

ALP (U/L)	Laparoscopic cholecystectomy	Percentage	Conversion	Percentage	Total	Chi-square value	Risk estimate	Confidence interval	*P*-value
42–98	162	59.55	6	15.4	168	26.7970	8.1000	3.2835–19.9816	<0.0001
>98	110	40.45	33	84.6	143				
Total	272	100	39	100	311				

ALP: Alkaline phosphatase

Table 6: Distribution of mean hospital stay

Hospital stay	Number	Mean	SD	Minimum	Maximum	Median	*P*-value
Laparoscopic cholecystectomy	272	1.2096	0.4340	1.0000	3.0000	1.0000	< 0.0001
Conversion	39	4.1026	0.3074	4.0000	5.0000	4.0000	

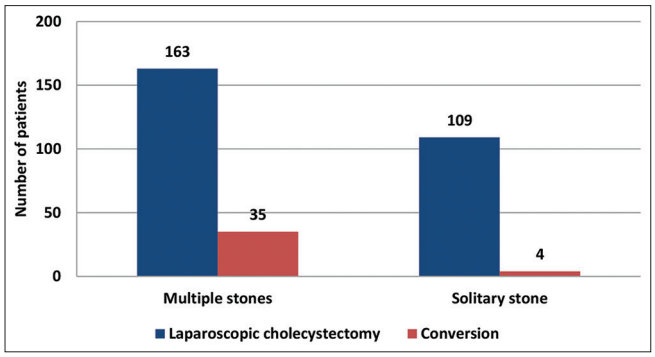

Figure 1: Association between GB stone and conversion

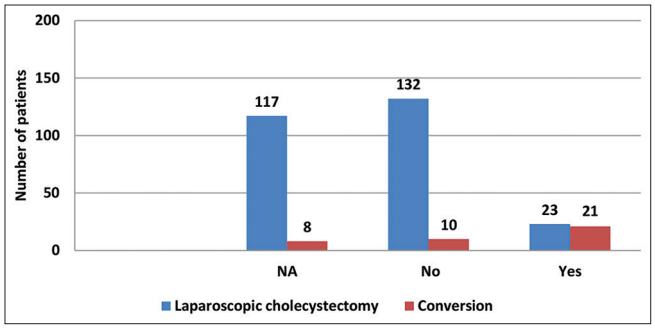

Figure 2: Association between MRCP finding (CBD stone) and conversion

value of each parameter contributed significantly and individually toward the conversion of LC to OC.

The mean post-operative hospital stay in laparoscopic group was 1.2096 days, whereas for the conversion group, it was 4.1026 days as shown in Table 6.

CONCLUSION

The rate of conversion was 12.5% and the mean age was 48.0900 ± 14.8818 years. A higher incidence of conversion was seen among individuals in the age group of 31–60 years and 61–90 years. Women are twice as likely as men to develop gallstones. Out of 311 patients, 199 (63.98%) were female and 112 (36.01%) were male. Thirty-nine patients underwent conversion and 25 of them were female. Similarly, conversion to OC was seen to be high in individuals with diabetes mellitus.

In ultrasonography, it was observed that a thick and edematous gallbladder wall in conjunction with multiple gallbladder stones was an ideal predictor for conversion to OC. Moreover, the presence of CBD stones on MRCP followed by stenting during ERCP sustainably increased the chances of conversion.

Among bloods, decreased hemoglobin, increased total blood count along with increased neutrophil count in differentiated leukocyte count, and decreased platelet count were found to be significant factors contributing toward conversion of LC to OC.

The following parameters were included in liver function test for this study: Total protein, serum albumin, total bilirubin, direct bilirubin, SGOT, SGPT, GGT, and ALP. Deranged value of each parameter contributed significantly and individually toward the conversion of LC to OC.

This finding coincided with the those of Yetkin *et al.*[7] Among 108 patients, 19 required conversion to OC and the average hospital stay period was 1.48 days for the LC group and 5.79 days for the conversion group. Studies by Kim *et al.*[6] and Peters *et al.*[8] also showed similar findings. In this study, the hospital stay of the patients that were converted was 4.1026 ± 0.3074.

The mean post-operative hospital stay in laparoscopic group was 1.2096 days, whereas for the conversion group, it was 4.1026 days.

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Original Article

Treatment and Survival of Malignant Ovarian Germ Cell Tumors: A Retrospective Single Institution Experience

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Abstract

Purpose of the Study: Malignant ovarian germ cell tumors (MOGCTs) are rare comprising <5% of ovarian tumors. We present our experience and data in MOGCT in government aided hospital, analyzing series of cases with respect to the patient characteristics, clinical profile, treatment, and survival. Since these tumors occur in young age, it affects the psychological status of the patients, but the outcome and significant disease free interval is unremarkable which is emphasized in this study as proven in similar studies.

Materials and Methods: We retrospectively analyzed the case records of patients diagnosed to have MOGCTs.

Results: Between 2012 and 2018, 41 patients were diagnosed with MOGCT. The median age was 20 years. The predominant pathology was dysgerminomas followed by yolk sac tumors, mixed germ cell tumors, and immature teratomas. Majority had either stage I or III disease. Most of the patients (*n* = 35) underwent conservative surgery, while six patients had total abdominal hysterectomy with bilateral oophorectomy. Thirty-one patients received adjuvant chemotherapy with Bleomycin, Etoposide, and Cisplatin (BEP) for three cycles. Surveillance was opted for stage I dysgerminoma and immature teratoma. Four patients had received neoadjuvant chemotherapy followed by fertility sparing surgery. After follow-up period of 24–84 (mean of 46 months), there was no evidence of disease in 37 patients. Three patients had recurrence or distant metastasis within 1 year and they were treated with second-line chemotherapy. One patient had progressive disease since she had defaulted after surgery. Disease-free survival was reasonably high and even in relapse, they are managed with salvage chemotherapy.

Conclusion: Germ cell tumor of the ovary is an adequately treatable disease and selected patients can be managed with fertility preserving surgery and adjuvant chemotherapy with BEP. Even recurrences can be managed with second-line chemotherapy resulting in good response.

Key words: Adjuvant chemotherapy, Fertility sparing surgery, Malignant ovarian germ cell tumors

INTRODUCTION

Malignant ovarian germ cell tumors (MOGCTs) arise from the primordial germ cell of the ovary and are rare comprising <5% of ovarian cancer.[1] The incidence is common in young females especially in the second and third decade.[1] MOGCT is classified into dysgerminoma and non-dysgerminomas which include yolk sac tumor (endodermal sinus tumor), immature teratoma, embryonal cell carcinoma, polyembryoma non-gestational choriocarcinomas, and mixed germ cell tumor (GCT).[2] Most MOGCT presents at earlier stage. Patients with Stage I have excellent prognosis with long-term disease-free status of more than 90%.[3] Even in advanced stage, the survival rates are considerable ranging from 60% to 80%. The presentation of MOGCTs may vary from pelvic pain which may be acute or subacute, menstrual irregularities, or abdominal mass. Evolution of management for MOGCT with conservative surgery and Cisplatin-based chemotherapy has dramatically improved the survival and preservation of fertility, especially in young patients.

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With Bleomycin, Etoposide, and Cisplatin (BEP), the 5-year survival has considerably increased to 100% for dysgerminoma and 85% for non-dysgerminomas.[4-6] Most of the patients resume their normal menstrual cycle and become pregnant after the entire treatment.[7,8] Stage Ia and grade 1 immature teratoma and Stage I a dysgerminoma do not require adjuvant chemotherapy after surgery[3] and can be kept under surveillance. In this paper, we have analyzed our experience of MOGCT including clinicopathological features, treatment, and outcomes.

MATERIALS AND METHODS

All patients with malignant ovarian cell tumors registered in our medical oncology department from January 2012 to December 2018 for 6 years were included and retrospectively reviewed. The data were retrieved from the medical record books and hospital-based cancer registry. The data collected included the age, presenting symptoms, details of investigations including imaging, tumor markers, treatment received (neo-adjuvant chemotherapy, surgery and adjuvant chemotherapy, and histopathological diagnosis were documented. The tumors were staged according to the Federation of Gynecology and Obstetrics staging system. The follow-up details were analyzed to record the data regarding resumption of menstrual cycles, ability to conceive in the patients who were eager for the same following fertility sparing surgery. The disease-free interval was derived. Five patients who had lost for follow-up were contacted through phone. Out of them one patient could not be contacted for recent updates. In majority of the patients, surgical procedure done was staging Laparotomy and unilateral salpingo-oophorectomy or total abdominal hysterectomy with bilateral salpingo-oopherectomy in patients who had advanced disease at presentation or completed their family due to the patient's preference. Peritoneal biopsies, omentectomy, and peritoneal washings were performed in those patients, where disease extended to the abdomen. The adjuvant chemotherapy offered was BEP given every 3 weeks with Inj. Bleomycin 30 units IV bolus given on days 1, 8, and 15, Inj. Etoposide 100 mg/m^2 IV infusion on days 1–5 and Inj Cisplatin 20 mg/m^2 IV infusion on days 1–5 with appropriate prehydration, premedications, and posthydration for 3–4 cycles depending on the risk stratification. Neoadjuvant chemotherapy with BEP was offered in few patients who were that the disease was inoperable or extensive/bulky disease. Salvage chemotherapy was administered with VIP every 3 weeks with Etoposide 75 mg/m^2 IV infusion, Ifosphamide 1500 mg/m^2 IV infusion with mesna days 1–5, and Cisplatin 20 mg/m^2 IV infusion days 1–5. All statistical analysis were performed using the Statistical Package for the Social Science, version 17 for Microsoft windows. Descriptive statistics was presented as numbers and percentages. The data were expressed as mean and standard deviation. A Chi-square test was used for comparison between two attributes. Kaplan–Meier survival analysis was used for analysis of disease-free interval and overall survival (OS). A two-sided $P < 0.05$ was considered statistically significant.

RESULTS

Patient's Characteristics

The patient's age ranged between 9 and 65 years with a median age of 20 years. There was only one patient who was 65 years and post-menopausal. Two patients were in prepubertal age. With regard to the clinical features, abdominal pain was the most common symptom which was either acute or chronic. One patient aged 17 years presented with the primary amenorrhea and she was found to be syndrome 45,X. Four patients (9.8%) were incidentally diagnosed to have ovarian masses during pregnancy. Two patients (4.9%) presented with secondary infertility. Twenty-eight patients were unmarried (68.3%). Of the 13 women (31%) who were married, nine patients (22%) had completed their family. The patients' characteristics are enumerated in Table 1.

Disease characteristics

The most predominant pathology was dysgerminoma followed by equal distribution of yolk sac tumors and mixed GCT's. Immature teratoma was less observed. Most of the patients had unilateral disease, but three patients with dysgerminoma had bilateral disease. Majority were documented as Stage I followed by Stage III. Moreover, only two of them had Stage IV at presentation. Disease characteristics are enlisted in Table 2. Two patients had ascites and abdominal nodes diagnosed in the initial imaging and one patient had pleural effusion at presentation. All the ten cases of yolk sac tumors had significantly elevated serum Alphafetoprotein (AFP) levels (levels varying from 380 ng/ml to 190,000 ng/ml. 5/10 patients with

Table 1: Characteristics of patients with malignant ovarian germ cell tumors

Patient characteristics	No. of patients (%)
Total	41 (100)
Median age (range) years	20 (9–65)
Presentation	
Acute or subacute abdominal pain	19 (46.3)
Abdominal distention	9 (22)
Amenorrhea	2 (4.9)
Pregnancy	4 (9.8)
Infertility	2 (4.9)
Menstrual irregularity	5 (12.2)

mixed GCT also had raised S.AFP. 11/15 patients with dysgerminoma had raised serum lactate dehydrogenase.

Treatment Characteristics

Majority of them (n = 35, 85.4%) underwent unilateral salpingo-oopherectomy, conservative surgery with preservation of opposite ovary and uterus. Rest had total abdominal hysterectomy with bilateral oopherectomy. Thirty-one patients (75.6%) received adjuvant chemotherapy with BEP for three cycles. The patients who had Stage IA dysgerminoma and grade 1 and Stage IA immature teratoma did not receive chemotherapy and were kept under surveillance. Four patients had received neoadjuvant chemotherapy with three cycles of BEP due to advanced disease and then were amenable to fertility-preserving surgery, and postoperatively, there was no residual disease in the pathological specimen. The treatment details are given in Table 3.

Follow-Up

The follow-up period ranged from 24 to 84 (mean of 46 months), there was no evidence of disease in 37 patients. Three patients had recurrence within 1 year and they had advanced disease at presentation. One patient with yolk sac tumor presented with mediastinal and mesenteric lymphnodes after 9 months. The next patient who had mixed GCT presented with pericardial effusion. One patient with mixed GCT presented with metastases in the lung. The patients with recurrent disease received salvage chemotherapy with VIP regimen. Of them, one of the patient lost for follow-up and two were alive in their last follow-up. One patient with immature teratoma had residual disease postoperatively and finally had progressive disease since she had delayedly presented for adjuvant chemotherapy. She was started on salvage chemotherapy with VIP regimen. She lost for follow-up and died due to progressive disease. The follow-up and outcome data are enumerated in Table 4.

In our study, 34 patients resumed their regular menstruation. The mean time to resume their periods was 4 months from the time of their last chemotherapy. Excluding the six patients who had total abdominal hysterectomy, and 20 who were still unmarried on follow-up, 15 patients who were planning for pregnancy had conceived. One of the two patients who were in the pre pubertal age attained their menarche. Out of the four patients who were pregnant in their first trimester, three patients completed their treatment and delivered normal healthy babies after completing their gestation period. The other patients had preterm delivery at 26 weeks and the baby succumbed to death.

Survival Analysis

Disease-free survival (DFS) and OS were analyzed and the Kaplan–Meier survival curves were plotted. The

Table 2: Disease characteristics in the patients

Pathology	No. of patients (%)
Dysgerminoma	15 (36.6)
Yolk sac tumor	10 (24.4)
Immature teratoma	6 (14.6)
Mixed GCT	10 (24.4)
Stage	
I	21 (51.2)
II	5 (12.2)
III	13 (31.7)
IV	2 (4.9)

Table 3: Treatment given to the patients

Treatment received	No. of patients (%)
Surgical treatment	
Fertility sparing surgery	35 (85.4)
TAH/BSO	6 (14.6)
Chemotherapy	
Adjuvant chemotherapy/BEP	31 (75.6)
Neo adjuvant chemotherapy/BEP	4 (9.8)
No chemotherapy/surveillance	6 (10.6)
Salvage chemotherapy in recurrence	4/4

Table 4: Treatment outcome on follow-up

Outcome	No. of patients (%)
No evidence of disease	37 (90.2)
Disease Recurrence/metastatic disease	3 (7.3)
Disease, progression/delayed chemotherapy	1 (2.4)

OS rate for the entire cohort is 95.3% [Figure 1] and the DFS for 2 years is 92.5%. There was no significant difference in survival between patients who had fertility sparing surgery versus TAH/BSO (P = 0.361). The survival rate for dysgerminoma, yolk sac tumor, immature teratoma, and mixed GCT was 100%, 100%, 90%, and 90%, respectively, but there was no significant survival difference between the various histologies (P = 0.276). This survival curve is illustrated in Figure 2. The survival for Stages I, II, III, and IV was 100%, 87%, 84%, and 82%, respectively.

DISCUSSION

MOGCTs comprise a minor spectrum among the ovarian malignancies, their immense response after surgery and chemotherapy better long-term survival rates soars their importance. In our retrospective study, for 6 years from January 2012 to December 2018 which includes 41 patients, we have analyzed the epidemiological, disease, treatment characteristics, and their impact on disease-free and OS. At our hospital, the annual incidence of MOGCTs was approximately on average six cases per annum constituting 3–4% of the all ovarian tumors which

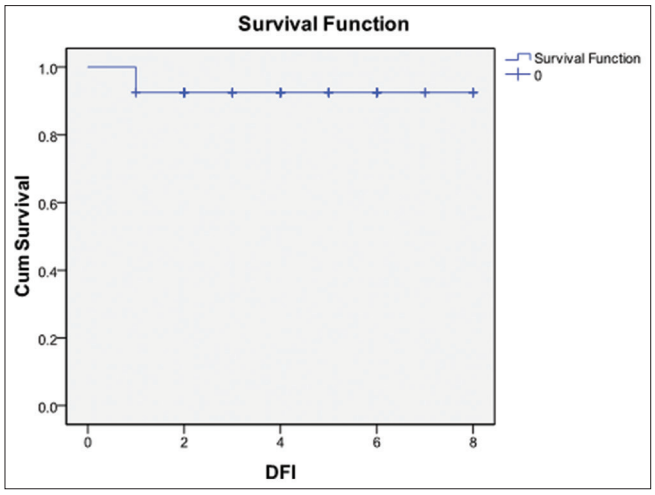

Figure 1: Disease-free survival for 2 years of our patients

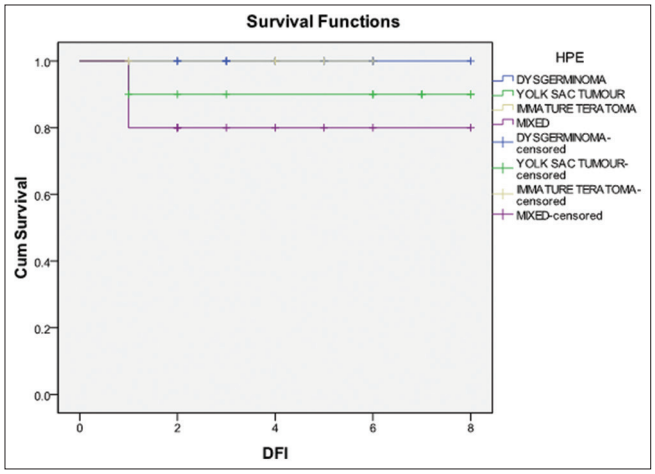

Figure 2: Disease-free survival for various histologies

are almost in par with the data given by Smith *et al*.[1] In our series, the median age is 20 years and most of the patients are in the second and third decade.[9] In this study, dysgerminoma comprises about 36.6 % (n = 15) which coincides with the Indian data. The predominant stage grouping in our retrospective cohort was stage I (n = 21, 51.2%). Out of this, there were six patients who did not receive chemotherapy. They were diagnosed as Stage I dysgerminoma and Stage I grade 1 immature teratoma and it is well established that surveillance is the management for the same. ESMO and NCCN also advocate that Stage IA pure dysgerminoma can be treated with surgery only. Recurrence rate following only surgery in the early stage is low (15–25%) and can be treated at the time of relapse with a high probability of cure.[3] In our series of patients, 35 (85.4%) had fertility sparing surgery that is unilateral salpingo-oopherectomy. Evidence is already there that conservative surgery does not increase risk of progression or any events.[10] Three out of four patients who had received neoadjuvant chemotherapy for advanced disease have also undergone conservative surgery. In view of the incidental age group of MOGCTs and established evidence of chances of fertility after treatment, emphasis should done for conservative surgery.[11] Adjuvant chemotherapy with BEP was administered in 31 patients (75.6%) which has been established earlier in number of trials.[4-6] Thirty-four of 35 patients resumed normal menstrual cycles after chemotherapy in a median period of 4 months. Recent studies have also reported that 80–90% of patients achieved a normal menses after fertility sparing surgery followed by chemotherapy.[12-14] Thirteen out of 15 patients who were eager to conceive were able to become pregnant. Many of our patients who were in second decade were still unmarried on follow-up. Recurrence occurred in only three patients which suggest its good prognosis.

Due to its rare incidence, the sample size in this study is also small to analyze the survival among our patients.

CONCLUSION

GCTs are typically occurring in younger girls and women with definite longevity of life after appropriate and adequate treatment with revival of fertility and menstrual functions in most of the individuals. Emphasis should be suggested to the patients on long-term follow-up also.

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Original Article

Comparative Study on Transcervical Foley's Catheter and Intracervical PGE_2 Gel for Cervica Ripening for Induction of Labor

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Abstract

Introduction: Induction of labor (IOL) is a common obstetric intervention. It involves the use of mechanical or pharmacological methods to achieve cervical ripening, regular contractions, cervical dilatation, and subsequent delivery. Therefore, we decided to compare the efficacy of transcervical Foley's catheter and intracervical PGE_2 gel in cervical ripening for IOL.

Aims and Objectives: Aim of our study was to compare the efficacy of transcervical Foley's catheter and intracervical PGE_2 gel (0.5 mg) in cervical ripening for successful IOL.

Materials and Methods: This was a prospective case control study comprising 200 antenatal cases (ANC) admitted to labor ward for IOL. The ANC were divided into two groups, with one group of 100 pregnant women (cases) subjected to IOL by transcervical insertion of Foley's catheter while the second group of 100 pregnant women (controls) received intracervical PGE_2 for IOL. It was conducted in Department of Obstetrics and Gynaecology, M.K.C.G Medical College and Hospital, Berhampur, Odisha from October 2015 to September 2017. The following outcomes were studied: Maternal outcomes including maternal side effects, Labor Complications, Mode of delivery whether vaginal or cesarean section, need for augmentation, induction to delivery interval and neonatal outcomes including still or live birth, APGAR score at 5 min and neonatal intensive care unit admission and cost of the procedure.

Results: There was no statistically significant difference in terms of majority of maternal outcomes between cases and controls except for induction to delivery interval which was significantly shorter in PGE_2 gel. There was also no statistical significance between two groups in terms of neonatal outcomes. Foley's catheter was cost effective when compared to PGE_2 gel.

Conclusion: Both Foley's catheter and PGE_2 gel proved to be equally effective methods for pre-induction ripening for unfavorable cervix with comparable results.

Key words: Cervical ripening and induction of labor, Intracervical PGE_2 gel, Transcervical Foley's catheter

INTRODUCTION

Over the past several decades, obstetricians are fascinated with the process of parturition. Over the years, various professional societies have recommended the use of induction of labor (IOL) in circumstances in which the risks of waiting for the onset of spontaneous labor were judged to be greater than the risks associated with shortening the duration of pregnancy by induction. Although current guidelines do not recommend this, IOL is being used more and more at the request of pregnant women to shorten the duration of pregnancy or to time the birth of the baby according to the convenience of the mother and/or healthcare workers.[1,2]

In the course of a normal pregnancy, softening and dilatation of the cervix are the result of complex of biochemical reactions including decreased collagen and glycosaminoglycan concentrations as well as increased water content. This, in turn, results in a cervix favorable for normal or induced labor. In a normal pregnancy, these changes accelerate toward the end of the pregnancy and pave way for spontaneous labor. When this process fails at term, cervix must be ripened through artificial means.[3]

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The role of cervical ripening in success of IOL is well established, an unripe cervix is associated with high risk of induction failure, failure to progress in labor, cesarean section, infections, fetal distress, and postpartum hemorrhage.[4-6] When the cervix is ripe, induction of labor is done by artificial rupture of membrane (ARM) and intravenous Oxytocin. Numerous techniques have been used to ripen the unfavorable cervix to achieve the changes necessary for labor. At present, pharmacological and mechanical agents are used to modify the cervical status. Non-pharmacologic approaches for cervical ripening and labor induction have included herbal compounds, castor oil, hot baths, enemas, sexual intercourse, breast stimulation, acupuncture, acupressure, transcutaneous nerve stimulation, mechanical, and surgical modalities.

IOL has previously been considered to increase the rate of caesarean section, but more recent research demonstrates that IOL is in fact associated with a decrease in caesarean section rates compared to expectant management at or beyond term.[7-11]

As per NICE clinical guideline 70 (2008), the most common method of pre-induction cervical ripening is pharmacological, with the administration of prostaglandin E_2 (PGE_2) intravaginaly or intracervically. Rath *et al.* (1993) revealed that PGE_2 work through increasing collagenase and proteinase activity within the cervix with a resultant fall in collagen concentration, allowing dilatation. Clinically, when compared to placebo or no treatment, IOL with PGE_2 pre-ripening is more likely to result in cervical change and achievement of vaginal delivery within 24 h. Prostaglandin preparations used for cervical ripening are expensive and unstable, requiring refrigerated storage. Feasibility to use prostaglandins was found to be limited largely due to its higher cost and inadequate infrastructure to maintain the narrow temperature range to keep its potency.[12-14]

Mechanical method in IOL is most commonly the insertion of extra-amniotic transcervical Foley's catheter. Lin *et al.* (2007) revealed that this method generated a change in cervical condition through both a direct mechanical dilatation and stretch induced release of endogenous prostaglandins.

Recent Cochrane review has concluded that IOL using mechanical methods such as Foley's catheter results in similar caesarean section rates to prostaglandins and yields a lower risk of hyper stimulation with or without fetal heart rate changes compared to prostaglandins. When compared with oxytocin, mechanical methods reduce the risk of caesarean section. Mechanical methods are as effective in achieving delivery within 24 h of intervention as any prostaglandins. According to the limited data available, there is no evidence of an increased risk of infectious morbidity with mechanical methods. Foley's catheter for cervical ripening is a far cheaper option than prostaglandin in terms of medication or device cost. The latter method also incurs significant additional cost in monitoring the maternal and fetal well-being during the process. Therefore, Foley's catheter is a logical option to consider in limited resource settings with a relative lack of monitoring facilities.[15,16]

Aims and Objectives

The aim of our study was to compare the efficacy of transcervical Foley's catheter and intracervical PGE_2 gel (0.5 mg) in cervical ripening for successful IOL.

MATERIALS AND METHODS

This was a prospective case control study comprising 200 antenatal cases (ANC) admitted to labor ward for IOL. The study was conducted in the Department of Obstetrics and Gynaecology, M.K.C.G Medical College and Hospital, Berhampur, Odisha from October 2015 to September 2017 after obtaining approval from Institute Ethics Committee and informed written consent from the subjects. The following outcomes were studied: Maternal outcomes including maternal side effects, labor complications, mode of delivery whether vaginal or caesarean section, need for augmentation, induction to delivery interval and neonatal outcomes including still or live birth, APGAR at 5 min, and neonatal intensive care unit (NICU) admission and cost of the procedure.

Inclusion Criteria

Subjects who fulfilled the following criteria were included in the study:

i. Pregnant women with gestational age between 37 and 42 weeks
ii. Singleton pregnancy
iii. Primigravida or multigravida
iv. Vertex presentation
v. Age above 18 years
vi. Modified bishop's score <6.

Exclusion Criteria

Subjects who fulfilled the following criteria were excluded from the study:

i. Pregnant women with gestational age <37 weeks and more than 42 weeks
ii. Multiple pregnancy
iii. Non vertex presentation
iv. Antepartum hemorrhage
v. Premature rupture of membranes
vi. Modified bishop's score >6.

The ANC were divided into two groups, with one group of 100 pregnant women (cases) subjected to cervical ripening and IOL by transcervical insertion of Foley's catheter while the second group of 100 pregnant women (controls) received intracervical PGE_2 (0.5 mg) gel for IOL.

Cases

Patient was placed in dorsal position. Under aseptic precautions, sim's speculum was placed in posterior vaginal wall and retracted. Anterior lip of cervix was held with sponge holder. Foley's catheter of No.18 was inserted directly into endocervical canal beyond internal os extra amniotically and inflated with 30 ml distilled water. Catheter was taped on medial aspect of thigh by traction.

Fetal heart rate and uterine contraction were monitored, if no abnormalities were detected then patient was allowed to ambulate. Foley's catheter if spontaneously expelled, modified bishop's score was reassigned. Immediately following such expulsion or alternatively when the modified bishop's score attained a value of ≥6, for acceleration of labor the membranes were ruptured artificially or oxytocin was begun if necessary.

If not expelled in 12 h, catheter was adjusted to maintain continuous traction. Once again modified bishop's score was reassigned after 12 h. Cases were taken as failure if patient was not in active labor within 24 h.

Controls

After assigning modified bishop's score, sterile sim's speculum was introduced into vagina. Cervix and upper vagina were examined. Excess mucus was removed.

Anterior lip of cervix was held with sponge holder. About 0.5 mg of PGE_2 gel was administered intracervically. Patient was instructed to lie in left lateral position following gel administration for half an hour. Fetal heart sound and uterine contractions were monitored and then patient was made to ambulate. After 6 h, per vaginal examination was done and modified bishop score was reassigned.

If modified bishop's score was not favorable 12 h after the first dose, second dose of 0.5 mg PGE_2 gel was administered. Women received maximum of 2 doses only. When modified bishop's score attained a value of ≥6, for acceleration of labor the membranes was ruptured artificially or oxytocin was begun if necessary. Oxytocin was given 4 h after the last dose of PGE_2 gel. Controls were taken as failure if patient was not in active labor within 24 h.

For both groups, maternal pulse rate, blood pressure, temperature, and fetal heart rate were monitored. Frequency and duration of uterine contraction were assessed for regular uterine contraction and uterine tachysystole (>5 contractions per 10 min averaged over 30 min).

Any subjective adverse effects reported by patient sich as pain, nausea, and vomiting were also recorded. Inj. Tramadol (100 mg) or Inj. Pentazocine (30 mg) for pain relief was given on maternal request.

Need for augmentation of labor was done by methods such as ARMs, oxytocin drip, or both.

Statistical Analysis

Differences between the case and control groups were evaluated using student '*t*' test and Chi-square test. Statistical significance was deemed at a $P < 0.05$ with the confidence limit of 95%.

RESULTS

As shown in Table 1, there was no difference between cases and controls with respect to age group. The *P* value is not significant ($P = 0.569$). As shown in Table 2, there was no difference between cases and controls with respect to gravidity status. The *P* value is not significant ($P = 0.560$). As shown in Table 3, there was no difference between cases and controls when pre-induction modified bishop's score was compared between the two groups. The *P*-value

Table 1: Age matching

Age group (years)	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
18–21	17	23	0.569
>21–25	53	49	
>25–30	30	28	
Total	100	100	

Table 2: Gravidity status

Gravidity status	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
Primigravida	64	60	0.560
Multigravida	36	40	
Total	100	100	

Table 3: Pre-induction modified bishop's score.

Pre-Induction modified Bishop's Score	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
1	22	25	0.770
2	28	29	
3	24	20	
4	12	16	
5	14	10	
Total	100	100	

is not significant ($P = 0.770$) by Chi-square test. As shown in Table 4, there was no difference between cases and controls in terms of reason for induction. The *P* value is not significant ($P = 0.641$). Hence, the cases (subjects undergoing induction by transcervical Foley's catheter) and controls (subjects undergoing induction by intracervical PGE_2) in our study were comparable in terms of maternal age, gravidity status, pre-induction modified bishop's score, and reasons for IOL.

Maternal Outcomes

As given in Table 5, in terms of maternal side effects, 17% of cases and 26% of controls had side effects and 83% of cases and 74% of control group did not have maternal side effects. The difference between the cases and controls was not statistically significant ($P = 0.1214$). As given in Table 5, labor complications were present in only 12% of cases and absent in remaining 88% of cases. Among the controls, labor complications were present in only 16% of cases and absent in remaining 84% of cases. The difference between the cases and controls was not statistically significant ($P = 0.4150$). As given in Table 5, vaginal delivery was seen in 80% of cases and 68% of controls. The difference between the cases and controls was not statistically significant ($P = 0.0531$). As given in Table 5, cesarean section was done in 20% of cases and 32% of controls. The difference between the cases and controls was not statistically significant ($P = 0.0531$).

As shown in Table 6, there was no difference between cases and controls with respect to need for augmentation. The *P* value is not significant ($P = 0.763$).

Table 4: Reason for induction

Reason for induction	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
Pregnancy induced by hypertension	46	52	0.641
Oligohydramnios	24	26	
Intrauterine growth retardation	19	14	
Bad obstetric history	11	08	
Total	100	100	

As shown in Table 7, there was a statistically significant difference between cases and controls in induction to delivery interval. The *P* value is significant ($P = 0.047$).

Neonatal Outcomes

As shown in Table 8, live birth was seen in all the 100 cases and 100 controls, no still births were present in both the groups. The difference between the cases and controls was not statistically significant ($P = 1.000$). As shown in Table 8, APGAR score at 5 min of <7 was observed in only 5% of cases and 6% of controls. This difference is statistically insignificant ($P = 0.7564$). As shown in Table 8, NICU admission was seen among 14% of neonates of cases and 17% of neonates of controls. The difference between the cases and controls was not statistically significant ($P = 0.5578$).

As shown in Table 9, the cost of Foley's catheter (Rs.180) is lesser when compared to PGE_2 gel (Rs.240).

DISCUSSION

Maternal Outcomes

In our study, as shown in Figure 1, maternal side effects were less in Foley's catheter group (17%) when compared to PGE_2 group (26%). However, the difference between the two groups is statistically insignificant ($P = 0.1214$). This is contrary to studies done by Baloch *et al.*[17] which revealed more side effects in PGE_2 group compared to Foley's catheter group. However, similar results to our study were seen in studies done by Alam and Ahmed[18]

As shown in Figure 2, labor complications were less in cases (12%) when compared to controls (16%). This finding of ours is similar to observations seen in a study done by Baloch *et al.*[17]

As shown in Figure 3, in our study vaginal delivery was seen in 80% of Foley's catheter group and in 68% of PGE_2 gel group. However, the difference between the two groups was statistically insignificant. Our study results were in accordance with studies done by Anupma *et al.*[19]

As shown in Figure 4, in our study, cesarean section was done in 20% of cases and 32% of controls. However, the difference

Table 5: Maternal outcomes

Parameter	Cases (induction by Foley's Catheter)			Controls (induction by PGE_2 gel)			*P*-value
	Present	Absent	Total	Present	Absent	Total	
Maternal side effects	17	83	100	26	74	100	0.1214
Labor complications	12	88	100	16	84	100	0.4150
Vaginal delivery	80	20	100	68	32	100	0.0531
Cesarean section	20	80	100	32	68	100	0.0531

Table 6: Maternal outcome-need for augmentation

Need for augmentation	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
Only ARM	22	20	0.763
Only oxytocin	27	34	
ARM+Oxytocin	40	36	
None	11	10	
Total	100	100	

Table 7: Maternal outcome-induction to delivery interval

Induction to delivery interval (h)	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
<12	22	38	0.047*
>12–24	66	52	
>24	12	10	
Total	100	100	

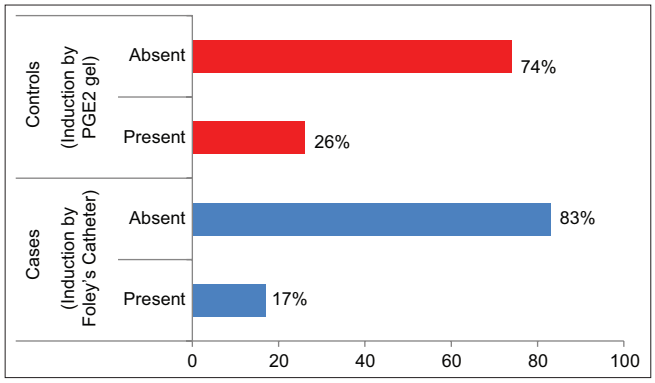

Figure 1: Maternal side effects

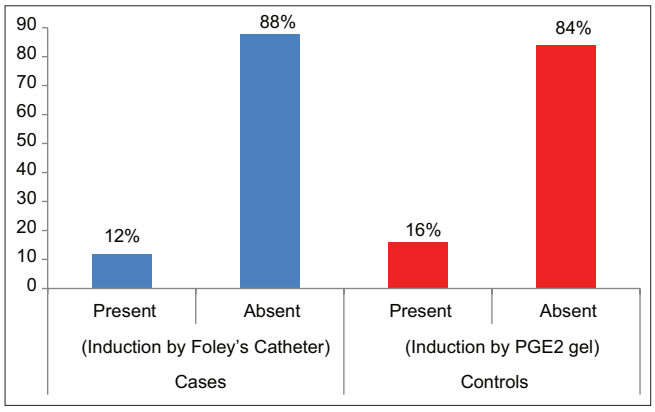

Figure 2: Labour complications

between the cases and controls was not statistically significant. Our study results were in accordance with studies done by Alam and Ahmed,[18] Anthony *et al.*,[20] and Pennell *et al.*[15]

In our study, in terms of need for augmentation of labor, as shown in Figure 5, 27 cases and 34 controls needed only oxytocin, while 22 cases and 20 controls needed only

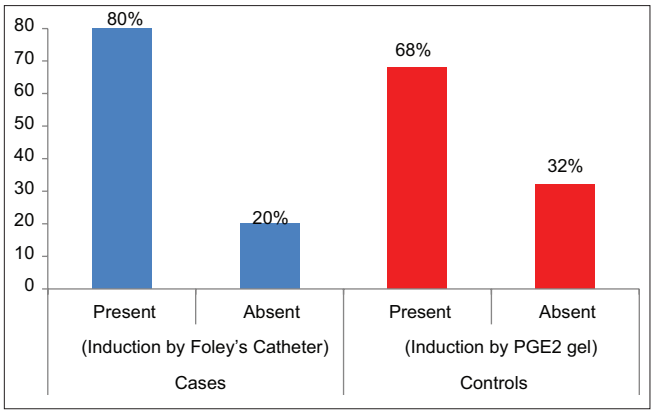

Figure 3: Vaginal delivery

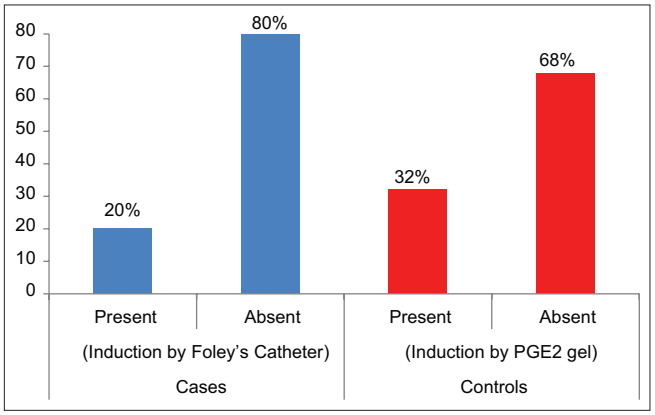

Figure 4: Cesarean section

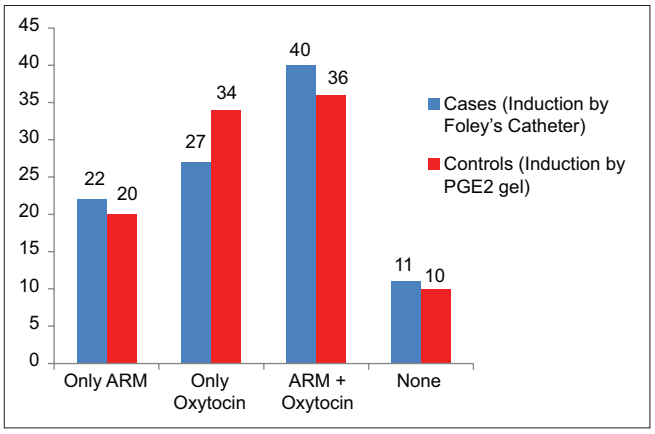

Figure 5: Need for augmentation

ARM and 40 cases and 36 controls needed both ARM and oxytocin for augmentation of labor. There was no need for augmentation in 11 cases and 10 controls. However, these differences were not statistically significant between cases and controls. Our study results were in accordance with studies done by Anupma *et al.*[19]

As shown in Figure 6, when comparing induction to delivery interval between two groups, induction to delivery interval was more in cases when compared to controls.

Table 8: Neonatal outcomes

Parameter	Cases (induction by Foley's Catheter)			Controls (induction by PGE_2 gel)			*P*-value
	Present	Absent	Total	Present	Absent	Total	
Still birth	0	100	100	0	100	100	1.000
APGAR score at 5 min (<7)	05	95	100	6	94	100	0.7564
Neonatal intensive care unit (NICU admission)	14	86	100	17	83	100	0.5578

Table 9: Cost of induction

Parameter	Cases (induction by Foley's catheter)	Controls (induction by PGE_2 gel)
Cost of induction (in INR)	180	240

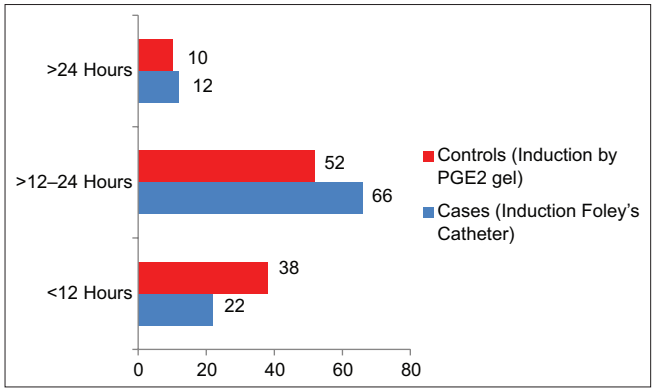

Figure 6: Induction to delivery interval

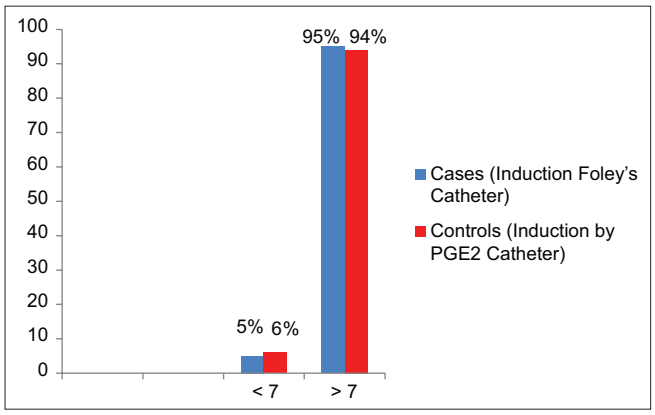

Figure 7: APGAR at 5 min

The difference between the two groups was statistically significant. Our study results were in accordance with studies done by Jozwiak *et al.*[16] and Kadam *et al.*[21]

Neonatal Outcome

As shown in Figure 7, in our study, data revealed that 5% of cases and 6% of controls had APGAR score at 5 min of <7. Hence, there is no statistically significant difference between Foley's catheter group and PGE_2 gel group in terms of APGAR score at 5 min. As shown in Figure 8, all the babies were born alive; there were no still births in both the groups. As shown in Figure 9, in our study, NICU

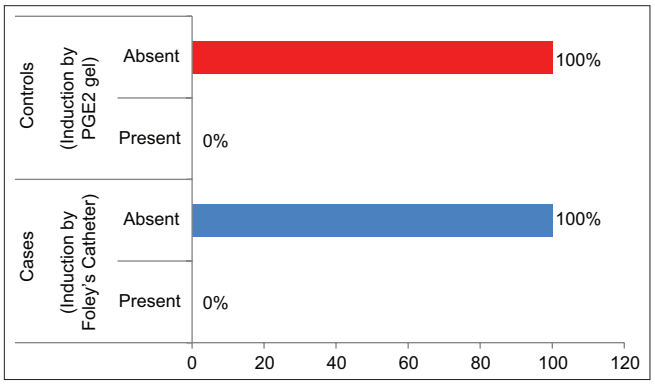

Figure 8: Still birth

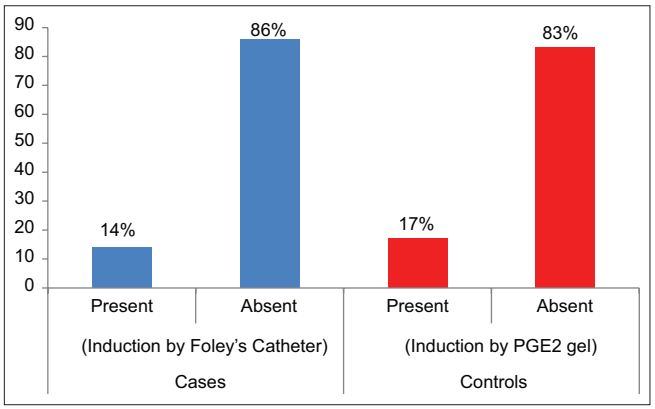

Figure 9: Neonatal intensive care unit admission

admission was seen in 14% of cases and 17% of controls. This meager increase of 3% among PGE_2 group had no statistical significance when compared to Foley's catheter group. All these neonatal outcomes were similar to studies done by Anupma *et al.*[19]

The average cost of induction was more in PGE_2 group (Rs.240) when compared to Foley's catheter group (Rs.180). This was consistent with studies done by Dewan *et al.*[22] Dahiya *et al.*,[23] and Dharmavijaya *et al.*[24]

CONCLUSION

Majority of the outcomes between the two groups were comparable and similar except for the induction to delivery interval. This duration was shorter for PGE_2 group when compared to Foley's catheter group. However, this outcome

alone does not make PGE_2 better than Foley's catheter in cervical ripening for IOL. In light of these results, in terms of maternal and neonatal outcomes in our study, we conclude that both Foley's catheter and PGE_2 gel had proved to be equally effective methods for pre-induction ripening for unfavorable cervix.

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Original Article

Autopsy Findings of Myocardium in Correlation with Coronary Arteries in Cases of Sudden Cardiac Deaths

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Abstract

Background: The most common autopsy findings in cases of sudden and unexpected deaths are cardiac wall and coronary artery changes. Therefore, cardiac autopsy is conducted to study various histomorphological changes in normal and diseased heart, as it remains the main diagnostic tool.

Aims: The aim of the study is to find the changes in cardiac wall as well as coronary arteries in all postmortem received hearts in different age groups.

Materials and Methods: A retrospective study of 216 postmortem hearts received from August 2020 to February 2022 in the Department of Pathology, GMERS Medical College, Sola, and Sola Civil Hospital, Ahmedabad.

Results: There are discrepancies in findings of heart wall in correlation with coronary artery findings. The age group of 3–39 years shows 9 discrepancies (9%), age group of 40–59 shows 6 discrepancies (7.4%) while there is no any discrepancy in the age group of 60–99.

Conclusion: During macroscopic and microscopic examination of a postmortem hearts, it is particularly important to discover the causes of the wall and artery changes effectively for the proper identification of cause of the death.

Key words: Autopsy, Cardiac wall, Coronary artery

INTRODUCTION

Cardiovascular disease continues to be the most common cause of sudden and unexpected deaths.[1]

Despite advances in therapy, mortality rates remain high, with annual rates of 10–20% in patients with moderately severe-to-severe failure. Sudden unexpected death constitutes 30–50% of all deaths.[2]

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Therefore, cardiac autopsy is conducted to study various histomorphological changes in normal and diseased heart, as it remains the main diagnostic tool.[3,4]

Coronary artery disease, ischemic heart disease, cardiomyopathy, valvular heart disease, and congenital heart disease can be the possibilities of sudden cardiac death. These diseases are frequently concealed and discovered with postmortem by means of a thorough macroscopic and microscopic investigation.[5,6]

MATERIALS AND METHODS

The study was done from August 2020 to February 2022 in the Department of Pathology, GMERS Medical College, Sola, and Sola Civil Hospital, Ahmedabad.

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This study included a total of 216 postmortem hearts received in the department of pathology.

Inclusion Criteria

All postmortem hearts received in the pathology department were included in the study.

Exclusion Criteria

All postmortem hearts which were autolyzed ($n = 22$) were excluded from the study.

The following variables were considered: Sex, age, medical history, and autopsy findings to macroscopic and histological evaluation of the heart. The autopsies were performed according to standard techniques. In all subjects, the heart was dissected and grossed following standard autopsy protocol.

Heart tissue sections were processed and stained with hematoxylin and eosin and reviewed by pathologist.

For sake of analysis, patients were divided in the age groups of <2 years, 3–39 years of young adults, 40–59 years group of middle-aged adults, and 60–99 years group of old adults.

RESULTS

A total of 216 postmortem hearts were received in autopsy section of pathology department, out of which 22 autolyzed postmortem hearts were excluded from the study.

The hearts of remaining 194 postmortem hearts were examined and taken into consideration.

As Table 1 shows, age group 3–39 years comprise maximum number of autopsies ($n = 90$) followed by age group 40–59 years ($n = 81$) and lastly age group 60–99 years ($n = 23$).

Table 1: Age group wise distribution

Age group	No. of autopsies (%)
3–39	90 (46.39)
40–59	81 (41.75)
60–99	23 (11.85)
Total	194

As per Table 2, there are discrepancies in findings of heart wall in correlation with coronary artery findings. The age group of 3–39 years shows 9 discrepancies (9%), age group of 40–59 shows 6 discrepancies (7.4%) while there is no any discrepancy in the age group of 60–99.

Among nine cases of discrepancies in the age group of 3–39 years, there are five cases in which coronary arteries show mild atherosclerosis while heart walls show change of myocardial infarction. There are four cases in which there are no significant findings in coronary arteries still heart wall shows changes of myocardial infarction.

Among six cases of discrepancies in the age group of 40–59 years, there are four cases in which coronary arteries show mild atherosclerosis or normal histology while heart walls show change of myocardial infarction. There are two cases in which coronary arteries show severe atherosclerosis still there are no changes in cardiac wall.

In the age group of 60–99 years, there are not any discrepancies in findings of heart wall in correlation with coronary arteries.

DISCUSSION

The objective of this study is to correlate heart wall and coronary arteries findings. Our study reports on the largest autopsy cohorts of individuals with sudden death due to myocardial infarction in which the postmortem was performed following a standardized protocol. Most deaths occurred at rest, although almost half of the decedents reported cardiac symptoms.

Apart from myocardial infarction, other findings are myocardial fibrosis, hypertrophic cardiomyopathy, myocarditis, old healed myocardial infarction, and rheumatic heart disease. There are also cases in which there is no significant coronary artery or heart wall changes.

In the age group of 3–39 years, there are 38 cases (42.2%) in which heart shows normal histology, while the age group

Table 2: Findings in heart wall according to age group

Age group	Fibrosis	Myocardial infarction	Old myocardial infarction	Hypertrophic cardiomyopathy (hocm)	Carditis	Rheumatic heart disease (rhd)	Discrepancy in findings of cardiac wall in correlation with coronary arteries	Normal	Total
3–39	1	13	10	6	12	1	9	38	90
40–59	1	37	11	8	2	0	6	16	81
60–99	1	11	5	2	2	0	0	2	23

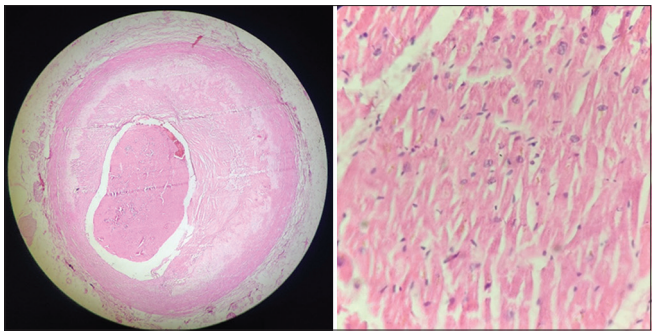


Figure 1: Normal cardiac wall findings with severe coronary artery atherosclerosis

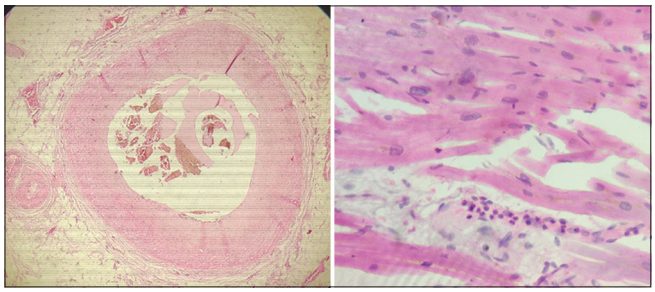
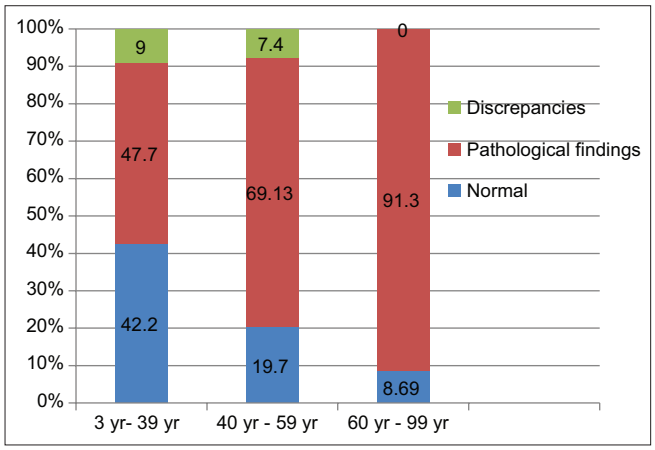


Figure 2: Changes of myocardial infarction in cardiac wall with normal coronary artery



Graph 1: Age group wise distribution of cardiac wall findings

of 40–59 years shows 16 and age group of 60–99 years shows two cases of normal cardiac histology. In these cases, cause of death can be homicidal, due to respiratory failure, poisoning, genetic anomalies, severe infections, or malignant diseases.

In our study, the age group of 3–39 years suggests more discrepancies in heart wall corresponding to coronary artery findings (Graph 1).

The pathogenetic mechanism of myocardial infarction with normal coronary artery remains unknown. It has been concluded that coronary artery spasm may initiate myocardial infarction but only in one-third of such patients. Spasm associated with alcohol intake as well as prothrombotic state and endothelial damage related to cigarette smoking may be mechanisms leading to myocardial infarction in these cases.

There are few cases in which we found that there is severe atherosclerosis in coronary arteries but still there are no significant changes in cardiac wall. By taking a history of such cases, we have found that these decedents had a history of COVID-19 months ago.

A study by Roshdy *et al.*[7] highlighted that the most important finding is the intracardiac, coronary arterial, and venous thrombosis which may be explained by COVID-19-associated coagulopathy. Myocardial ischemia can be aggravated by preexisting coronary artery disease and myocardial supply-demand mismatch.

Figures 1 and 2 show discrepancy in cardiac wall in correlation with coronary artery.

CONCLUSION

Myocardial infarction without significant coronary artery changes is a syndrome with several causes. An accurate and appropriate diagnostic work-up is essential for early identification of cause in each individual patient, and in young population, it is necessary to know avoidable and treatable causes for the prevention of cardiac wall changes.

During macroscopic and microscopic examination of a postmortem hearts, it is particularly important to discover the causes of the wall and artery changes effectively for the proper identification of cause of the death.

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Original Article

Efficacy of Fetal Transverse Cerebellar Diameter/Abdominal Circumference (AC) Ratio versus Head Circumference/AC Ratio in Predicting Intrauterine Growth Retardation

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Abstract

Background: The study was planned to compare the accuracy of transverse cerebellar diameter/abdominal circumference (AC) with head circumference (HC)/AC in predicting intrauterine growth retardation.

Methods: This study was conducted as a hospital-based prospective observational study at Department of Radio diagnosis, NSCB Medical College and Hospital Jabalpur (M.P.) who were referred from the Department of Obstetrics and Gynecology to the our department for antenatal ultrasound. With ultrasonogram, the HC, TCD, and AC of fetus were measured in addition to anomaly scanning, routine biometric parameters, and liquor volume. The HC/AC ratio and TCD/AC ratio was calculated. These women were informed about the results of the scan.

Results: Sensitivity and, positive predictive value (PPV), of TCD/AC ratio in diagnosing intrauterine growth retardation (IUGR) were 90.91% and 97.56%, respectively. Sensitivity and PPV of HC/AC ratio in diagnosing IUGR were 82.22% and 97.37%, respectively. Overall, the accuracy of TCD/AC is higher (89%), than that of HC/AC (82%) in predicting IUGR antenatally. Our study documented a significant correlation of gestational age with TCD, HC as well as AC.

Conclusions: TCD shows linear correlation with the advancing gestational age. TCD/AC and HC/AC ratio remains content throughout the gestational age. However, ratio increased in cases of growth restricted fetuses (due to brain sparing effect). TCD is least affected in the process of growth restriction, while HC is affected less frequently. However, AC is the most affected parameter, and hence, TCD/AC and HC/AC ratio is increased in the cases of IUGR. As TCD/AC and HC/AC ratio remains constant throughout in normal pregnancy, hence, they becomes gestational age in-dependent parameter for diagnosing IUGR, even in pregnancies of unknown dates. Hence, both methods can be used to screen the cases of IUGR, antenatally. However among the two discussed method above, TCD/AC is better parameter for screening of IUGR cases.

Key words: Abdominal circumference, Diagnostic accuracy, Head circumference, Intrauterine growth retardation, Transcranial diameter

INTRODUCTION

The process of birth is the most dangerous journey an individual undertakes. A healthy new born is the goal of every expectant mother and her treating obstetrician. The high incidence of intrauterine growth retardation (IUGR) in general obstetric population (~10%) and its low recognition (< 40%) together lead to increasing risk of perinatal morbidity and mortality. Regular surveillance and timely management decisions are the goal for optimum outcome in these cases, which rely mainly on accurate determination of gestational age.[1] Chances of *in utero* fetal demise, meconium aspiration, birth asphyxia, neonatal hypoglycemia, and hypothermia are all increased in the fetus showing growth restriction. In addition, it has been also found that

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these growth restricted infants have higher 1-year infant mortality rate and abnormal neurological development.[2] The desire to prevent such maloccurrences during pregnancy has prompted the clinician to develop various methods of assessing the fetal condition in utero itself as early as possible with accuracy. Best investigation ideally must be simple, safe, reproducible, reliable, non-invasive, and accurate and should cause no damage to the mother and her fetus.[3] Prenatal ultrasonography fulfills almost all these prerequisites and, hence, plays a crucial role in antepartum fetal surveillance. A near accurate determination of gestational age, identification of major anatomical congenital anomalies up to possible level, evaluation of fetal growth, and assessment of fetal well-being and maturity are all possible due to the availability of good quality ultrasound.[2,3]

The assessment of fetal growth is important to the provision of optimum prenatal care. As the clinical estimation of the fetal growth is not reliable, prenatal USG provides an opportunity to more accurately assess the fetal growth. The most commonly used parameters to evaluate fetal growth are biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), and femur length (FL). Of all the ultrasound derived biometric parameters, the AC seems to be the best predictor of fetal growth restriction (FGR). However, all these parameters can be correlated only if gestational age is accurately known. However, uncertainty of the gestational age (either by known accurate last menstrual period (LMP) or availability of dating ultrasound) occurs frequently and makes four the differentiation between the appropriate for gestational age (AGA) and the small for gestational age fetus difficult and challenging. Transverse cerebellar diameter (TCD) is the maximum transverse diameter of the fetal cerebellum. The fetal cerebellar hemispheres are located in the posterior cranial fossa which is resistant to external pressure and growth deviations[1] that are not affected in FGR, because the – brain sparing effect – thus making it a better indicator for determination of gestational age.[3]

Measurement of TCD is an near accurate method of estimating gestational age in cases of uncertain dates and even in dolicocephaly or brachycephaly, where biparietal diameter could not be used accurately. In contrast to TCD, fetal AC is the earliest affected parameter in the process of impaired fetal growth.[4] Thus, a ratio of TCD/AC which is gestational age independent is very useful in predicting IUGR. Hence, TCD/AC ratio increases in FGR which fairly remains constant throughout normal pregnancy.[5] HC is another parameter which remains minimally affected by external pressure effects causing deformation of fetal head and by 5 growth alterations. Hence, HC/AC ratio is another gestational age independent parameter which may be used in predicting IUGR. Hence, as the both parameters were gestational age independent criteria for the determining the IUGR, the study was planned to compare the accuracy of TCD/AC with HC/AC in predicting intrauterine growth retardation.

MATERIALS AND METHODS

This study was conducted as a hospital-based prospective observational study at the Department of Radio diagnosis, NSCB Medical College and hospital Jabalpur (M.P.) during the study period of January 2019–August 2020 on 50 clinically suspected cases of IUGR who were referred from the department of obstetrics and Gynecology to the our Department for Antenatal Ultrasound. Any gravid women with singleton pregnancy, history of regular menstrual cycle, presenting after 20 weeks of gestation (preferably third trimester), and suspected for IUGR (according to the ACOG guideline OR estimated fetal weight below the 10th percentile of the gestational age according to the USG) with lack of interval growth as compared to the LMP OR Previous USG with accurately determined gestational age by LMP or by dating ultrasound were included in the study. However, anomalous pregnancies and pregnant females not willing to participate in the study were excluded from the study.

Antenatal women were enrolled after written informed consent. A detailed history of the patients was taken. A thorough systemic and obstetric examination was made in the referring department. All preliminary investigations were done. The antenatal women were made aware of the benefits of ultrasonogram. The scans were carried out by the single trained sonologist. All the 50 patients underwent antenatal ultrasound scan on MINDRAY DC 30 ultrasound and color Doppler system with a curvilinear probe of frequency 2–6 MHz, optimized according to the gestational age of the fetus for optimum contrast and better visualizations [Figure 1].

With ultrasonogram, the HC, TCD, and AC of fetus were measured in addition to anomaly scanning, routine biometric parameters, and liquor volume. The HC/AC ratio and TCD/AC ratio was calculated. These women were informed about the results of the scan.

The patients were followed up until delivery for fetal birth weight. All babies at birth were assessed by the neonatologist and grouped as AGA or FGR according to birth weight 10th–90th percentile and <10th percentile for gestational age, respectively. The cutoff of value of TCD/AC and HC/AC ratio for diagnosing FGR is taken according to the previous studies. In addition, we also perform uterine artery Doppler, UA Doppler, MCA Doppler, and DV Doppler study on all the cases and all relevant parameters such as RI, PI, and S/D were calculated. Grades of Doppler changes assigned accordingly.

Statistical Analysis

Data were compiled using Microsoft Excel and analyzed using IBM SPSS software version 20 (IBM; Illinois Chicago). Categorical and continuous data were expressed as frequency (proportion) and mean (standard deviation), respectively. Diagnostic accuracy of TCD/AC and HC/AC was calculated and expressed as percentage in terms of sensitivity, specificity, positive predictive value (PPV), and negative predictive value. Correlation of TCD, AC, and HC with gestational age was done using Pearson Correlation Coefficient. $P < 0.05$ was considered statistically significant.

RESULTS

A total of 50 suspected cases of IUGR pregnancy were included in our study. Majority of the study subjects were below the age of 30 years. About 44% were below the age of 25 years. Out of all antenatal women, 54% were primigravida. Approximately 56% were associated with Preeclampsia, while in 24% of cases, no identifiable risk factor was found. In our study, we found 36% severe growth restricted births. In the present study, 90% cases were delivered as IUGR babies. Any grade of Doppler changes are associated with the 50% of cases, in the present study [Table 1]. In the present study, 52% subjects had Grade II changes, followed by 20%, 16%, and 12% cases with Grade III, IV, and V changes, respectively [Table 2].

Out of total cases with cutoff of TCD/AC% of >16.50, 60% show any grade of Doppler changes and with cutoff of HC/AC of >1.10, 61.50% show any grade of Doppler changes [Table 3]. TCD/AC ratio is able to diagnose 41 true cases of IUGR among the 45 actual cases. At the same time, this ratio over diagnosed one case. HC/AC ratio accurately diagnosed 37 cases out of the 45 actual cases of IUGR, and accurately exclude the four normal cases out of five cases [Table 4].

Sensitivity and, PPV, of TCD/AC ratio in diagnosing IUGR were 90.91% and 97.56%, respectively. Sensitivity and PPV of HC/AC ratio in diagnosing IUGR were 82.22% and 97.37%, respectively [Figure 2]. Overall, the accuracy of TCD/AC is higher (89%), than that of HC/AC (82%) in predicting IUGR antenatally. Our study documented a significant correlation of gestational age with TCD, HC, as well as AC [Table 5].

DISCUSSION

IUGR refers to the condition, in which a fetus is unable to achieve the genetically endorsed growth. A fetus is termed growth restricted if weight is below the 10th percentile for that gestational age.[6] In the present study, there are total 50 pregnant woman were included, having high suspicion of intrauterine growth restriction, who were fulfilling the

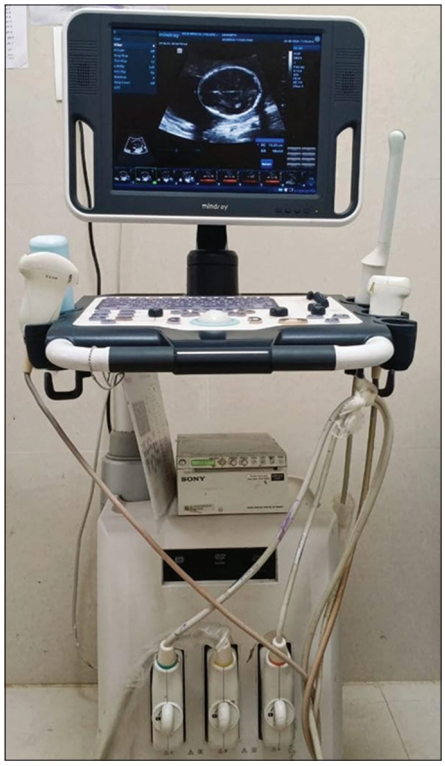


Figure 1: MINDRAY DC 30 ultrasound and color Doppler system

Table 1: Distribution according to maternal and fetal factors

Maternal and fetal factors	Number of cases (*n*=50)	Percentage
Age (years)		
20–25	22	44
25–30	19	38
>30	9	18
Parity		
Primi	27	54
Multi	23	46
Risk factor		
No associated risk factor	12	24
Pre-eclampsia	28	56
Chronic hypertension	1	2
Pre-eclampsia with GDM	3	6
Preeclampsia with chronic HTN	6	12
Oligohydramnios		
Normal liquor (>10th centile)	9	18
Oligohydramnios (<10th–5th percentile)	34	68
Severe oligohydramnios (<5th percentile)	7	14
Birth weight		
>10th percentile	5	10
<10th percentile	27	54
<5th percentile	18	36
Fetal growth retardation		
Normal	5	10
FGR	45	90
Associated Doppler changes		
Present	25	50
Absent	25	50

FGR: Fetal growth restriction

Table 2: Grading of IUGR according to Doppler changes

Grades			Cases	Percentage
Grade II	Moderate increased resistance, no redistribution	Cerebro placental ratio (cpr) <p5 or/and uterine artery pi >p95	13	52
Grade III	Severely increased resistance and/or redistribution	Absent end diastolic flow in umbilical artery and mca pi <p5	5	20
Grade IV	Severe hemodynamic alteration	Reverse end diastolic flow in umbilical artery	4	16
Grade V	High risk of death	Reverse a flow in ductus venosus	3	12

IUGR: Intrauterine growth retardation

Table 3: Distribution of cases with respect to Doppler changes in case of TCD/AC and HC/AC%

Parameters	Number of cases	Cases shows Doppler changes (of any grade)
TCD/AC%		
<16.50	20 (40%)	35%
>16.50	30 (60%)	60%
HC/AC%		
<1.10	24 (48%)	37.5%
>1.10	26 (52%)	61.5%

TCD/AC: Transverse cerebellar diameter/Abdominal circumference, HC/AC: Head Circumference/Abdominal circumference

Table 4: Diagnostic accuracy of TCD/AC and HC/AC for IUGR

Parameters	True positive Cases	False positive Cases	True negative Cases	False negative Cases
TCD/AC	41	1	4	4
HC/AC	37	1	4	8

IUGR: Intrauterine growth retardation, TCD/AC: Transverse cerebellar diameter/Abdominal circumference, HC/AC: Head circumference/Abdominal circumference

Table 5: Correlation of gestational age with TCD, HC and AC

Correlation	TCD	HC	AC
Pearson's correlation	$r = 0.7185$	$r = 0.7887$	$r = 0.634$
Coefficient of correlation	$r^2 = 0.5162$	$r^2 = 0.622$	$r^2 = 0.402$
P value	<0.00001	<0.00001	<0.00001

TCD: Transverse cerebellar diameter, HC: Head circumference, AC: Abdominal circumference,

inclusion criteria and with informed written consent. In the present study, 45 (90%) fetuses were found with IUGR, while 5 (10%) were born normal, according to the their birth weight. This is not in-line with general incidence[7] of IUGR, which might be due to the patient selection criteria in the present study.

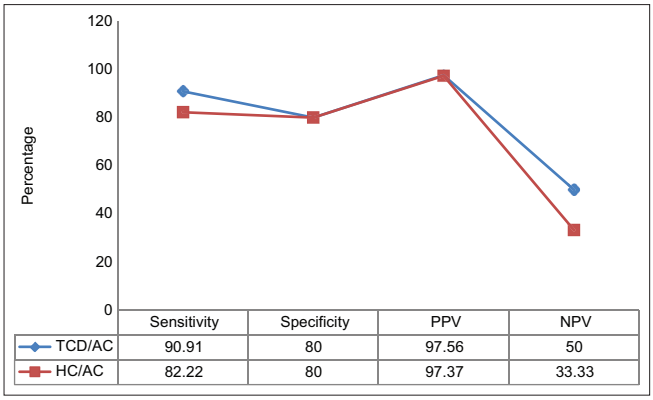
In this study, 82% of the patients were found to have Oligohydramnios, and 18% had adequate liquor (according to AFI). Of the patients having low liquor, 34 cases that are 68% cases were classified as moderate Oligohydramnios (AFI < 10th percentile to > 5th percentile), while seven cases as severe Oligohydramnios (AFI < 5th percentile). Therefore, a strong correlation was found between reduced amount of liquor and FGR in the present study. Results were similar to the study conducted by the Chauhan *et.al.*[8]

There is linear increase in the TCD with the advancing gestational age with a strong positive correlation ($r = 0.7213$) between Gestational Age and TCD in present study ($P < 0.00001$, significant at $P < 0.05$). This is in-line with study conducted by Haller *et al.*, where they found a positive correlation between the same of $r = 0.955$.[9] Furthermore, there is the strong positive correlation exist between gestational age determined by LMP and the HC obtained at ultrasound ($r = 0.7887$), with the $P = 0.00001$, highly significant (significant <0.05). TCD remains unaffected by the growth restriction and serves as the age independent criteria for estimating the gestational age.[9] Similar findings could be observed in our study, where we documented that TCD is very less affected in the process of IUGR.

Our study showed a significant positive correlation exist between the gestational age determined by the LMP and AC at the time of ultrasound ($r = 0.634$) with $P < 0.00001$ (significant below the level of 0.05). In the study conducted by Heller *et al.,* there was strong correlation exist between gestational age and AC ($r = 0.9453$), which is similar to our study.[9]

The sensitivity of TCD/AC ratio in diagnosing IUGR antenatally is 90.91% with specificity of 80.00%, PPV is 97.56%, and negative predictive value (NPV) is 50.00%, which is comparable to the study conducted by the Meyar *et al.,* in which sensitivity, specificity, and PPV, respectively, are 83.9%, 96.8%, and 94.5%.[10] However, NPV is nor comparable with our study, possibly due to selection criteria of patient in present study. Similar study conducted by Bhimarao *et al.* and found, the sensitivity, specificity, and PPV are 88%, 93.5%, and 77.1% which are similar to the present study.[11] Results were also comparable with the study conducted by Campbell *et al.*, where sensitivity, specificity, and PPV were found to be 71%, 77%, and 79%, respectively.[12]

According to the present study, the sensitivity, specificity, PPV, and NPV of the HC/AC in diagnosing IUGR was 82.22%, 80%, 97.30%, and 33.33%, respectively. This is quite comparable with the study of Bhimarao *et al.*[11] and Benson and Doubilet,[13] Where they found that sensitivity, specificity, and PPV are 84%, 92%, and 77.1% and 82%, 94%, and 62%, respectively. Cabbad *et.al.*, in another study



	Sensitivity	Specificity	PPV	NPV
TCD/AC	90.91	80	97.56	50
HC/AC	82.22	80	97.37	33.33

Figure 2: Diagnostic accuracy of transverse cerebellar diameter/abdominal circumference and head circumference/ abdominal circumference for diagnosis of fetal growth restriction

with suspected IUGR, demonstrated that, fetal weight is affected at greatest extent in the process of IUGR, while TCD affected least. Hence, the discordance between TCD and fetal weight can diagnostic of almost all IUGR fetuses with sensitivity of 95.6 % and specificity of 96.3%. In contrast, HC/AC remains normal in about more than 50% of fetuses.[14] Comparable results are drown from our study, where the birth weight kept as the diagnostic criteria for IUGR, TCD/AC ratio perform good than HC/AC ratio with positive likely hood ratio of 4.5 and 4.11, respectively. We also found that higher the discordance between TCD and fetal weight, higher the severity of growth restriction.

Khan *et al*.**,** in their study, involved 30 high-risk patients, with known accurate gestational age and singleton pregnancy found that raise of TCD/AC ratio was observed in 15 patients, that is, in 50% cases with sensitivity of 77.8%, which was comparable to our study, where sensitivity is 90.91%.[15]

Cutoff value of TCD/AC ratio for diagnosing IUGR, in our study, was 14.83 (13.63+-1.2), which is (derived from) similar to the study of Ghazala *et al*.,[16] where ratio was (14.06 ± 0.59). Furthermore, studies conducted by Bhimarao *et al*.[11] and Khan *et al*.,[15] the cutoff values for diagnosing FGR were 13.63 and 16.03, respectively, which were closure to present study cutoff values.

As regards HC/AC in predictiction of IUGR, in our study, cutoff value was taken as 1.09 (from 1.04 ± 0.05), which was similar to the (derived from) cutoff value of HC/AC for SGA infants of the study conducted by the Takoka *et al*.,[17] is 1.15.

In the present study, the efficacy of the TCD/AC ratio is proven more, than HC/AC ratio in diagnosing IUGR, with diagnostic accuracy is 89.80% and 82%, respectively. It is similar to the study conducted by the Bhimarao *et al.,*[11] where the diagnostic accuracy found to be 92.4% and 90.4 %, respectively. In the present study, we also perform Doppler correlation on selected cases and found that, cases having TCD/AC % ratio < 16.50, only 35% show any grade of Doppler changes, while cases having TCD/AC % ratio > 16.50, 60% show positive Doppler changes. However, we observed that out of cases with HC/AC ratio < 1.10, 37.5% cases show any grade of Doppler changes and out of cases HC/AC ratio > 1.10, 61.5% had any grade of Doppler changes. These findings suggested that as both ratio (TCD/AC% ratio and HC/AC ratio) increases, the doppler changes tend to increase suggesting redistribution of blood to save the vital organs.

CONCLUSIONS

TCD shows linear correlation with the advancing gestational age. TCD/AC and HC/AC ratio remains content throughout the gestational age. However, ratio increased in cases of growth restricted fetuses (due to brain sparing effect). TCD is least affected in the process of growth restriction, while HC is affected less frequently. However, AC is the most affected parameter, and hence, TCD/AC and HC/AC ratio is increased in the cases of IUGR. As TCD/AC and HC/AC ratio remains constant throughout in normal pregnancy, hence, they becomes gestational age in-dependent parameter for diagnosing IUGR, even in pregnancies of unknown dates. Hence, both methods can be used to screen the cases of IUGR, antenatally. However, among the two discussed method above, TCD/AC is better parameter for screening of IUGR cases.

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Original Article

Effectiveness of Epworth Sleepiness Score in the Diagnosis of Obstructive Sleep Apnea – A Cross-sectional Study

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Abstract

Background: Delayed diagnosis of obstructive sleep apnoea (OSA) in patients can cause neurocognitive and cardiometabolic sequelae, hence, requiring early diagnosis and treatment. One of the concurrent symptoms of OSA is excessive, daytime sleepiness can be clinically assessed by Epworth's sleepiness scale (ESS). However, the gold standard for OSA diagnosis is polysomnography (PSG).

Objective: The aim of the study was to measure the effectiveness of ESS among OSA patients and to compare the results of ESS with PSG.

Methods: It was a hospital-based cross-sectional study of 50 patients. After obtaining ethical committee approval and informed consent, patients were interviewed using the ESS questionnaire during their clinical assessment and later subjected to the PSG test. The data were analyzed using SPSS (Version_24) Software.

Results: The mean age of the study participants was 59.10 ± 8.51 years. The majority of them were obese (42%) and pre-obese (42%). In ESS scoring, 28% had severe daytime sleepiness and in apnea-hypopnea index (AHI) shows that 24% had severe OSA. The correlation between ESS and AHI to assess OSA severity shows medium strength ($r = 0.414$; $P < 0.001$).

Conclusions: ESS was efficient in diagnosing the moderate and severe OSA cases. Although it might miss diagnosing mild OSA cases, it can be used to rule out OSA in high-risk patients or for pre-operative assessments.

Key words: Apnoea-hypopnea index, Daytime sleepiness, Epworth sleepiness scale, Obstructive sleep apnoea, Polysomnography

INTRODUCTION

Sleep-disordered breathing is characterized by episodes of absent or reduced breathing, and/or by sustained reductions in breathing during sleep compared with wakefulness. It results from the closure of the upper airway during sleep and is called obstructive sleep apnea (OSA). Polysomnography (PSG) is a comprehensive multi-parameter study of sleep and is considered as a gold standard for OSA diagnosis.[1]

OSA severity is based on the apnea-hypopnea index (AHI), which is calculated as the number of apneas and hypopneas during sleep divided by total sleep time, represented in events per hour. The grading was normal (no OSA): AHI < 5; mild sleep apnea: 5–15; moderate sleep apnea: 15– 0; and if >30 is severe sleep apnea.[2]

The term sleep apnea syndrome refers to the concurrence of OSA with symptoms, classically excessive daytime

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sleepiness.[3] The latter is often identified by the Epworth sleepiness scale (ESS), in which the respondent indicates the likelihood of dozing (scale from 0 to 3) in eight common circumstances.[4] A score of 11 or greater is accepted as indicative of excessive sleepiness. At present, the international classification of sleep disorders identifies a diagnosis of adult OSA as an AHI of five or greater with symptoms, or an AHI of 15 or greater regardless of symptoms.[3]

The ESS currently plays an important role in the screening process for the determination of whether a patient should be referred to a sleep laboratory for PSG.[5] PSG is considered as a gold standard for diagnosing OSA. The test can be done in a laboratory with technologist-attended complete overnight testing.[5] Henceforth, our study aims to find out the effectiveness of Epworth's sleep score in diagnosing OSA.

MATERIALS AND METHODS

Study Area

The study was conducted in the Department of Pulmonary Medicine in a Tertiary Care Teaching Hospital in Telangana, India. This tertiary care institute is equipped with state-of-the-art equipment to understand and study OSA.

Study Design

It was a hospital-based analytical cross-sectional study.

Sample Size and Sampling Technique

Considering the prevalence of OSA in the Indian population to be 4.4%[6] with 6% absolute precision and 10% non-response rate, the sample size was 50 (calculated using OpenEpi software version 3.01; Open-Source Epidemiologic Statistics for Public Health). A consecutive sampling technique was used to include the study participants based on the inclusion criteria until the desired sample size was achieved.

Study Participants and Duration

Patients who were admitted to the Department of Pulmonary Medicine were considered for the study. Inclusion criteria used to select the participants include both genders aged > 35 years, body mass index (BMI) >18.5 kg/m^2, and patients who had complaints of obstructive sleep apnea symptoms. The patients who presented with central sleep apnea, restless leg syndromes, circadian rhythm disorders, parasomnias, hypersomnia, or narcolepsy were excluded from the study. Data collection was done for 6 months.

Data Collection Procedure

After obtaining informed consent, data were collected using a pretested structured questionnaire. It included demographic details, a general clinical assessment and ESS questionnaire.[7] All the patients underwent overnight PSG at the hospital and the results were collected and compared with the ESS data. Principle investigator conducted a face-to-face interview on the day of the clinical assessment. Confidentiality, anonymity, and privacy of the participants were guaranteed throughout the study.

Data Analysis

The collected data were entered in MS Excel and analyzed using IBM SPSS Statistics Version_24.0 (IBM Co., Armonk, NY, USA). Categorical variables were measured and expressed in frequencies and percentages, while the continuous variables were expressed in mean and standard deviation. Pearson's bivariate correlation (*r*) was done to find out the strength and direction of the association that exists between the dependent variable PSG and independent variables such as ESS, BMI, and AHI. Scatterplots were used to check the linear relationship between PSG and ESS. Correlation is significant at the 0.01 level (*P* value).

Ethical Consideration

Ethical clearance was obtained from the Institutional Ethics Committee (IEC) of Shadan Institute of Medical Sciences Teaching Hospital and Research Centre, Telangana.

Guidelines Used for Reporting the Study

To ensure the present hospital-based cross-sectional study's systemic reporting, STROBE (Strengthening The Reporting of an Observational study in Epidemiology) guideline was followed.[8]

RESULTS

The sociodemographic details of the study participants were given in Table 1. The mean age of the participants was 59.10 ± 8.51 (SD) years. The clinical assessment shows that 58% of patients had diabetes and the majority of 88% presented with hypertension.

Among 50 patients, the assessment of daytime sleepiness using ESS shows that 28% had excessive and 28% had

Table 1: Sociodemographic details of the study participants (*n*=50)

Variables	*n* (%) or mean (SD)
Gender	
Male	38 (76.0)
Female	12 (24.0)
Body mass index (kg/m^2)	
Normal weight (18.5–22.9)	6 (12.0)
Overweight (23–24.9)	7 (14.0)
Pre-obese (25–29.9)	16 (32.0)
Obese (≥30)	21 (42.0)

severe daytime sleepiness. About 15% had mild daytime sleepiness. Then, the patients were subjected to PSG, where only 42% were diagnosed to have OSA. AHI calculated through PSG, showed that 12% had moderate and 24% had severe OSA [Table 2].

In Table 3, the results from ESS and PSG were compared and found to be significant ($\chi^2 = 2.56$; 95% CI: 2.517–43.11; $P < 0.001$), showing that PSG can be used to diagnose OSA 2.56 times even in the milder form than ESS scale. Similarly in Table 4, the relationship between AHI (obtained from PSG) and ESS was positive with moderate strength and it was statically significant at 0.001 ($r = 0.414$; $P < 0.001$). This finding shows that patients with higher ESS will subsequently increase the severity of the OSA.

Table 2: Assessment of obstructive sleep apnea among the study participants (*n*=50)

Variables	*n* (%) or mean (SD)
Epworth sleepiness scale (ESS)	
Normal daytime sleepiness (0–10)	7 (14.0)
Average daytime sleepiness (11–12)	15 (30.0)
Excessive daytime sleepiness (13–15)	14 (28.0)
Severe daytime sleepiness (16–24)	14 (28.0)
Apnea – Hypopnea Index (AHI)–OSA severity	
Normal sleep (<5)	29 (58.0)
Mild sleep apnea (5–15)	3 (6.0)
Moderate sleep apnea (15–30)	6 (12.0)
Severe sleep apnea (≥30)	12 (24.0)
Polysomnography	
OSA absent	29 (58.0)
OSA present	21 (42.0)

Table 3: Comparison between polysomnography and Epworth sleepiness scale (ESS) among the study participants (*n*=50)

Variables	PSG		χ^2 95% CI *P* value
	Present, *n* (%)	Absent, *n* (%)	
ESS scale			
Abnormal (>11)	13 (76.5)	4 (23.5)	12.56; 2.517–43.11<0.001*
Normal (≤11)	8 (24.2)	25 (5.87)	

*Pearson's chi-square test; 95% CI - Confidence Intervel; p value < 0.05 is statistically significant

Table 4: Pearson correlation coefficients of obstructive sleep apnea with other clinical variables (*n*=50)

Variables	Pearson's correlation (r)	*P* value# (2-tailed)
*AHI and BMI	0.715	<0.001
^ESS and BMI	0.509	<0.001
AHI and ESS	0.414	<0.001

*AHI: Apnea-Hypopnea index, ^ESS: Epworth sleepiness scale, BMI: Body mass index. #Correlation is significant at the 0.01 level (2-tailed).

Furthermore, BMI, a risk factor for OSA shows that an increase in BMI results in the severity of OSA and had a stronger relationship ($r = 0.715$; $P < 0.001$). Receiver operating characteristic curve demonstrating the sensitivity of ESS. Area under curve is found to be 0.741 and shows 74% sensitivity for ESS [Figure 1].

DISCUSSION

Our study shows that ESS was efficient in diagnosing the moderate and severe undiagnosed OSA cases. Although, the ESS questionnaire missed to diagnose mild OSA cases, the questionnaire can be used to rule out OSA in high-risk patients or for pre-operative assessments.

In our study, it has been shown that increase in ESS, there was an increase in AHI which was similar to the study done by Guo *et al.*,[9] where the higher the ESS item score, the closer the relationship with the corresponding AHI.

Similarly, the sensitivity of the ESS was found to be 74% in our study which was in concordance with the study findings by Rosenthal *et al.*,[10] where the ESS obtained a relatively low sensitivity (66%) in the identification of an AHI of five and above at the suggested cutoff of 10 and increased to 76% if the score is eight. Furthermore, our study results showed the fair discriminatory ability of the ESS as a screener for OSA rather than a diagnostic tool which is PSG.

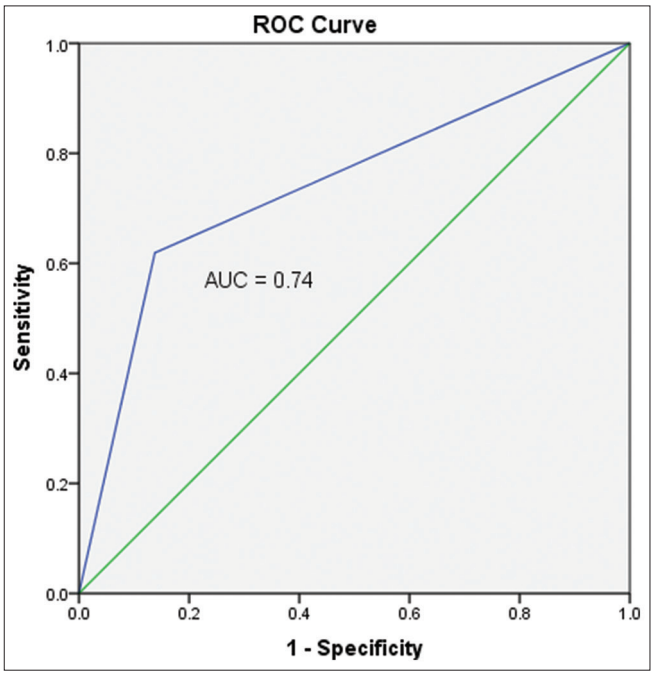

Figure 1: Receiver operating characteristic of polysomnography and Epworth's sleepiness scale

In another study done by Chakrabarti *et al.*,[11] the ESS had 53% sensitivity and 60% specificity for diagnosing OSA using a cutoff of 13 and they also concluded that questionnaires such as the ESS and STOP-BANG questionnaire which cannot replace the gold-standard PSG.

Several questionnaires such as the Epworth's sleep scale, Berlin, and STOP-BANG questionnaires have been developed to grade OSA risk.[12] These models tend to be relatively sensitive (76–96%) but not very specific (13–54%) when compared with PSG.[13] Thus, although questionnaires or prediction models are useful for screening or estimating pre-test probability, objective sleep recording is required to establish a diagnosis of OSA.

Our study supports the position of the AASM guideline that stated that clinical tools, questionnaires, and prediction algorithms should not be used to diagnose or exclude the presence of sleep apnea.[14]

The limitation of this study was due to the small sample size. ESS is non-specific as symptoms may be downplayed by patients, as only speculative questions are asked.

CONCLUSION

Thus, ESS can be taken as a helpful screening tool for OSA rather than to diagnose it. Due to the lack of resources and not many PSG laboratories in many areas of the country, along with the need to diagnose OSA to avoid complications, a questionnaire than can predict OSA with surety is needed.

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Original Article

Study of Renal Function in Patients with Modified Anatrophic Nephrolithotomy

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Abstract

Introduction: Anatrophic lithotomy (ANL) with its excellent stone clearance rate is a reasonable option in cases in which if a reasonable number of percutaneous approaches are not likely to be successful or several endourological approaches have been attempted unsuccessfully. Although excellent stone-free rates can be achieved with ANL, there is possibility of a reduction in renal function postoperatively. In this study, we assess the functional results after anatrophic nephrolithotomy.

Materials and Methods: The study was prospective and observational in nature and carried over a period of 2 years. A total of 50 patients (meeting the inclusion and exclusion criteria) underwent open modified ANL for partial or complete staghorn calculus and were assessed during the study period.

Results: The study included 50 patients with a mean age of 47.26 ± 7.17 years of which 62% (31) were males and 38% (19) were females. The percentage change in dimercaptosuccinic acid differential renal function postoperatively was 8.66% and creatinine level was 11.65%, both of which were statistically significant ($P < 0.001$). Complete stone clearance occurred in 94% (47) and 6% (3) had incomplete stone clearance postoperatively. Complications occurred in 14 patients out of 50 postoperatively. All complications were managed conservatively. No patient died during this study period.

Conclusion: Although associated with slight decrease in renal function postoperatively, ANL is the most appropriate method for one-stage management of a selected group of patients with large staghorn calculi and is associated with the highest stone-free rates.

Key words: Anatrophic nephrolithotomy, Renal function, Stone

INTRODUCTION

The surgical treatment of urolithiasis has changed significantly over the past 30 years. Previously, most patients requiring stone removal underwent open surgery.[1] Advances in the endoscopic management of stone disease have made open stone surgery second or third-line treatment option which is being done in only 1–5.4% of cases.[2] However, if a reasonable number of percutaneous approaches are not likely to be successful or several endourological approaches have been attempted unsuccessfully, open surgery might be a valid primary treatment option.

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According to the European association of urology guidelines, the most common indications for open surgery are – failure of ESWL or PCNL or URSL; intrarenal anatomical abnormalities such as infundibular stenosis; stone in the calyceal diverticula; obstruction of the ureteropelvic junction; obesity; skeletal deformity; concomitant open surgery; and non-functioning lower pole when partial nephrectomy is indicated or nonfunctioning kidney where nephrectomy is required; patient's choice following failed minimally invasive procedures and stone in an ectopic kidney where percutaneous access and ESWL might be difficult or impossible.[3]

According to American Urological Association's guidelines (AUA guidelines), the current indications for anatrophic nephrolithotomy (ANL) are in unusual situations when a struvite staghorn calculus is not expected to be removed by a reasonable number of percutaneous lithotripsy or ESWL procedures.[4]

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Although excellent stone-free rates can be achieved with ANL, some drawbacks may be of concern. Morbidity related to intraoperative and post-operative complications is one of them. Another great concern is the possibility of a reduction in renal function related to the procedure itself. This may be related to nephron injury during nephrotomy and parenchymal closure or to ischemic injury. In this study, we assess functional results after anatrophic nephrolithotomy.

MATERIALS AND METHODS

The study was conducted at the Department of Urology, King George Hospital, Andhra Medical College, Visakhapatnam, Andhra Pradesh over a period of 2 years from January 2019 to December 2020. It was a prospective and observational study and included a total of 50 patients who were assigned to undergo open modified ANL for partial or complete staghorn calculus and were assessed during the study period. Inclusion criteria included all patients more than 18 years of age and presenting with partial or complete renal staghorn calculus who underwent modified ANL. Exclusion criteria included patients with bilateral renal calculus, patients with anomalous kidney or solitary functioning kidney, patients who have undergone previous renal surgery, patients with non-functioning kidney (dimercaptosuccinic acid [DMSA] function <20%), patients with uncured coagulopathies or sepsis, pregnant women, and patients not giving consent for open surgery. Patients meeting the inclusion and exclusion criteria underwent thorough evaluation with history, examination, hematological, and radiological investigations. The patients underwent open modified ANL. All patients were evaluated with non-contrast computed tomography scan and DMSA scan preoperatively and 1-month postoperatively to assess the change in renal function. All the data collected were analyzed through Microsoft Excel 2007 Software. Statistical data were analyzed through SPSS Software Version 26. The pre- and post-operative creatinine and DMSA values were compared using a paired *t*-test. Categorical variables were examined using a simple Chi-square analysis. $P < 0.05$ was considered statistically significant.

RESULTS

The study included 50 patients with a mean age of 47.26 ± 7.17 years (range of 32 years to 62 years) of which 62% (31) were males and 38% (19) were females. The left-sided stone disease was present in 42% of patients and 58% had right-sided disease with only 4% (two cases) having history of prior ipsilateral stone surgery. Pre-operative positive urine culture was present in 68% of patients who received antibiotics in accordance with the culture and sensitivity report. Only 32% of patients had sterile urine culture preoperatively. In this study, the mean operative time for modified ANL was 180.40 ± 14.70 min with a range of 150–210 min. The mean duration of cold ischemia was 36.62 ± 3.74 min with a range of 25 to 42 min. The mean pre-operative creatinine level was 1.03 ± 0.16 mg/dl and post-operative creatinine level was 1.15 ± 1.15 mg/dl. The percentage change in creatinine level postoperatively was 11.65% which was statistically significant ($P < 0.001$). The mean pre-operative hemoglobin levels were 11.52 ± 1.65 g/dl and post-operative hemoglobin levels were 10.58 ± 1.45 g/dl. The percentage change in hemoglobin level postoperatively was 8.88% which was statistically significant ($P < 0.001$). The mean pre-operative DMSA differential function of the diseased kidney was 39.02 ± 3.44, and post-operative DMSA function was 35.64 ± 3.49. The percentage change in DMSA differential renal function postoperatively was 8.66% which was found to be statistically significant ($P < 0.001$). Out of 50 patients, eight patients had no change in DMSA renal function (16%), three patients had improved renal function (6%), and 39 patients had decreased DMSA renal function (78%) 1 week after surgery. No correlation was found between cold ischemia time and post-operative DMSA renal function. The above relationship was also found to be statistically insignificant ($P > 0.05$). No correlation was found between post-operative creatinine level and cold ischemia time and the above relation was also found to be statistically insignificant ($P > 0.05$). Complete stone clearance occurred in 94% (47) and 6% (3) had incomplete stone clearance postoperatively. These three patients required later additional procedure for complete stone clearance. Complications occurred in 14 patients out of 50 postoperatively. Most of the patients had a single complication. Three patients developed more than one complication. About 12% of patients developed acute kidney injury, 10% developed fever, 6% had hematuria, 4% had surgical site infection, and 2% had a urinary leak. All complications were managed conservatively. No patient died during this study period. Table 1 representing the various complications and there frequency.

DISCUSSION

The treatment of patients with staghorn calculus is a complex and challenging problem. Management options include minimal access procedures such as ESWL and PCNL, open nephrolithotomy, and ANL. ANL has been found to be more reliable than ESWL or PCNL in terms of stone removal when treating a large staghorn calculus with stone-free rates of 80–100% having been reported.[5,6] The better stone free rate comes at the cost of decrease in renal function postoperatively. In our study, we performed

Table 1: Various complications and there frequency

Complications	Frequency	Percentage
Acute kidney injury	6	12.00
Fever	5	10.00
Haematuria	3	6.00
Surgical site infection	2	4.00
Urinary leak	1	2.00

the modified ANL in 50 patients and prospectively studied the change in renal function following the procedure.

In our modification, we avoided dissection of the renal artery and its branches and made the parenchymal incision along the kidney's avascular plane between the anterior and posterior vascular segments because the segmental blood supply to the kidney is relatively constant and is not affected by the number of renal arteries thereby minimizing the danger of vasospasm of renal artery.[7] We approximated the collecting rather than closing as our opinion is that meticulous closure of the pelvicalyceal system carries the risk of compromising blood supply by ligating the vessels around the caliceal infundibuli.[8] We also avoided using various instruments (drum elevators, nerve hooks, and brain spatulas) and techniques suggested by others because our philosophy was to reduce renal ischemia time by avoiding unnecessary manipulations.[9,10]

In our study, the majority of patients were between the age group 40–60 years. About 48% of total patients were between 41–50 years and 32% of total patients were between 51–60 years. The mean age of the patients in the study was 47.26 ± 7.17 years which included 68% males and 32% females. The patient characteristics were similar to study done by Morey *et al.* (1999), Melissourgos *et al.* (2002), and Aminsharifi *et al.* (2016).[11-13]

About 4% of our study's total patients had recurrent stone. The recurrent rate was quite low because staghorn stones are more commonly infectious. If completely removed and infection completely eradicated, they tend to recur less compared with other metabolic stones.

Our study found that 68% of patients had positive pre-operative urine culture for bacterial growth. In comparison, only 32% of patients had sterile urine culture preoperatively. Out of positive patients – 70.59% were positive for *Proteus mirabilis*, 17.65% for *Escherichia Coli*, and only 11.76% for *Pseudomonas aeruginosa*. Melissourgos *et al.* (2002), in their study, found that all 24 patients had positive pre-operative urine culture (*P. mirabilis*, $n = 15$; *P. aeruginosa*, $n = 3$; and *E. coli*, $n = 6$) which was very similar to ours.[12]

In our study, mean cold ischemia time is 36.62 ± 3.74 min and there was no significant correlation between cold ischemia time and post-operative creatinine or post-operative DMSA function which was similar to the study by Melissourgos *et al.* (2002).[12] El-Nahas *et al.* (2018) studied the effect on renal function after ANL in 50 patients, and the mean cold ischemia time in their study for 29 patients was 45.2 min and for the remaining 21 patients was 54.8 min probably because they performed complete pelvicalyceal reconstruction in every surgery.[14] Similarly, Aminsharifi *et al.* (2016) ANL and recorded an average ischemia time of 32.8 min in their study, rather quite close to our studies.[13]

In our study the percentage change in pre-operative and post-operative creatinine level was 11.65% which was statistically significant. The previous studies by Morey *et al.* (1999), Melissourgos *et al.* (2002) and El-Nahas *et al.* (2018) showed similar result as ours.[11,12,14] It may be probably due to AKI in the immediate post-operative period or some renal function loss due to permanent nephron loss in open surgery. The long-term result of the change in creatinine function post-surgery is unknown; it may need further studies in the future.

In our study, the mean pre-operative DMSA differential function of the diseased kidney was 39.02 ± 3.44, and post-operative DMSA function was 35.64 ± 3.49. This difference was found to be statistically significant ($P < 0.001$). The percentage reduction in DMSA differential renal function postoperatively was 8.66% in our study. Reduction of renal function may be attributed to injury during renal parenchymal incision and closure or due to renal ischemia during clamping of its blood supply.[15] The long-term evaluation after PCNL for staghorn stones showed better results than ANL, as deterioration of the affected kidney function was reported in 8.5–20%.[14] As shown in Table 2, the most of the previous studies also showed a decline in renal function postoperatively.

The main disadvantage of ANL is the high rates of complications that are mainly related to the open approach through a long muscle cutting lumbar incision. In the present study, the overall complication was 34% which is more than complication rates of 22–32.5% reported for PCNL in the treatment of staghorn stones.[18,19] The need for blood transfusion (18%) after ANL was also more than the reported rates of 9–14% blood transfusion in the PCNL series.

In our study, a total of 14 patients out of 50 developed complications postoperatively. Most of the patients had a single complication. Three patients developed more than one complication; 12% of patients developed acute kidney injury, 10% developed fever, 6% had hematuria, 4% had surgical site infection, and 2% had a urinary leak. No patient died during this study period. All the complications were managed conservatively.

Table 2: Comparison of change in DMSA renal function of various studies

Name of study	Mean % change in renal function	Remark
Our study	8.66	Decline
Morey *et al*.[11]	4	Decline
Melissourgos *et al*.[12]	4	Decline
Aminsharifi *et al*.[13]	8.66	Decline
Kawamura *et al*.[16]	12	Decline
Ramakrishnan *et al*.[17]	NA	55% stable, 32% improved, 13% worsened (% of cohort)

DMSA: Dimercaptosuccinic acid

Renal function improvement may occur after stone treatment. Possible mechanisms related to the increase in renal function are the relief in obstruction, resolution of infection and inflammatory process, and compensatory hypertrophy of the remaining tissue. Nevertheless, the stone-extraction procedure may itself negatively compromise the functional condition of the surgically treated kidney.

Regarding ANL, a decrease in renal function may occur because of direct injury to parenchymal tissue, leading to a permanent scar at the nephrotomy site. Another possible mechanism is the ischemia-reperfusion injury related to occlusion of the renal artery and vein. Protection measures as ice-slush hypothermia and mannitol have been used, as well as restriction of ischemia time to no longer than 30 min. However, the impact of those measures on renal function is not fully known.

Despite the emphasis placed on minimally invasive approaches, we believe that ANL, although still a major operative procedure and associated with slight decrease in renal function postoperatively, is the most appropriate method for one-stage management of a selected group of patients with large staghorn calculi and is associated with the highest stone-free rates.

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Original Article

A Study of Hepatic Involvement in Dengue Fever Along with Other Biological Changes in Relevance with Severity of Dengue Fever

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Abstract

Introduction: Dengue is the most important arthropod-borne viral infection of humans. Worldwide, an estimated 2.5 billion people are at risk of infection, approximately 975 million of whom live in urban areas in tropical and sub-tropical countries in Southeast Asia, the Pacific and the Americas. Dengue viral infections are known to present a diverse clinical spectrum, ranging from asymptomatic illness to fatal dengue shock syndrome. Symptoms usually begin about four to 7 days after the initial infection. In many cases, symptoms will be mild. They may be mistaken for symptoms of the flu or another infection.

Aims: The aims of this study were to know the demographic profile of dengue patients, to know the incidence of liver involvement in dengue fever, to measure aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase (ALP), serum albumin, platelet count, prothrombin time, and International Normalized Ratio, to find out the correlation between alteration of these biochemical parameters with severity of the disease, and to find out the morbidity and mortality along with hospital stay of the dengue patients with the severity of hepatic involvement.

Materials and Methods: The study was conducted in Burdwan Medical College and Hospital situated in Burdwan district (West Bengal) from March 2016 to February 2017. A total number of 102 patients diagnosed as cases of dengue fever were taken for this study.

Results: In our study, hepatomegaly in dengue infection is reported to be seen more frequently in complicated dengue in comparison to classical dengue fever. In the present study, 100% of cases in DSS group had hepatomegaly, whereas 88% in DHF group presented with hepatomegaly and only 25% cases of DF had hepatomegaly indicating that hepatomegaly may be used as a predictor for assessing the severity of the disease.

Conclusion: This study showed that dengue fever was seen in all age groups and that AST and ALT levels were raised in the majority of these patients. It was also found that AST levels were more than ALT levels, which were commonly observed in all those patients who developed complications such as DHF, DSS, ARDS, renal failure, and septicemia.

Key words: Dengue, Hepatomegaly, Jaundice and ARDS

INTRODUCTION

Dengue is the most important arthropod-borne viral infection of humans. Worldwide, an estimated 2.5 billion people are at risk of infection, approximately 975 million of whom live in urban areas in tropical and sub-tropical countries in Southeast Asia, the Pacific, and the Americas.[1] Transmission also occurs in Africa and the Eastern Mediterranean, and rural communities are increasingly being affected. It is estimated that more than 50 million infections occur each year, including 500,000 hospitalizations for dengue hemorrhagic fever, mainly among children, with the case fatality rate exceeding 5% in some areas.[2]

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Dengue is a mosquito-borne viral disease that has rapidly spread in all regions of the WHO in recent years. Dengue virus is transmitted by female mosquitoes mainly of the species *Aedes aegypti* and, to a lesser extent, *Aedes albopictus*. This mosquito also transmits chikungunya, yellow fever

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and Zika infection. Dengue is widespread throughout the tropics, with local variations in risk influenced by rainfall, temperature, and unplanned rapid urbanization. Severe dengue (also known as Dengue Hemorrhagic Fever) was first recognized in the 1950s during dengue epidemics in the Philippines and Thailand. Today, severe dengue affects most Asian and Latin American countries and has become a leading cause of hospitalization and death among children and adults in these regions.

Dengue viral infections are known to present a diverse clinical spectrum, ranging from asymptomatic illness to fatal dengue shock syndrome.[3] Symptoms usually begin about 4 to 7 days after the initial infection. In many cases, symptoms will be mild. They may be mistaken for symptoms of the flu or another infection. Young children and people who have never experienced infection may have a milder illness than older children and adults. Symptoms generally last for about 10 days and can include:

- Sudden, high-grade biphasic fever (up to 40°C)
- Severe headache
- Retro orbital pain
- Swollen lymph glands
- Severe joint and muscle pains (break bone fever)
- Skin rash (appearing between 2 and 5 days after the initial fever)
- Mild-to-severe nausea
- Mild–to-severe vomiting
- Mild bleeding from the nose or gums
- Mild bruising on the skin
- Febrile convulsions.[4]

Jaundice in dengue infection has been associated with fulminant liver failure and by itself is a poor prognostic factor.[5] However, there are only a few studies concerning liver dysfunction in children with liver dysfunction.

Although the number of patients affected by the virus is increasing each year, little work has been done in the studied area (regarding the pathogenicity, the liver changes, and the complication of dengue infection). Hence, it is with this objective that this present study was undertaken.

Aims and Objectives

This study aims to evaluate the effects of dengue fever, dengue hemorrhagic fever, as well as dengue shock syndrome on the hepatobiliary system in cases of dengue infections admitted to a tertiary setup in Burdwan, West Bengal, India. In this prospective observational cross-sectional study, I hereby intend to assess the frequency and degree of hepatobiliary dysfunction in adult patients with 26 dengue infections presenting to a tertiary care medical facility, as evident by the clinical manifestations, radiologic findings, and different laboratory workups. It will also aim to compare their outcome (mortality, length of stay, and complications) between patients with classical dengue fever and dengue hemorrhagic fever/dengue shock syndrome, with respect to their overall prognosis, morbidities, and mortality.

Specific Objective of the Study

The objectives of this study were as follows:

1. To know the demographic profile of dengue patients.
2. To know the incidence of liver involvement in dengue fever.
3. To measure aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase (ALP), serum albumin, platelet count, prothrombin time, and International Normalized Ratio.
4. To find out the correlation between alteration of these biochemical parameters with severity of the disease.
5. To find out the morbidity and mortality along with hospital stay of the dengue patients with the severity of hepatic involvement.

MATERIALS AND METHODS

Study Area

The study was conducted in Burdwan Medical College and Hospital situated in Burdwan district (West Bengal).The Institution serves as the only tertiary care teaching Hospital encompassing the whole Burdwan, Birbhum, some parts of Bankura district and parts of adjoining Jharkhand state.

Study Population

Patients had been admitted in Medicine indoor of our hospital, diagnosed as having dengue fever, clinically and by serological tests, selected as cases for this study satisfying both the inclusion criteria and exclusion criteria designed to be appropriate for this study.

Study Period

This study was March 2016–February 2017.

Sample Size

A total number of 102 patients diagnosed as cases of dengue fever were taken for this study.

Inclusion Criteria

Patients more than 12 year age admitted in Medicine ward in Burdwan Medical College and diagnosed as dengue fever clinically and confirmed serologically with the help of either dengue IgM or NS1 positive or both were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patient suffering from hep B, C, E, or A.

AQ6 **Table 1: Dengue classification**

Parameters	Petechial rash		Statistic	*P* value at df 2
	Present (%)	Absent (%)		
Dengue classification				
DF (n_1=60)	0 (0)	60 (100)		
DHF (n_2=33)	31 (94)	2 (6)	χ_2=110.07	0.00
DSS (n_3=9)	7 (78)	2 (22)		
Parameters	**Tourniquet test**		**Statistic**	***P* value at df 2**
	Positive (%)	**Negative (%)**		
Dengue classification				
DF (n_1=60)	0 (0)	60 (100)		
DHF (n_2=33)	28 (84)	6 (15)	χ_2=93.58	0.00
DSS (n_3=9)	7 (78)	2 (22)		

2. Patient suffering from malaria or typhoid.
3. Patient is with chronic liver disease.
4. Patient with bleeding disorder.
5. Patient received any blood or blood product recently.
6. Patient receiving hepato toxic drugs.

Study Design

This study was prospective, observational cross-sectional study.

RESULTS AND DISCUSSION

Our data show that liver injury was almost universally present in a predominantly adult group of patients with DI. In most patients, liver dysfunction was mild-to-moderate, presenting primarily as elevation of serum aminotransferases. However, some patients had clinical manifestations of liver disease, namely, jaundice, hepatomegaly, and ascites.

Recent studies suggest that there is an upsurge of complicated dengue infections, especially in South East and South Asia. Recognition of varied presentations of dengue infections is important so as not to miss the diagnosis. Clinical features suggesting dengue-related hepatic involvement are the presence of liver enlargement and elevated transaminases.[6]

Hepatomegaly in dengue infection is reported to be seen more frequently in complicated dengue in comparison to classical dengue fever. In the present study, 100% of cases in DSS group had hepatomegaly, whereas 88% in DHF group presented with hepatomegaly and only 25% cases of DF had hepatomegaly indicating that hepatomegaly may be used as an predictor for assessing the severity of the disease.

The WHO guidelines of 1997 state that enlarged liver is observed more frequently in dengue shock than in non-shock cases.[7] Senevinatne *et al.* observed a higher incidence of hepatomegaly with DHF than DF. A similar study performed by Wallace *et al.* concluded 21% of cases in DF group with hepatomegaly and 48% in DHF group presented with hepatomegaly. Study by Chairrulfatah *et al.* concluded that number of patients with hepatomegaly was significantly higher in DSS as compared to non DSS cases.[8] Fadilah *et al.* showed hepatomegaly in 40% cases of DF and 60% of DHF cases.

In our study, hepatomegaly in dengue infection is reported to be seen more frequently in complicated dengue in comparison to classical dengue fever. In the present study, 100% of cases in DSS group had hepatomegaly, whereas 88% in DHF group presented with hepatomegaly and only 25% cases of DF had hepatomegaly indicating that hepatomegaly may be used as a predictor for assessing the severity of the disease.

de Souza *et al.* found that 45% of cases had raised ALT levels with mean value of 100.2 U/L in DHF and 84.6 U/L in DF. In the present study, it was observed that hepatic dysfunction in the form of elevated liver enzymes was seen more in DSS as compared to non DSS cases suggesting that apart from dengue virus, hypoxemia as a result of hypovolemic shock or hosts response to infection remains to be to be determined as it may contribute to the adverse effects on the liver. Kuo *et al.* have reported that 82.2% of cases of dengue infection had elevated ALT levels. Parkash *et al.* reported 86% cases with raise AST level. Lee *et al.*, Trung *et al.*, and Wong *et al.* reported 86%, 97%, and 90.60% cases with raised AST.

Our study showed that AST levels were elevated in more number of patients in all the three groups compared to ALT values. Similar study done by Kuo *et al.* reported similar results with elevation of AST and ALT in 93.3% and 82.2% patients, respectively.[9] Like other studies in the present study, majority of our patients had elevated liver

enzymes, with AST being more elevated than ALT values. Patients with severe and complicated dengue had higher level of hepatic enzyme dysfunction.

Study by Mohan *et al.* also observed deranged AST levels frequently in DSS cases in comparison to non-shock cases. de Souza *et al.* found that mean value of AST in DHF was 127.1U/L and in DF was 89.8 U/L. Souza *et al.* have reported an incidence of 63.4%cases with elevated AST. Kuo *et al.* have reported that 93.3% of cases of dengue infection had elevated AST levels. Parkash *et al.* reported 95% cases with raise AST level. Lee *et al.*, Trung *et al.*, and Wrong *et al.* reported 86%, 97%, and 90.60% cases with raised AST.[10]

We observed that the maximum value of AST shown is 1326 and the mean AST amng DF cases 59.81, DHF cases 216.12, and DSS cases is 455.55.

Patwari *et al.* reported higher incidence of 25% 66 as compared to 16% by Itha *et al.* Ding The Thrung *et al.* reported an incidence of <2% 78, whereas none of the patients had jaundice in a study by W.Petedachai.[11]

We examined that among them two patients of DHF and eight patients of DSS show hyper bilirubinemia. The mean serum bilirubin among DSS group is 2.91 and the highest measured bilirubin is 5.1 mg/dl.

Study by Fadilah *et al.* showed that the mean percentage of T (CD3) cells was significantly lower in DHF compared to DF patients. Similarly, the mean percentage of B (CD19), CD4, CD8, and CD5 cells was also significantly lower in DHF patients compared to DF patients and controls. This study confirmed the significance of decrease in T, CD4, and CD8 cells in DHF and demonstrated that these lymphocyte subsets were of some value in differentiating DHF from DF. Marked activation of immunoregulatory T lymphocyte subsets may contribute to the severe complications seen in DHF/DSS including fulminant hepatitis.[12]

Platelet Count

It was also observed that the median lowest platelet count was lowest in DHF and DSS as compared to DF ($P = 0.000$). About 22.22% DF cases and 100% of DHF and DSS cases shown low platelet count. The mean platelet count among DF, DHF, and DSS group were 138,870, 49,560, and 43,077/μl accordingly. Wichmann *et al.* also inferred that patients with DHF had significantly lower platelet values than DF.[13]

Clinical Outcome

Out of 102 serology confirmed cases of dengue infection with 60 cases in dengue fever group, 33 being in DHF group and nine presented to us in dengue shock syndrome. There were ten cases with clinical evident jaundice with deranged liver function parameters. Six of our patients had ARDS and were shifted and treated in the ICU. Among those six patients, two patients died who require ventilatory support for severe respiratory distress and very low blood oxygen saturation. Another one patient expired secondary to DIC, multiorgan involvement, renal failure, dengue shock, coagulopathy, and deranged hepatic function profile. His liver enzymes were elevated above 5 fold the normal values. He had altered coagulation profile with prolonged PT and APTT values and thrombocytopenia. All those three patients referred from local health center with fever, severe respiratory distress, hemorrhagic manifestation, bilateral pedal edema, ascites, and pleural effusion. Other 99 cases were treated and cured completely and discharged from the hospital with stable hemodynamics.

CONCLUSION

This study showed that dengue fever was seen in all age groups and that AST and ALT levels were raised in the majority of these patients. It was also found that AST levels were more than ALT levels, which was commonly observed in all those patients who developed complications such as DHF, DSS, ARDS, renal failure, and septicaemia, proving he fact that severity of hepatic involvement can be a major contributing factor in morbidity and mortality of such patients with dengue fever. Hence, AST and ALT can be a useful early marker to assess the severity of the disease which can thus lead to early recognition of high-risk cases.

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Original Article

Comparative Study between Spinal Anesthesia versus Local Anesthesia for Lateral Internal Sphincterotomy for Chronic Fissure in ANO

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Abstract

Introduction: Anal fissure cases are commonly encountered in routine clinical practice, where patients present with hematochezia, intense, and painful anal spasm lasting for several hours after bowel movement. Conventionally, lateral sphincterotomy under spinal anesthesia is the procedure of choice for failed medical therapy. At present, there are few attempts to perform lateral sphincterotomy on an Ambulatory basis under local anesthesia. This study will assess the post-operative pain, average duration of hospital stays, and cost effectiveness of open lateral anal sphincterotomy under local anesthesia over spinal anesthesia.

Materials and Methods: Patients admitted in surgical wards GGH, Mahabubnagar, Telangana diagnosed as case of chronic fissure in ano by through clinical history and per rectal examination, are included in this study by applying the following inclusion and exclusion criteria. The study was conducted during the period June 2018 to July 2022 with 90 numbers of cases which are assigned to Group A (local) and Group B (spinal) randomly. A pre-structured pro forma is used to collect relevant information of each individual patient selected. Data are tabulated in Excel sheet and analyzed using SPSS software.

Results: LIS can be done under both spinal anesthesia and local infiltration. However, LA patient has lower duration of hospital stay, less expensive when compared to SA. Post-operative pain scores more in LA group in early post-operative time, whereas we do not find any difference at 5 h post-operative and post-operative day-1. Patient's satisfaction is good in LA group, whereas surgeon's satisfaction is similar in both groups.

Conclusion: LIS can be effectively and safely done as day care procedure under local anesthesia and provides alternative to SA, which is beneficial in terms of less hospital stay and less cost.

Key words: Chronic fissure in ano, Local anesthesia, Open lateral internal sphincterotomy, Spinal anesthesia

INTRODUCTION

Fissure in ano is a common anal disorder and causes significant agony and distress to the patient. An anal fissure is a linear ulcer in the mucosa of anal canal distal to dentate line and present with anal pain, spasm and/or with bleeding during defecation.[1] The cause of fissure is multifactorial. Most commonly, the fissure is single and located in the posterior midline, but it can also develop in the midline anteriorly, especially in parous females. There is no clear definition between acute and chronic fissure in ano, but many authorities believe that more than 6 weeks of persistence despite with conservative treatment is considered chronic fissure in ano. Most of fissure heal with conservative management within 4–6 weeks and some persist beyond 6 weeks and chronic.

Many believe that nonhealing of fissure is due to compromised blood circulation to the anoderm which is due to hypertonia of internal anal sphincter.[2] There is an increase in resting anal pressure in most of the patients as measured by anal manometry.[3,4] Blood flow to internal anal sphincter is also decreased in those patients as evidenced by muscle probes.[5,6] This explains how disruption of

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internal anal sphincter by surgery decreases anal tone and increases blood flow and promotes healing. Anal fissures with chronicity are unlikely to heal with conservative treatment as significant irreversible changes will happen in sphincter including fibrosis. Acute fissures usually heal with medical management but for reasons not well understood some fissures do not heal and become chronic and fail to respond to medical/conservative management.

Internal anal partial sphincterotomy (open or closed) is reserved for chronic fissures that fails or recurs frequently after non-surgical management.[7] Sphincterotomy using local anesthesia instead of spinal or general anesthesia has been proposed as an alternative method that does not lead to increases in associated morbidity or recurrence.[8,9] Until recently surgeons were hesitant to perform anal and rectal procedures in an ambulatory setting because of fear of postoperative pain and retention of urine.

This study is aimed at comparing the advantages and disadvantages of conducting open lateral anal sphincterotomy for chronic fissure in ano under local anesthesia versus spinal anesthesia.

Aim and Objectives

The aim of the study was to assess the post-operative pain, average duration of hospital stay, and cost effectiveness of open lateral internal sphincterotomy under local anesthesia over spinal anesthesia.

Anal Canal Anatomy

The anal canal is a continuation of the rectum and about 4 cm long. It extends from anorectal junction to anal verge. Interior of the anal canal shows many important features. The upper half of anal canal above dentate line is lined by columnar mucosa of the rectum and insensitive to pain. The mucosa below the dentate line is lined by squamous epithelium and is highly sensitive to pain and touch. Hence, any pathology below dentate line such as fissure in ano is very painful, and any pathology above dentate line such as hemorrhoids is painless in nature.

The anal canal is a muscular tube and has internal and external anal sphincters. The internal anal sphincter is a thickened involuntary muscle which is surrounded by voluntary external anal sphincter which is derived from the pelvic diaphragm. The external anal sphincter is divided into deep, superficial, and subcutaneous parts by longitudinal muscle of rectum which becomes fibrous in between anal sphincters.

Anal canal has a good blood supply and is supplied by the superior rectal artery above the dentate line and by the inferior rectal artery below the dentate line.

Above dentate line anal canal mucosa is supplied by autonomic nerves from both sympathetic (L1–L2) and parasympathetic (S2, 3, 4) through pelvic splanchnic nerves. Below pectinate line, it is supplied by inferior rectal nerve (S2, 3, 4) and carry pain, touch, and temperature sensations. Sympathetic nerves cause contraction of the internal anal sphincter and parasympathetic causes relaxation of internal sphincter. Contraction of external sphincter is effected by inferior rectal nerves and perineal branch of fourth sacral nerve.

METHODS

Randomized prospective comparative study conducted on patients diagnosed with chronic fissure in ano, admitted in surgical ward at GGH, Mahabubnagar, Telangana during the period of 3 years from 2018 to 2021, was taken for study considering the inclusion and exclusion criteria.

According to the study done by Kulkarni, *et al.*[10,11] proportion of proportion of patients getting discharged on day one operated under pudendal block; 93%. Proportion of proportion of patients getting discharged on day one operated under spinal anesthesia: 70%. At 95% confidence limit, 80% power of the study, sample size calculated is 44 and approximated to 45 in each group. Calculation was done using open Epi software version 2.3.1. This study included a total of 90 patients randomly divided into two groups each consisting of 45 patients: 45 patients undergoing surgery in local anesthesia (Group-A) and 45 patients undergoing surgery in spinal anesthesia (Group-B).

Inclusion Criteria and Exclusion Criteria

In this study, both male and female patients between the age group of 15 and 70 years with complaints of severe pain in the anal region, bleeding during defecation, constipation, and failed treatment in the past for fissure in ano were included in the study. In all cases, diagnosis of acute and chronic fissure was made by clinical examination only.

Patients with other, coexisting anal problems such as malignancy, anal incontinence, hemorrhoids, and fistula in ano were excluded from this study.

Patients with diagnosed hypersensitivity to local anesthesia, perineal infection in the area of local anesthesia, Patients on anticoagulant therapy and associated anal pathologies such as malignancy, incontinence, stenosis, fistula, hemorrhoids, and medical comorbid conditions such as with the history of coronary artery disease and chronic obstructive respiratory diseases were excluded from the study.

Informed written consent is taken for both procedures, that is, surgery either by local or spinal anesthesia from all

patients who are included in study. Ethical clearance was obtained. The data were analyzed using statistical software SPSS. It is a single blinded RCT, decision of surgery under local or spinal anesthesia to the patient is taken by cheat method, computer generated random numbers.

Before administration of local anesthesia, all patients were given a single dose of ceftriaxone and metronidazole. During surgery, one unit of fluid-containing normal saline with dextrose was administered. No special pre-operative investigations were done except routine blood and urine investigations.

Group A - Surgery Under Local Anesthesia

Patient in lithotomy position, under aseptic precautions, parts are painted and draped. 15–20 cc 2% of local anesthesia, lignocaine hydrochloride without adrenaline is infiltrated using 25 G needle including skin and over line of incision, intersphincteric space, and internal anal sphincter in left side of anal canal.

Group B - Surgery under Spinal Anesthesia

Intrathecal injection of 0.5% bupivacaine heavy is given at L3–L4 space in sitting position with aseptic measures; patient is then put in lithotomy position. Parts are painted and draped. Surgical procedure is common in both groups.

All the patients underwent standard open lateral internal anal sphincterectomy in lithotomy position irrespective of the groups. Intersphincteric groove was felt and radial incision was taken. Sphincter was divided to the length of fissure, under direct vision using surgical blade or electrocautery. Details regarding duration of hospital stay, intra and post-operative pain, complications, patient, and surgeons satisfaction were recorded.

RESULTS

Most of the patients were aged between 20 and 50 years in both groups. Maximum age in the study was 70 years and minimum was 19 years. The mean age in Group A (those who underwent local anesthesia) was 38.8 years and the mean age in Group B (those who underwent spinal anesthesia) was 41.33. In the Group A, there were 57.8% males and 42.2% females and in Group B, 60% were males and 40% were females. And the two groups were comparable and there is no statistical significance $P = 0.83$. In Group A, minimum number of days stayed in hospital was 1 day and maximum was 3 days with mean 1.92 days. In Group B, minimum number of days stayed in hospital was 3 days and maximum was 5 days with mean 3.73 days. It was noted that surgery under local infiltration had discharged earlier compared to Group B patients with $P < 0.001$, which is significant (Table 1).

Intra operative pain

Pain was assessed using visual analog scale (VAS). All the patients operated under spinal anesthesia had no intra-operative pain, but the patients operated under local infiltration has intra-operative pain score 2 (VAS score 2). $P < 0.001$ which is statically significant, that is, Group A (local) patients had experienced more pain compared to Group B (spinal) intra-operative. Surgery under local infiltration had little more pain and discomfort due to lithotomy position as limbs are not paralyzed, during giving local anesthesia, and during use of cautery compared to spinal anesthesia (Table 2).

Post-operative pain at 30 min

At 30 min of operation, patients operated under spinal anesthesia had no pain as they were still under effect of spinal anesthesia, whereas patients operated under local infiltration had VAS-2 in 11 patients (24.4%) and VAS-0 in remaining 34 patients (75.6%). $P < 0.001$ which is statically significant, that is, Group A (local) patients had experienced more pain compared to Group B (spinal) at 30 min post-operative (Table 3).

Post-operative pain at 5 h

At 5 h after operation, patients operated under spinal anesthesia had VAS-2 in 7 (15.5%) patients and VAS-0 in 38 (84.5%) patients, whereas patients operated under local

Table 1: Number of days stayed in the hospital

Days stayed					
Anesthesia	**N**	**Minimum**	**Maximum**	**Mean**	**SD**
Local infiltration	45	1.0	3.0	1.96	0.30
Spinal anesthesia	45	3.0	5.0	3.73	0.72

Z=8.6; *P*<0.001

Table 2: Intraoperative pain

VAS-intra operative	Local infiltration		Spinal anesthesia		Total	
	Count	%	Count	%	Count	%
No pain	10	22.2	45	100.0	55	61.1
Mild pain	35	77.8	0	0.0%	35	38.9
Total	45	100.0	45	100.0	90	100.0

P<0.001. VAS: Visual analog scale

Table 3: Post-operative pain at 30 min

VAS-post-operative 30 min	Anesthesia				Total	
	Local infiltration		Spinal anesthesia			
	Count	%	Count	%	Count	%
0	34	75.6	45	100.0	79	87.8
2	11	24.4	0	0.0	11	12.2
Total	45	100.0	45	100.0	90	100.0

P<0.001. VAS: Visual analog scale

infiltration had VAS-2 in 10 patients (22.2%) and VAS-0 in remaining 35 patients (77.8%). P =0.419, which is not statically significant, that is, spinal anesthesia is wear off in group B at 5 h post-operative period, and both group experienced same pain score (Table 4).

Post-operative pain at POD-1

After 1 day, patients operated under spinal anesthesia had VAS-2 in 8 (17.8%) patients and VAS-0 in 37 (82.2%) patients, whereas patients operated under local infiltration had VAS-2 in 9 patients (20%) and VAS-0 in remaining 36 patients (80%). P =0.7977, which is not statically significant, that is, both group experienced same pain on post-operative day 1 (Table 5).

In the all the patients underwent open lateral internal sphincterotomy, about 80% of patients were free of symptoms such as pain and bleeding during defecation on the next post-operative day. Rest 20% of patients had mild pain or bleeding during defecation, which are relieved on conservative treatment.

DISCUSSION

Medical management is the first line of treatment for fissure in ano. Even the in the advance of conservative management of chronic fissure in ano, the lateral internal sphincterotomy is considered as the gold standard. The surgical care definitely provides best healing rate and reduce the recurrence. The preference of anesthesia is also shifting towards the LA.[12-14] On the other hand, LA safely carried out by surgeon, and has virtually no complications.[12] Studies done by Ahmed *et al.* showed that there was no significant difference in post-operative pain. Whereas, study done by Towliat *et al.* found a significant difference ($P < 0.05$) in post-operative pain score after 6 h of LIS (group local - 1.90 ± 1.07 and group Spinal - 1.90 ± 1.07).

It is generally accepted that today the majority of minor ano rectal diseases such as chronic anal fissure should be performed on ambulatory basis.

Requirements for ambulatory basis are: Rapid onset, lack of intra operative and post-operative complications.[15] We all know that spinal anesthetic associated with hypotension more than 33% and bradycardia around 13%. However, post-dural puncture headache is most common complication of spinal anesthesia and although not life threatening, restricting daily life and causing hospital admission. In our study also, hospital stay is statistically significant ($P < 0.001$).

Bell from the University of British Columbia is of opinion that as the experience of surgeon increases, so does his confidence and ability to perform the lateral internal Anal sphincterotomy under LA.[16] In the present study, we firmly believe that patient with anal fissure should be admitted to hospital 1 day prior to surgery, those patients underwent under spinal anesthesia and post-operative recovery requires 3–5 days added 1-week rest at home. Hence, total loss of work may be 2 weeks, while patients operated under LA admitted on same day of surgery and discharged on same on ambulatory basis. All in all, pain is one of the postoperative complications that leads to longer hospital stay.[17]

Internal sphincter is not relaxed under LA. As the sphincter is in spasm, the length of the sphincter could be appreciated easily and the adequacy of the length of division verified distinctly. This benefit is lacking under spinal or general anesthesia where the sphincter is fully relaxed, presenting difficulties in defining its length. Since, we performed conservative or limited sphincterotomy in the study, defining the length of the sphincter carried major importance. Longer division of sphincter would lead to a higher rate of incontinence while shorter division may not relieve the spasm or heal the fissure.[18]

Considering the cost of pre-operative evaluation, surgery cost and postoperative medications and stay in spinal group patients spent at least 3 times more money than the local group patients for the same surgery. This carries greater significance in this setting where most of the patients come from poor economic backgrounds. In view of these benefits with LA, Hiltunen and Matikainen called it ambulatory treatment for CAF where patients were allowed to leave the clinic immediately after the surgery.[9]

Table 4: Post-operative pain at 5 h

VAS-post-operative 5 h	Anesthesia				Total	
	Local infiltration		Spinal anesthesia			
	Count	%	Count	%	Count	%
0	35	77.8	38	84.5	73	81.1
2	10	22.2	07	15.5	17	18.9
Total	45	100.0	45	100.0	90	100.0

P<0.419. VAS: Visual analog scale

Table 5: Post-operative pain on POD-1

VAS-post -operative POD–1	Anesthesia				Total	
	Local infiltration		Spinal anesthesia			
	Count	%	Count	%	Count	%
0	36	80	37	82.2	73	81.1
2	09	20	08	17.8	17	18.9
Total	45	100.0	45	100.0	90	100.0

P<0.7877. VAS: Visual analog scale

CONCLUSION

Better post-operative pain relief could be achieved by local anesthesia in ambulatory surgery in lateral anal sphincterotomy. LA provides adequate pain relief for the procedure apart from the advantage of easy palpability of the sphincter. It can be done as an outpatient procedure without the need for an anesthetist. There is no significant difference in the complications or the healing of the fissure as compared to SA, but LA procedure carries a significant cost benefit.

Ethical Approval

The study was approved by the Institutional Ethics Committee.

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Original Article

Retrospective Study of Cholecystectomy Performed in Rural Medical College in India

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Abstract

Background: Gall stones are common in Indian population. Cholecystectomy has become the universal standard for the treatment of cholecystitis and cholelithesis. We conducted this study to find out method of cholecystectomy in a developing countries like ours. In a rural area where patients usually present late, one, or other complications of cholelithesis before surgery.

Materials and Methods: Patients operated for gall stone between January 2017 and December 2019 were retrospectively analyzed in-term and demographic profile, clinical presentation, post-operative pain and analgesic requirement, and post-operative hospital stay and complications.

Results: Open cholecystectomy (OC) was performed in 110 patients between January 2017 and December 2019. All OC performed between the age 20 and 60 year age. 2/3rd (67%) were female. The mean operating time was 70.50 min. Comparable to laparoscopic cholecystectomy (LC) in Group B. Post-operative pain slightly more in Group A than Group B. Oral feeds time taken in Group A is 12 h comparable to Group B. Over all complications rate was comparable between Group A and Group B. No death in any group.

Conclusion: In this study, analysis emphasized OC can be safely performed in all patients with cholelithesis. Coming early or late with or without complications. May be from low socioeconomic group or rural areas. Here, (IIMS and R medical college) treatment is free and post-operative minimum minor complications. Hence, patients acceptability for OC is 100% in laparoscopic era (LC).

Key words: Open cholecystectomy, Laparoscopic cholecystectomy, Retrospective study

INTRODUCTION

Gall stone disease is a common health problem. The management of symptomatic gall stone disease was improved by the introduction of laparoscopic cholecystectomy (LC).[1] Nowadays, LC is considered the gold standard for the treatment of symptomatic gallbladder stones and has replaced the traditional open cholecystectomy (OC).[2,3] The laparoscopic technique has many advantages over the open approach such as decrease in post-operative pain, reduction of postoperative complications, shorter hospitalization with earlier mobility and return to normal work activity, and better cosmotic results. The duration of LC has continuously decreased as a result of increasing the learning curve of surgeons.[4]

In spite of these advantages, OC still has a place in the laparoscopic surgery era.[5,6] OC is principally preserved for the challenging cases in which laparoscopy fails.[5] Most OCs are performed as a result of conversion from LC.[7] Conversion rates for LC vary widely, with a reported range of 2–15% in the previous series, mostly due to bleeding and unclear anatomy.[5,8,9] Conversion is not be a complication, but it represents a valuable choice to avoid an additional risk.[10] Risk factors of conversion to OC included old age, male sex, obesity, acute cholecystitis, previous upper abdominal surgery, the presence of diabetes and high glycosylated hemoglobin levels, and a less experienced surgeon.[11]

OC is still indicated from the start in selected cases without any laparoscopic trials. Some indications for open operation include suspected or confirmed gall- bladder cancer

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preoperatively or intraoperatively anticipating the possibility of a portal lymph node dissection, as well as an en bloc resection of the gallbladder, a portion of the liver, and perhaps a segment of the bile duct.[12-15] The older patients with comorbidities are more susceptible for OC from the start.[16] In patients with bleeding disorders and portal hypertension, potential bleeding may be difficult to control laparoscopically, and an open approach may be mandatory.[14]

Although LC has been proven to be safe in all trimesters of pregnancy, an open operation should be considered, especially in the third trimester, since laparoscopic port placement and insufflation may be difficult. Consequently, OC is generally necessary during the late stages of pregnancy, if the operation cannot be delayed until after delivery of the baby.[15] An open operation is also necessary in Type II Mirizzi syndrome (cholecystobiliary fistula) and gallstone ileus.[16]

Few studies in the literature have reported the role of OC in the management of gallbladder stones in the laparoscopic era. Hence, the aim of this retrospective study is to study safety and efficacy of OC in patients of cholelithiasis by comparing with results of LC in terms of use of post-operative analgesia, operative time, post-operative hospital stay, morbidity, mortality, and factors responsible for conversion.

MATERIALS AND METHODS

This study was a retrospective type of observational study included 110 patients with gall stones and gall bladder related disease who were admitted in Gen Surgery in IIMSR and NOOR Hospital between January 2017 and December 2019 for OC. In our institute only OC done due to lack of resources, LC cases taken from other studies. Among them patients who matched with our inclusion criteria (mentioned below) were selected for our study and those having any of the exclusion criteria were rejected. Incomplete and missed data were also removed from analysis. The study population was then divided into two groups, that is, Group A and Group B. Patients subjected to OC were grouped in Group A and those subjected to LC were in Group B. By this above mentioned method, we selected 110 patients taken for OC and for LC compared with other studies.

Inclusion Criteria

The following criteria were included in the study:

- Acute cholecystitis
- Chronic cholecystitis
- Cholelithiasis
- Gangrenous gall bladder
- Mucocoele and empyema of gall bladder.

Exclusion Criteria

The following criteria were excluded from the study:

- Choledocholithiasis
- Carcinoma of gall bladder
- Perforated gall bladder
- Uncontrolled coagulopathy and end stage liver disease.

Data collected for our study population were age, gender, duration of surgery, intra and post-operative complications, post-operative pain and analgesic use, and duration of hospital stay.

Statistical Analysis

All statistical analyses will be performed using IBM SPSS v.20 software. $P < 0.5$ will be considered statistically significant. The Shapiro–Wilk test is used to assess normality of data. Numerical data are presented as means and standard deviations or as medians with ranges. Chi-square test and Mann–Whitney U test are used when appropriate.

RESULTS

The mean age of study population was 41.00 ± 11.00 years with a range of 20 years–80 years, median age being 40 years. Mean age of Group A was 40.50 ± 11.25, ranged from 20 years to 80 years, median 40 years. According to other studies, while mean age of Group B was 42.02 ± 11.67 years with a range between 22 years and 72 years, median 40 years.

Age

Open cholecystectomy Group A

Age	No of points	Percentage
20–40	60	54.54
41–60	46	41.82
more 60	04	3.64
Total	110	100

Laparoscopic cholecystectomy Group B (different studies[17])

Age	No of points (Bhar *et al.*) (%)	No of points (Ranjan *et al.*)
20–40	43 (53.75)	11 (18.33)
41–60	28 (35)	41 (68.33)
More 60	9 (11.25)	08 (13.33)
Total	80	60

In Group A, 60 (54.54%) patients were in age group of (20–40) years, 46 patients (38.18%) in (41–60) years group while 4 (3.62%) of them were above 60 years according to different studies. In Group B, 43 cases (53.75%) were in the first group, that is, 20–40 years, 28 patients (35%) in 41–60 years Group, and 9 (11.25%)

were above 9 years[17] 12R. Another study shows 11.48 and 8, respectively, with age.

Gender

Group A		
	Group A	Percentage
Male	36	32.72
Female	74	67.27
Total	110	100

Group B different studies			
Group B different Studies	Male (%)	Female (%)	Total patient
Bhar *et al*.	24 (30)	56 (70)	80
Shukla *et al*.	11 (22)	39 (78)	50

Among the study population, Group A contains 36 (32.72%) were male and 74 (67.27%) female and in Group B taken from different studies, it was 24 (30%) male and 56 (70%) female[17] 12R. In another study shows 11 male (22%) patient and 39 female (78%)14.

Duration of Surgery

Group A (OC)	
Mean duration of surgery	70.50 min

Group B (LC) different studies	Mean duration of surgery
Karim *et al*.	46.27
Bhar *et al*.	70.25
Shukla *et al*.	52.32
Karim *et al*.	103.98
Ranjan *et al*.	72.50

The mean duration of surgery in Group B was (69.06). No statistically differences between Group A (70.50) and Group B (69.06)

The mean duration of surgery for Group A was 70.50 min. For B group taken from different studies 46.27, 70.25, 52.32, 103.98, and 72.50 min. 20r, 12r, 14, 17, and 13.

Intra and Post-operative Complications

	Group A	Different studies Laparoscopic Group B			
Complications	Open	Ranjan *et al*.	Bhar *et al*.	Shukla *et al*.	Karim *et al*.
Intraoperative bleeding	1	2	3	0	1
Bile duct injury	0	1	1	0	2
Wound dehiscence	0	0	0	0	0
Wound infection	0	5	2	0	3
Abdominal infection	0	0	0	0	0
Post-operative ileus	1	3	2	0	3
Pulmonary problems	1	2	1	0	2
Cardiac problems	0	0	0	0	0
Death	0	0	0	0	0

In above table, we can see that post-operative complication is more in Group B compared to that in Group A which is statistically significant. Laparoscopic surgery depends on experience also in Shukla *et al*. There is no any complication.

Duration of Analgesia Use (days) and Hospital Stay

The mean duration of analgesic use after operation was much more in Group A (3.36 days) compared to that in Group B (1.47 days) and this was found to be statistically significant.

The mean duration of post-operative hospital stay was much higher in Group A (3.34 days) compared to that in Group B (2.54 days) and which was found to be statistically significant.

DISCUSSION

Until quite recently, standard OC still was considered the treatment of choice for symptomatic gallstone disease. Mortality rates have declined to between 0% and 1% in most recent reports and in an elective setting, the rate of major complications is approximately 4.5%.[6-8] Despite these favorable data for OC, LC has become a popular and common method for removing the gallbladder in all Western countries. A shorter stay in hospital, faster recovery, less postoperative pain, and smaller scar are major advantages.

At the department of surgery at the Noor Hospital and IIMS and R Medical College, Warudi Jalna, for acute cholecystitis with cholelithiasis is by treating early OC and for elective also OC. Although LC for acute cholecystitis is feasible safe and beneficial in terms of shorter hospital stay compared with delayed LC.

There are studies which show natural history of incidentally discovered gallstone is not only benign but even when they do develop complications; it is usually preceded by at least one episode of biliary pain and longer the stones remain asymptomatic, the less likely that complications will occur. In about 30% patients who have had pain do not have further episode of pain; thus for persons with asymptomatic gallstone, the natural history is so benign that not recommended.[1,7,12] However, our experience with long standing cases of cholelithiasis is different and more often than not they present with one or other complications preoperatively and pose difficulty in surgery. LC changed the view of surgeons and the patients toward the asymtomatic gallstone. The wide spread use of LC a significant change has been observed possibly due to the attitude of surgeons to relax the induction of surgery, including for asymptomatic gallstone, resulting in an increase in cholecystectomies worldwide. LC in young patients with uncomplicated asymptomatic gallstone is safe with greater patient acceptance and this approach in early

	Group A (mean)	Group B (mean) Different studies				
		Bhar *et al.*	Karim *et al.*	Ranjan *et al.*	Shukla *et al.*	Karim *et al.*
Duration of Analgesic Use (Days)	3.36	1.52	2.00	1.80	0.56	1.50
Hospital stay (days)	3.34	2.36	2.56	3.60	1.18	3.00

age eliminates the need for problematic surgery at a later date when a patient is older with associated disease or with complications.[7,10] The chance of slipping on to the CBD is high and complications such as obstructive jaundice, cholangitis, and pancreatitis likely.[2,4,7] Conversion rate in LC ranges from 3% to 4% in well trained hand.

The frequency of bile duct injury is 0.1–0.2% for OC and 0.3–0.6% for LC. In our study, bile duct injury is nil comparable groups Ranjan *et al.*, Bhar *et al.*, and Karim *et al.* Bile duct injury was present (11 and 2) the majority patients coming from rural area, low socioeconomic group, coming late and ready for any type surgery. In this institute IIMS and R Medical College and Noor Hospital, free treatment is given (free surgery, bed charges, and free food). So no financial burden to the patient for surgery and hospital stay. Most important thing about the OC patients is negligible post-operative complications. All surgeries performed by senior surgeons. No mortality. Patient tolerance is good.

The findings in the present study showed that though LC is a viable, less complicated, more effective, and more satisfactory procedure that shortens the hospital stay and assures, early return to work. However, the usefulness of LC in a variable profile of patients' needs to be evaluated. In OC, no variable profile needed, no exclusion criteria. All patients can undergo OC; here, hospital stay is significantly longer and early return to work.

CONCLUSION

In the study, analysis emphasize OC can be safely performed in all patients with cholecystitis and cholelithisis coming early or late with or without complications. May be from low socio-economic group or rural areas. Here, (IIMS and R Medical College) treatment is free and post-operative minor complication. Hence, patients acceptability for OC is 100%. As per other comparable LC study groups, difficult LC is relatively common in India. There is need to stick to maximum time limit in difficult cases to avoid complications due to surgery or prolonged anesthesia. During study period, operation time for LC has shown a tendency to become shorter and conversion rate has shown a decreasing trend probably due to better planning and experience.

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Original Article

Rehabilitation after Stroke: Practicable Functionalities and Benefiting Patients of Brain-computer Interfaces in Combination with Functional Electrical Stimulation – A Qualitative Interview Study

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Abstract

Introduction: Brain-computer interfaces in combination with functional electrical stimulation (BCI-FES) is currently researched whether it is a viable approach for post-stroke rehabilitation, but it is important to know which patient groups can benefit from such systems and what features it should have to be accepted and used in a clinical context.

Materials and Methods: A qualitative interview study with eight staff members from a regional hospital with a supraregional stroke unit was conducted. Categories where independently extracted from the answers.

Results: The results indicate that such systems must be easy to operate, quick to setup, and should possibly be usable at home. The interviewees state that Phases A and B patients (acute rehabilitation and early rehabilitation) may not benefit from such systems as they usually do not have the cognitive abilities to understand and implement the instruction.

Conclusion: BCI-FES system is currently not useful for inpatient rehabilitation routine of a stroke unit due to the lack of time and complexity of such systems. Furthermore, it should be evaluated how Phases C and D patients (follow-up rehabilitation) can benefit from such systems.

Key words: Brain-computer interfaces, Electrical stimulation, Electroencephalography, Rehabilitation, Stroke

INTRODUCTION

Stroke is the second leading cause of death worldwide and one of the most common causes of severe disability in adulthood.[1] Up to three-quarters of those affected survive the stroke and must then be provided with specific drug therapies and rehabilitative or nursing services.[2]

In Germany, a phase model (A-G) exists for the different stages of stroke rehabilitation. Phase A includes acute care, in which the patient is treated in a stroke unit, intensive care unit, or normal ward. Phase B is the beginning of early rehabilitation, in which intensive treatment and rehabilitation with medical and therapeutic focus is carried out. In Phase C, the patient needs much less help in coping with everyday life, so that mobilization and the restoration of independence are the main focus here. The purely medical rehabilitation ends with Phase D, the follow-up rehabilitation treatment, in which the main focus is the reduction of existing disability.[3]

However, up to 40% of the surviving stroke patients have long-term limitations in the activities of daily living and thus suffer from problems with mobility, personal hygiene, independent dressing, and eating.[4] For this reason, early, effective rehabilitation is crucial for the long-term quality of life of those affected.[5] Consequently, there is a constant need for the development of new therapeutic strategies that will enable a significant improvement in rehabilitation procedures.[6]

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At present, brain-computer interfaces (BCIs) are increasingly important in rehabilitation therapy after stroke. BCIs aim to create a new communication channel between the brain and external devices without any neuromuscular intervention.[7] They may fill the gap between patient expectations and therapy results. BCIs capture, analyze, and use electroencephalography (EEG) activity in real-time. Patients imagine a certain movement and the corresponding brain activity is recorded by EEG electrodes and sent to an amplifier. When the correct movement is interpreted by the classification algorithm of the BCI, sensory feedback is provided by external devices.[8]

Based on this, BCIs are currently being researched in combination with functional electrical stimulation (FES) in post-stroke patients.[9-11] FES is a technique in which electrical currents are applied to produce artificially controlled muscle contractions.[12] The main advantage of rehabilitation based on BCI-FES over conventional therapies is that it is based on the patient's active intention to move, which simultaneously activates sensory and motor pathways and thus promotes neuroplasticity.[9] The enhancement of neuronal plasticity after a stroke by BCI-FES is a sustainable approach that opens up new possibilities for stroke rehabilitation.[13] However, according to a systematic review, a positive effect of BCI and FES is only marginally detectable and has to be compared to a very high therapy effort. None of the studies conducted to date have provided clinically convincing results with regard to improved motor rehabilitation.[13]

For this reason, it is important to know in which phase and for what patient groups the application of BCI in combination with FES should be considered. It is also necessary to check which functions a system must have to be used sensibly in everyday rehabilitation practice.

To elaborate these questions, a qualitative interview study at a regional hospital with a supraregional stroke unit was conducted. The aim of the study was to ask employed neurologists and non-medical staff about rehabilitation therapy after stroke. The survey focused on the question of which patient groups, according to the experts, can benefit from BCIs in combination with FES, what weaknesses such systems currently have, and what functionality it should have in order to be used in practice. The interview took place in the overall project "Technische Innovation in der Schlaganfall Rehabilitation" (Technical innovation in stroke rehabilitation) (04/2019–12/2021), where a BCI-FES device is developed.

MATERIALS AND METHODS

The present study is based on eight guideline-based expert interviews with neurologists ($n = 5$), physiotherapists ($n = 2$) and a nurse from the neurology department of a stroke unit [Table 1] and was approved by the ethics committee of the University of Applied Sciences Zwickau. A guideline was developed, which was used as a basis for all interviews. Thus, individual interviews are easily comparable, since the survey situation is similar and the same questions were asked.[14] The guideline was divided into six topics:

1. Current forms of therapy
2. Wishes and requirements for stroke rehabilitation
3. Experiences with BCI and FES
4. How the system should work in practical application
5. Concerns about the use of BCI and FES
6. Benefiting patient group.

Interviewees were referred in 2020 by the head of the participating hospital using the gatekeeper method, where the gatekeeper provides pre-selected interview partners.[15] Following common qualitative sampling strategies, the selection of the interview partners aimed at a composition of the group that was as heterogeneous as possible.[16] The target groups were experts from the professional groups of medicine, physiotherapy, and nursing. The experts had different hierarchical levels. The fields of work of the professional groups are accordingly heterogeneous and range from medical care and therapeutic procedures to basic and treatment care. After the pre-selection process, the respondents who had agreed in principle to participate received information material on the topic of the interview. All interviewees gave their consent to participate in the study after having been informed in advance.

The interviews were conducted by a nursing and a computer scientist and recorded with a tape recorder and transcribed according to the rules of transcription. During transcription, all personal data were anonymized. The evaluation of the data was carried out according to the systematic and rule-guided procedure of Mayring.[17] The focus was on the development of a category system. Categories are developed in a reciprocal relationship between the question and the concrete material, defined by construction and assignment rules, and revised and re-examined during the analysis. Through the inductive category definition, the categories were derived directly from the material without referring to previously defined theoretical concepts.[17] The categories were created independently by two scientists and then compared

Table 1: Sample structure with regard to assignment and duration of activity

Assigned professional role	Duration of activity
Neurologists (*n*=5)	Mean 19.8 (±7.02) years
Physiotherapists (*n*=2)	Mean 14 (±4) years
Nurse (*n*=1)	15 years

with each other. The deductively formed categories and inductively formed subcategories that were found out by both scientists were coded during the analysis of the interview material [Table 2].

RESULTS

On behalf of the interview material, it could be determined that the most frequently used therapy after a stroke is physiotherapy. In the following occupational therapy, speech therapy and neuropsychology are used as rehabilitation therapy in the first phases after the stroke, depending on the type of stroke. In the field of outpatient rehabilitation, occupational therapy and sports therapy were also mentioned.

In the beginning, it was of interest to find out what wishes and requirements result from the view of the hospital staff for the stroke rehabilitation. Half of the respondents stated that the therapies should be patient-oriented and individualized. Three of eight also had the opinion that it would be useful to implement digitization in stroke rehabilitation. With reference to this, one member of the physiotherapy staff (T/P1, personal interview, July 15, 2020) expressed the following opinion:

- We need modern, contemporary tools … adapted … electronically controlled through apps, adaptable to the patient.

BCI in combination with FES is unknown to all respondents. Only one physiotherapists and two neurologists are familiar with similar procedures, mainly from Parkinson disease rehabilitation therapy. Brain stimulators have been named for this purpose, which are invasive and should lead to improved mobility.

In spite of the limited experience, all respondents can imagine working with a BCI in combination with FES. To design therapy units in a meaningful way, however, the systems should be easy and quick to set up and operate. One neurologist (A4, personal interview, July 23, 2020) summarized the following functions:

- It must be quick to put on. It does not make sense that it takes half an hour of preparation time to put on the hood, etc. This is not possible in the general therapy concept.

In terms of ease of use, several respondents could imagine that the device would also have to be operable at home by the patient himself or a relative. For this purpose, however, an exact electrode placement would have to be defined. However, this is not easy to implement, since the correct electrode location is different for each person with regard to anthropometric data, such as length and mass of the forearm.[18] A physiotherapist (T/P2, personal interview, July 15, 2020) expressed the following functionalities:

- It should have the ability that the electrodes stay where they are or set a marker where they have to go … so that you can use it at home.… It has to be constructed so simply that the patient or the relatives can understand what they have to do with three switches..., otherwise it quickly leads to frustration.

According to several interviewees, another major benefit of this system lies in the area of motivation. Especially for cognitively unrestricted patients, the additional feedback triggered by the electrical muscle stimulation can lead to an increased feeling of therapeutic success. For many patients, it is sufficient to stimulate a movement to standardize it.

The application should be wireless, so that the risk of falling is minimized and ease of use is simplified. In addition to the therapeutic benefits, all those involved have sometimes very different concerns about such systems. According to the respondents, this system cannot be used for every stroke patient.

According to the interviewees, it is mainly patients who belong to Phases C and D who benefit from the system, that is, who can have a certain mobility and alertness.

Participation in the therapy requires not only motivation but also certain cognitive abilities of the patient. For example, old age, multimorbidity, depression, and fatigue often play a decisive role.[13]

One neurologist (A4, personal interview, July 23, 2020) summarized the concerns as follows:

Table 2: Categories and subcategories ordered by importance (how often it was named)

Categories	Subcategories
Stroke therapy wishes and requirements (WR)	WR1 – Patient-oriented therapy (4)
	WR2 – Digitalization (3)
	WR3 – Longer therapy sessions (3)
	WR4 – Interdisciplinary collaboration (2)
Requirement for BCI-FES Systems (RS)	RS1 – Quick to set up (6)
	RS2 – Easy to operate (5)
	RS3 – Usable at home (4)
	RS4 – Useful movements (2)
	RS5 – Entertainment value for patients (1)
	RS6 – Evidence based (1)
Concerns BCI-FES Rehabilitation Systems (CBF)	CBF1 – Lack of effect (4)
	CBF2 – Comprehension problems (3)
	CBF3 – Risk of falling (2)
	CBF4 – Damage by current (2)
	CBF5 – Therapist substitution (1)
Patient group (PG)	PG1 – Adequate, cognitively fit patients (5)
	PG2 – Patients with affinity for technology (2)

BCI-FES: Brain-computer interfaces in combination with functional electrical stimulation

- I am concerned that patients simply do not understand this in the acute phase. After all, patients are asked to actively cooperate. I think that this is difficult in the acute phase. In the end, it is mainly about the severely affected patients. Those who have mild paresis are more likely to benefit from active therapy. It is more about the patients who have severe paresis. They are usually also severely affected. They simply have to have the cognitive abilities to implement this at all.

A member of the physiotherapy staff had the opinion that the system should not be seen as the only sensible therapy. Only in combination with classical rehabilitation methods, it could be an asset for the practice. These applications must not suggest to the patient that these are the only rehabilitation options.

DISCUSSION

One of the main concern against using a BCI System in a clinical context is the technical complexity[19] which our interviewees stated indirectly with RS1 and RS2. BCI in combination with FES is not feasible for every stroke patient as Hashimoto *et al.* state that "patients with early stroke are not able to activate the sensorimotorcortex enough to affect their EEGs"[10] which correlates to PG1 and is also supported by Hernandez-Rojas *et al.*[11] A meta-analysis of different clinical trials indicates a positive effect using BCI and FES in a clinical context;[20] however, the effect in contrast to the effort was not evaluated. Other literature state that it can be difficult for clinicians to select a beneficial BCI method as "the specific mechanisms underlying functional improvements remain largely unknown"[21] which can lead to frustration because of a lack of effect. Despite the fact that interviewees were naive about BCI in combination with FES, they gave valuable information that is supported by literature and contain new aspects that should be considered in designing a BCI-FES therapy.

CONCLUSION

Post-stroke rehabilitation through BCI-FES can open up new possibilities for stroke rehabilitation. However, the results of the survey and Simon *et al.*[21] indicate that the system is not practicable in its current application for use in the inpatient rehabilitation routine of a stroke unit. A too long preparation time disturbs an efficient flow of the therapy units. Due to the complex location of the electrode placement and the time limited therapy units, the therapy is difficult to implement. This is also reflected in a systematic review: The application of BCI and FES means a high therapy effort, which is opposed by a so far only marginally demonstrable therapy success.[13]

Furthermore, from the perspective of physical therapists, finding the correct location of the electrodes prevents a quick and easy therapy session. Furthermore, according to a systematic literature review, this has been identified as a problem in the use of BCI in conjunction with FES. Most of the research studies reviewed did not accurately define the exact electrical placements.[18] Patients who are hospitalized shortly after a stroke often belong to Phases A and B, where medical care and early rehabilitation are generally the first priority. In many cases, the severely affected patients are not able to understand and implement instructions. Therefore, it should be investigated to what extent patients of Phases C and D benefit from the therapy compared to Phases A and B patients which is also supported in the literature.[10,11]

Furthermore, the use of therapy at home by relatives or outpatient physiotherapy would also be conceivable. However, even in this case, the system should follow simple structures in its application and usability.

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Original Article

A Comparative Assessment of Bite Pressure between Implant Prosthesis and Natural Teeth: An *In vivo* Study

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Abstract

Aim of the Study: This study aims to evaluate and compare bite pressure among individuals with implant prosthesis on one side and natural dentition on the contralateral side in mandibular 1st molar region using NUPAI bite scan system.

Materials and Methods: A total of 30 subjects (15 in which implant prosthesis on the right side and 15 in which implant prosthesis on the left side) with implant prosthesis on the one side and natural dentition on the contralateral side participated in the study. The bite pressure was measured at the first molar area on both the sides using NUPAI bite scan.

Results: Maximum bite pressure, average bite pressure, and the amount of the pressed area were found to be more on the natural dentition side in comparison to the side with implant prosthesis. Average pressure on natural teeth was 25.33 MPa and on implant prosthesis 21.27 MPa.

Conclusion: The present study concludes that the measured bite pressure at the natural dentition side is found to be higher than those at the fabricated implant prosthesis side. *P*-value for average bite pressure is 0.033, which is significant ($P < 0.05$).

Key words: Bite pressure, Bite sensor, Group function occlusion, Screw-retained implant prosthesis

INTRODUCTION

Determination of individual bite force level in dentistry has been widely used to understand the mechanics of mastication for the evaluation of the therapeutic effects of prosthetic devices and to provide reference values for studies on the biomechanics of prosthetic devices. The measurement of bite force is useful in evaluating muscle function and is also an adjunct in assessing the performance of prosthesis. Measurements related to bite force are difficult to detect and the reliability of the result depends on large number of factors, such as gender, age, craniofacial morphology, occlusal factors, presence of pain, and temporomandibular disorder. Apart from these physiological factors, recording devices and techniques play major role and are important factors in bite pressure measurement. To evaluate bite pressure, various techniques and devices are utilized including portable hydraulic pressure gauges, the bite fork, force sensing resistors, strain gauge transducers, pressurized rubber tube, foil transducers, pressure-sensitive sheets, and the gnathodynamometer.[1]

The fitness of the masticatory framework relies mostly on alignment and occlusion of dentition. Improper occlusal contacts and inappropriate head postures are considered to be the main causes for the start of pain in the temporomandibular joint (TMJ) later followed by TMJ disorders.[2] Bone is the ultimate bearer of the occlusal load as dental implants are placed. Maximum bite force generated by patients is not uniform. Posterior jaw occlusal

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biting load is about 3 times more than that of anterior biting load. Bone loss around implant and failure of fixture can be due to overloaded implant prosthesis by patients' biting force. When planning dental implant treatment, bite force measurement may be an important parameter. Luxation of the fixture and subsequent loss of osseointegration may occur in patients generating extreme biting loads. Long-term successful outcome even with poor anatomical bone qualities can be seen in patients with low biting force. There is an increased risk for late component fracture or implant failure in patients with a high bite force.[3]

It has been documented that human mean maximum bite force is 738 N. Significant values were found for gender related mean maximum bite force, whereas the correlation coefficients for age, stature, weight, and body type were found to be low. Raadsheer *et al.* (1996) reported similar results and average values of the maximal voluntary bite forces in men were 545.7 N, and in females, it was reported 383.6 N.[4,5] In a dentate person, the average force has been measured 150–250 psi in the first molar region.[6] Forces of mastication are not constant in all the individuals and vary person to person according to these studies.

NUPAI bite scan enables anyone to measure pressure easily, just by inserting sensor between two surfaces. Measures pressure by color density. Not just force at a single location, it measures the distribution of it. No power source required just cut and fit any dimensions. Computer digital reading of sensor by scanner that convert pressure density dots into quantity values. Precise measurement of bite pressure, pressure distribution, and pressure balance can be done with the help of prescale film. Pressurized area of film will change its color to red on application of pressure and the color density varies according to the various pressure levels. The present study compares the biting pressure within the same patient on the mandible where one side has natural dentition and the contralateral side has been restored with an implant prosthesis using NUPAI bite scan system.

MATERIALS AND METHODS

The present study is an *in vivo* study which was conducted in the Department of Prosthodontics and Crown and Bridge and SN Enterprise (NUPAI bite Scan), Delhi. Thirty patients were selected for the study.

Inclusion Criteria

The following criteria were included in the study:

- Successfully osseointegrated single posterior dental implant prosthesis with respect to any of the mandibular 1st molar region in occlusion with natural dentition
- Sound natural mandibular 1st molar tooth on contralateral arch in occlusion with natural dentition
- Proper neuromuscular coordination.

Exclusion Criteria

The following criteria were excluded from the study:

- Temporomandibular disorders
- Implant prosthesis other than mandibular 1st molar
- More than 1 implant prosthesis
- History of bruxism and traumatic occlusion
- Faulty implant prosthesis
- Oral infection
- Soreness
- Ulceration
- Inflammation.

Materials

1. Articulating paper (Bausch, Germany)
2. NUPAI bite sheets (Fuji, Tokyo, Japan)
3. Bite sheet holder (NUPAI, S.N Enterprise, Delhi [Figure 1]).

Methodology

A thorough case history of the patient was taken. Clinical examination of the patient was done to meet the inclusion criteria and rule out the exclusion criteria. Thirty patients were divided into two groups: Group 1: Having implant prosthesis on the right side and Group 2: Having implant prosthesis on the left side.

In the 1st appointment, occlusion of the implant prosthesis was checked and health of implant and peri-implant tissues was evaluated with the help of orthopantomogram [Figure 2]. As natural teeth are periodontaly sound and embedded in bone while implant prosthesis has no periodontal ligaments. There is difference in vertical movement of the natural tooth and implant prosthesis. The patient is asked to bite into centric relation with a very light force on thin articulating paper to evaluate occlusal contacts. The implant crown should have

Figure 1: Holder with sensor (bite sheet)

no contact in light biting force. Any contact with the implant prosthesis is removed. Then, the patient was asked to apply greater occlusal force to the articulating paper as equal to normal food chew force so that equal contact of implant crown and natural teeth occurs. This "timed" contact will account for the mobility differences between the teeth and implant prosthesis.

In the 2nd appointment, the bite of the patient was taken. The patient was asked to sit straight and the position of the head was adjusted so that it was straight. The bite sheet within a thin plastic pouch [Figure 1] to prevent saliva contamination was inserted in the holder so that the shiny surface of the sheet would face downward. The sheet and holder were inserted in the patient's mouth [Figure 3]. The patient was asked to bite a single time over the bite sheet with maximum force. The red markings [Figure 4] on the sheet as a result obtained were sent for NUPAI bite scan analysis. Figures 5–13 depict the different stages of the *in vivo* study.

Statistical Analysis

The data were entered into a Microsoft Excel spreadsheet and imported into Statistical Package for the Social Sciences (SPSS) version 22 for statistical analysis. Data were present

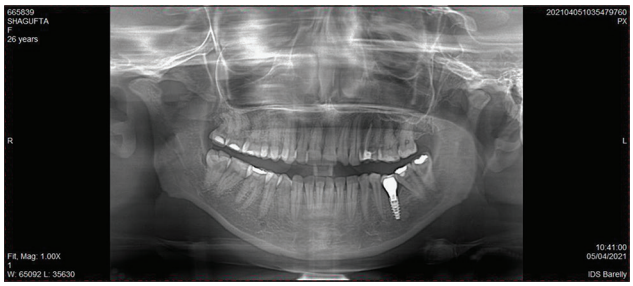


Figure 2: Post-operative orthopantomogram

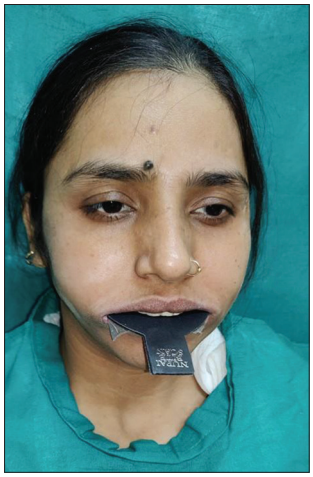


Figure 3: Patient biting on sensor

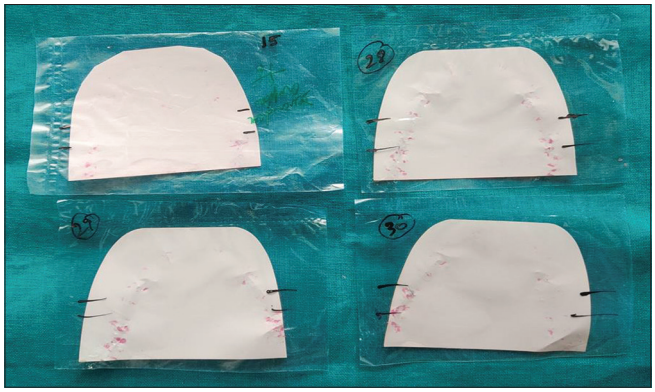


Figure 4: Sensors with bite pressure recorded (red markings)

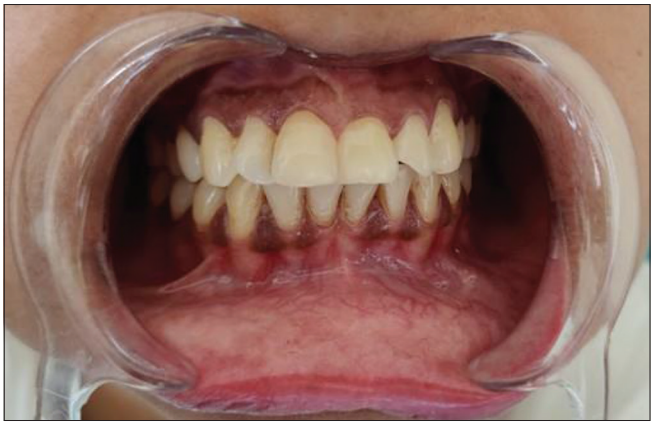


Figure 5: Centric occlusion

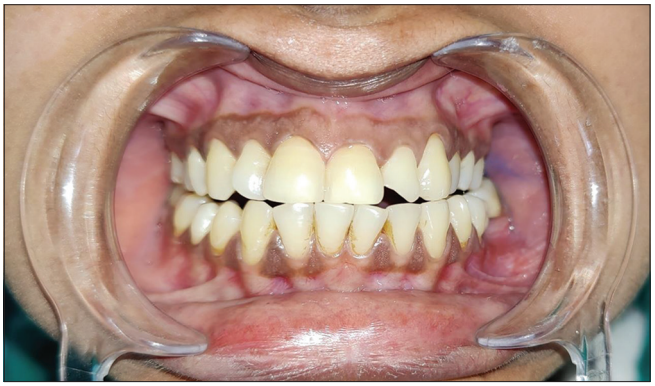


Figure 6: Protrusive occlusion

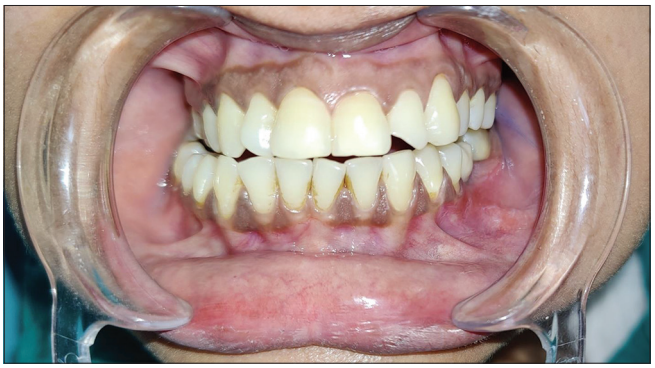


Figure 7: Left lateral: Protrusive occlusion

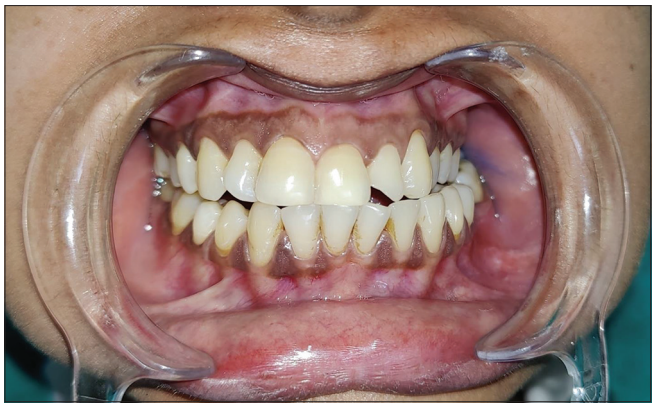


Figure 8: Right lateral: Protrusive occlusion

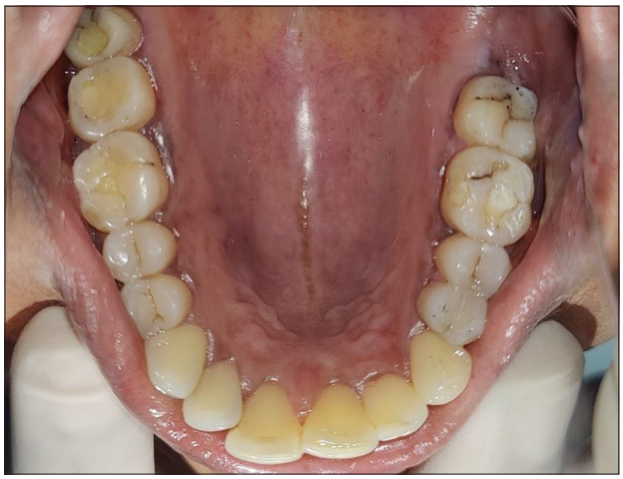


Figure 9: Maxillary occlusal view

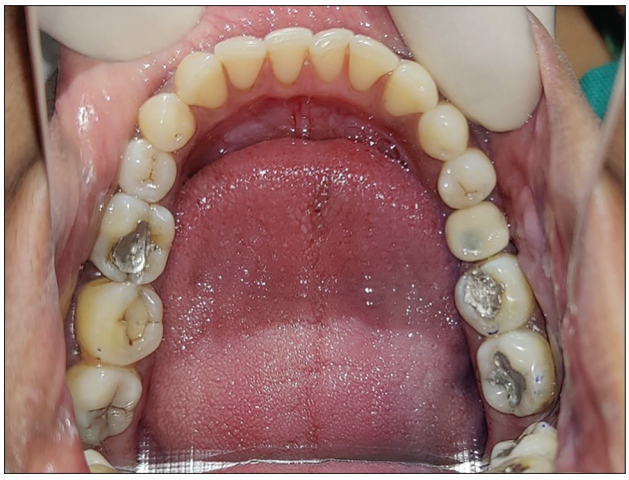


Figure 10: Mandibular occlusal view

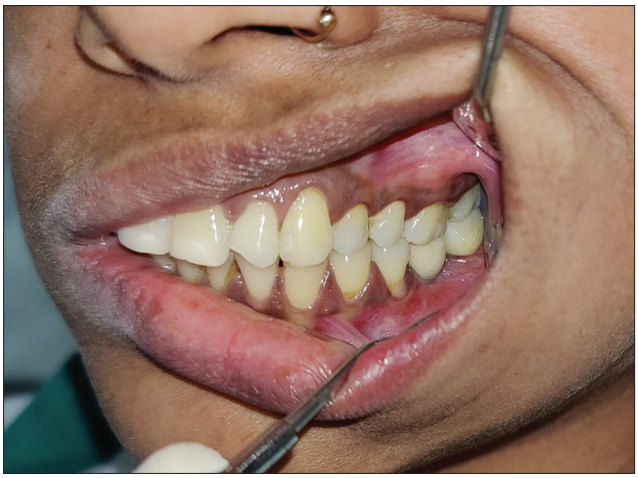


Figure 11: Left occlusion view: Centric relation

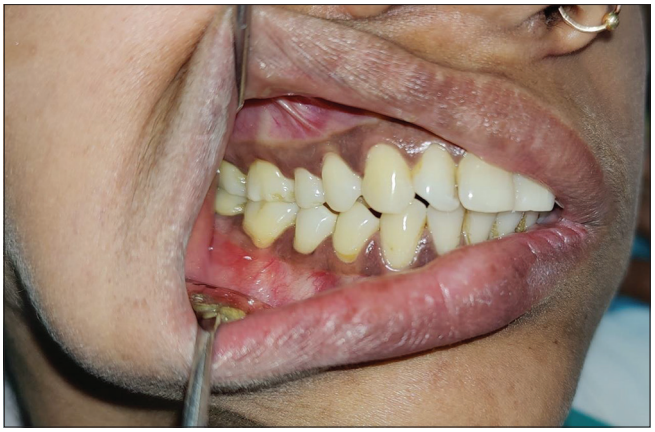


Figure 12: Right occlusion view: Centric relation

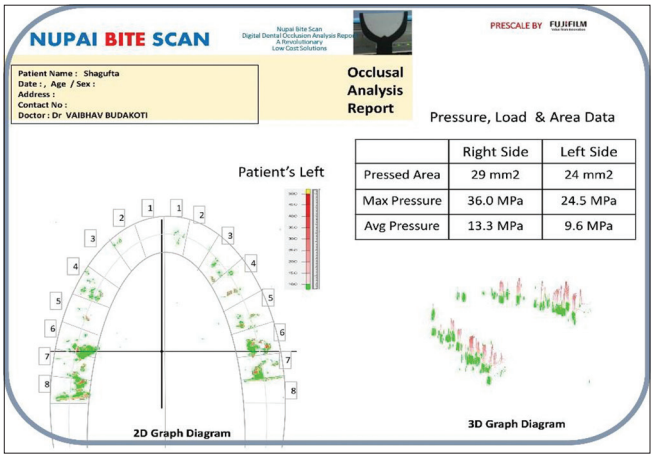


Figure 13: Result showing right and left side bite pressure values

in mean and standard deviation. Independent *t*-test was performed to find significant difference in different variables in group. $P = 0.05$ was considered as a baseline. Tables 1-10 are the collected data (patients) and statistical analysis tables.

OBSERVATION AND RESULTS

Amount of pressed area at right angle implant prosthesis was 26.27 ±11.83 and in contralateral side natural teeth was 30.27 ±11.83. Mean amount of the pressed area was

Table 1: Group 1 – Mandibular pressure record: Implant prosthesis on the right side and contralateral side natural teeth

Particulars	Pressed area (mm^2)		Maximum pressure (MPa)		Average pressure (MPa)	
	Natural	Implant	Natural	Implant	Natural	Implant
Subject 1	28	22	33.8	31.3	11.3	7.0
Subject 2	40	37	35	33.8	9.8	7.8
Subject 3	48	43	31.3	33.3	10.5	7.5
Subject 4	24	22	40.3	38	13	11.5
Subject 5	54	46	39	37.8	11.3	10.5
Subject 6	30	26	33.8	30.5	12.5	10.0
Subject 7	17	14	35	31.8	10.5	10.3
Subject 8	28	25	32	31	13	12
Subject 9	23	20	40	36.7	13	11.5
Subject 10	29	24	34	30	10	8.7
Subject 11	18	16	32	28	10.5	10
Subject 12	21	16	28	25	12	9.9
Subject 13	48	36	34	30	14.5	12
Subject 14	18	22	36	27	11	12.5
Subject 15	28	25	31	30	13	11

Table 2: Group 2 – Mandibular pressure record: Implant prosthesis on the left side and contralateral side natural teeth

Particulars	Pressed area (mm^2)		Maximum pressure (MPa)		Average pressure (MPa)	
	Natural	Implant	Natural	Implant	Natural	Implant
Subject 1	22	20	30	23.3	6.5	5.3
Subject 2	39	30	36	34.5	11.3	10.3
Subject 3	31	24	40	37.5	12.5	10
Subject 4	28	26	40.5	38.8	13.5	11.2
Subject 5	29	20	35.5	29.5	9.3	8.5
Subject 6	22	19	37	33.3	12	11
Subject 7	18	16	33.8	31.0	12.3	12
Subject 8	23	21	41	36	14	12.5
Subject 9	16	14	32	28	10	9
Subject 10	20	17	37	30	13.5	11
Subject 11	34	27	39.6	34	12	10
Subject 12	29	28	32	36	11.7	11.9
Subject 13	22	18	27	24	10.8	8.3
Subject 14	26	22	40	36	13	10.5
Subject 15	21	17	33	29	12	10

found more in contralateral side natural teeth as compared to implant prosthesis and there was a significant difference in mean amount of the pressed area in between right side implant prostheses and contralateral natural teeth .

Maximum bite pressure at right side implant prosthesis was 31.61 ±3.78 and in contralateral side natural teeth was 34.35 ± 3.44. Maximum bite pressure was found more in contralateral side natural teeth as compare to implant prosthesis and there was significant difference in maximum bite pressure in between right-side implant prosthesis and contralateral side natural teeth.

Average bite pressure at right side implant prosthesis was 10.15 ± 1.72 and in contralateral side natural teeth was

Table 3: Descriptive Table: Group 1 – Implant prosthesis on the right side and contralateral side natural teeth

Descriptive statistics					
Right side implant prosthesis	*n*	Mean	SD	Minimum	Maximum
Pressed area natural	15	30.27	11.83	17.00	54.00
Pressed area implant	15	26.27	9.79	14.00	46.00
Maximum pressure natural	15	34.35	3.44	28.00	40.30
Maximum pressure implant	15	31.61	3.78	25.00	38.00
Average pressure natural	15	11.73	1.39	9.80	14.50
Average pressure implant	15	10.15	1.72	7.00	12.50

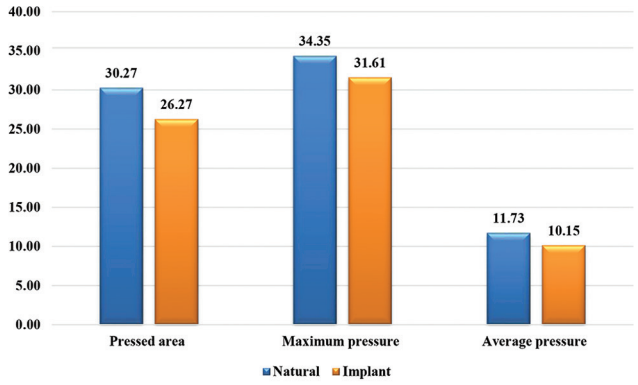
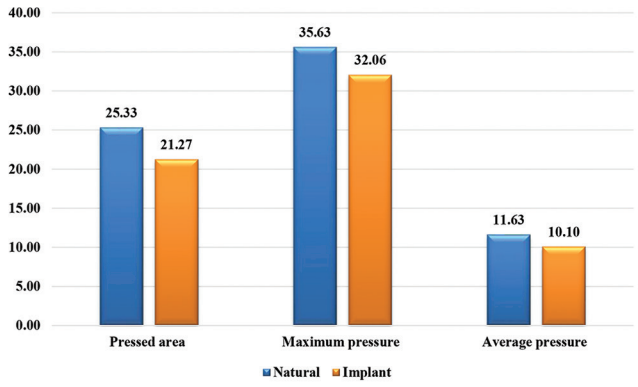


Table 4: Descriptive Table: Group 2 – Implant prosthesis on the left side and contralateral side natural teeth

Descriptive statistics					
Left side implant prosthesis	*n*	Mean	SD	Minimum	Maximum
Pressed area natural	15	25.33	6.30	16.00	39.00
Pressed area implant	15	21.27	4.79	14.00	30.00
Maximum pressure natural	15	35.63	4.25	27.00	41.00
Maximum pressure implant	15	32.06	4.72	23.30	38.80
Average pressure natural	15	11.63	1.91	6.50	14.00
Average pressure implant	15	10.10	1.81	5.30	12.50



11.73 ± 1.39. Average mean bite pressure was found more in contralateral side natural teeth as compared to implant prosthesis and there was significant difference in average

Table 5: Mandibular pressure record: Implant prosthesis on the right side and contralateral side natural teeth (pressed area)

Particulars	Pressed area			
	n	Mean	Std. deviation	*P*-value
Natural	15	30.27	11.83	0.032*
Implant	15	26.27	9.79	

*Statistically significant

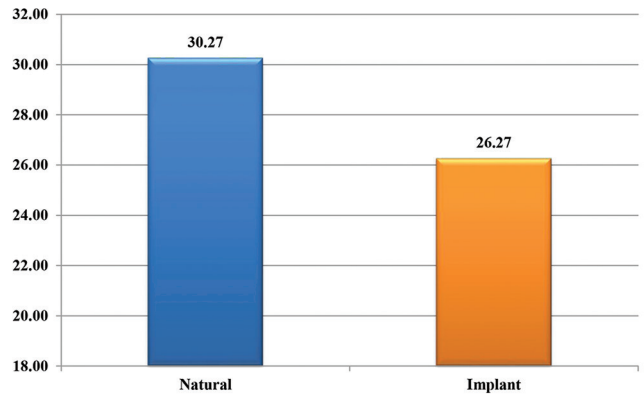


Table 6: Mandibular pressure record: Implant prosthesis on the right side and contralateral side natural teeth (maximum pressure)

Particulars	Maximum pressure			
	n	Mean	Std. deviation	P-value
Natural	15	34.35	3.44	0.048*
Implant	15	31.61	3.78	

*Statistically significant

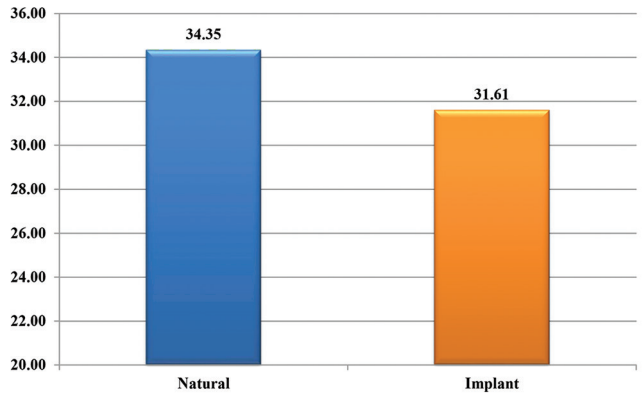


Table 7: Mandibular pressure record: Implant prosthesis on the right side and contralateral side natural teeth (average pressure)

Particulars	Average pressure			
	n	Mean	Std. deviation	*P*-value
Natural	15	11.73	1.39	0.010*
Implant	15	10.15	1.72	

*Statistically significant

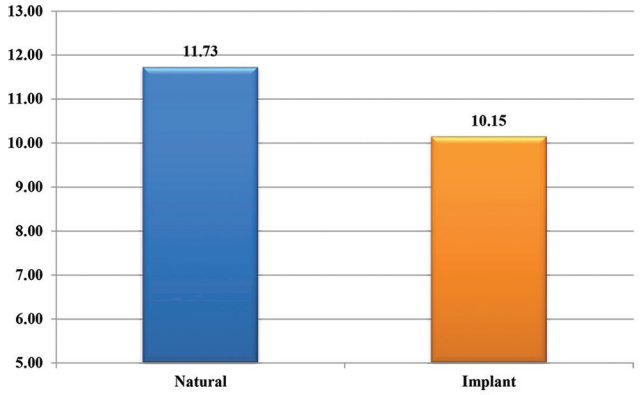
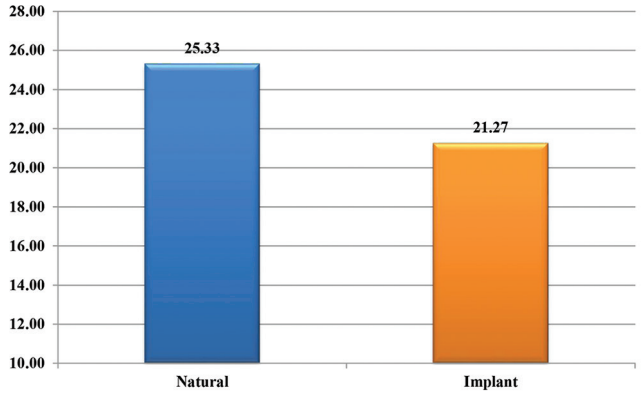


Table 8: Mandibular pressure record: Implant prosthesis on the left side and contralateral side natural teeth (pressed area)

Particulars	Pressed area left			
	n	Mean	Std. deviation	*P*-value
Natural	15	25.33	6.30	0.045*
Implant	15	21.27	4.79	

*Statistically significant



mean bite pressure between right side implant prosthesis and contralateral side natural teeth.

Amount of the pressed area at left side implant prosthesis was 21.2 ± 4.79 and in contralateral side natural teeth was 25.33 ± 6.30. Mean amount of the pressed area was found more in contralateral side natural teeth as compared to implant prosthesis and there was significant difference in mean amount of the pressed area in between left side implant prosthesis and contralateral side.

Maximum bite pressure at left side implant prosthesis was 32.06 ± 4.72 and in contralateral side natural teeth 35.63 ± 4.25. Maximum bite pressure was found more in contralateral

Table 9: Mandibular pressure record: Implant prosthesis on the left side and contralateral side natural teeth (maximum pressure)

Particulars	Maximum pressure			
	n	Mean	Std. deviation	*P*-value
Natural	15	35.63	4.25	0.038*
Implant	15	32.06	4.72	

*Statistically significant

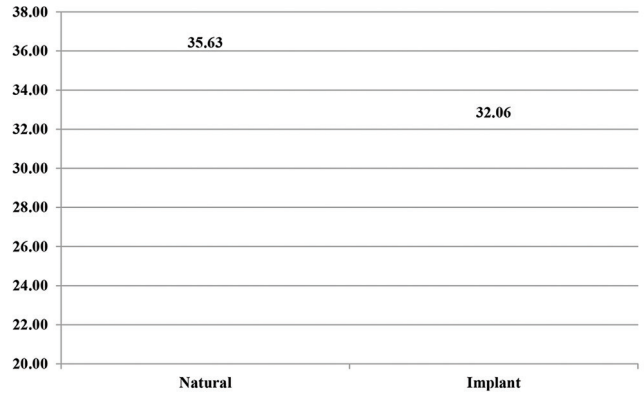


Table 10: Mandibular pressure record: Implant prosthesis on the right side and contralateral side natural teeth (average pressure)

Particulars	Average pressure			
	n	Mean	Std. deviation	*P*-value
Natural	15	11.63	1.91	0.033*
Implant	15	10.10	1.81	

*Statistically significant

side natural teeth as compared to implant prosthesis and there was significant difference in maximum bite pressure in between left side implant prosthesis and contralateral side natural teeth.

Average bite pressure at left side implant prosthesis was 10.10 ± 1.81 and in contralateral side natural teeth was 11.63 ± 1.91. Average mean bite pressure was found more in contralateral side natural teeth as compared to implant prosthesis and there was significant difference in average mean bite pressure in between left side implant prosthesis and contralateral side natural teeth

DISCUSSION

At present, there are two types of bite force measuring techniques available, that is, direct and indirect. Direct techniques include gnathodynamometer, lever spring, manometer spring and lever, micrometered devices, electronic transducers, strain gauges, digital occlusal force-meters, pressure-sensitive foils (PSFs), pressure transducers, digital dynamometers, and dental pre-scale system (NUPAI bite scan system). They use of a suitable transducer placed between a pair of teeth. It is a convenient way to measure the bite force.

In the indirect method that includes electromyography, functional relationship between the bite force and physiological variables is evaluated as these variables are known to be functionally related to the bite force.[7] There are many factors that influence the magnitude of the biting force of an individual. These factors can be categorized into subject-related factors such as age, gender, body mass index, craniofacial morphology, temporomandibular disorders and pain, dental status, and psychological factors. Device-related factors include type of recording devices, amount of jaw separation as determined by thickness of device, type of measurement, device position, and patient position. The bite pressure also varied according to the occlusal schemes.

In the present study, bite force was measured using the NUPAI bite scan system. It consists of pressure-sensitive sheets. These sheets consist of pigment microcapsules placed one over the other, which burst according to the amount of pressure applied. The exposed PSFs are analyzed in the occlusal scanner. The scanner reads the area and color intensity of the red dots to assess occlusal contact area and pressure. It has following advantages as follows:

1. The thin material induces only a small change in the occlusal vertical dimension (98 μ thickness) and makes it available to measure at a position near the intercuspal position
2. It is not necessary to prepare special measurement equipment
3. Many patients may be examined for a short time
4. Recording storage, even for an extended period, is simplified and
5. It is easy to explain the treatment to patients using dental images.[8]

The study also demonstrated that the maximum bite pressure values at the natural dentition side were significantly different from those of the implant prosthesis side using NUPAI bite scan. In the present study, a within-subject study design was applied and the other side of the jaw of the same patients was used as control. Pressure values were lesser on implant prosthesis side. The detected difference between implant treated and the natural dentition sides could have been influenced by the chewing side preference as implant side was edentulous for longer time.[9,10] Furthermore, the potential of jaw flexure as well as variations in muscle tonicity during unilaterally closing down on hard objects might potentially affect the recorded bite force value. The present study demonstrated that the maximum bite pressure values at the natural dentition sides were significantly different from those at the implant

prosthesis. The accuracy and precision of bite pressure measurements might be influenced by the mechanical features of the used bite pressure measuring system.

In this study for Group-1: Implant prosthesis on the right side and natural teeth on contralateral side pressed area $P = 0.032$, which is significant ($P < 0.05$). *P*-value for maximum bite pressure is 0.048, which is significant ($P < 0.05$). *P*-value for average bite pressure is 0.010, which is significant ($P < 0.05$). For Group-2: Implant prosthesis on the left side and natural teeth present on contralateral side pressed area $P = 0.045$, which is significant ($P < 0.05$). *P*-value for maximum bite pressure is 0.038, which is significant ($P < 0.05$). *P*-value for average bite pressure is 0.033, which is significant ($P < 0.05$).

CONCLUSION

In the present cross-sectional study, NUPAI bite scan system has been used to compare the maximum biting pressure within the same patient on the mandible where one side has natural dentition and the contralateral side had been restored with an implant prosthesis. Within the limitations of this study, the following conclusions are drawn relative to the bite pressure on mandibular implant prosthesis on the 1st molar region and natural mandibular 1st molar tooth on contralateral arch.

- There is significant difference between pressed area on implant prosthesis and on natural tooth. For Group-1: $P < 0.05$ was considered and for Group-2: $P < 0.05$ was considered
- There is significant difference between maximum bite pressure on implant prosthesis and on natural tooth. For Group-1: $P < 0.05$ was considered and for Group-2: $P < 0.05$ was considered
- There is significant difference between average bite pressure on implant prosthesis and on natural tooth. For Group-1: $P < 0.05$ was considered and for Group-2: $P < 0.05$ was considered.

Maximum bite pressure values can be used to compare and evaluate health of implant and peri-implant tissues. Implant prosthesis should be prevented from being overload with heavy masticatory forces. Poor occlusal system selection can lead to biological and mechanical complications. Heavy masticatory forces can lead to implant failure, early crestal bone loss, screw loosening, uncemented restorations, component failure, porcelain fracture, prosthesis fracture, and peri-implant disease. For prevention of such consequences, NUPAI bite scan system is very helpful and has following advantages:

- The thin material induces only a small change in the occlusal vertical dimension (98 μ thickness)
- Makes it available to measure at a position near the intercuspal position
- It is not necessary to prepare special measurement equipment
- Many patients may be examined for a short time
- Recording storage, even for an extended period, is simplified and
- It is easy to explain the treatment to patients using dental images.

Thus, it can be concluded that maximum bite pressure records using NUPAI bite scan system can be very helpful in maintaining health of implant and peri-implant tissues.

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Original Article

Knowledge, Acceptance, and Affordability of COVID-19 Vaccines: A Cross-sectional Survey

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Abstract

Introduction: To improve public acceptance and decrease vaccine hesitancy in fighting COVID-19, it is important to quantify the general knowledge of the population on COVID-19 vaccine. Thus, the present study focused to evaluate the knowledge, acceptance, and affordability of COVID-19 vaccination.

Materials and Methods: A cross-sectional survey was conducted, using online questionnaire among the general population to evaluate the knowledge, attitude, and practices of people regarding the COVID-19 vaccination program. The participants aged 18 and above were included in the study and were representing different sociodemographic characteristics.

Results: Among a total of 300 complete responses, majority of the study population are females aged between 18 to 40 years (69.6%). About 44% of the study participant belongs to upper-lower socioeconomic status according to Kuppuswamy scale. Nearly 97.3% of the study population were aware on COVID-19 vaccination and the source of COVID vaccine-related information were from television, newspaper, and social media (35.66%). The awareness of available vaccines was significantly associated ($P < 0.01$) with gender and socioeconomic status. Acceptance of vaccination is significantly associated with age and socioeconomic status ($P < 0.01$). Perhaps, 30% still hesitate for vaccinated. Awareness of groups which needs vaccine was significantly associated with socioeconomic group. Availability of vaccine in nearby health-care center is significantly associated with socioeconomic group ($P < 0.01$).

Conclusion: COVID-19 vaccine knowledge could be improved, as there is a room for improvement, people need to understand about the vaccination and overcome the vaccination hesitancy. This can be achieved by addressing the fear factors and creating more vaccine awareness campaigns.

Key words: Acceptance, Awareness, COVID-19 vaccine, Knowledge

INTRODUCTION

Worldwide, the COVID-19 pandemic alert is a major challenge confronted and many efforts have been initiated to prevent and control the infection. In recent years, effective vaccines have been discovered[1-4] and also showed significant protection against the infection. In addition, with the supportive care, government guidelines were also been implemented based on the need for the massive vaccination. World's largest vaccination program was initiated by the Indian government for COVID-19 to ensure that 900 million population was vaccinated.[5] In India, the vaccination campaign starts from January 2021 and used CoviShield (AstraZeneca) and Covaxin (Bharat Biotech). The first vaccine was produced by Bharat Biotech and was approved for restricted emergency use in priority-based vaccination program.[6] The success of the mass COVID-19 vaccination program depends on the turnover of eligible candidates at the vaccination centers. Unfortunately, a significant proportion of eligible candidates is not turning up to get their dose of vaccine, which indicates hesitancy amongst people to participate in the COVID-19 vaccination program.[7,8]

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In general, the mass vaccination program was a great success, which purely depends on the eligible candidates in the vaccination center. The COVID-19 vaccination drive faces a threat from vaccine hesitancy.[8] The knowledge, awareness, concerns on risk, safety, and benefits of the COVID-19 vaccination program of the general population largely affect the rate of acceptance and hesitancy.[9] Few studies accessed the opinion of the general population using the semi-structured survey on the vaccination program before the introduction and implementation of the vaccine.[10-12] Apart from the participation of the COVID-19 vaccination program, it is also depending on the socioeconomic and demographic characteristics of the population.[11] There is a dearth of Indian data in evaluating the knowledge and acceptance of COVID-19 vaccine. The present study focused to evaluate the knowledge, acceptance, and affordability of COVID-19 vaccination.

MATERIALS AND METHODS

This prospective cross-sectional survey was conducted between June 2021 and August 2021 through an online platform among the general population to evaluate the knowledge, attitude, and practices of people regarding the COVID-19 vaccination program. The online-based survey was preferred to ensure timely, comprehensive, and high-yield data acquisition and analysis. This study was approved by the Institutional Ethics Committee, Apollo research and Innovations, Hyderabad.

All the responses were collected through a Google Forms and telephonic interviews. All the participants were well informed pertaining the study objectives, duration of participation, declaration of confidentiality, and the voluntary participation before administration of the questionnaire. Participants providing informed consent were directed to the main questionnaire. This web link was sent by investigators to their personal and social contacts through email or WhatsApp messenger. We deployed a snowball sampling technique, a non-probability sampling method which yields a convenient sample. In cases where participants had limited technical knowledge and/or limited literacy level, investigators conducted the telephonic interview and filled the Google Forms on their behalf.

The participants aged 18 and above were included in the study and were representing different sociodemographic variables such as age, gender, and socioeconomic status. The socioeconomic status was calculated using Kuppuswamy scale (2020).[13] Descriptive statistics were used. A total of 335 responses was received (include both Google Forms and telephonic interview), perhaps, certain responses were excluded as they are duplicate and invalid entries, and the final data includes were 300 responses.

A 14-item structured questionnaire was used in the study to obtain the required data. The information related to demographic details such as age, gender, and the socioeconomic status such as education, occupation, and family income was recorded, further the knowledge, acceptance, and availability of the COVID-19 vaccine were also recorded accordingly. The baseline characteristics of the participants were presented as frequency and percentages. The data were analyzed using SPSS version 22.0 (IBM). $P \leq 0.05$ was considered statistically significant for all analyses.

RESULTS

A total of 335 responses, 300 were completed and include in the study. Majority of the study population were aged between 18 and 40 (69.6%) followed by age between 40 and 60 (26%) and greater than 60 years of age (4.34%). Predominantly, majority of the study population was female (64%). According to Kuppuswamy scale (2020), the socioeconomic status was calculated and majority of the study participant belongs to upper-lower socioeconomic status (44%), followed by upper-middle (33.33%), lower-middle (16%), upper (5.33%), and lower class (1.33%) [Table 1].

Awareness of vaccination plays a major role in the vaccination program, about 97.3% of the study population was aware of the COVID-19 vaccine. Majority of the study population got to know the COVID vaccine-related information from television, newspaper, and social media (35.66%) followed by television (31.66%) and 18.3 social media (19%) alone. Among the study population, 51% were aware of all the three vaccines (Covaxin, CoviShield, and Sputnik), followed by 18.3% of the individuals were two vaccines (Covaxin and CoviShield) and 21% were aware about only CoviShield and 9% were about Covaxin. About 92.6% of the study population was aware of one or more doses which were required for vaccine. Majority of the study population were aware about the groups which required COVID vaccination. Individuals has diagnosed

Table 1: Socioeconomic status of the study population

S. No.	Socioeconomic class	Score	*n*=300
1.	Upper (I)	27.43±1.20	16 (5.33%)
2.	Upper-middle (II)	18.92±1.76	100 (33.33%)
3.	Lower-middle (III)	13.145±1.64	48 (16%)
4.	Upper-lower (IV)	7.9±1.39	132 (44%)
5.	Lower (V)	3.5±0.57	4 (1.33%)

with COVID positive already (54.33%), pregnant women (51.66%), and adult with comorbid conditions (73.3%) required vaccination [Table 2]. Majority of the study population were vaccinated (68.33%), and nearly half of the study population were not concern about anything, perhaps, the other half were concern about the side effects (23%), non-availability of the vaccine (13%), rumors (13%), and financial reason (1%). Among the study population, 83.3% of the responders were known about the availability of the vaccine in the nearby health-care centers [Table 2].

The source of information on COVID vaccination was obtained from the reliable sources such as the news from

Table 2: Demographic characteristics, knowledge, acceptance, and affordability of COVID-19 vaccine based on SES

Variables	N (%) *n*=300	Upper (I) *n*=16	Upper-middle (II) *n*=100	Lower-middle (III) *n*=48	Upper-lower (IV) *n*=132	Lower (V) *n*=4
Demographic characteristics						
Age						
18–40	209 (69.6%)	4	67	37	99	2
40–60	78 (26%)	10	29	11	28	-
>60	13 (4.34%)	2	4	-	5	2
Gender						
Male	108 (36%)	10	37	17	44	-
Female	192 (64%)	6	63	31	88	4
Knowledge on COVID						
Awareness of COVID-19 vaccine						
Yes	292 (97.34%)	16	99	46	127	4
No	8 (2.66%)	0	1	2	5	-
Source of information						
Television	95 (31.66%)	5	27	13	58	4
Newspaper	41 (13.66%)	4	12	8	17	-
Social media	57 (19%)	3	23	3	29	-
TV and NP and SM	107 (35.66%)	8	38	24	28	-
Vaccine you aware						
CoviShield	65 (21.6%)	1	13	5	46	-
Covaxin	27 (9%)	1	6	5	15	-
CoviShield+Covaxin	55 (18.3%)	2	21	7	21	4
CoviShield+Covaxin+Sputnik	153 (51%)	12	60	31	50	-
Awareness of vaccine dose						
Yes	278 (92.6%)	15	97	45	117	4
No	22 (7.3%)	1	3	3	15	-
Do the following group need vaccine						
COVID positive						
Yes	163 (54.33%)	61	61	31	59	-
No	137 (45.66%)	39	39	17	73	4
Pregnant women						
Yes	155 (51.66%)	53	53	26	63	1
No	145 (48.33%)	47	47	22	70	3
Children						
Yes	145 (48.33%)	53	53	20	60	-
No	155 (51.66%)	97	47	28	72	4
Adults with comorbidity						
Yes	220 (73.33%)	78	78	37	86	4
No	80 (26.66%)	22	22	11	46	-
Acceptance and affordability						
Have you got vaccinated						
Yes	205 (68.33%)	14	79	36	74	2
No	95 (31.66%)	2	21	12	58	2
Concerns about vaccine						
Side effects	69 (23%)	6	19	6	38	-
Financial reason	3 (1%)	-	-	2	1	-
Non-availability	39 (13%)	1	12	1	24	1
Rumors	39 (13%)	1	15	11	12	-
None	150 (50%)	8	54	28	57	3
Vaccine availability in nearby health-care center						
Yes	250 (83.33%)	16	89	43	99	3
No	50 (16.66%)	-	11	5	33	1

national television and all sources (TV, newspaper, and social media) radio ($P < 0.01$) and newspaper ($P < 0.05$) and social media ($P < 0.05$) were found to be significantly associated with the age. The awareness of available vaccines was significantly associated ($P < 0.01$) with the gender and socioeconomic groups [Table 3]. Similarly, the awareness of groups which needs vaccine was significantly associated with socioeconomic group (COVID positive [$P < 0.01$], pregnant women [$P < 0.05$], children [$P < 0.01$], adults with comorbidity [$P < 0.01$]). Acceptance of vaccine is significantly associated with age and socioeconomic status ($P < 0.01$), whereas availability of vaccine in nearby health-care center is significantly associated with socioeconomic group ($P < 0.01$) [Table 3].

DISCUSSION

Worldwide still COVID-19 pandemic is a great threat, vaccine comes as a great hope for controlling COVID virus. Perhaps, vaccine must be acceptable and usable among majority of the population.[14] Mass vaccination is considered to be an effective public health measure to control the COVID-19 pandemic. However, the halfhearted participation of the general population in this campaign is a matter of concern and has potential to defy the whole purpose. It is important to understand the factors that affect people's decision/opinion to take the vaccine.

In the present study, the demographic distribution of the study showed that there is a higher percentage of females when compared to males, this showed that the females care more toward the infection and are more interested in sharing their knowledge about COVID vaccine. Majority of the responders belong to the upper-lower socioeconomic status and when comparing to the other SES comparatively the having knowledge on vaccination and awareness, still there is a lack of knowledge on the groups who are eligible for vaccine. Majority of the responders were aware about the vaccine, this showed that the success of the awareness campaigns. Similar study findings were observed in the study conducted in northern part of India[15] and West Bengal.[16]

To promote public education, it is first necessary to be aware of the cause.[17] To eradicate coronavirus infection, it is important that the public is informed about the transmission of disease, prevention, and most importantly vaccine information. This will help in promoting vaccine acceptance among the population and decreasing vaccine hesitancy.[18] Further, there is ample source of information from which the details of vaccination can be obtained such as the national news television, newspaper, and social media, which also significantly affect the study population knowledge on COVID-19 vaccine. More than 30% of the participants responded that they get to know the vaccine-related information from television, newspaper, and social media. Perhaps, other studies highlighted that the major source of information are social media and the scientific articles published in media.[19,20] Perhaps, even though many trusts on the reliable sources, there arises a concern on the false information obtained from the social media, which may increase the willingness for vaccination among general population.

Table 3: Knowledge, acceptance, and affordability of COVID-19 vaccine and its association with sociodemographic characteristics of the study population

Variables	Association with sociodemographic correlates		
	Age	Gender	Socioeconomic group
Knowledge on COVID			
Do you know about COVID-19 vaccine	n. s	n. s	n. s
Source of information			
Television	*P*<0.01	n. s	n. s
Newspaper	*P*<0.05	n. s	n. s
Social media	*P*<0.05	n. s	n. s
TV and NP and SM	*P*<0.01	n. s	*P*<0.01
Vaccine your aware	n. s	*P*<0.01	*P*<0.01
Awareness of 1 or more dose of vaccine	*P*<0.05	n. s	*P*<0.05
Group need vaccine			
COVID positive	n. s	n. s	*P*<0.01
Pregnant women	*P*<0.01	*P*<0.05	*P*<0.05
Children	n. s	n. s	*P*<0.05
Adults with comorbidity	*P*<0.01	*P*<0.01	*P*<0.05
Acceptance affordability			
Have you got vaccinated	*P*<0.01	n. s	*P*<0.01
Concerns about vaccine	n. s	n. s	n. s
Vaccine availability in nearby health-care center	n. s	n. s	*P*<0.01

n. s: Non-significant

Majority of the responders were aware about either any one of the vaccines (Covaxin/CoviShield/Sputnik) and are associated with gender and socioeconomic status. Nearly half of the study population knows that children under the age of 18 were not vaccinated. This is due to the fact that there is a reduced chance of complications if they are infected. About 70% of the responders in the present study know that adults with comorbid conditions need vaccination. Socioeconomic status is significantly associated with the group of individuals who need vaccination such as COVID positive, pregnant women, children, and adults with comorbid conditions. The main focus for the mass vaccination programs is to protect the high-risk individuals such as elderly people, individuals with comorbid conditions, frontline workers, and individuals in service industries.[21]

About 68.33% of the study population were vaccinated, rate of acceptance of vaccination is significantly associated with age and socioeconomic status ($P < 0.01$). Despite the willingness for the vaccination there exist a hesitance among a group of responders (31.66%). The fear of the infection against COVID infection and the awareness of COVID vaccination shown in this study were the motivators for the people to take the vaccine.[18]

A recent study in 2021, highlighted that many peoples depends on the social media for COVID-19 Vaccine related information's and there were group of individuals who were unwilling for vaccination.[9] Thus, there is a need to communicate the updates on COVID-19 vaccine through authenticated source to the general public, specifically to individuals belonging to the lower socioeconomical Stata. Further, government might use a social media platform to increase the awareness on COVID vaccine, which will increase the willingness.

In the present study, 83.3% of the individuals responded that the vaccine is available in the nearby health-care centers. Even though, there is an availability of COVID vaccine, safety precautions cannot be replaces, for instance, personal hygiene, face mask/shield, and social distancing play a major role in public health and awareness against COVID.[22] Indian government authorities should ensure that vaccines are available for those belonging to lower socioeconomic classes at either no cost or at subsidized rates so as to ensure national vaccination coverage for all. As the present study shows that trusted the national news channels, print media, and social media, they should provide the reliable information on the vaccine development and efficacy. Thus, the general public confidently talks about the concerns of the public to understand the need for the vaccination against COVID infection.

The study has few limitations; first, we have used snow ball technique, rather than the stratified random sampling method, hence, it is difficult to generalize the study finding. As a cross sectional, the study finding could not able to predict the future acceptance rate of vaccine, which may vary based on the phrases of pandemic and disease consequence.[23] Second, the study is a self-reported questionnaire which could lead to more socially desirable responses from participants.

CONCLUSION

The present cross-sectional survey is an attempt to understand the knowledge and acceptance of COVID vaccination based on socioeconomic state. The present study has increased the concern on vaccine acceptance which might affect the mass vaccination program drive. The study finding would shed more light on the public health policymakers and the government authorities in implementing the various strategies to achieve acceptance of mass vaccination. COVID-19 vaccine knowledge could be improved, as there is room for improvement, people need to understand about the vaccination and overcome the vaccination hesitancy. This can be achieved by the addressing the fear factors and creating more vaccine awareness campaigns. As the present study was the cross-sectional survey at the particular point of time, similar studies at different point of time with the representation from different socioeconomic status would provide the clear insight on the knowledge, attitude, and acceptance of the vaccine in the developing country India.

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