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Original Article

Modified Computed Tomography Severity Index in Acute Pancreatitis - Its Correlation with Patient Morbidity (A Study of 40 Cases)

Manisha Lokwani[1], N A Patel[2]

[1]Assistant Professor, Department of Radiodiagnosis, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India, [2]Professor, Department of Radiodiagnosis, Medical College Baroda, Vadodara, Gujarat, India

Abstract

Background: In the past two decades, several radiologic prognostic scoring systems have been developed. This study was aimed to study the correlation of modified computed tomography severity index (MCTSI) with patient's morbidity and comparison of the CTSI with the MCTSI and to evaluate necrosis as a predictor of patient morbidity.

Methods: The patients clinically suspected to have acute pancreatitis subjected to contrast-enhanced computed tomography (CECT) abdomen. The morphologic severity of pancreatitis was assessed using the CTSI, developed by Balthazar and the MCTSI. CTSI and MCTSI were compared in their ability to individually predict hospital stay, the development of local complications, systemic complications, a fatal outcome and their ability to pick up patients who eventually had severe disease. Necrosis on CECT was evaluated as a separate index in its usefulness in the prediction of severe course of the disease and mortality.

Results: Both the indices CTSI and MCTSI did not show an association with duration of hospital stay or the need of surgery or intervention in a patient. Both indices (CTSI and MCTSI) showed association with the development of local complications and organ failure. MCTSI showed better sensitivity than CTSI and shows good specificity, positive, and negative predictive values as a predictor of local complications and organ failure. Necrosis showed an association with patient morbidity (development of local complications) with high positive and negative predictive values (84.6% and 81.4%, respectively) and sensitivity of 68.7 % and specificity of 91.6%.

Conclusions: MCTSI is more accurate index to predict the development of local complications or organ failure. However, both are less accurate in their ability to predict the need for surgical intervention and longer hospital stay. Necrosis as an independent index is a useful marker for predicting the development of local complications.

Key words: Acute pancreatitis, Complications, Computed tomography severity index, Modified computed tomography severity index

INTRODUCTION

Acute pancreatitis is a common and typically mild, self-limiting disease with only minimal or transient systemic manifestations.[1] However, approximately 15–20% of patients develop clinically severe acute pancreatitis with local and systemic complications.[2] A number of clinical and laboratory prognostic scoring systems have been designed for the early identification of patients at greatest risk of developing clinically severe acute pancreatitis. Overall, these scoring systems have an accuracy varying between 70% and 80%.[3] Imaging by computed tomography (CT) or magnetic resonance imaging in the assessment of acute pancreatitis is useful not only for diagnosis but also for detecting local pancreatic complications and guiding interventional procedures.

In the past two decades, several radiologic prognostic scoring systems have been developed. Among them, the CT severity

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Corresponding Author: Dr. Manisha Lokwani, Department of Radiodiagnosis, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India. Phone: +91-8224050111. E-mail: manisha.khimnani@gmail.com

index (CTSI), designed by Balthazar *et al.*,[4] in 1990, is the most widely adopted for clinical and research settings. The CTSI is a numeric scoring system that combines a quantification of pancreatic and extrapancreatic inflammation with the extent of pancreatic necrosis. In 2004, a modified CTSI (MCTSI) was designed to account for several potential limitations of the CTSI.[5] In contrast to the CTSI, the MCTSI incorporates extrapancreatic complications in the assessment and simplifies the evaluation of the extent of pancreatic parenchymal necrosis (none, ≤30%, or >30%) and peripancreatic inflammation (presence or absence of peripancreatic fluid). The present study evaluates the accuracy of Modified CTSI (MCTSI) as a predictor of patient morbidity. This study was aimed to characterize appearance of pancreatitis and its complications on CT, to study correlation of MCTSI with patient's morbidity, to compare CTSI with the MCTSI, and study evaluation of necrosis as a predictor of patient morbidity.

METHODS

This was a prospective observational study was carried out on a total of 40 patients in our department. Ethical committee approval from the institution was obtained, and the criteria of selection of cases were as follows:

- The patients clinically suspected to have acute pancreatitis subjected to contrast-enhanced computed tomography (CECT) abdomen.

Relevant history of each patient was taken regarding alcohol abuse. All CT examinations were obtained using 16-slice multidetector CT scanner (GE, BRIGHT SPEED).

Tube voltage was 120 kVp and tube current was in the range of 150–300 mA. Each scan was obtained in a single breath hold from the domes of the diaphragm to pubic symphysis using a 1.5 mm collimation.

A written informed consent was taken from all patients, and they were given intravenous contrast typically 60–70 ml of non-ionic iodinated contrast material at 3–5 ml/s with a scan delay of 70 s for the acquisition of portal venous phase. All three phases (arterial, portal venous phase, and delayed phase) were taken.

Axial, coronal, and sagittal reformatted images were analyzed and imaging characteristics were recorded in all patients.

Image Analysis

Pancreatic findings

- Pancreatic enlargement (Figure 1 and 2)
- Presence and extent of areas lacking enhancement (Figure 8 and 9)

Peripancreatic findings

- Peripancreatic fat stranding (Figure 1).
- Presence and number of collections (Figures 2,4,6,7 and 13)

Extrapancreatic complications

Ascites (Figure 6, 10 &13)
Pleural effusion (Figure 10)
Pericardial effusion,
Vascular complications

- Hemorrhage (Figure 14)
- Venous thrombosis (Figure 15 &16)
- Arterial pseudoaneurysm formation

Gastrointestinal complications

- Adynamic ileus or mechanical obstruction
- Signs of ischemia
- Marked bowel-wall thickening (Figure 7 &18)
- Perforation
- Intramural fluid collection

Extrapancreatic parenchymal complications

- Infarction
- Hemorrhage
- Subcapsular fluid collection (Figure 17)

The morphologic severity of pancreatitis was assessed using the CTSI, developed by Balthazar *et al.*[4] and the MCTSI, developed by Mortele *et al.*[5]

CT Severity Index[4]

Prognostic indicator	Score
Pancreatic inflammation	
Grade A: Normal pancreas	0
Grade B: Focal or diffuse enlargement of the pancreas	1
Grade C: Intrinsic pancreatic abnormalities with inflammatory changes in peripancreatic fat	2
Grade D: Single, ill-defined fluid collection or phlegmon	3
Grade E: Two or more poorly defined collections or presence of gas in or adjacent to the pancreas	4
Pancreatic necrosis	
None	0
≤30%	2
<30–50%	4
≥50%	6

0–3 points: Mild pancreatitis, 4–6 points: Moderate pancreatitis, 7–10 points: Severe pancreatitis

Modified Computed Tomography Index[5]

Prognostic indicator	Points
Pancreatic inflammation	
Normal pancreas	0
Intrinsic pancreatic abnormalities with or without inflammatory changes in par pancreatic fat	2
Pancreatic or peripancreatic fluid collection or peripancreatic fat necrosis	4
Pancreatic necrosis	
None	0
<30%	2
≥30%	4

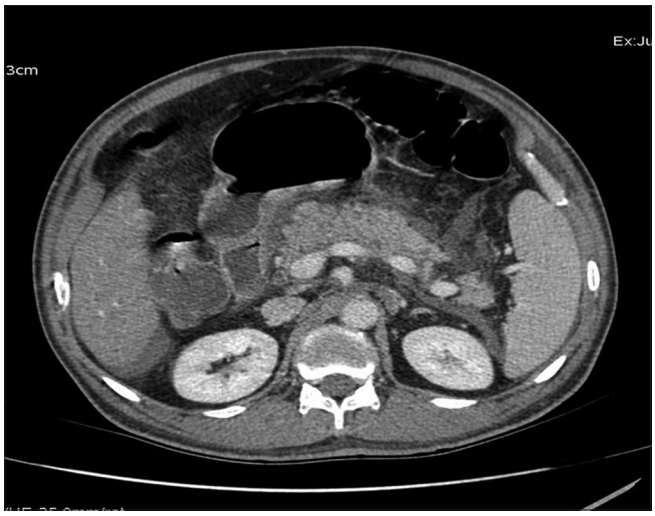


Figure 1: Bulky pancreas with peripancreatic fluid, fat stranding, and fluid in Morrison's pouch

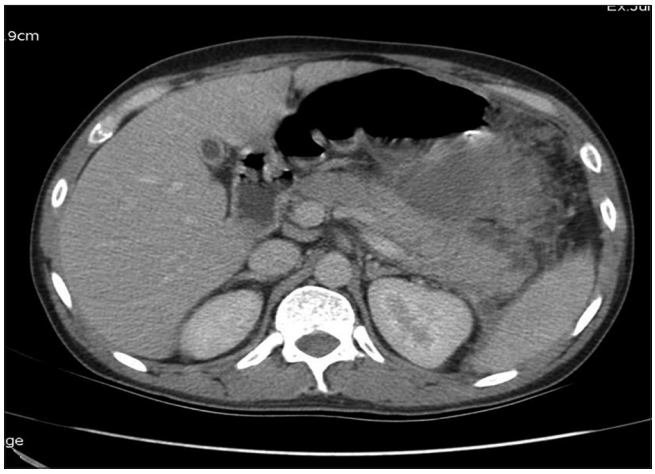


Figure 2: Bulky pancreas with homogenous enhancement. There is peripancreatic fat stranding and a collection in lesser sac without a well-defined wall

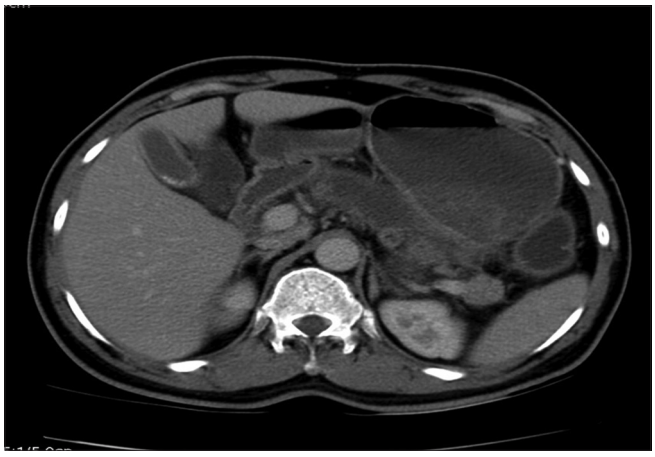


Figure 3: Acute pancreatitis secondary to gallstones

Extrapancreatic complications (one or more of pleural effusion, ascitis, vascular complication, parenchymal calcification, or gastrointestinal tract involvement)	2

0–2 points: Mild disease, 4–6 points: Moderate pancreatitis, 8–10 points: Severe pancreatitis

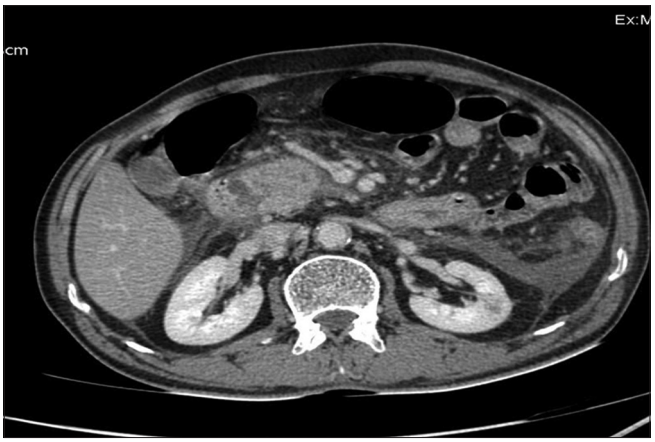


Figure 4: Thickening of bilateral Gerota's fascia and lateroconal fascia with fluid collection in bilateral anterior pararenal space. There is mesenteric and retroperitoneal fat stranding

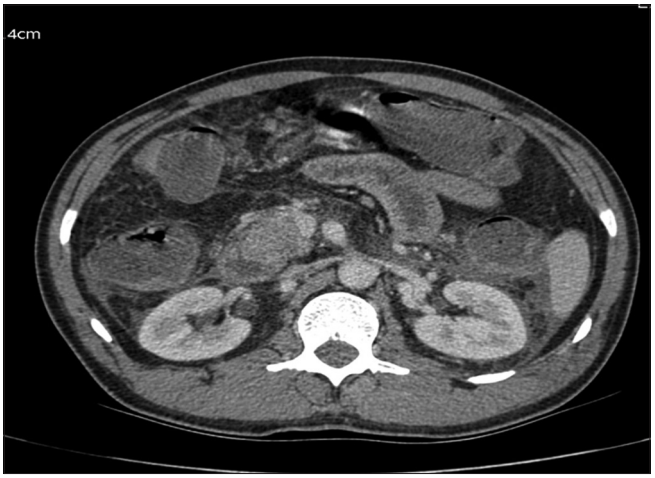


Figure 5: Mesenteric and retroperitoneal fat stranding

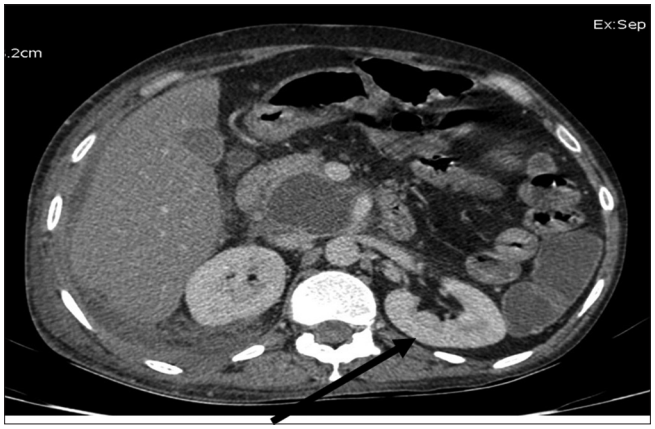


Figure 6: Right posterior pararenal space collection with fat stranding and ascites (arrow)

Analysis of Accuracy of CTSI and MCTSI as Prognostic Indicators and Comparison between the Two Indices

CTSI and MCTSI were calculated in the patients on the single scan. Patients with MCTSI score ≥8, and those with CTSI score ≥7 were graded as having severe pancreatitis.

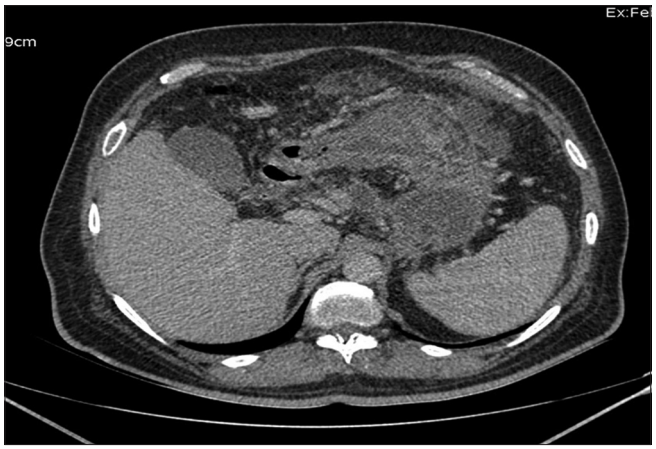


Figure 7: There is edematous symmetrical thickening of the wall of the stomach with ill-defined fluid collection in lesser sac

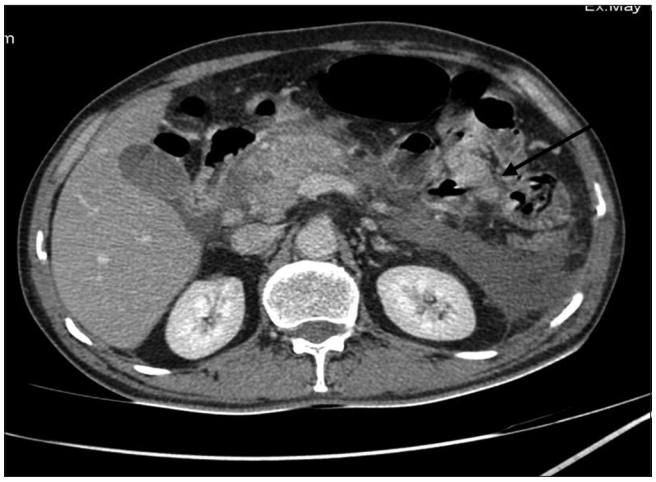


Figure 8: A nonenhancing area in the region of head of pancreas (arrow) suggesting <30% necrosis. There is peripancreatic fat stranding and a fluid collection in left anterior pararenal space

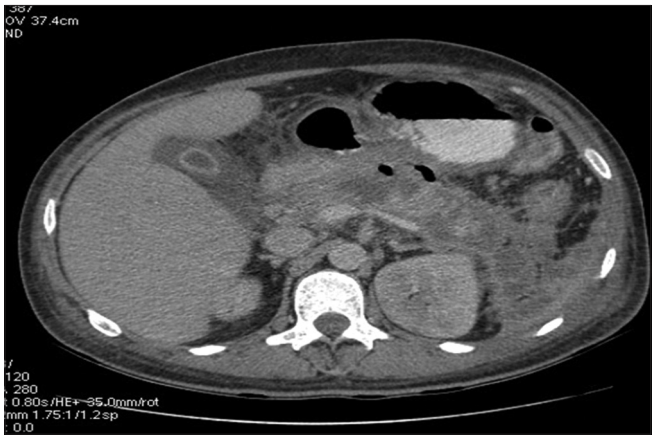


Figure 9: A case of necrotizing pancreatitis. There are nonenhancing areas in body and tail >30% necrosis with thickening of the posterior wall of body of stomach. Thickening of left Gerota's fascia and later oconal fascia with fluid collection in left anterior pararenal space

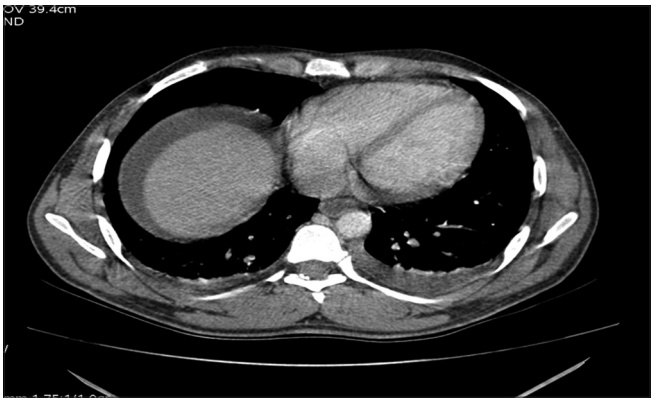


Figure 10: Bilateral pleural effusions and ascitis

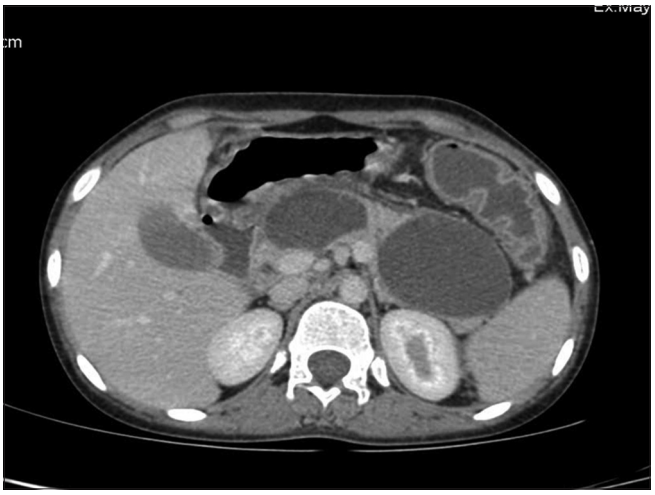


Figure 11: There are two well-defined thin walled pseudocysts in the head and tail region of pancreas. Note the inflammatory thickening of the transverse colon

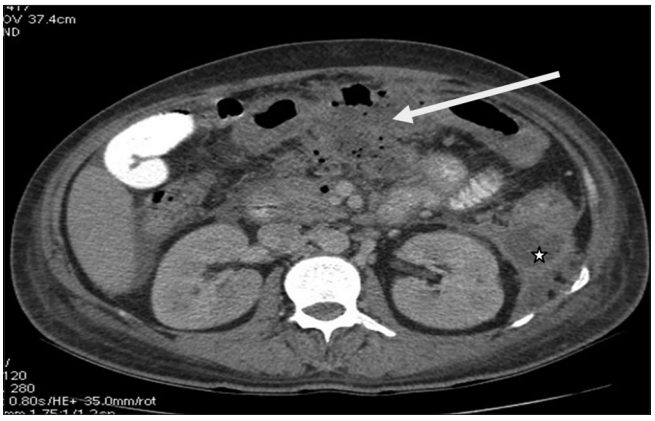


Figure 12: A fluid collection in the transverse mesocolon with ill-defined enhancing wall with air foci and surrounding fat stranding within suggesting infection (arrow). Another collection with enhancing wall is noted in the left paracolic gutter (asterisk)

Patients who developed any local and/or systemic complication (organ failure) were taken to have complicated pancreatitis.

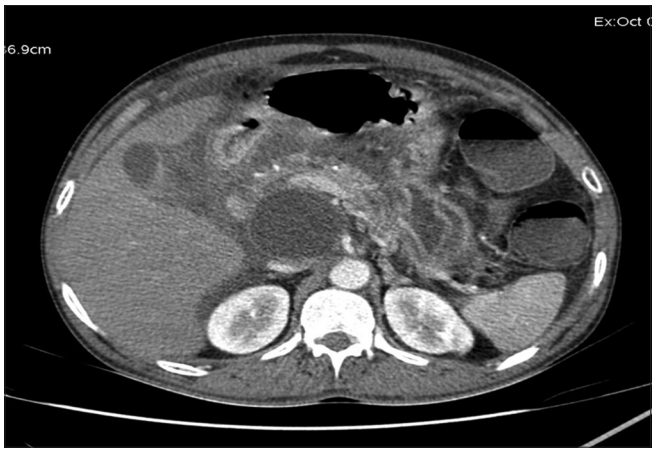


Figure 13: Acute on chronic pancreatitis. Calcifications in pancreatic parenchyma with a pseudocyst in the region of uncinate process. There is also a peripancreatic fluid collection with ascitis

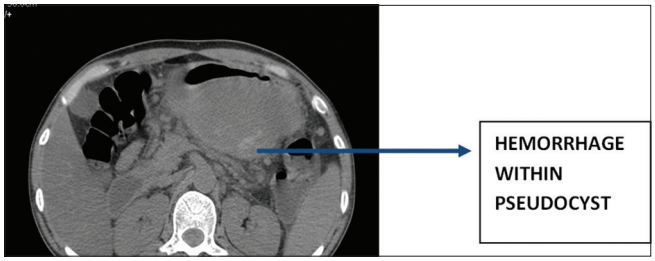


Figure 14: Non-enhanced computed tomography showing high attenuation areas within pseudocyst suggesting hemorrhage

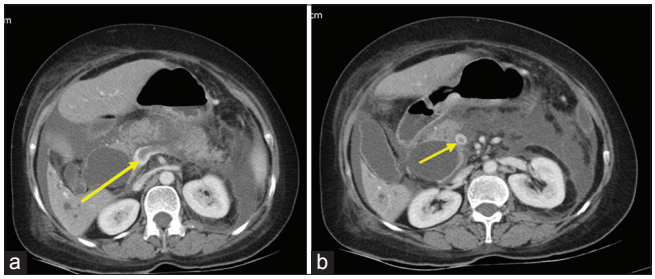


Figure 15: (a) A case of necrotizing pancreatitis with peripancreatic fluid and fat stranding and dilated common bile duct with gradual narrowing at its distal end. There is filling defect in the splenic vein, portal venous confluence (arrow in fig a), and superior mesenteric vein (shown by arrow in figure b below) suggesting thrombosis. (b) A case of necrotizing pancreatitis with filling defect in superior mesenteric vein (thick yellow arrow).

CTSI and MCTSI were compared in their ability to individually predict hospital stay, the development of local complications, systemic complications, a fatal outcome, and their ability to pick up patients who eventually had severe disease.

Outcome Parameters

For mortality

In hospital death.

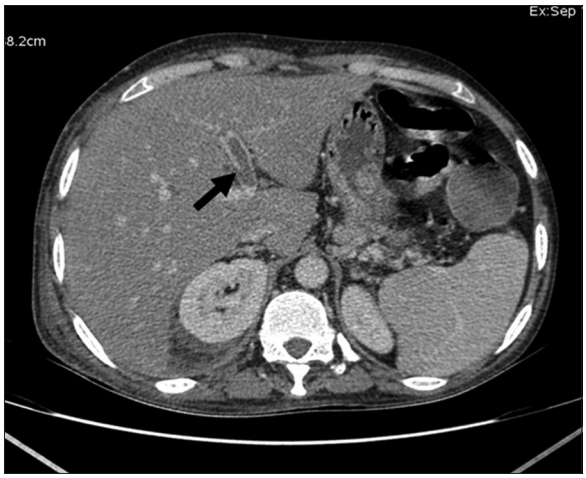


Figure 16: Multiple vascular channels noted at splenic hilum replacing splenic vein suggesting collaterals - a complication of splenic vein thrombosis following acute pancreatitis. There is filling defect in the left branch of the portal vein (yellow arrow) and right perinephric fat stranding

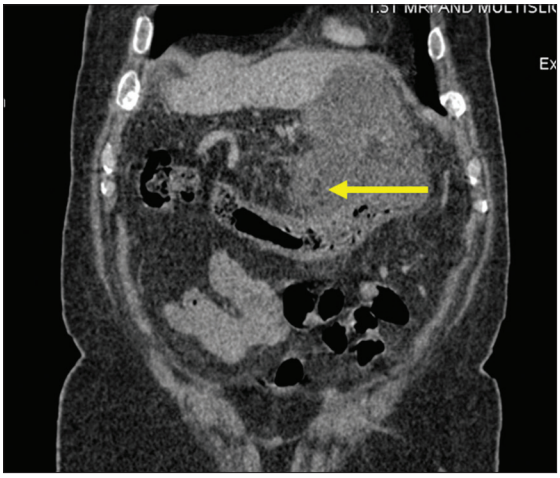


Figure 17: A subcapsular collection indenting the surface of liver suggesting a pseudocyst (shown by *asterisk)

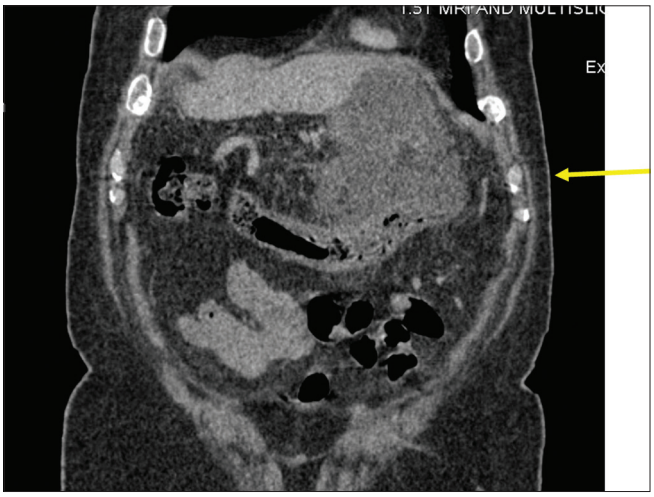


Figure 18: Inflammatory thickening involving mid and distal transverse colon with fluid collection and fat stranding in transverse mesocolon (yellow arrow)

For morbidity

- Length of the hospital stay (in days): A study by Mortele *et al.* 2004 had shown that the average duration of hospital stay in most patients predicted to have a severe clinical course was 12 days. However, these figures are arbitrary and do not define severity in the true sense. The cutoff 10 taken in the present study is arbitrary
- Development of local complications (pseudocyst, hemorrhage within pseudocyst, infected necrosis, ileus, hematemesis, splenic vein/portal vein/superior mesenteric vein thrombosis, pseudoaneurysm, and splenic infarct)
- Need for surgical intervention/percutaneous intervention (aspiration and drainage)
- Evidence of infection in any organ system (positive results on a Gram stain or culture or the combination of a fever >100°F, and an elevated white blood cell [WBC] >11,000/mm^3), and
- Evidence of organ failure patient records was retrospectively reviewed for the presence or absence of dysfunction in six separate organ systems as defined by Fagon *et al.*[7]

i. Respiratory failure was defined as a PaO_2 of <60 mm Hg or by the need for ventilatory support.
ii. Cardiovascular system failure was defined as a systolic blood pressure of <90 mm Hg in the absence of hypovolemia with signs of peripheral hypoperfusion or by the need for a continuous infusion of vasopressor or inotropic agents to maintain a systolic blood pressure of more than 90 mm Hg.
iii. Renal failure was defined as either a serum creatinine level >1.4 mg/dl or need for hemodialysis or peritoneal dialysis.
iv. Central nervous system failure was defined poor Glasgow coma scale score in the absence of sedation or by the sudden onset of confusion or psychosis.
v. Hepatic failure was defined as serum bilirubin levels >1.2 mg/dl or alkaline phosphatase levels >3 times the upper limit of the normal range.
vi. Hematologic system failure was defined as a hematocrit level of <20%, WBC of <2,000/mm^3, or platelet count of <40,000/mm^3.

Necrosis on CECT was evaluated as a separate index in its usefulness in the prediction of the severe course of the disease and mortality.

Data Analysis

Age- and sex-wise analysis of patients was done.

Mean hospital stay of patients with different severity (mild, moderate, severe as per the CTSI, and MCTSI) was calculated. Patients were divided into appropriate disease groups as having either mild, moderate, or severe acute pancreatitis.

Correlation between the severity of pancreatitis and the patient outcome measures was obtained with Fisher's exact test.

For correlation between the two indices (CTSI and MCTSI) as a predictor of patient morbidity parameters, McNemar's test was applied.

RESULTS

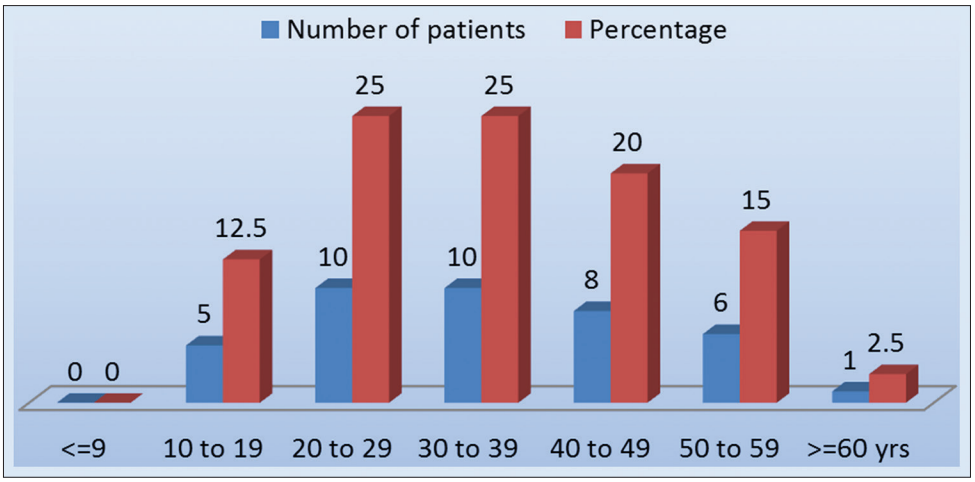
The study included patients from all age groups, youngest patient was aged 11 years, and the eldest was 71 years. The mean age was 35 years. The highest number of patients belonged to 20–29 and 30–39 age group. Thus, the maximum number of patients was in the range of 20–50 years [Graph 1]. Present study showed a male predominance (male:female ratio as 9:1) [Graph 2]. The most common etiology of acute pancreatitis was alcohol (75%) followed by the idiopathic cause [Graph 3]. The most common presenting symptom was an epigastric abdominal pain (100%) followed by distension (75%) and nausea (50%) [Graph 4]. All the patients showed epigastric tenderness and 37 patients showed abdominal guarding as the most common sign [Graph 5]. Majority of patients had peripancreatic fat stranding (87.5%) and irregular pancreatic margins (80%) followed by gland enlargement (70%) [Graph 6]. 27 of 40 had interstitial pancreatitis [Graph 7 and Table 1]. Ratio of interstitial:necrotizing pancreatitis = 2:1. 67.5% of patients had no necrosis [Table 2]. Ascitis and pleural effusion were most common extrapancreatic complication (77.5 and 70%, respectively) followed by vascular and gastrointestinal complications [Graph 7]. The length of the hospital stay ranged from 5 to 25 days (mean, 13.9 days). Majority of patients had hospital stay between 11 and 15 days followed by ≤10 days [Graph 8]. As per CTSI, the highest mean duration of hospital stay was in the mild disease (14.6 days) followed by moderate and severe disease [Table 3]. As per MCTSI, the mean duration of

Table 1: Types of pancreatitis

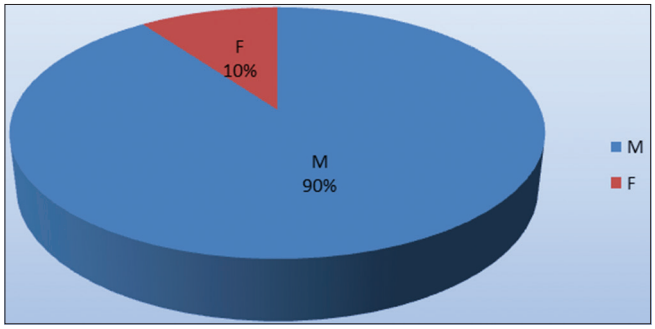
Types of pancreatitis	No. of patients (%)
Interstitial pancreatitis	27 (67.5)
Necrotizing pancreatitis	13 (32.5)

Table 2: Incidence of necrosis

Necrosis	Number of patients (%)
None	27 (67.5)
<30%	11 (27.5)
>=30%	2 (5)



Graph 1: Age distribution



Graph 2: Sex distribution

hospital stay was highest (14.8 days) in moderately severe disease followed by that in severe disease [Table4]. As per CTSI, 24 patients, i.e., 60% patients had moderately severe disease followed by mild disease (11 patients, i.e. 27.5%) [Table 5 and Graph 9]. As per MCTSI, majority patients had the moderately severe disease (26 patients, i.e., 65%) followed by severe disease (13 patients, i.e., 32.5%) [Table 6 and Graph 10]. There was no mortality during the hospital stay of 40 patients. Since there was not a significant number of patients who died, the severity indices could not be studied as a predictor of mortality as outcome only one patient of 40 developed organ failure signs of liver dysfunction [Table 7 and Graph 11]. 5 of 40 underwent surgical/other intervention. One underwent laparoscopic cholecystectomy for gallstones [Figure 3], one underwent nasogastric jejunal feeding tube insertion, two underwent cystogastrostomy, and one underwent surgical debridement for infected necrosis [Graph 12 and Figure 12].

Correlation of CTSI and MCTSI was done with respect to the following morbidity parameters:

1. Duration of hospital stay
2. Development of local complications
3. Development of complicated pancreatitis
4. Incidence of surgical intervention.

Table 3: Mean duration of hospital stay according to severity by CTSI

Severity according to CTSI	Mean duration of hospital stay (days)
Mild	14.6
Moderate	14
Severe	13.1

CTSI: Computed tomography severity index

Table 4: Mean duration of hospital stay according to severity by MCTSI

Severity according to MCTSI	Mean duration of hospital stay (days)
Mild	10
Moderate	14.77
Severe	12.33

MCTSI: Modified computed tomography severity index

Table 5: Severity according to CTSI

Severity	No. of patients (%)
Mild	11/40 (27.5)
Moderate	24/40 (60)
Severe	5/40 (12.5)

CTSI: Computed tomography severity index

Table 6: Severity according to MCTSI

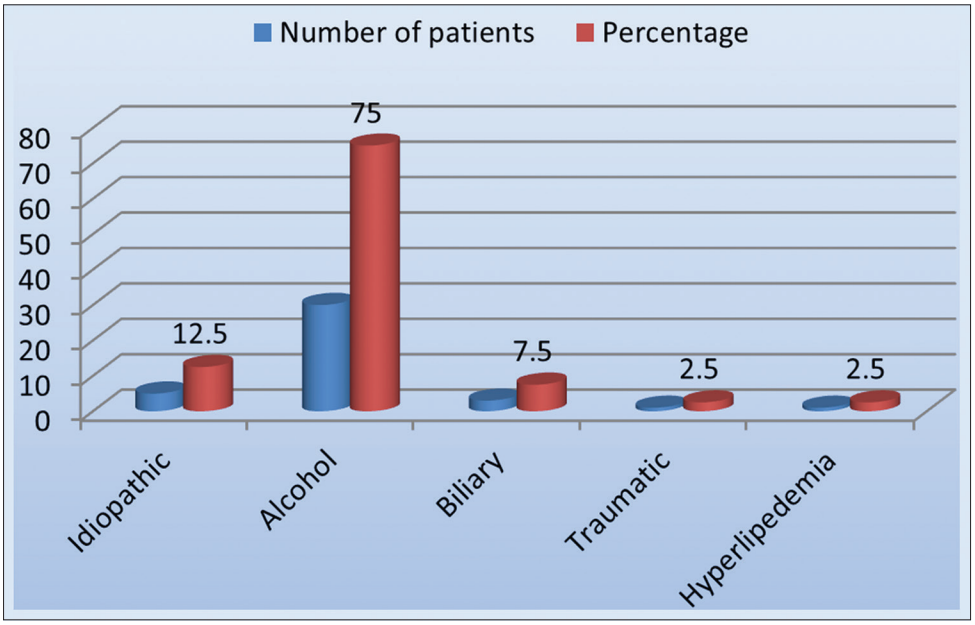
Severity	Number of patients (%)
Mild	1/40 (2.5)
Moderate	26/40 (65)
Severe	13/40 (32.5)

MCTSI: Modified computed tomography severity index

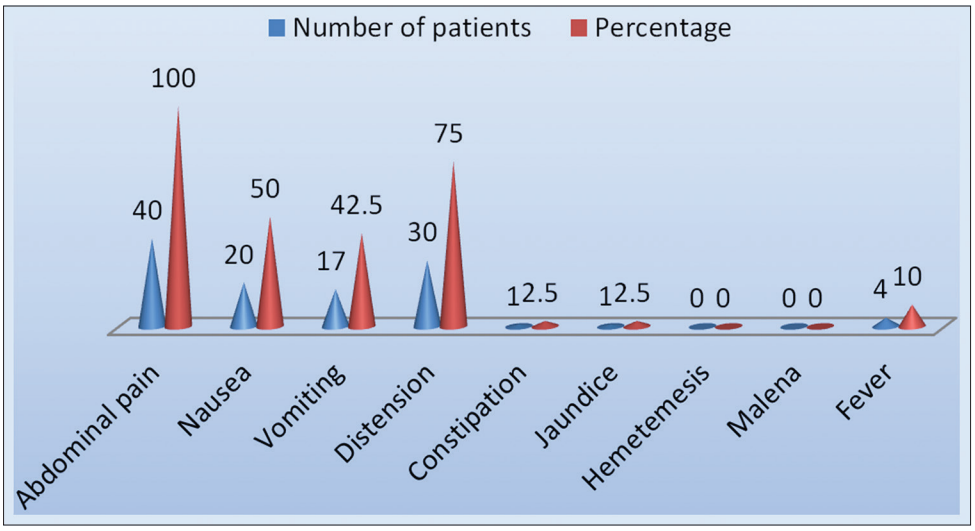
Table 7: Outcome: Recovery and death

MCTSI	Expired	Recovered (%)
≥8	0	11 (27.5)
<8	0	29 (72.5)

MCTSI: Modified computed tomography severity index



Graph 3: Etiological analysis



Graph 4: Symptomatology

No association could be found either between CTSI and longer duration of hospital stay or between MCTSI and duration of hospital stay [Tables 8 and 9]. Both CTSI and MCTSI show poor sensitivity as a predictor of longer duration of hospital stay in this study [Table 10]. On comparing CTSI and MCTSI in their ability to predict a longer duration of hospital stay, they were found to be discordant [Table 11].

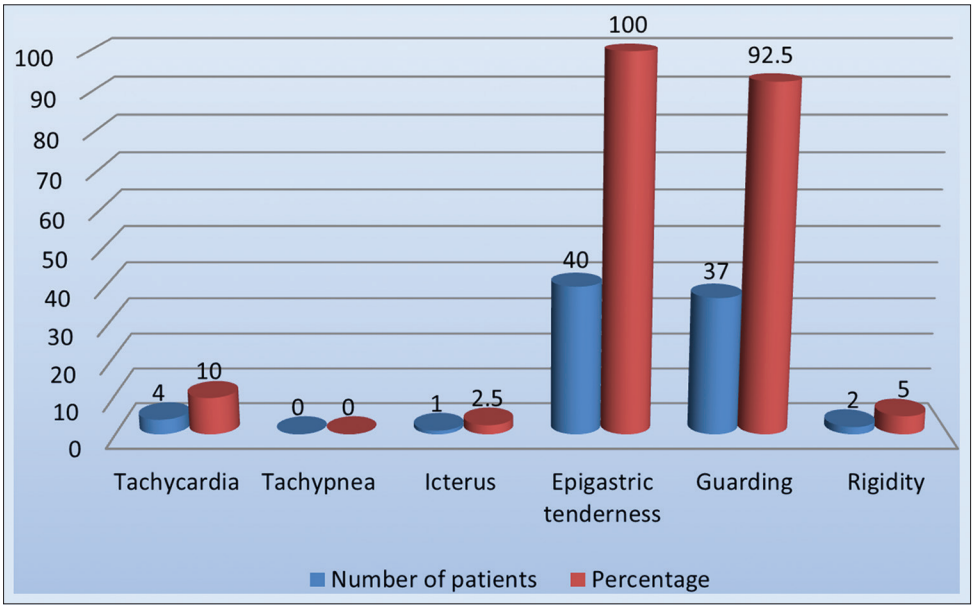
Both CTSI and MCTSI showed an association with the development of local complications [Tables 12 and 13]. MCTSI showed better sensitivity than CTSI and showed good specificity, positive and negative predictive values as a predictor of local complications [Table 14]. On applying McNemar's test for comparison between CTSI and MCTSI, the two were found to be discordant [Table 15].

Table 8: CTSI as a predictor of duration of hospital stay

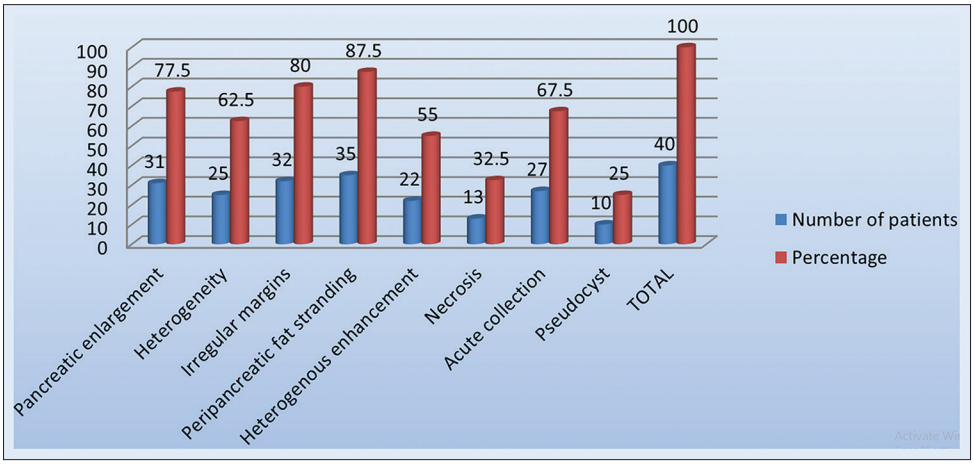
CTSI	Duration of hospital stay >10 days	Duration of hospital stay ≤10 days
≥7	2	2
<7	25	11
P value	0.583926 (not significant)	

CTSI: Computed tomography severity index

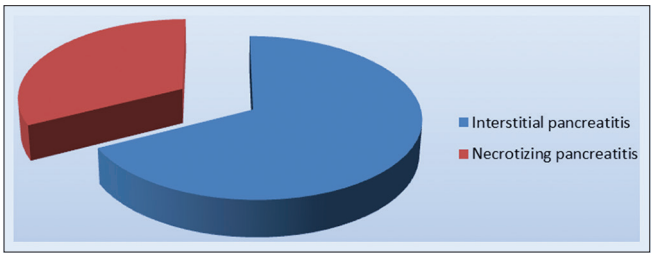
Both CTSI and MCTSI showed an association with the development of complicated disease [Tables 16 and 17]. MCTSI showed greater sensitivity compared to CTSI in the prediction of complicated disease [Table 18]. On applying McNemar's test for comparison between CTSI and MCTSI, the two were found to be discordant [Table 19].



Graph 5: Signs



Graph 6: Imaging findings



Graph 7: Types of pancreatitis

Table 9: MCTSI as a predictor of hospital stay

MCTSI	Duration of hospital stay >10 days	Duration of hospital stay ≤10 days
≥8	8	3
<8	22	7
P value	1.0 (not significant)	

MCTSI: Modified computed tomography severity index

Table 10: Comparison of accuracy for duration of hospital stay

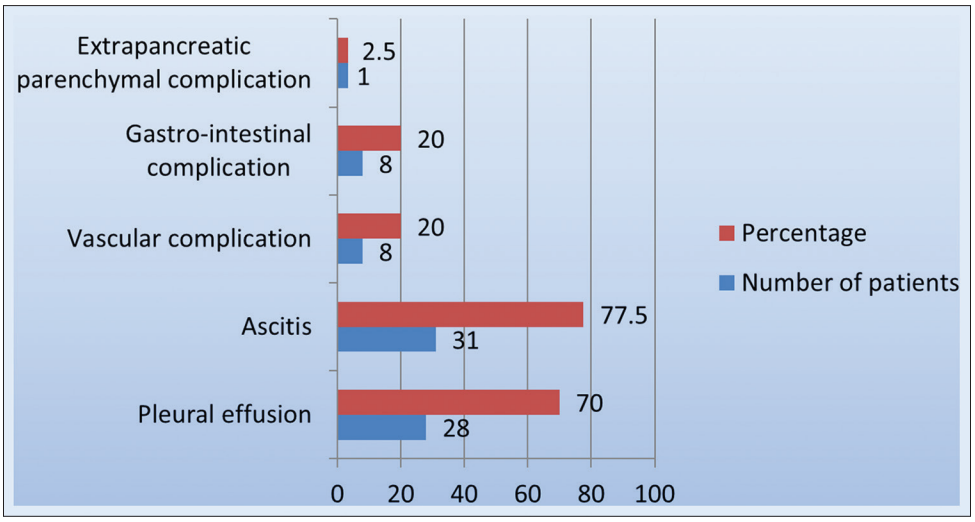
Statistical Measure	Percentage	
	CTSI	MCTSI
Sensitivity	7.4	26.6
Specificity	85	70
PPV	50	73
NPV	30	24
P values	1	1

CTSI: Computed tomography severity index, MCTSI: Modified computed tomography severity index, PPV: Positive predictive value, NPV: Negative predictive value

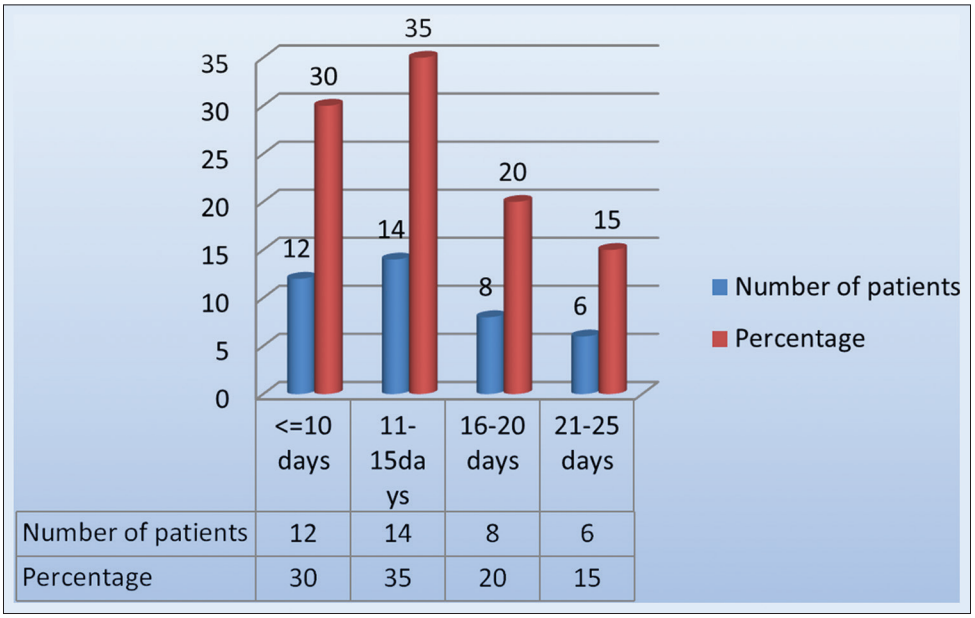
Table 11: CTSI versus MCTSI in the prediction of duration of hospital stay

MCTSI	CTSI ≥7	CTSI <7
≥8	3	7
<8	0	18

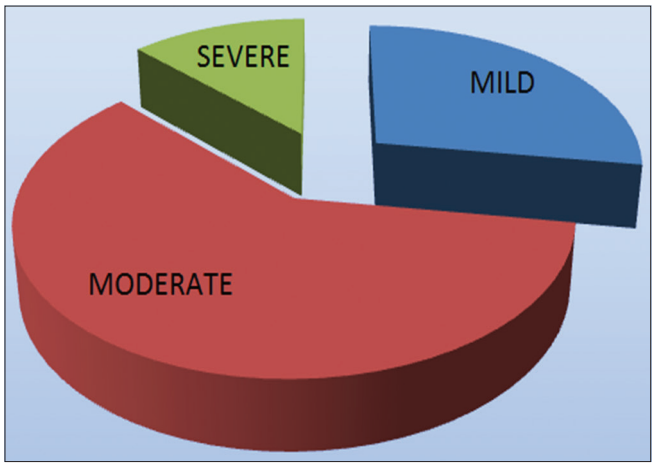
McNemar's test: *P*=0.01. CTSI: Computed tomography severity index, MCTSI: Modified computed tomography severity index



Graph 8: Extrapancreatic complications



Graph 9: Duration of hospital stay



Graph 10: Severity according to computed tomography severity index

Table 12: CTSI correlation with local complications

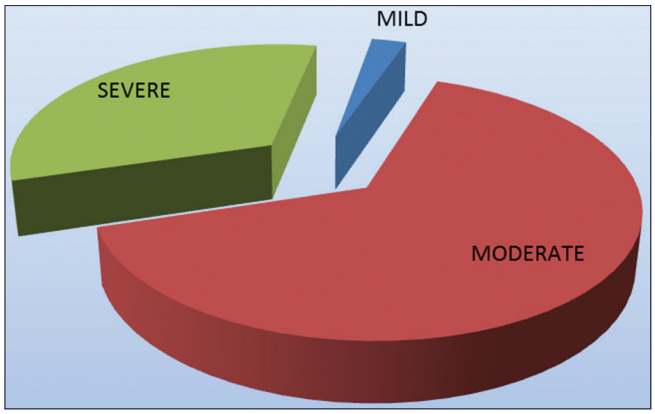
CTSI	Local complications present	Local complications absent
≥7	5	0
<7	11	24
P value	0.006 (Significant)	

CTSI: Computed tomography severity index

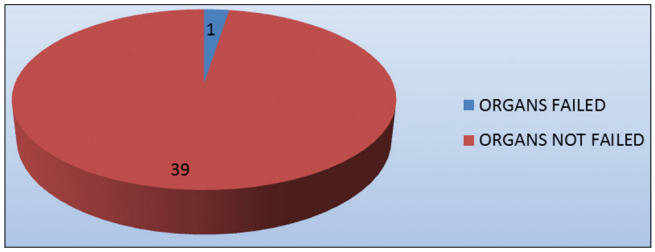
Table 13: MCTSI correlation with local complications

MCTSI	Local complications present	Local complications absent
≥8	11	2
<8	5	22
P value	0.0001 (Significant)	

MCTSI: Modified computed tomography severity index



Graph 11: Severity according to modified computed tomography severity index



Graph 12: Incidence of organ failure

Table 14: Comparison of accuracy of the two indices for local complications

Statistical Measure	Percentage	
	CTSI	MCTSI
Sensitivity	31	68.7
Specificity	100	91.6
PPV	100	84.6
NPV	66.6	81.4
P values	0.006	0.0001

CTSI: Computed tomography severity index, MCTSI: Modified computed tomography severity index, PPV: Positive predictive value, NPV: Negative predictive value

Table 15: CTSI versus MCTSI in the prediction of local complications

Statistical measure MCTSI	CTSI ≥7	CTSI <7
≥8	5	6
<8	0	5

McNemar's test: *P* value=0.03. CTSI: Computed tomography severity index, MCTSI: Modified computed tomography severity index

Table 16: CTSI correlation with complicated pancreatitis

CTSI	Complicated disease	Uncomplicated disease
≥7	5	0
<7	12	23
P value	0.049 (Significant)	

CTSI: Computed tomography severity index

Table 17: MCTSI correlation with complicated pancreatitis

MCTSI	Complicated disease	Uncomplicated disease
≥8	11	2
<8	6	21
P value	0.00036 (Significant)	

MCTSI: Modified computed tomography severity index

Table 18: Comparison of accuracy of the two indices for complicated disease

Statistical Measure	Percentage	
	CTSI	MCTSI
Sensitivity	29.4	64.7
Specificity	100	91.3
PPV	100	84.6
NPV	65.7	77.7
P values	0.049	0.00036

CTSI: Computed tomography severity index, MCTSI: Modified computed tomography severity index, PPV: Positive predictive value, NPV: Negative predictive value

Table 19: CTSI versus MCTSI in the prediction of complicated disease

Sex Distribution MCTSI	CTSI ≥7	CTSI <7
≥8	5	6
<8	0	6
P value	0.03	

CTSI: Computed tomography severity index, MCTSI: Modified computed tomography severity index

Table 20: CTSI correlation with surgical intervention

CTSI	Surgical Intervention	No Surgical Intervention
≥7	1	4
<7	4	31
P value	1 (Not significant)	

CTSI: Computed tomography severity index

Table 21: MCTSI Correlation With Surgical Intervention

MCTSI	Surgical intervention	No surgical intervention
≥8	2	11
<8	3	24
P value	1 (Not significant)	

MCTSI: Modified computed tomography severity index

Table 22: Necrosis as a predictor of local complications

Necrosis	Local complication	No local complication
Necrosis present	11	2
No necrosis	5	22
P value	0.0001 (Significant)	

Both CTSI and MCTSI did not show any association with incidence of surgical intervention [Tables 20 and 21]. An association was found between necrosis and development of local complications [Table 22]. Sensitivity and specificity of necrosis as an independent predictor of local complication were 68.7% and 91.6%, respectively [Table 23].

Table 23: Comparison of accuracy of necrosis for predicting local complications

Statistical Measure	Percentage
Sensitivity	68.7
Specificity	91.6
PPV	84.6
NPV	81.4
P value	0.0001 (Significant)

PPV: Positive predictive value, NPV: Negative predictive value

Table 24: Age range

	Mortele *et al*.[5]	Present study
Age range	19–87 years	11–71 years

Table 25: Mean age

	Baig *et al.*	Mortele *et al*.[5]	Present study
Mean age	30 years	49.2 years	34.97 years

Table 26: Sex distribution

Statistical measure	Baig *et al*.[8]	Mortele *et al*.[5]	Present study
Number of males (%)	33/45 (73.4)	29/66 (43.9)	36/40 (90)
Number of females (%)	12/45 (26.6)	37/66 (56)	4/40 (10)
Male:female ratio	2.7:1	0.78:1	9:1

Except as noted, data are numbers of patients with their percentages in parenthesis

Table 27: Etiology

Etiology	Birgisson[9] (%)	Bollen *et al*.[6] (%)	Present study (%)
Alcohol	16/50 (32)	43/196 (22)	30 (75)
Biliary	21/50 (42)	66/196 (34)	3 (7.5)
Idiopathic	1 (2)	26/196 (13)	5 (12.5)
Post ERCP	-	16/196 (8)	0
Drug-induced	-	14/196 (7)	0
Misce.	12 (24)	31/196 (16)	2 (5)

ERCP: Endoscopic retrograde cholangiopancreatography

Table 28: Symptoms

Symptom	Malfertheiner And Kemmer[10] (%)	Corsetti and Arvan[11] (%)	Present study (%)
Abdominal pain	90	95	100
Nausea, vomiting	70	75	67.5
Abdominal distension	60	-	75
Jaundice	30	15	2.5
Neurological symptoms	10	-	0
Hematemesis	-	10	0

DISCUSSION

The present study included patients over a wide age range as in studies by Mortele *et al.* [Table 24]. The mean age in the present study is comparable to Baig *et al.* but is slightly lower than the study by Mortele *et al.* [Table 25].[5]

The present study showed alcohol to be the most common etiology followed by an idiopathic group [Table 26]. The study by Birgisson *et al.*[9] and Bollen *et al.*[6] showed biliary cause to be the most common followed by alcohol [Table 27]. The reason for the discrepancy could be because alcohol abuse is very common in the low socioeconomic

Table 29: Signs

Abdominal guarding	Malfertheiner and Kemmer[10] (%)	Corsetti and Arvan[11] (%)	Present study (%)
	80	50	92.5

Table 30: Types of pancreatitis

Type	Mortele *et al*.[5] (%)	Present study (%)
Interstitial	161/196 (82)	27 (67.5)
Necrotizing	35/196 (18)	13 (32.5)

Table 31: Incidence of extrapancreatic complications

Extrapancreatic complication	Number of patients (%)	
	Mortele *et al*.[5]	Present study
Pleural effusion	69 (35)	28 (70)
Ascites	80 (41)	31 (77.5)
Vascular complication	16 (8)	8 (20)
Gastro-intestinal complication	10 (5)	8 (20)
Extrapancreatic parenchymal complication	3 (2)	1 (2.5)

Table 32: Mean hospital stay

Severity	Mortele *et al*.[5]	Present study
Mild	3	10
Moderate	8	14.77
Severe	14	12.33

Table 33: Mortality

Number of patients died	Mortele *et al*.[5] (%)	Present study (%)
	1/66 (1.5)	0

Table 34: Surgical intervention

Number of patients	Mortele *et al*.[5] (%)	Present study (%)
	10/66 (15)	5/40 (12.5)

Table 35: Outcome

Outcome	Mild (0–3)		Moderate (4–6)		Severe (≥8)	
	Mortele *et al.*[5] (%)	Present study (%)	Mortele *et al.*[5] (%)	Present study (%)	Mortele *et al.*[5] (%)	Present study (%)
Number of patients	34	1	22	28	10	11
Hospital stay	3	10	8	14.8	10	12
Intervention/Local complication	3	0	2	3	5	2
Organ failure	2	0	0	1	5	0
Mortality	0	0	0	0	1	0

Table 36: Outcome

Outcome parameters	MCTSI as a outcome predictor	
	Mortele *et al.*[5] (60 patients) *P* values	Present study (40 patients) *P* values
Length of hospital stay	0.0054–0.0714	1
Intervention/surgery/local complications	0.0112	0.0001
Organ failure	0.0024	-

MCTSI: Modified computed tomography severity index

Table 37: Necrosis as a predictor of local complications

Statistical Measure	Casas *et al.*[12]	Present study
Sensitivity	53.3%	68.7%
Specificity	90.2%	91.6%

group to which the patients enrolled in the present study belonged. The frequency of the symptoms in the present study is comparable to previous studies. In all the three series, abdominal pain was the most common symptom followed by nausea vomiting and distension [Table 28]. The present study showed a higher number of patients with abdominal guarding [Table 29]. The present study had a higher number of patients with necrotizing pancreatitis compared to study by Mortele *et al.*[5] [Table 30]. There is a higher frequency of most of the extrapancreatic complications in this study compared to study by Mortele *et al.* [Table 31]. The mean hospital stays for mild and moderate disease are higher in the present study [Table 32]. No patient died during hospital stay [Table 33]. The reason for this is the small sample size in the present study.

The incidence of surgical intervention is comparable with other studies [Table 34]. *P* values relating to the development of local complications/need for intervention obtained in the present study and that obtained by Mortele *et al.*[5] (0.0001 and 0.0112, respectively) are comparable [Tables 35 and 36]. This present study showed an association between MCTSI and development of local complications. *P* value relating to hospital stay are not comparable thus showing that there was no association between duration of hospital stay and modified CT severity index [Table 37]. The reason for this could be the difference in the treatment protocols of the different units of the surgery department of the hospital in which the study is performed. The policies or the protocols followed by the treating consultants could be different. Moreover, the point to be noted is that duration of hospital stay is not in real indicator of patient's severity of illness. In both the studies, the sensitivity and specificity of necrosis as a predictor of local complications are comparable.

SUMMARY AND CONCLUSION

Following findings are drawn from the study.

The majority of patients with acute pancreatitis were in the range of 20–50 years. Mean age of presentation was 35 years. Alcohol was the leading cause of pancreatitis. It was followed by idiopathic group. Acute pancreatitis showed male predominance. All the patients presented with epigastric pain and majority patients had a complaint of distension and nausea. Epigastric tenderness and guarding were the most common signs. Most common imaging feature was peripancreatic fat stranding followed by irregular pancreatic margins and gland enlargement. Majority patients have interstitial pancreatitis. The most common extrapancreatic complication was ascites followed by pleural effusion. The majority of patients had hospital stay between 11 and 15 days.

Mild and moderately severe disease was more common than severe disease.

Both the indices CTSI and MCTSI did not show an association with duration of hospital stay or the need for surgery or intervention in a patient.

Both indices (CTSI and MCTSI) showed association with the development of local complications and organ failure.

MCTSI showed better sensitivity than CTSI and shows good specificity, positive and negative predictive values as a predictor of local complications and organ failure.

Necrosis showed an association with patient morbidity (development of local complications) with high positive and negative predictive values (84.6% and 81.4%, respectively) and sensitivity of 68.7 % and specificity of 91.6%.

Thus, CE CT is useful modality in assessing the severity of acute pancreatitis and both the CT severity indices serve as an accurate index to predict the development of local complications or organ failure. And among the two, MCTSI is more accurate. However, both are less accurate in their ability to predict the need for surgical intervention and longer hospital stay. Necrosis as an independent index is a useful marker for predicting the development of local complications.

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Original Article

Computed Tomography-based Morphometric Analysis of Cervical Pedicle, Lateral Mass, and Cervical Facet in Subaxial Spine (C3-C7) to Assess Feasibility of Screw Fixation in Indian Population

Ambarish Mathesul[1], Vijay Waghmare[2], Ajay Chandanwale[3]

[1]Associate Professor, Department of Orthopaedics, B. J. Government Medical College, Sassoon General Hospitals, Pune, Maharashtra, India, [2]Resident, Department of Orthopaedics, B. J. Government Medical College, Sassoon General Hospitals, Pune, Maharashtra, India, [3]Dean and Professor, Department of Orthopaedics, B. J. Government Medical College, Sassoon General Hospitals, Pune, Maharashtra, India

Abstract

Background: Posterior cervical spine fixation is indicated in the unstable cervical spine as a result of trauma, infection, degeneration, and neoplastic conditions. Laminar Wiring, lateral mass screw, pedicular screw, and recently transfacet screws are common methods; however, these techniques are associated with disastrous complications such as vertebral artery injury, spinal cord injury, nerve root damage facet, and pedicle breach. It is recommended to do thorough planning by doing a pre-operative computed tomography (CT) scan, especially for cervical pedicle screw insertion. A 3.5 mm diameter screw is commonly used which is based on the morphometric studies carried out in the western population, studies in Indian population have shown smaller sizes and dimensions in subaxial cervical spine. With this background, we undertook this study with an attempt to measure standard dimensions and also to actually measure the screw dimensions by adjusting the CT axes accordingly.

Methods: This cross-sectional study enrolled 50 patients (male and female) who were admitted to our institution for reasons other than cervical spine injury or complaints. All selected patient underwent CT scan of the cervical spine in our institute. A CT scan-based attempt was made to measure the exact length and diameter of screw required for lateral mass, cervical pedicle, and transfacet fixation at each level of subaxial spine (C3-7) by adjusting the axes to mimic three-dimensional form, not earlier attempted in literature. CT cuts are taken parallel to the upper endplate of the vertebral body using helical CT scanner at 2.5 mm intervals. Nine important parameter dimensions have been calculated. Measurement is taken both for right and left side pedicle axis length (PAL), pedicle length plus lateral mass length, pedicle width (PW), pedicle height (PH), lateral mass longitudinal diameter, lateral mass transverse diameter, lateral mass height, lateral mass screw length, and transfacet screw length.

Results: Our results are in agreement with the majority of studies that there is no difference between right and left side values. Mean values of PW progressively increasing for both male and female from C3 to C7 level, also it is found that female has smaller value compare to male. PH in the sagittal plane is found to be larger than PW, at each vertebral level, and for both male and female. Hence, PW should be important parameter to determine pedicle screw size. PAL is found to be progressively increasing from C3 to C7 for both male and female, but pedicle length is found to increasing from C3 to C6, and slightly decreasing at C7 vertebral level. The study also shows that dimension of subaxial cervical vertebrae is smaller than western population.

Conclusions: As the difference is found between sex, level, and ethical variation, pre-operative CT should be performed to know the dimension of cervical vertebrae to avoid complication.

Key words: Cervical Pedicle, Computed Tomography, Spine

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INTRODUCTION

The cervical spine consists of seven vertebrae joined by an intervertebral disc. Third to seventh cervical vertebra (C3-C7) are named as subaxial cervical spine. The first and second vertebrae are atypical since each possesses specific feature for self-identification.

Corresponding Author: Dr. Vijay Waghmare, Niranjan, Nivrutti Devkar Residency, Opposite Stella Maris High School, Mahavir Nagar, Wadgaon Sheri, Pune - 411 014, Maharashtra, India. Phone: +91-9920483232. E-mail: math.amb123@gmail.com

The cervical spine instability caused by fracture, deformity or degenerative disease is treated with neurovascular decompression, anatomic reduction, rigid spinal fixation, solid fusion, and early rehabilitation. Anterior fixation (stabilization) of the cervical spine includes anterior cervical plating with screws and cages; posterior fixation includes posterior cervical wiring, laminar screw fixation, lateral mass screw fixation, pedicle screw, and transfacet screw fixation with their merit and demerit.[1-5]

Roy - Camille first introduced lateral mass screw fixation provide strong posterior fixation useful in patients whose pedicle and lamina are deficient. Lateral mass screw fixation is contraindicated in any traumatic or pathological process that compromises the integrity of the lateral mass.[2] Pedicle screws in cervical spine offer superior fixation, with a high complication rate of the vertebral artery and cord injury.[6] Transfacet screws are lag screws that do not require a rod to immobilize the spine. This technique can be used for percutaneous fixation. To use this technique percutaneous placement, anatomical parameter data are needed.[7]

Pre-operative computed tomography (CT) is recommended for a quantitative understanding of subaxial cervical spine morphology for pedicle screw fixation, lateral mass, and transfacet screw fixation to improve accuracy and minimize complication which includes vertebral artery injury, spinal cord injury, and nerve root injury.

Differences in cervical spine morphology have been reported across different study population.[8] Some studies also reported that sex, race, and geographic occurrence play a significant role in cervical anatomy, Asians trends to be smaller than Europeans and Americans. Female has smaller pedicle than male.[9] The morphology of cervical spine has been studied extensively using both cadavers and CT films; however, CT scan provides the most accurate rendering of anatomy for assessing the accuracy of screw placement.[10]

The data regarding CT based morphometric measurement of the cervical spine are focused on Caucasian population. Indian studies are mainly focused on thoracic and lumbar spine. Very few studies have been done to study the morphology of cervical spine in relation to screw placement.

The objective of this study was to determine morphometric characteristics of subaxial cervical spine in Indian population to assess the feasibility of screws fixation in pedicle, lateral mass, and transfacet. A CT scan-based attempt was made to measure the exact length and diameter of screw required for lateral mass, cervical pedicle, and transfacet fixation at each level of subaxial spine (C3-7) by adjusting the axes to mimic the three-dimensional form, not earlier attempted in literature.

MATERIALS AND METHODS

This cross-sectional study enrolled 50 patients (male and female) who were admitted to our institution for reasons other than cervical spine injury or complaints. Approval from hospital ethics committee was taken to conduct this study. Patients were enrolled after obtaining written, informed consent.

The inclusion criteria of selected patients were - non-pregnant females, age between 18 and 35, and trauma other than cervical. Following were the exclusion criteria - patients with poor general conditions, patients with cervical spine trauma/tumor/pathology, pregnant females, and congenital anomaly of spine.

All selected patient underwent CT scan of the cervical spine in our institute. CT was performed with patient supine and neck at the neutral position. CT scan of the patients was studied and measurement of that parameter which is considered to be significant for assessing the feasibility of screw fixation done. A CT scan-based attempt was made to measure the exact length and diameter of screw required for lateral mass, cervical pedicle, and transfacet fixation at each level of subaxial spine (C3-7) by adjusting the axes to mimic the three-dimensional form, not earlier attempted in literature. CT cuts are taken parallel to the upper endplate of the vertebral body using helical CT scanner at 2.5 mm intervals.

Nine important parameter dimensions have been calculated. Measurement is taken both for right and left side.

1. Pedicle axis length (PAL) - Distance from the posterior cortex of the pedicle axis projection on lateral mass to the anterior margin of the vertebral body.
2. Pedicle length plus lateral mass length - Distance from the posterior cortex of the pedicle axis projection on lateral mass to the junction of the vertebral body.
3. Pedicle width (PW) - Medio-lateral diameter of pedicle isthmus at the narrowest point.
4. Pedicle height (PH) - Superoinferior diameter of pedicle isthmus on sagittal cuts.
5. Lateral mass longitudinal diameter (LMLD) - Which is the distance from the posterior cortex of the lateral mass to the posterior edge of the transverse foramen.
6. Lateral mass transverse diameter (LMTD) - Which is the distance from lateral cortex of the lateral mass to the medial edge of the osseous spinal canal.
7. Lateral mass height (LMH) - Sagittal height as considered as the anatomical height at the center of lateral mass.

8. Lateral mass screw length (LMSL) - Three fixed parameters were used for measuring LMSL - (1) The point of screw insertion was the midpoint of the lateral mass. It was crossing point between the sagittal and axial planes of lateral mass, (2) the direction of screw in craniocaudal plane was 30° to avoid facet joint penetration, and (3) the exist point of screw was located on ventral cortex of lateral mass just lateral to roof transverse process in mid-axial cut of each lateral mass to make a sound bicortical fixation without injuring the vertebral artery of nerve root.
9. Transfacet screw length (TSL) - On reconstructed sagittal images to determine screw length trajectory perpendicular to facet joint in cephalocaudal direction, screw length was measured from midpoint of the facet to ventral cortex of facet below immediately adjacent to vertebral artery foramen.

Statistical Analysis

Data obtained were analyzed using statistical package for the social sciences (SPSS) software version 20 for Windows (SPSS). All the results were expressed as mean, standard deviation and $P < 0.05$ was considered as significant. Unpaired *t*-test was used determine any significant difference in parameter, according to sex and side and level.

RESULTS

A present cross-sectional study comprises 50 patient studies of this 29 were male and 21 were female. All selected patient underwent routine CT in our institute from July 2015 to November 2017. The mean age of males (30.5 years) and females (30.29 years) was similar. There were 29 (58%) males and 21 (42%) females in the study.

PW and PH

On application of unpaired *t*-test, there was a significant difference between male and female individual cervical vertebrae except PW of both sides in third and fourth cervical vertebrae and left side PW of fifth cervical vertebrae among study subjects. There was no significant difference between the vertebral dimensions of left and right sides of individual cervical vertebra among the study subjects.

Mean PW progressively increase from C3 to C7. The mean value for females is smaller than males for both left and right sides. Highest value found at C7 and lowest at C3. C3 and C4 PW, especially in female population, was <5 mm. Mean PH has been found to be progressively increasing from C3 to C7 vertebrae level. The mean value for females is smaller than males. However, the difference between left and right sides is very little for both male and female. Value of PH is found to be larger than PW at each level and in both sex, so for planning pedicle screw size attention should be given especially on PW [Table 1, Figures 1 and 2].

Pedicle Length Plus Lateral Mass Length

Increase from C3 to C6 slightly decrease at C7 for both male and female. Highest value of pedicle length plus lateral mass at C6 Level.

Table 1: Pedicle width and height (mm) of studied part (mean±SD)

Level	Sex	Pedicle width		Pedicle height	
		Right	Left	Right	Left
C3	Male	4.91±0.52	4.95±0.54	6.27±0.45	6.28±0.44
	Female	4.59±0.75	4.67±0.80	5.67±0.57	5.62±0.59
C4	Male	5.0±0.49	5.05±0.53	6.40±0.40	6.39±0.37
	Female	4.75±0.60	4.67±0.69	5.85±0.52	5.80±0.55
C5	Male	5.29±0.47	5.27±0.43	6.56±0.39	6.66±0.44
	Female	4.95±0.57	5.06±0.63	6.06±0.46	6.08±0.52
C6	Male	5.52±0.48	5.48±0.49	6.54±0.43	6.53±0.41
	Female	5.16±0.47	5.20±0.44	6.11±0.49	6.14±0.58
C7	Male	5.90±0.52	5.9±0.62	6.71±0.42	6.66±0.44
	Female	5.50±0.43	5.53±0.53	6.31±0.47	6.33±0.43

SD: Standard deviation

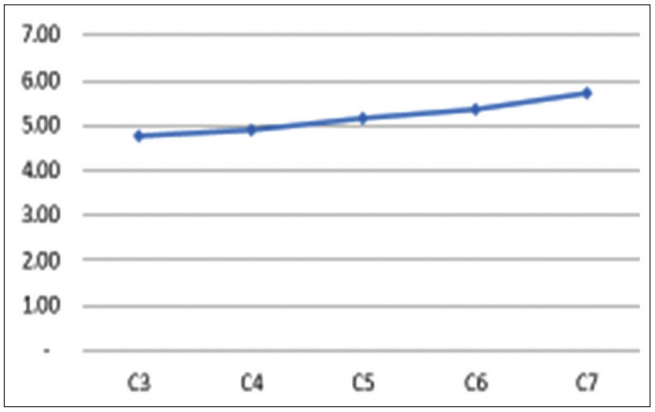

Figure 1: Line diagram sowing nature of variation of pedicle width vertebrae wise

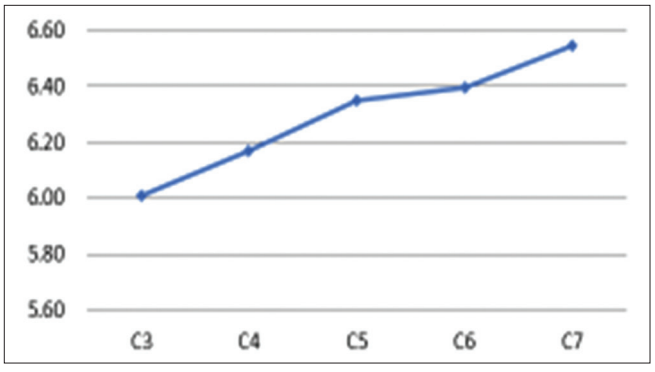

Figure 2: Line diagram sowing nature of variation of pedicle height vertebrae wise

PAL

Progressively increasing from C3 to C7 both for male and female. Female has a smaller value than male [Table 2, Figures 3 and 4].

Table 2: Dimension of pedicle length plus lateral mass and pedicle axis length (mean±SD)

Level	Sex	Pedicle and lateral mass length		Pedicle axis length	
		Right	Left	Right	Left
C3	Male	15.56±1.96	15.64±1.93	28.35±1.93	28.26±1.90
	Female	14.05±1.07	14.07±1.12	26.69±1.41	26.47±1.56
C4	Male	15.98±2.03	15.95±2.04	28.75±1.68	28.62±1.71
	Female	14.21±0.97	14.24±0.90	27.03±1.93	26.38±1.85
C5	Male	16.61±2.21	16.60±2.24	29.45±1.73	29.36±1.94
	Female	14.78±1.03	14.79±1.0	27.55±1.72	27.36±1.94
C6	Male	16.90±2.65	16.91±2.62	30.20±1.79	30.15±1.71
	Female	14.92±0.99	15.00±0.98	27.83±1.70	27.74±1.83
C7	Male	15.94±2.27	15.82±2.85	30.98±1.74	30.97±1.74
	Female	14.62±1.02	14.32±1.11	28.55±1.47	28.93±1.75

SD: Standard deviation

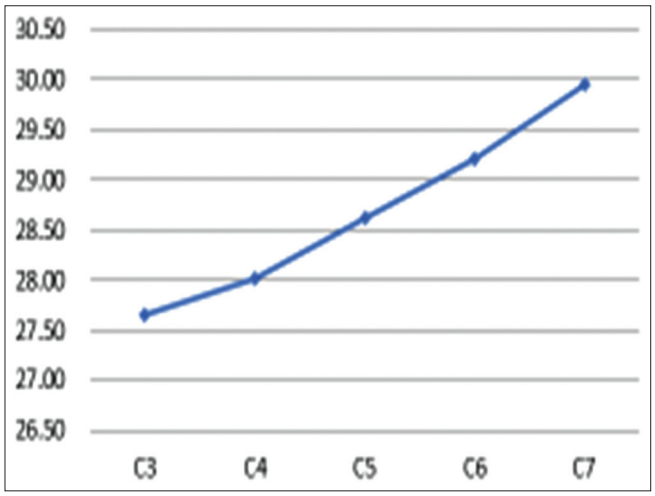

Figure 3: Line diagram sowing nature of variation of pedicle axis length vertebrae wise

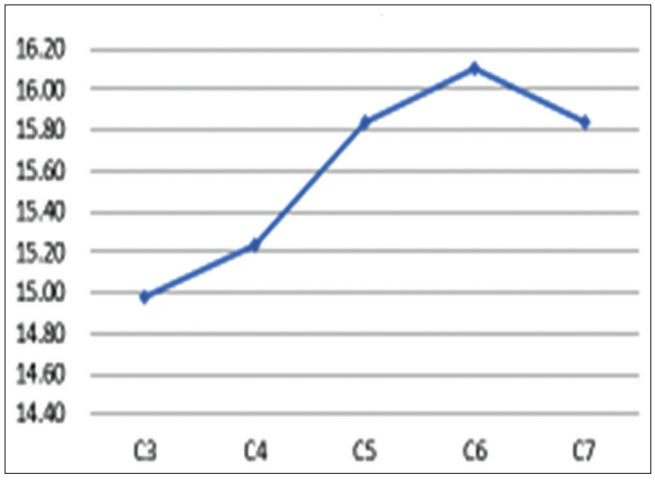

Figure 4: Line diagram sowing nature of variation of pedicle length vertebrae wise

LMTD and LMLD

C6 had larger transverse and longitudinal diameter measurement than other vertebrae. C7 has a minimum longitudinal diameter, and C3 has a minimum transverse diameter [Table 3, Figures 5 and 6].

LMH

There was a minimum difference of LMH between each vertebral level, C7 has a higher value compared to another level. Showing that there was no significant difference

Table 3: Dimension of LMTD and LMLD (mean±SD)

Level	Sex	Tranverse diameter (mm)		Longitudinal diameter (mm)	
		Right	Left	Right	Left
C3	Male	12.88±0.95	12.89±0.97	11.97±1.00	11.94±1.01
	Female	11.23±0.55	11.12±0.59	10.53±0.50	10.50±0.49
C4	Male	12.85±0.95	12.78±0.59	12.07±0.90	12.06±0.90
	Female	11.29±0.47	11.26±0.49	10.58±0.50	10.06±0.43
C5	Male	13.42±0.97	13.12±0.98	12.60±0.93	12.64±0.96
	Female	11.72±0.59	11.70±0.57	10.88±0.53	10.97±0.49
C6	Male	13.51±0.98	13.32±0.99	12.78±0.83	12.77±0.88
	Female	11.87±0.58	11.88±0.60	11.09±0.43	11.14±0.50
C7	Male	13.06±0.8	12.96±0.88	11.82±0.92	11.83±0.85
	Female	11.58±0.51	11.56±0.51	10.51±0.60	10.6±0.67

LMTD: Lateral mass transverse diameter, LMLD: Lateral mass longitudinal diameter, SD: Standard deviation

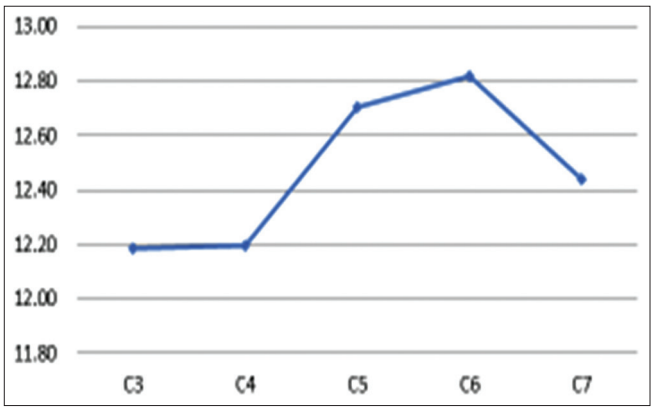

Figure 5: Line diagram showing variation of lateral mass transverse diameter vertebrae wise

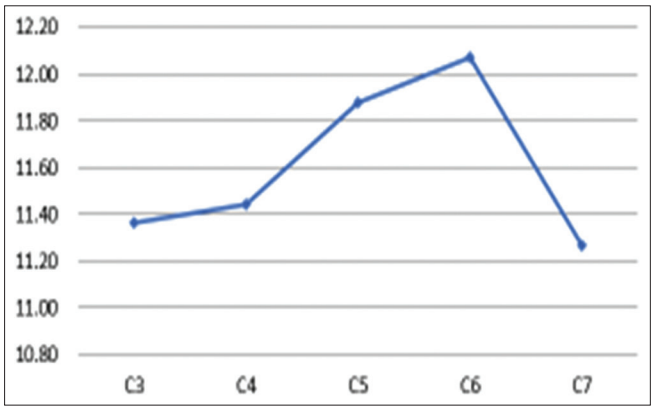

Figure 6: Line diagram showing lateral mass longitudinal diameter vertebrae wise

of LMSL between C3 and C6 but value decrease at C7. Maximum screw length found to be at a C6 level and minimum value at C7 level [Table 4, Figures 7 and 8].

TSL

Decrease as one moves to lower levels of the cervical spine. Female has lower value compare to male. Maximum screw length found at C3-C4 level, and minimum value at C6-C7 [Table 5 and Figure 9].

Table 4: Dimension of LMH and screw length (mean±SD)

Level	Sex	Lateral mass height (mm)		Lateral mass screw length (mm)	
		Right	Left	Right	Left
C3	Male	11.70±1.16	11.69±1.16	12.88±0.93	12.86±0.94
	Female	10.11±0.30	10.21±0.55	11.21±0.55	11.89±0.71
C4	Male	11.71±1.12	11.71±1.10	12.91±0.91	12.91±0.91
	Female	10.10±0.34	10.20±0.58	11.88±0.73	11.91±0.70
C5	Male	12.10±0.93	12.09±1.14	13.15±0.98	13.11±0.97
	Female	10.43±0.48	10.46±0.53	12.12±0.80	12.16±0.73
C6	Male	12.08±1.14	12.07±1.14	13.40±0.93	13.41±0.93
	Female	10.45±0.48	10.49±0.53	12.40±0.81	12.49±0.80
C7	Male	11.91±1.07	11.90±1.07	12.26±1.06	12.33±1.11
	Female	10.11±0.39	10.21±0.52	10.89±0.97	11.05±1.03

LMH: Lateral mass height, SD: Standard deviation

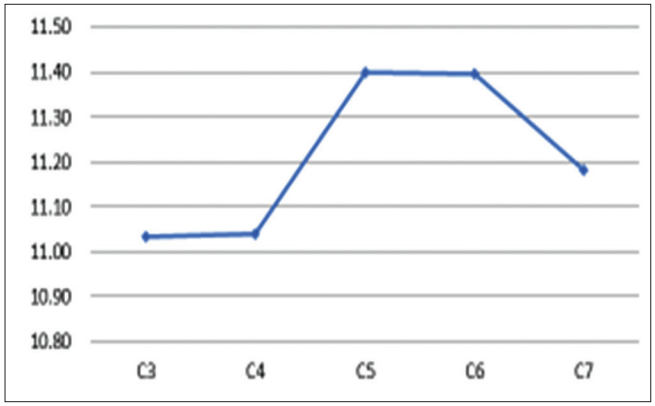

Figure 7: Line diagram showing variation of lateral mass height

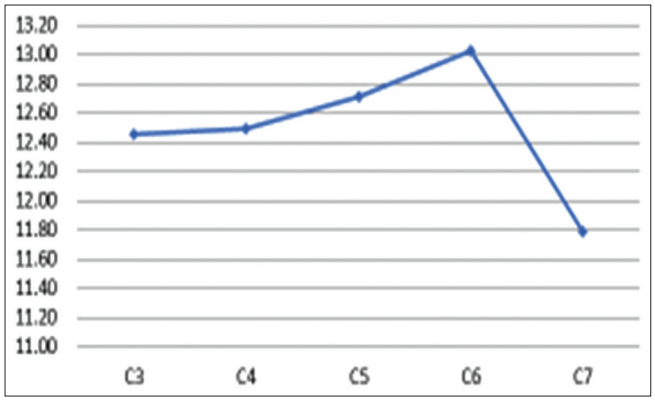

Figure 8: Line diagram showing variation of lateral mass screw length

DISCUSSION

Posterior fixation of the cervical spine is commonly performed for cervical spine instability; four common fixation techniques are posterior cervical wiring, laminar screw, lateral mass screw fixation, and pedicle screw fixation. New method alternative to lateral mass fixation is transfacet fixation.[7]

Abumi *et al.* first described a technique for pedicle screw fixation in 1994.[4] The starting point was 1 mm lateral to the center of articular mass, near the cranial end of the superior articular process. A high-speed burr is used to decorticate the starting point to expose the pedicle canal. A probe is then inserted into the canal with the help of image intensifier. The pedicle is tapped finally an appropriately sized screw is inserted. Complication associated with pedicle screw fixation is an injury to the vertebral artery, spinal cord, or exiting nerves. The main complication can be minimized with appropriate pre-operative imaging. Pre-operative cervical CT scan should be done to assess pedicle morphology therefore safe subaxial cervical pedicle screw placement requires instruction and appropriate supervision from experienced surgeons.

Table 5: Dimension of transfacet screw length in mean and SD

Level	Sex	Transfacet screw length (mm)	
		Right	Left
C3-C4	Male	17.77±1.78	17.73±1.79
	Female	15.06±1.79	15.02±1.80
C4-C5	Male	17.44±1.78	17.43±1.80
	Female	14.74±1.83	14.70±1.85
C5-C6	Male	16.36±1.82	16.36±1.83
	Female	14.12±1.67	13.98±1.68
C6-C7	Male	13.37±1.67	13.32±1.69
	Female	11.53±1.57	11.50±1.56

SD: Standard deviation

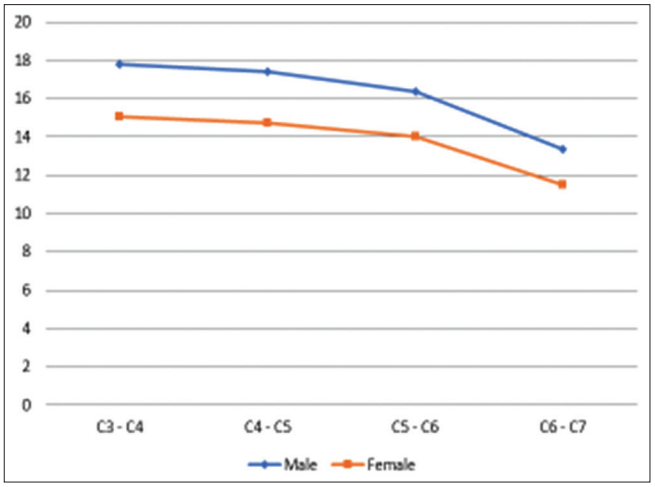

Figure 9: Line diagram showing variation of transfacet screw length

Roy - Camile first introduced lateral mass fixation technique[2] the starting point for Roy -Camille technique is at the midpoint of lateral mass. An entry hole is created using 2 mm drill bit, angling perpendicular to posterior lateral mass 10-degree lateral to the sagittal plane. Next, the drill hole is tapped with 3.5 mm tap, and probe is inserted to measure the screw length, and appropriate size screw is inserted. Lateral mass fixation is common and safe technique than transpedicular screw fixation; however, misplacement of lateral mass screws can cause injury to the spinal cord, vertebral artery, spinal nerves, and facet joint.

Transfacet fixation,[7] technique originally described by Takayasu *et al.*[5] the facet screw is lag screw that does not require a rod to immobilize. Technique of transfacet screw fixation - with the patient in prone position, posterior exposure of the cervical spine is done. The entry point is 2 mm above the middle of the lateral mass without any lateral angulation. Under fluoroscopic guidance, the facet is drilled until all the four cortical surfaces are purchased. Then, the depth is measured to assess the length of the screw required. This is followed by tapping and screw insertion both of which are done under fluoroscopic control. All screws are placed before laminectomy to decompress the cervical cord.

Pre-operative CT study is crucial for avoiding complications during surgeries. Various studies conducted on the western population have shown the dimension of subaxial cervical spine was adequate for a 3.5 mm screw.[11] Singh *et al.* studied Indian population in the mid-thoracic region, found that smallest diameter screw and shortest available screw may not be safe in the majority of Indian population.[12]

Few CT based studies are done on Indian population to study the morphology of cervical spine.[13] This study was done to understand the morphology of subaxial cervical spine to assess the feasibility of screw fixation.

In the present study, 50 patients CT of subaxial cervical spine has been done for measuring the selected anatomical parameter. The results of our study were compared with earlier morphological studies.

In CT comparison with the western population, PW is smaller in Indian population. However, the previous study done on Indian population PW, the resulting values are very close to present study.

Ludwing *et al.* demonstrated that if pedicle diameter in cervical spine was >5.0 mm 79% were pedicle, 19% had non-critical breeches, and only 2% had critical breach.[11] thus if 3.5 mm pedicle screw is to be inserted into the cervical pedicle, the minimum PW desired is 5 mm to allow at least 0.75 mm bony bridge medially and laterally to avoid injury to the adjacent vital structure.

In our study, especially in female population PW at C3, C4 level is found to be <5.0 mm so if we use the 3.5 mm chance of neurovascular injury is high.

Table 6 value shows that each pedicle may differ individually, so the dimension of screw should be measured at each level.

In CT comparison with the western population PH is smaller in Indian population. However, a study done on Indian population PH, the resulting values are very close to present study. Similar trend found regarding the progressive increase in value from C3 to C7 level [Table 7].

Pedicle dimension of Indian population found to be smaller than western population. Thus, this smaller size of pedicle is taken into account for planning a surgical procedure.

Lateral mass length and pedicle length and PAL are important measurement for correct and controlled pedicle screw length. There is the very small difference between each vertebral level. Value of pedicle length increase from C3 to C6 level and decrease at C7 level [Table 8].

As shown in table value of PAL progressively increase from C3 to C7 level [Table 9].

Table 6: Comparisons of previous and present measurement of PW of cervical vertebrae

Study (years)	PW (mean, in mm)				
	C3 level	C4 level	C5 level	C6 level	C7 level
Rao *et al.*[14]	5.3	5.3	5.75	6.1	7.05
Liu *et al.*[9]	5.26	5.33	5.68	5.91	6.64
Banerjee *et al.*[15]	4.89	4.87	5.09	5.42	6.19
Patwardhan *et al.* (2015)[13]	5.2	4.95	5.15	5.45	5.85
Asadhi *et al.*[16]	4.62	4.57	4.8	5.09	6.60
Present study	4.75	4.81	5.12	5.34	5.70

PW: Pedicle width

Table 7: Comparison of previous and present measurement of PH of cervical vertebrae

Study (years)	PH (mean, in mm)				
	C3 level	C4 level	C5 level	C6 level	C7 level
Ugur *et al.*[17]	6.3	6.5	6.4	6.6	NA
Panjabi *et al.* (2003)[18]	6.7	7.1	6.3	6.2	NA
Liu *et al.*[9]	6.7	6.78	6.95	7.25	7.63
Banerjee *et al.* (2010)[15]	6.66	6.69	6.95	6.43	6.75
Asadhi *et al.*[16]	6.32	5.99	6.17	6.14	6.39
Present study	5.99	6.12	6.31	6.32	6.51

PW: Pedicle width

Table 8: Comparison of previous and present measurement of pedicle length and lateral mass of cervical vertebrae

Study (years)	Pedicle length±lateral mass length (mean in mm)				
	C3 level	C4 level	C5 level	C6 level	C7 level
Liu *et al*.[9]	16.8	15.6	16.3	16.2	16.4
Banerjee *et al*. (2010)[15]	15.06	15.50	16.64	16.96	15.84
Present study	15.77	15.69	15.91	15.97	15.38

Table 9: Comparisons of previous and present measurement of PAL of cervical vertebrae

Study (years)	PAL				
	C3 level	C4 level	C5 level	C6 level	C7 level
Liu *et al*.[9]	29.9	28.9	31.3	31.2	32.5
Banerjee *et al*. (2010)[15]	28.72	28.77	30.51	31.92	32.79
Present study	27.52	27.89	28.50	29.02	29.76

PAL: Pedicle axis length

Table 10: Comparisons of previous and present measurement of LMTD of cervical vertebrae

Study (years)	LMTD (mean, in mm)				
	C3 level	C4 level	C5 level	C6 level	C7 level
Wang *et al*.[19]	12.25	12.15	12.70	12.60	12.62
Present study	12.05	12.07	12.57	12.66	12.36

LMTD: Lateral mass transverse diameter

There was some difference between current study and Wang *et al*. study regarding maximum and minimum transverse diameter of lateral mass.

The highest value of LMTD found at C5 level in Wang *et al*. study; in our study, it is at C6 level [Tables 10 and 11].

Our results are in agreement with the majority of studies that there is no difference between right and left sides values. Mean values of PW progressively increasing for both male and female from C3 to C7 level, also it is found that female has smaller value compared to male [Table 12].

PH in the sagittal plane is found to be larger than PW, at each vertebral level, and for both male and female. Hence, PW should be important parameter to determine pedicle screw size. PAL is found to be progressively increasing from C3 to C7 for both male and female, but pedicle length is found to increasing from C3 to C6, and slightly decreasing at C7 vertebral level. The study also shows that dimension of subaxial cervical vertebrae is smaller than western population. As the difference is found between

Table 11: Comparisons of previous and present measurement of LMTD of cervical vertebrae

Study (years)	LMLD (mean, in mm)				
	C3 level	C4 level	C5 level	C6 level	C7 level
Wang *et al*.[19]	11.90	11.75	12.60	13.25	10.65
Present study	11.25	11.37	11.74	11.96	11.16

LMLD: Lateral mass transverse diameter

Table 12: Comparisons of previous and present measurement of TSL of cervical vertebrae

Study (years)	TSL (mean in mm)			
	C3-C4	C4-C5	C5-C6	C6-C7
Milchteim *et al*.[20]	17.9	15.87	16.25	13.05
Present study	16.42	16.09	15.23	12.34

TSL: Transfacet screw length

sex, level, and ethical variation, pre-operative CT should be performed to know the dimension of cervical vertebrae to avoid complication.

Limitations of the study are study population (n = 50) which may not be large enough to generalize the results to the greater population, but it provides useful information regarding the morphometric variation of subaxial cervical vertebrae in Indian population.

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Original Article

Toothache of Non-dental Origin: A Review of Its Mechanism and Clinical Characteristics

Abhishek Soni

Senior Lecturer, Department of Oral Medicine & Radiology, Modern Dental College and Research Center, Indore, Madhya Pradesh, India

Abstract

Objective: To review the clinical presentations of the various types of non-odontogenic pains which may be mistaken as dental pain in clinical practice.

Materials and Methods: A search was initiated on web using PubMed/Medline database searching for articles written in English. Peer-reviewed articles were chosen using the key terms “Orofacial pain," and “Non-odontogenic toothache." Available full-text articles published in relevant journals were read, and related articles were scrutinized and finally the search was subsequently refined to articles concerning to “Non-odontogenic toothache."

Results: Non-odontogenic toothaches are frequently encountered in clinical practice and its diagnosis can be challenging to the dental clinician. For appropriate diagnosis, the clinician should be well aware of various causes of the non-odontogenic toothache and be able to differentiate them.

Conclusion: In conclusion, for precise and correct diagnosis of non-odontogenic toothache, understanding of the nature of pain and its specific clinical characteristics is recommended. Knowledge of the various presentations of non-odontogenic pains will ultimately prevent the misdiagnosis and the institution of incorrect and sometimes irreversible treatment to the patients.

Key words: Heterotopic pain, Non-odontogenic toothache, Orofacial pain, Referred pain

INTRODUCTION

Chronic orofacial and head pain are a common clinical problem, and appropriate diagnosis and management are a challenge for health-care professionals. Patients often first seek the care of dentists because of pain localization in the oral cavity and surrounding structures. Most of the toothaches are originated from specific pulpal or adjacent periodontal tissues. The orofacial pain from dental origin was specifically called “odontogenic toothache.”[1] However, some toothaches may non-dental origin. Toothache of non-dental origin is not true dental pathology; rather it is the pain referred to the dentition from distant location.[2]

The term “non-odontogenic toothache” defined as the pain which is perceived on tooth and adjacent structure but is not originated from the pulpal and periodontal tissues.[1] Non-odontogenic toothache is the type of heterotopic pain.[3] In clinical practice, it is often common for pain in the orofacial region to be mistaken for a toothache, as they mimic odontogenic pain. Therefore, orofacial pain may sometime pose a diagnostic dilemma for the oral physicians and clinicians. Understanding the complex mechanism of odontogenic and non-odontogenic pain and the manner in which other orofacial structures may simulate pain in the tooth is of paramount importance in determining the correct diagnosis and appropriate treatment.

The aim of this article is to provide a brief overview of the various presentations of the non-odontogenic pain which may be mistaken for a toothache with an understanding of mechanism of pain referral and the specific clinical characteristics that have been consider when developing differential diagnoses for pain affecting the orofacial region.

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METHODS

To get up-to-date information, a web-based search was initiated by the author using PubMed/Medline database

Corresponding Author: Dr. Abhishek Soni, 263-Balaji Villa, Shivom Estate, Station Road, Dewas - 455 001, Madhya Pradesh, India. Phone: +91-9827511672/9340477983. Tel.: 07272-224403. E-mail: drabhishek_soni@rediffmail.com

searching for articles written in English. Peer-reviewed articles were targeted using the key terms "Orofacial pain," and "Non-odontogenic toothache" to determine the scope of coverage in well-documented articles. The search was subsequently refined to articles concerning to "Non-odontogenic toothache." The sites of specialized scientific journals in the areas of oral and facial pain were also assessed. The available full-text articles published in relevant journals such as journal of orofacial pain, journal of oral medicine, and surgery were read, and related articles were scrutinized. The bibliographies were also reviewed to identify additional relevant studies.

Non-odontogenic Toothache

Odontogenic pains are usually inflammatory in origin and arise from either two tissues: The pulp and the periodontal supportive structures. These are considered to be the musculoskeletal type of pain.[4] But sometimes, orofacial pain that is perceived as toothache does not always originate from the dental structures; therefore to provide accurate diagnosis it is important to distinguish between site and source of pain [Figure 1]. The site of pain is the location where the patient feels the pain, and it is easily located by asking the patient to point out the region of the body that is painful; whereas the source of pain is the structure of the body from where the pain actually originates.[5]

Primary pain and heterotopic pain

When the site and source of pain are in the same location, it is described as "primary" pain, i.e., the pain occurs where damage to the structure has occurred. On the contrary, when the site and source of pain are different, it is described as "heterotopic" (or "referred") pain. It is thought to be related to central effects of constant nociceptive input from deep structures such as muscles, joints, and ligament.[5] Once diagnosed, treatment should be posed at the source of pain, rather than the site. Although the terms heterotopic pain and referred pain are often used interchangeably, there are specific distinctions between these terms. Heterotopic pain can be divided more specifically into three types, namely central pain, projected pain, and referred pain [Table 1].[3]

Clinical characteristics

The following four clinical characteristics of non-odontogenic toothache (heterotopic or referred pain) help in differentiate it from an odontogenic toothache (primary pain):[6]

1. Local provocation of the site of pain does not increase the pain.
2. Local provocation at the source of pain increases the pain not only at the source but also increases the pain at the site.
3. Local anesthetic blocking of the site of pain does not decrease the pain.

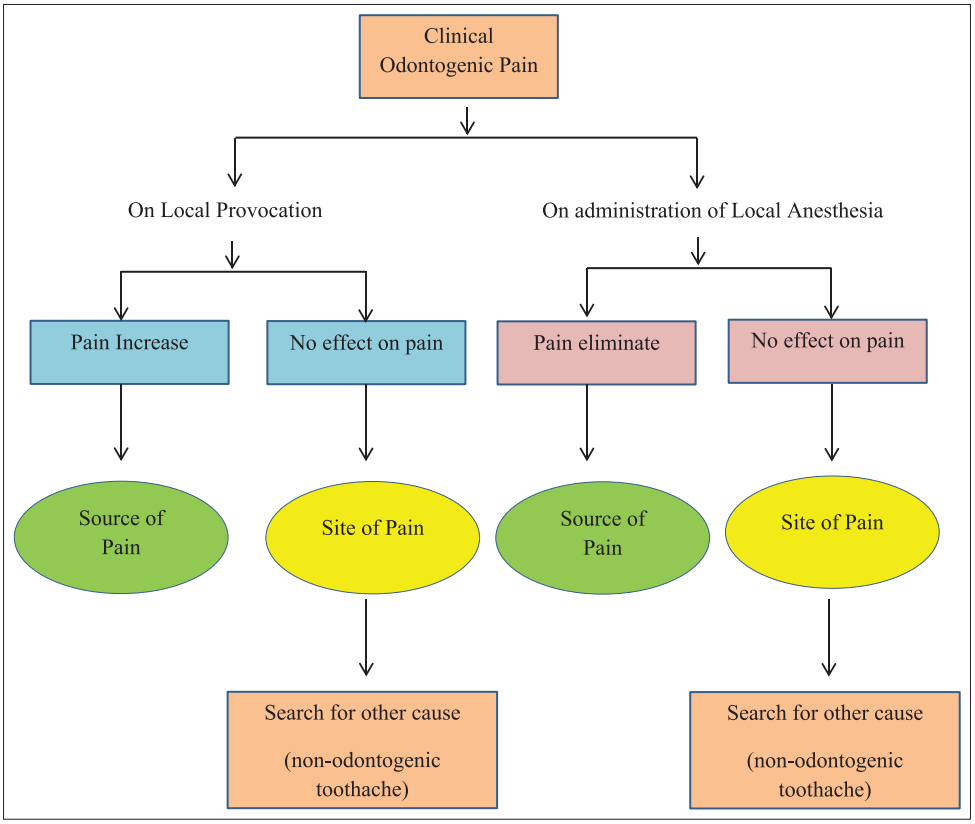

Figure 1: Algorithm to differentiate an odontogenic toothache from non-odontogenic toothache. Therapy should always be directed to treat the source of pain rather than the site of pain

Table 1: Types of heterotopic pain

Central pain:
Pain derived from the CNS
Pain perceived peripherally
E.g., an intracranial tumor - this will not usually cause pain in the CNS because of the brain's insensitivity to pain, but rather it is felt peripherally.
Projected pain
Pain perceived in the peripheral distribution of the same nerve that mediated the primary nociceptive input
E.g., pain felt in the dermatomal distribution in postherpetic neuralgia.
Referred pain
Spontaneous heterotopic pain felt at a site of pain with separate innervation to the primary source of pain
Mediated by sensitization of interneurons located within the CNS
E.g., pain referred from the sternocleidomastoid muscle to the temporomandibular joint.

CNS: Central nervous system

4. Local anesthetic blocking of the source of the pain decreases the pain at the source, as well as the site.

Types of non-odontogenic toothache

The various types of non-odontogenic pains which may be mistaken as dental pain includes:[5,7,8]

1. Myofascial toothache
2. Neurovascular toothache
3. Cardiac toothache
4. Neuropathic toothache
5. Sinus toothache
6. Psychogenic toothache.

Myofascial Toothache

The myofascial toothache is a non-pulsatile and aching pain and occurs more continuously than pulpal pain. In such type of pain, patients are often unable to precisely locate the source of the pain and often consider that pain is originating from the tooth.[4]

Mechanism of pain referral

The theory of convergence supports the mechanism that is thought to cause pain referral to the trigeminal sensory complex from other areas of nociceptive input although it is not well understood. It has been reported that at least half of the trigeminal nociceptive neurons are able to be activated by stimulation outside their normal receptive field.[5,9]

It is evident from the studies on myofascial pain referral to other regions of the orofacial region that pain is triggered by palpating the strained muscles (source of pain) which may perceive as toothache involving any region of oral cavity and in and around the surrounding structures (site of pain) [Table 2].[8,10-12]

Clinical characteristics

The clinical characteristics of the toothache of myofascial origin are as follows:[4,8]

1. Pain is dull aching, non-pulsatile, and typically more constantly aching than that of pulpal pain.

Table 2: Myofascial pain referral: Trigger points in the involved muscle and referred site in the oral cavity

Source muscle	Referred site in oral cavity
Superior belly of the masseter	Maxillary posterior teeth
Inferior belly of the masseter	Mandibular posterior teeth
Temporalis muscles	Maxillary anterior or posterior teeth
Lateral pterygoid muscles	Maxillary sinus region and TMJ
Anterior digastric muscles	Mandibular anterior teeth
Sternocleidomastoid muscles	Oral structures and the forehead
Trapezius muscle	Mandible or temporalis muscle regions

TMJ: Temporomandibular joint

2. There is lack of dental pathology to explain the pain.
3. Pain is not increased by local provocation of the tooth.
4. Pain is increased with the function of involved muscle (trigger point). Pain is increased with extended use of involved muscle or by palpating the affected muscles, and may have tendency to exacerbate with emotional stress.
5. Tooth sensitivity to temperature, percussion, or occlusal pressure may be felt as a result of referred pain from the offending muscle.
6. Local anesthetic of the tooth does not decrease the toothache.
7. Local anesthetic of the involved muscle decreases the toothache.

It has been reported that 37% of patients diagnosed with muscular orofacial pain had previously undergone endodontic or exodontic treatment in an attempt to alleviate their pain.[13,14] Ehrmann[15] also reported that 7% of cases were referred for endodontic treatment when the primary source of pain was the muscle of mastication.

Treatment involves elimination of the trigger points found in the involved muscles. Warm or cold compresses, muscle

stretching, massage, and a restful sleep may alleviate both the muscle and tooth pain.[5]

Cardiac Toothache

Cardiac pain (cardiac ischemia) more commonly presents with substernal pain and radiation of pain to the left shoulder and arm.[4] It is considered to be the source of referred pain involving the jaw. When pain present is of cardiac origin, most commonly affected areas in the orofacial region are neck, throat, ear, teeth, and mandible.[16-21]

In patients suffering from cardiac ischemia, sometimes, orofacial pain may be the only complaint. In one study, 6% of patients presenting with coronary symptoms had pain solely in the orofacial region while 32% had pain referred elsewhere. Interestingly, bilateral referred craniofacial pain was noted more commonly than unilateral pain at a ratio of 6:1.[17]

Mechanism of cardiac referral

- The cause of the cardiac pain referred to the orofacial region can be explained by the convergent mechanisms of the trigeminal complex.[21] Cardiac afferents and somatic inputs from the upper limbs, chests, and face converge on spinothalamic tract neurons in the central nervous system. This convergence input leads to pain nociceptive input from visceral structures, such as the heart through the spinal cord to the trigeminal region. The information is then projected to the thalamus. Convergence mechanisms into the trigeminal brainstem complex and/or in the thalamus can explain referred pain to the face.
- There may be a physiologic association between vagal stimulation initiated by cardiac ischemia and odontogenic pain.[5] Based on the anatomic distribution, when the inferoposterior surface of the heart is affected vagal afferent is activated; and stimulation of the anterior portion results in sympathetic response.[22]
- Another possible mechanism of cardiac pain involves multiple nociceptive mediators which induce a sympathetic response of the heart[23-25] by evoking a sympathoexcitatory reflex.[26] The most important nociceptive mediator being the bradykinin. Studies on patients who underwent sympathectomies demonstrated a 50–60% complete relief of angina pectoris, while 40% obtained a partial relief, and 10–20% experienced no relief.[22]

Clinical characteristics

The clinical characteristics of the toothache of cardiac origin are as follows:[5,27]

1. The presence of aching pain in the jaw or tooth is cyclic.
2. Pain may be episodic, lasting from minutes to hours, and varies in intensity.
3. The toothache is increased with physical exertion or exercise.
4. The toothache is alleviated with rest.
5. The toothache is associated with chest, arm, or neck pain.
6. The toothache is decreased with nitroglycerin tablets.
7. Local provocation of the tooth does not alter the pain.

Intriguingly, patients experiencing cardiac pain reported the descriptor of "pressure" more often when compared to any other disorder.[28]

Orofacial pain of cardiac origin is most often relieved by giving sublingual nitroglycerin tablets. An immediate referral to a physician or cardiologist is mandatory.

Sinus Toothache

Sinusitis is a common disease, of which maxillary sinusitis is more prevalent. About 10% of maxillary sinusitis cases are diagnosed as having pain of odontogenic origin.[11] It has been characterized by constant dull aching pain in and around the zygoma and tenderness of the teeth on percussion due to inflammation of the maxillary sinus. Acute sinusitis can induce referred pain to maxillary teeth particularly maxillary premolar and molar regions because of closeness of the apices of the teeth to the sinus region.[1] According to a study of the symptoms of acute sinusitis, maxillary toothache was highly specific (93%), but only 11% of patients with sinusitis actually had pain from the tooth.[29]

Mechanism of pain referral

Due to the proximity of the roots of maxillary teeth with the sinus, it is conceivable that the maxillary dentition could be a potential source of inflammation and infection of maxillary sinus. The final point of growth of maxillary sinus is fortuitous with the growth of the maxillary alveolar process and eruption of the permanent dentition, resulting in a protrusion of roots into the maxillary sinus cavity. Sometimes, the roots may be separated only by the Schneiderian membrane. Since the roots of the maxillary dentition are in intimate contact with maxillary sinus, any infectious process associated with the maxillary dentition or surrounding periodontal tissue may present as acute or chronic sinusitis; conversely, any inflammatory or infectious disease originating in the maxillary sinus may be anticipated as odontogenic pain.[5]

The sensory innervation of sinus mucosa and maxillary teeth could be responsible for the sinus pain referral. Sensory innervations of the nasal-PNS complex are supplied by the first and second divisions of the trigeminal nerve and secondary interneurons from sinus area shares

with those of teeth. The pain from the sinus complex is typical deep visceral pain, and it can cause central sensitization such as secondary hyperalgesia, referred pain, and autonomic response. In the early stage of sinusitis, facial pain and headache are common. Hyperalgesia on the affected region by central sensitization make the pain more chronic and more complex.[1]

Clinical characteristics

The clinical characteristics of the toothache of maxillary sinus origin are as follows:[10,30-33]

1. Dull, constant aching pain is present in several maxillary posterior teeth in one quadrant, i.e., tooth sensitive to percussion.
2. The patient reports pressure or pain below the eyes.
3. The toothache is increased with lowering of the head because of shifting of fluid in the sinus due to the gravitational effect.
4. Pain is experienced with palpation over the involved sinus or infraorbital regions.
5. There is a history of sinusitis or upper respiratory infection which may precede the onset of the toothache.
6. Toothache is increased by stepping hard on to the heel of the foot (e.g., walking down the steps).
7. The diagnosis can be confirmed by air-fluid level seen in appropriate imaging.

A simple maxillary sinus infection may be treated with a 10-day course of amoxicillin and 2- or 3-day use of a topical decongestant. A referral to an otolaryngologist may be indicated if the sinus infection is unresponsive to this therapy.

Rhinogenic Toothache

Non-odontogenic toothache of nasal mucosa origin is a related painful condition affecting the maxillary anterior teeth. This can occur if the nasal mucosa becomes edematous causing swelling of the turbinate and occluding outflow from the maxillary sinus ostium.

This referral pattern has been demonstrated experimentally. Anesthetic blocking by infiltration at the apex of the tooth in question does not completely arrest the toothache; however, the pain may be decreased by applying topical anesthetic to the area of the ostium with a cotton-tipped applicator or spray. If the nasal mucosa is the source of the pain, the toothache should be relieved [Figure 2].[30]

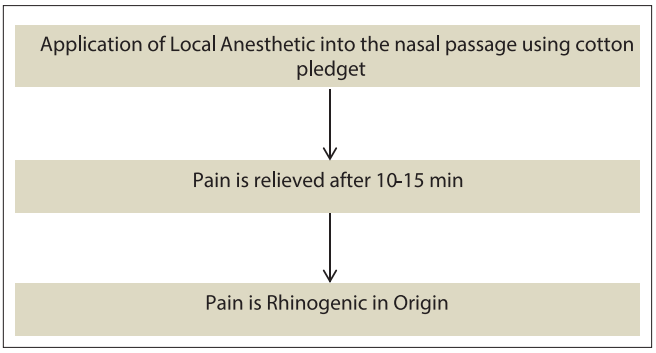

Figure 2: Diagnostic technique to locate pain of nasal mucosa origin

Neuropathic Toothache

Neuropathic pain can be described as a pain originated from abnormalities in the neural structures and not from the tissues that are innervated by those neural structures.

There are two types of neuropathic pains that can be felt in teeth: Episodic and continuous [Figure 3].[5,34]

Mechanism of pain referral

A number of mechanisms have been suggested for the causation of neuropathic pain in the orofacial region.

Change in excitability of primary nociceptive afferents may be the single most important factor in generation and maintenance of acute chemogenic pain or chronic neuropathic pain in humans.[35] Demyelination is a degenerative process that is associated with loss of integrity of the myelin sheath that normally protects nerve fibers. This may result in an aberration in nerve impulse generation and conduction. Demyelination can occur peripherally or centrally. Multiple sclerosis is the most well-known example of central demyelinating disease. When the disease affects the trigeminal ganglion, it can present as trigeminal neuralgia.

Neuropathic pain is due to abnormality in components of the nervous system itself rather than to noxious stimulation of otherwise normal neural structures. According to Robinson,[36] it has been shown that these pathologic entities can cause ectopic discharge or impulse generation from the sites along the axon where the damage has occurred, rather than just at the sensory nerve ending. Recent evidence revealed that there is a result of membrane hyperexcitability along the axon. Studies have recently demonstrated that membrane remodeling, particularly involving Na+ channels, is responsible for the ectopic repetitive firing. There are three primary ways in which sodium channels affect a change in membrane hyperexcitability and repetitive firing in damaged axons. First, there is a change in the rate of protein synthesis of various Na+ channels as a result of the neuronal injury. More Na+ channels mean more sensitivity. The elevated rate of synthesis of these proteins occurs concurrently with axonal ectopic firing and the initiation of allodynia. Second, there is an intracellular regulation of the Na+ channels that allow the channels to remain open longer and create more hypersensitivity and even spontaneous

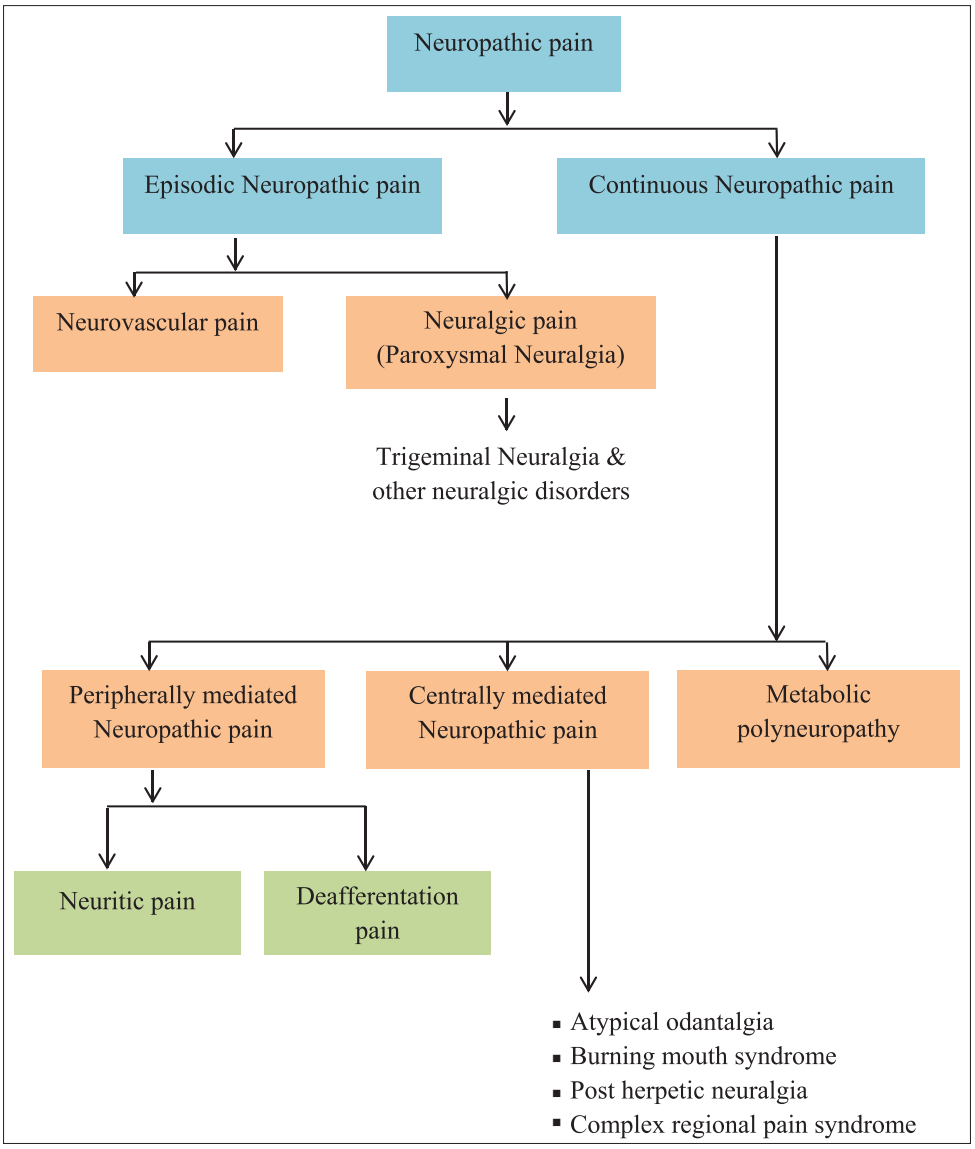

Figure 3: Classification of neuropathic pain (adapted from: Okeson JP. pains of dental origin. In: Okeson JP. Bell's Orofacial Pains: The clinical management of orofacial pain. 6th ed. Chicago: quintessence; 2005; p. 260)

firing of damaged neurons. The third way involves the interruption of axonal transport. If an axon is transected, exposed to certain toxins, or undergoes demyelination, then the axonal transport system responsible for moving Na+ channel proteins from the cell nucleus to the axon sensory nerve ending is disrupted. Once damage occurs, may result in the formation of neuroma.[36]

Episodic neuropathic toothache

Episodic neuropathic pain is characterized by sudden volleys of electric-like pain referred to as neuralgia. The most typical example of this type of pain is trigeminal neuralgia.[5]

The clinical presentation of an episodic neuropathic toothache involves:[5,34]

- Pain quality is described as severe, sharp-shooting, and electric-like pain that lasts only a few seconds.
- There are pain-free intervals between the episodes of pain
- Pain is provoked by peripheral stimulation of a "trigger zone."
- The pain is not always restricted to a tooth but often a broader area.
- The pain is not altered by intraoral thermal stimuli.
- It rarely awakes the patient from sleep, unlike dental pain.
- Often the patient is able to trace the pain radiating down the distribution of the nerve to the tooth.

Continuous neuropathic toothache

Continuous neuropathic pains are pain disorders that appear to have its origin in neural structures and are expressed as constant, ongoing, and unremitting pain. They will often have high- and low-intensity but no periods

of total remission. Patients with continuous neuropathic toothache often report a history of trauma or ineffective dental treatment in the area.[37]

It is not unusual for patients with continuous neuropathic toothache to have received multiple endodontic treatments or extractions for their dental pain. In many cases, the lack of response to treatment is a key factor in prompting a reassessment of the differential diagnosis.[38] Ram *et al.*[39] in their retrospective study involving 64 patients reported that 71% had initially consulted a dentist for their pain complaint, and subsequently 79% of patients received dental treatment that did not resolve the pain. In one case report, the lack of an effect of a local anesthetic injection on reducing the intensity of pain was a significant finding that prompted consideration of non-odontogenic tooth pain.[40]

In a study of 42 patients with atypical odontalgia, 86% of the patient population was female, and 78% reported maxillary pain. Of 119 reported areas of pain, the most common was the molar (59%), premolar (27%), and canine (4%) regions.[41,42] The pain may change in location over time; some studies have reported pain shifting location in up to 82% of the subjects.[43,44] A key to diagnose this is to recognize accompanying neurologic signs that involve other teeth or nearby structures served by the same nerve.[34]

The common types of neuropathic conditions that can produce continuous pain felt in a tooth are neuritic pain and deafferentation pain [Figure 4].[34]

The clinical presentation of a neuritic toothache involves:
- Pain is persistent, non-pulsatile, often burning pain felt in a tooth.
- Toothache accompanied by other neurologic symptoms (paresthesia, dysesthesia, and anesthesia)
- Other teeth may feel "dead" or "strange."
- Associated gingival tissue may get affected.

The clinical presentation of a deafferentation toothache involves:

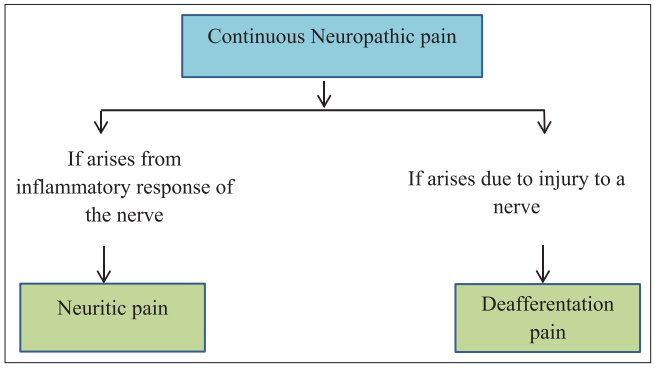

Figure 4: Types of continuous neuropathic pain

- Toothache is continuous, varies in intensity, with no periods of remission.
- Maxillary canines and the premolars are most commonly involved teeth.
- Condition is most commonly reported in middle-aged women with a history of trauma to the painful region.
- Pain is not changed by local provocation.
- Effect of local anesthesia is unpredictable.
- Toothache not responsive to dental therapies.

Continuous neuropathic pains that can be felt in teeth have been referred to as atypical odontalgia[45,46] or sometimes phantom toothache.[47,48]

Graff-Radford and Solberg[42] suggested the criteria for identification of atypical odontalgia:
- Pain in a tooth or tooth site
- Pain is continuous or almost continuous in nature
- Pain persisting for more than 4 months
- No signs of local or referred pain
- Equivocal results of somatic block.

The other clinical characteristics of an atypical odontalgia involves:[4,42,43,49-51]
- Pain quality is described a dull, aching, throbbing, or burning
- Pain is diffuse in nature and not altered by intraoral thermal stimuli
- Pain not always restricted to a tooth (e.g., the area may be edentulous)
- Pain that may or may not be relieved by a diagnostic intraoral local anesthetic block.

Neurovascular Toothache

Neurovascular pains are the group of visceral pain disorders that are generally characterized by episodic pains accompanied by neurologic, gastrointestinal, and psychological changes. The International Headache Society classifies these pain disorders as primary headaches.[52]

Mechanism of Pain Referral

Previously, it has been established that pain occurred as a result of dilatation of arteries, which distort and noxiously stimulate the sensory receptors and afferent fibers in vascular and perivascular tissues. However, recent investigations suggested that vascular changes that have been observed to be associated with the pain are merely a result of the condition and not the actual cause of the pain. The actual mechanism appears to be more closely related to a neurogenic phenomenon, and thus termed neurovascular pain.[52]

It has common mechanism involving the trigeminovascular system. The most common type of neurovascular pain is

migraine; other includes tension-type headache, cluster headache, and other trigeminal autonomic cephalgias.

Clinical characteristics

The clinical characteristics of the toothache of neurovascular origin are as follows:[53]

1. The pain is usually unilateral, spontaneous, variable, and throbbing-characteristics that stimulate pulpal pain
2. Toothache is characterized by periods of remission and exacerbations over months or years
3. Episodes of pain may possess a temporal behavior appearing at similar times during the day, week, or month
4. There is a lack of reasonable dental cause for the pain
5. The effect of local anesthesia is unpredictable
6. The pain is frequently initially felt in a tooth (the maxillary canine and premolar usually) as a toothache
7. Recurrence is a characteristic of neurovascular pains
8. It may spread to adjacent teeth, opposing teeth, or the entire face
9. If the pain experience is protracted, it may induce autonomic effects manifested as nasal congestion, lacrimation, and edema of the eyelids and face, which may be mistaken for sinusitis or a dental abscess
10. The pain may respond to ipsilateral carotid pressure or ergotamine tartrate.

The chief indicators that help distinguish this toothache from true odontogenous toothache are:

- Absence of adequate dental cause
- Tendency for it to be periodic and recurrent
- Patient's ability to precisely locate the painful tooth.

Psychogenic Toothache

Psychogenic pain can be described as a pain associated with psychologic factors in the absence of any physiologic cause. The American Psychiatric Association has classified this condition as a somatoform pain disorder.[5,54]

Mechanism

Orofacial pain of psychological origin is explained by "biopsychosocial model." In the biopsychosocial model, the "bio" component denotes the nociceptive input that arises from the somatic tissues; and the "psychosocial" component represents the effect of the interaction between the thalamus, cortex, and limbic structures. The neurotransmission of impulses between all these higher centers is responsible for the psychologic aspects of pain. A biologic factor that contributes to the pain experience includes genetics, fitness level, nutritional status, autonomic balance, and allostatic load. Allostatic load refers to the physical stress on an individual from repeated physiologic activation and inhibition that comes from responding to life stressors.[55,56]

Clinical characteristics

The clinical characteristics of the toothache of psychogenic origin are as follows:[4,5,51,57]

1. Multiple teeth are often involved.
2. The patient reports that multiple teeth are often painful with frequent change in character and location (pain jumps from one tooth to another). Pain can be described as diffuse, vague, and difficult to localize.
3. There is a general departure from normal or physiologic patterns of pain and presents without any identifiable pathologic cause. Pain may be sharp, stabbing, intense, and sensitive to temperature changes, all of which are similar to pain symptoms of odontogenic origin.
4. The patient presents with chronic pain behavior.
5. There is a lack of response to reasonable dental treatment
6. There is an unusual and unexpected response to therapy.
7. There is no identifiable pathology that can explain the toothache.

Given that psychogenic toothache is a somatoform disorder, dental treatment will not resolve symptoms of pain and may potentially elicit an unexpected or unusual response to therapy. Patients should be referred to a psychiatrist or psychologist for further management.[4,5]

CONCLUSION

In clinical practice, non-odontogenic toothaches may pose challenge to the oral physician in terms of diagnosis. If symptoms and clinical findings do not appear to be consistent with the typical oral disease, or if standard treatments do not alleviate the pain, the oral physician must consider other, more complex orofacial pain diagnosis. For appropriate diagnosis, pain must be considered in terms of quality, duration, referral pattern, exacerbating, and relieving factors. The characteristic clinical features and the perceived origin of the pain may be pathognomonic for specific sites. When patients present with diffuse pain and/or pain radiating to other areas of head and neck, non-odontogenic sources should be given additional consideration. To arrive at the correct diagnosis of toothache of odontogenic and non-odontogenic origin, precise understanding of specific clinical characteristics, and thorough evaluation of the nature of the pain are recommended. This will essential to deliver appropriate treatment and avoid unnecessary procedures that will aggravate the condition.

In summary, it is reasonable to conclude that:

- Therapy must not start without an appropriate diagnosis.
- Consider all pains in the mouth and face to be of dental origin until proved otherwise.
- Management is always directed by the presented symptoms, their course, and influencing factors.
- Successful therapy is achieved by treating the source of pain, not the site of pain.

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Original Article

Comparative Study of Patients Who Underwent Hemiarthroplasty of Hip by Anterolateral and Posterolateral Approach

Swapnil Bhise[1], Santosh Borkar[2], Sameer Desai[3], Nitin Kanode[4]

[1]Associate Professor, Department of Orthopaedics, Maharashtra Institute of Medical Education and Research Medical College, Talegaon-Dabhade, Pune, Maharashtra, India, [2]Professor, Department of Orthopaedics, Maharashtra Institute of Medical Education and Research Medical College, Talegaon-Dabhade, Pune, Maharashtra, India, [3]Resident, Department of Orthopaedics, Maharashtra Institute of Medical Education and Research Medical College, Talegaon-Dabhade, Pune, Maharashtra, India, [4]Senoir Resident, Department of Orthopaedics, Maharashtra Institute of Medical Education and Research Medical College, Talegaon-Dabhade, Pune, Maharashtra, India

Abstract

Introduction: Fracture neck of femur is an extremely common fracture in the geriatric population (>60 years). Bipolar hip replacement can be done by anterolateral or posterolateral approach. Proponents of both approaches say that their approach is better than the other, but there is no consensus reached so far. Hence, we decided to carry out a comparative study of results of patients operated for cemented bipolar hemiarthroplasty by anterolateral and posterolateral approach.

Material and Methods: We carried out a retrospective study of patients who underwent bipolar hemiarthroplasty between June 2013 and August 2017 by anterolateral and posterolateral approach. Pre-operative condition, radiographs, operative notes, post-operative complications, and clinical and functional outcome over a period of 1 month, 3 months, 6 months, and 12 months post-surgery were collected for all the cases. Patients in Group 1 were operated by posterolateral approach, and those in Group 2 were operated by anterolateral approach. We collected data of age, sex, trauma to surgery time, blood loss, infection, nerve injury, dislocation, hospital stay, time for returning to activities of daily living, etc.

Results: There were significant differences between two groups as regards dislocation rate and operative time and modified Harris Hip Score. Mean operative time in minutes was 20.63 min in anterolateral group and 25.885 min in posterolateral group. Modified Harris Hip Score was 78.077 in anterolateral group and 71.407 in posterolateral group. There were three cases of posterior dislocation in posterolateral approach (n = 26) but one in the anterolateral approach (n = 27).

Conclusion: We conclude that the anterolateral approach is slightly better compared to the posterolateral approach due to low dislocation rate and better functional recovery.

Key words: Anterolateral, Bipolar, Dislocation, Posterolateral

INTRODUCTION

Fracture neck of femur is an extremely common fracture in the geriatric population (>60 years) with an incidence of about 20% of all osteoporotic fractures.[1] Treatment options for fracture neck femur are mostly hemiarthroplasty or total hip replacement as results of osteosynthesis are not great in this age group, mainly due to poor vascularity after fracture.[1]

Hemiarthroplasty can be with unipolar or bipolar prosthesis with or without cement. Earlier, unipolar prosthesis was used for partial hip replacements. However, the recent trend is towards cemented bipolar replacement only as in this population osteoporosis is present invariably. Also, unipolar prosthesis has high incidence of protrusio acetabulae after few years as well as poor functional outcome, which is less in bipolar group.[1] Total hip replacement for fracture neck femur though quite popular in developed countries is not so

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Corresponding Author: Dr. Santosh Borkar, Department of Orthopaedics, Maharashtra Institute of Medical Education and Research Medical College, Talegaon-Dabhade, Pune, Maharashtra, India. Address: 7, Aryan Capital, Wada Road, Rajgurunagar, Khed, Pune - 410 505, Maharashtra, India. E-mail: santoshborkar197616@gmail.com

popular in India due to its high cost of surgery and expertise required along with better operation rooms required for total hip replacement.[2] Hence, only bipolar hip replacement is quite often done. Bipolar hip replacement can be done by anterolateral or posterolateral approach. Proponents of both approaches say that their approach is better than the other, but there is no consensus reached so far.[3,4] Furthermore, Indian patients have a habit of sitting cross-legged and squatting which is to be avoided, especially in the posterolateral approach.

Hence, we decided to carry out a comparative study of results of patients operated for cemented bipolar hemiarthroplasty by anterolateral and posterolateral approach.

MATERIALS AND METHODS

We carried out a retrospective study of patients who underwent bipolar hemiarthroplasty between June 2013 and August 2017 by anterolateral and posterolateral approach. We collected data of patients from hospital records. We excluded patients who had open fractures, pathological fractures, and extraarticular (intertrochanteric) fractures, those with neurovascular injury previously, and those patients who were under 60 years of age.

Pre-operative condition, radiographs, operative notes, post-operative complications, and clinical and functional outcome over a period of 1 month, 3 months, 6 months, and 12 months post-surgery were collected for all the cases. Most of the patients were operated about 3–7 days after trauma. Patients in Group 1 were operated by posterolateral approach, and those in Group 2 were operated by anterolateral approach.

Post-operatively, patients were given antibiotics and analgesics. Physiotherapy was begun from next day and weight bearing with walker was allowed. Patients operated by the posterolateral approach were instructed to avoid squatting and sitting cross-legged as it is given in the literature for this approach.

We collected data on age, sex, trauma to surgery time, blood loss, infection, nerve injury, dislocation, hospital stay, time for returning to activities of daily living, etc.

RESULTS

Data were represented as a mean and standard deviation for continuous variables or frequency and percentages for discrete variables. Statistical analysis of differences was performed using student paired *t*-test for continuous variables and Chi-square test for discrete variables. We calculated odds ratio and relative risk in posterolateral approach (dislocation). There were no complications such as thrombosis or pulmonary embolism in either group. Only one patient in anterolateral group and one in posterolateral group required blood transfusion and hence were not significant. There was the incidence of post-operative superficial infection in two patients of the posterolateral group, who had serious discharge. They responded to treatment with intravenous antibiotics alone.

A total of 53 patients were included, out of which 9 females and 18 males were operated by the Anterolateral approach and 9 females and 17 males were operated by the Posterolateral approach (Table 1).

There were three cases of posterior dislocation in posterolateral approach ($n = 26$), but one in the anterolateral approach ($n = 27$) odds ratio was 3.39.

As prevalence of dislocation is low, we used the odds ratio to estimate the relative risk of dislocation occurring in the posterolateral approach. We found that the relative risk that a patient with hemiarthroplasty with the posterolateral approach has dislocation is 3.39 times more than the patient with non-posterolateral (anterolateral in our study) approach as odds ratio is 3.39.

DISCUSSION

Table 2 and 4 cited – page 4 line 1 - From the results of our study, we note that there was no difference between the

Table 1: Number of Female and Male patients operated by Anterolateral or Posterolateral Approach

Sex	Anterolateral	Posterolateral	*P* value
Female	9	9	*P*=0.922
Male	18	7	
Total	27	26	

Table 2: Trauma to Surgery Time (in Days)

Anterolateral	Posterolateral	*P* value
4.333	3.769	*P*=0.432

Table 3: Mean Operative Time (in minutes)

Anterolateral	Posterolateral	P value
20.630	25.885	*P*=0.000

Table 4: Mean Duration of Hospitalisation (in Days)

Anterolateral	Posterolateral	P value
9 (7–14)	9.185 (5–22)	*P*>0.05

Table 5: Modified Harris Hip Score

Anterolateral	Posterolateral	*P* value
78.077 (72–80)	71.407 (60–78)	*P*<0.05

two groups as regards sex, trauma to surgery time (Table 2), infection, thrombosis, blood transfusions or duration of hospitalisation (Table 4). However, there were significant differences between two groups as regards dislocation rate and operative time and modified Harris Hip Score.

There were less dislocations in the anterolateral group. Also, operative time was less in anterolateral group (Table 3) and the Harris Hip Score was better in the anterolateral group (Table 5). Furthermore, operative time was less in anterolateral group, and the Harris Hip Score was better in the anterolateral group. Hence, functional results are better after anterolateral approach was used for hemiarthroplasty of the hip.

The direct lateral approach to the hip was described by Hardinge in 1982.[5] This approach provides adequate exposure of hip joint. A very low dislocation rate has also been reported in clinical follow-up.[6,7] The posterior approach to hip was popularized by Moore in 1950.

A recent survey of surgeons around the world suggests that it is more popular than the anterior or anterolateral approach.[8,9] It provides extensible exposure to the hip and spares adductor muscles during exposure. However, during this approach, the sciatic nerve has to be protected, and short external rotators and posterior capsule, which are cut, have to be repaired if necessary, through transosseous bony tunnels in the proximal femur.[10]

Many studies reported low dislocation rates in non-posterior approaches as static stabilizers of hip, such as posterior joint capsule and posterior soft tissue envelope, are preserved.[9,11] Our results are similar.

The risk of sciatic nerve injury is greater (1.3%) during the posterior approach.[12] However, femoral nerve injury due to anterior retractor placement can occur in both the approaches.[13] Superior gluteal nerve palsy can occur during the direct lateral approach to hip as it is about 5 cm proximal to the greater trochanter.[14] However, in our study, no nerve injury was observed.

Reduced blood loss and shorter stay in the hospital have been described with the anterior approach due to muscle sparing properties of this approach.[15] However, in modified Hardinge or anterolateral approach which we followed, this influence is not there as compared to posterior approach in literature.[10] Our study confirms this finding. Furthermore, incisions are of almost similar length. Special precautions such as avoiding sitting cross-legged and squatting are mainly for the posterior approach but are generally followed even for the anterolateral approach.

CONCLUSION

There is a significant difference between the anterolateral (modified Hardinge) approach and posterolateral approach to the hip joint as dislocation rate and operative time are less in the anterolateral approach. Furthermore, functional recovery is better after the anterolateral approach. However, there is no difference between the two approaches as regards other complications such as infection, thrombosis, blood loss, nerve injury, or duration of hospitalization. Hence, we conclude that the anterolateral approach is slightly better compared to the posterolateral approach due to low dislocation rate and better functional recovery. However, our sample size is small and duration of follow-up is less, and either of the approaches could be used as per the surgeon's choice and patient parameters.

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Original Article

A Gender-based Comparative Study of Visual and Auditory Reaction Time on 1st Year Medical Students "Before" and "After" Caffeine Intake

Chandan K Dey[1], Rameshwar G Daokar[2]

[1]Associate Professor, Department of Physiology, B. J. Government Medical College, Pune, Maharashtra, India, [2]Associate Professor, Department of Physiology, Dr. V. M. Government Medical College, Solapur, Maharashtra, India

Abstract

Introduction: The present study is a gender-based comparison of the auditory and visual reaction time (RT) in male and female 1st year medical students, before and after the administration of caffeine present in coffee.

Purpose: This study is aimed at checking out if there exist inherent gender differences in the visual and auditory RTs in the subjects and supplementing the study, by also studying the effect of caffeine presents in coffee on the RTs.

Materials and Methods: The study was conducted on 42 males and 35 females 1st year medical students. The 77 students were not habitual coffee drinkers and were tested for auditory and visual RT before and after the administration of caffeine present in coffee.

Results: We found that auditory and visual RTs did not differ significantly in either gender both before and after the administration of caffeine.

Conclusion: In this study, no significant differences in RTs were observed in either gender. Both genders performed equally well in their RTs, before and after the intake of caffeine.

Key words: Auditory reaction time, Caffeine, Coffee, Gender, Visual reaction time

INTRODUCTION

Reaction time (RT) is the time that elapses between a person being presented with a stimulus and the person initiating a motor response to the stimulus. It is a simple and effective method of studying central neuronal processing and is a simple method of determining sensory-motor association, performance, and cortical arousal. Apart from the time required for sensory-motor association, this is the time required by the brain for perceptual decision-making and motor planning.[1]

In daily life, one has to respond to various situations immediately and as the RT indicates the time taken by an individual to react to external stimulus, it can be important in case of various activities that are carried out on a day-to-day basis. These activities can be both of "normal" and "crucial" in nature. Normal ones could be like response to a phone call, a doorbell, and game consoles on computers or may be whistle of pressure cooker. Crucial ones could be like driving, maneuvering a fighter plane, responding to enemy fire, or even preventing an accident from occurring.

Literature, as well as plenty of studies, has conflicting reports about differences in RTs between males and females. Some studies are more favorable for men while some support female dominance and prowess. The present study was taken with a view in mind to explore the gender bias in the RT and shed more light in the matter.

Caffeine is one of the most commonly used substances found in everyday beverages such as tea and coffee. The scientific name for caffeine is 1,3,7-trimethylxanthine.[2] It is an alkaloid compound and is actually a bitter substance

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Corresponding Author: Dr. Rameshwar G Daokar, Department of Physiology, Dr. V. M. Government Medical College, Solapur, Maharashtra, India. Phone: +91-9221422748. E-mail: Daokarrg@gmail.com

found in coffee beans, cocoa beans, and many other plant products. Caffeine has mild cortical stimulation effects and appears to be beneficial, resulting in more clear thinking, and less fatigue. Desirable effects such as improvement of physical and cognitive functions are seen with low doses of caffeine. Judiciously used within safe limits it is known to have many beneficial effects. The USFDA considers moderate intake of caffeine to be "safe." Beneficial effects of caffeine which increased motor and mental performances are seen with about 65–130 mg of caffeine in a single dose. Around 300 mg/day of caffeine in an adult is considered to be safe.[3,4]

The usage of caffeine is also considered to be addictive in nature. Certain amount of habituation develops from the regular usage of caffeine. Daily use of caffeine is known to cause dependence for this substance in the form of nervousness, headache, and irritation.[5] However, grossly the benefits of moderate caffeine usage mostly outweigh the disbenefits.

After considering the above effects of caffeine, we decided to include it in the present study and thus have add-on information about the effects of caffeine present in a standard cup of coffee on visual and auditory RTs on the male and female subjects.

MATERIALS AND METHODS

The study was conducted in Grant Government Medical College on 42 males and 35 females 1st year medical students. Entire batches of 200 students were requested to enroll for the study. However, those who turned up for the study at their own "will" were primarily considered. The present study was conducted in the department of physiology, Grant Medical College, Mumbai, when the authors were posted in that institute. Informed consent from the subjects and approval from the institutional ethics committee were taken to conduct the study.

The 77 subjects being 1st year medical students were mostly of the same age range. Habitual coffee drinkers were excluded from the study to discard the effects of caffeine dependence. Too obese or too lean subjects were excluded from the present study. Studies were done on the female subjects after excluding the menstrual and premenstrual period of the subjects.

The coffee sachets from a well-known coffee brand were taken. We considered the fact that beneficial dose of caffeine for increased mental and motor performance is about 65–130 mg of caffeine.[6] Hence, 2 g of coffee powder was used to make one cup of coffee which contained around 63 mg of caffeine. Thus, our coffee dose came to near ideal doses.

Both the male and the female medical students were tested for RTs "before" and 30 min "after" the intake of coffee as the effects of caffeine are known to be more pronounced within the 1st h of coffee intake.[7] RT measurements were done in the form of auditory reaction time (ART) and visual reaction time (VRT).

RT apparatus (Anand Agencies, Pune) was used for the study. It has a built-in 4 digit chronoscope and displays accuracy of 1 ms. Recordings were taken in the morning time. Subjects came with routine normal breakfast. Recordings were taken "before" and 30 min "after" the intake of standard cup of coffee as mentioned before. ART was recorded for auditory beep sound stimulus and VRT for red light stimulus. To avoid the effect of lateralized stimulus, the subjects were given visual and auditory stimuli from the front. They were instructed to release the response key with their dominant hand as soon as they perceived the visual or auditory stimulus. Subjects were given adequate exposure to get acquainted with the working of the apparatus before starting with the actual test.[8,9]

Statistical analysis for the study was done using the popular software GraphPad Prism 5 software.

RESULTS

As the present study had 42 male and 35 female students, unpaired *t*-test was used for comparing the data between the two genders both before and after coffee intake. Data are presented here as mean ± standard deviation. $P > 0.05$ indicated statistically non-significant differences in the variances between the male and female medical students in both the pre- and post-coffee tests for ART and VRT.

Results are summarized in Table 1 (before caffeine intake) and Table 2 (after caffeine intake).

Data were analyzed separately as "before" and "after" caffeine intake. In both the cases, gender was not found to significantly affect either the auditory or visual RT.

DISCUSSION

The purpose of this study was to check if there exists an effect of gender on RTs between subjects. In our study, we included medical students as the subject of the study. Different studies examining the effect of gender on RTs have yielded contradictory findings. Some studies have pointed out to a female superiority[10,11] while others have

Table 1: Comparison of ART and VRT on 42 male and 35 female medical students "before" intake of caffeine

Before caffeine intake	Males (*n*=42)	Females (*n*=35)	*P* value
ART	243.5±10.43	243.0±10.35	>0.05
VRT	200.2±7.77	199.8±10.22	>0.05

ART and VRT values are in ms and expressed as mean±SD. ART: Auditory reaction time, VRT: Visual reaction time. SD: Standard deviation

Table 2: Comparison of ART and VRT on 42 male and 35 female medical students "after" intake of caffeine

After caffeine intake	Males (*n*=42)	Females (*n*=35)	*P* value
ART	231.5±12.38	228.8±11.32	>0.05
VRT	186.6±12.01	183.0±11.60	>0.05

ART and VRT values are in ms and expressed as mean±SD. ART: Auditory reaction time, VRT: Visual reaction time. SD: Standard deviation

been more generous in exhibiting a male advantage.[12-14]

The gender differences in RTs if they exist could reflect differences in processing strategy employed by the two genders. It might also be an effect of evolution which has seen males going out and hunt out for food for their families and thus relying on their RT to escape from potential wild animals and so on. Females, on the other hand, could be involved into tasks requiring lesser alertness and consequential evolutionary decrease in RTs. However, these postulations supporting male advantages in RTs could easily be counteracted on by alternate theories which see the fact that women endowed with a smaller frame and body size could have shorter axons corresponding to their limb length, leading to smaller transit time and hence having a positive impact on the RTs. Further, the modern women being involved in various activities at par with men have seemed to evolve in every possible manner equivalent to their male counterparts. Certain studies have also indicated that the females have a faster processing ability and hence have a shorter RT as compared to their male counterparts.[11]

In our study, no significant differences in RTs were observed in either gender. Male as well as female medical students did not differ much in their capability to react to either visual or auditory stimuli. Both genders fared equally well in their RTs both before and after the intake of caffeine. Decrease in RTs with caffeine intake was analogous in both the genders.

Keeping in mind the gender-based variability of RT seen in different studies, we undertook the present study to study the effect of gender on RTs. We also supplemented it with the introduction of caffeine to see if intake of caffeine modified the outcome in any way. Evidence for behavioral effects of caffeine is well documented in literature. It is associated with increased subjective alertness. Mental performance where speed, endurance, or vigilance was required showed reported benefits from caffeine intake.[15] Studies done by Tharion *et al*.[16] on both auditory and visual stimuli showed caffeine to significantly ignore distracting or irrelevant stimuli, thus helping the subjects focus more on the task, thereby giving rise to improved RTs. Keeping this in mind, we tried to see if improvement in RTs was significantly different in males and females.

The study thus sets aside the assumption that there exist gender-based differences in RTs and also reinforces it by studying the effect of consumption of caffeine in the form of coffee on the auditory and visual RT.

CONCLUSION

In this study, no significant differences in RTs were observed in either gender. Both genders performed equally well in their RTs, before and after the intake of caffeine. The present study thus undertaken tried to shed light on the conflicting reports and lacunae present in literature about the RTs in male and female subjects. It also busted the myth of male superiority in certain occupations and sports, by statistically refuting any differences in RTs in either gender.

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Original Article

A Hospital-based Clinical Study on Ilizarov Technique in the Treatment of Distal Fractures of Tibia

Sasikumar Sasidharan[1], Sathis Chandran[2]

[1]Assistant Professor, Department of Orthopaedics, Kannur Medical College, Kannur, Kerala, India, [2]Associate Professor, Department of Orthopaedics, Kannur Medical College, Kannur, Kerala, India

Abstract

Background: In spite of many advances in the surgical management of fractures of long bones, the management of displaced distal tibial fractures remains controversial. The various internal fixation techniques often described are burdened by relatively high complication rates. Alternate to these minimally invasive techniques with ring fixators has been introduced, allowing immediate reduction and stabilization and also avoiding a staged protocol in the surgical treatment of tibial shaft injuries.

Aim of the Study: The aim of this study is to analyze the clinical and functional outcome of the Ilizarov technique in patients with distal metaphyseal tibial fractures, with or without intra-articular involvement.

Materials and Methods: A total of 67 consecutive patients with isolated fractures of the lower end of tibia were included, treated with the Ilizarov technique, and followed prospectively for 1 year. 4 or 5 rings were used depending on the type of fracture; fracture; in some cases additional foot extension was used. Post-operative unrestricted weight-bearing was allowed in all patients. Pre- and post-operatively, X-rays of the fracture sites, post-operative pain, and complications were evaluated. The movement at the ankle was evaluated clinically at the end of 1 year.

Observations and Results: The common complication encountered was pin tract infection which was superficial and was treated with antibiotics and/or the removal of isolated pins. No patient developed compartment syndrome or deep venous thrombosis. Six patients required regular debridement. Two of these six patients had a deep infection and developed a residual deformity which was corrected and healed after reoperation. One patient had a severe residual deformity. The fixators were removed after a median period of 16 weeks (range 11–30). The final outcome was fair to good in 66/67 patients.

Conclusions: The Ilizarov method allowed early definitive treatment with a low complication rate and a good clinical outcome.

Key words: External fixators and internal fixation, Ilizarov, Tibia, Fracture

INTRODUCTION

The primary goal of any orthopedic surgeon in the management of distal fractures of tribia is to achieve normal axial alignment of tibia and to reduce articular displacement if present, thereby regaining a stable, mobile, and painless joint simultaneously avoiding infections and wound complications.[1] The fractures of the lower end of tibia remain a challenge to the orthopedic surgeons as it is difficult to assess their potential complications due to variations in the clinical findings. Hence, the injury may be more serious than expected even in patients without articular involvement.[2-5] The aim of the surgeon in lower tibial fractures is to maintain the length of the limb with joint bridging fixators or a fibular plate when the soft-tissue injuries permit; the definitive step is traditionally performed with screws and plates.[6-8] McFerran *et al.*[4] reported a 54% risk of major complications in less comminuted intra-articular fractures. Few authors recommend staged protocol to reduce the number and severity of complications.[9-12]

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Corresponding Author: Dr. Sathis Chandran, Kannur Medical College, Anjarakandy, Kannur, Kerala, India. Phone: +91-7907737959. E-mail: sathisv@gmail.com

Due to the presence of vulnerable soft,tissue in the distal region of the leg, there is an increased risk of complications in lower end compared with mid-shaft tibial fractures. When an Ilizarov technique is used, it is always possible to treat the patients with a single-stage procedure and avoid multiple-staged operations.[13,14] It has an added advantage being less invasive and less soft tissue exposure required, minimal blood loss. The external fixators allow for adjustment of the alignment and for compression/distraction of fracture ends, both during and after surgery; the fixation is stable enough to allow early weight-bearing.[15,16] In this context, the present study was conducted in a hospital-based setting to analyse the advantages and complications of fractures of lower end of tibia treated by using Ilizarov technique.

Period of Study

The study duration was from April 2011 to March 2014.

Institute of Study

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

Type of Study

This was a prospective, cross-sectional clinical study.

MATERIALS AND METHODS

A total of 67 consecutive patients with fractures of lower end of tibia with or without articular involvement, attending the orthopedic department of a tertiary teaching hospital, were included in the present study.

Inclusion Criteria

(1) Patients aged 18–75 years were included. (2) Patients with displaced distal metaphyseal tibial fractures with angulations of more than 10 degrees in any plane were included. (3) Patients with intra-articular fractures were included if the incongruence of the articular surface was more than 2 mm. (4) Patients with isolated fractures and without other disorders affecting gait were included in the study.

Exclusion Criteria

(1) Patients aged below 18 years and above 75 years were excluded. (2) Patients not willing to be included in the study were excluded. (3) Patients with skin infections or eczema were excluded. (4) Patients with bleeding tendencies were excluded from the study. All the patients underwent surgery without a tourniquet and without any traction table. Arthroscopy or arthrotomies were not used. A "C" arm was used to monitor the reduction, pin insertion, and assembly of the frame. The fractures were reduced with traction and manual external pressure. When it failed to get acceptable anatomical repositioning, the joint surfaces were reconstructed with percutaneously inserted elevators and/or a reduction forceps and/or wires with olives. The proximal ring was placed at the level of the fibular head. Additional stability was achieved using extra wires parallel to the articular surface with posts fixed on the distal ring (drop-wire technique). The syndesmosis and malleolar fragments could be stabilized with olive wires fixed to the ring on the lateral side or the medial side. All the wires were assembled and tensioned to a minimum of 120 kg. Steel rings connected with steel rods were used. Bone grafts were not used. Suitable I.V. antibiotic was administered at the start of the surgery and continued till 24 h. Low-molecular heparin prophylaxis was given from the day of admission until 10 days after leaving the hospital. Physiotherapy was started immediately post-operatively to maintain knee and ankle motion, and the patients were allowed to start unrestricted weight-bearing. The fractures were regarded as healed when anteroposterior and lateral radiographs showed a bridging callus in three of four cortices and/or the fracture was stable when stressed manually and the patients were able to walk without pain after the connecting rods had been removed. The patients were followed up clinically, and regular X-rays of the fractured site were taken whenever necessary 12 weeks and 1 year. At the end of 1st year, ankle movements were assessed using standard orthopedic protocol. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

Among the 67 patients included in the present study, males were 48 (71.64%) and the remaining 19 (28.35%) were females. The mean age was 38.45 ± 4.15 years in males and 32.56 ± 2.10 years in females. Majority of the fractures were observed in the age group of 25–40 years followed by 18–24 years age group. Road traffic accidents accounted for 49/67 (73.13%) patients followed by other injuries. High energy force was responsible in 48/67 (71.64%) patient's injury. The distance from the distal articular surface was 95–135 mm in 23/67 (34.32%) patients followed by 135–175 mm in 19/67 (28.35%) patients. The bone defect was found to be 35–55 mm in 29/67 (43.28%) patients followed by 15–35 mm in 21/67 (31.34%) patients. Foot extension was good in 55/67 (82.08%) patients and fair in 11/67 (16.41%) patients [Table 1].

Among the 67 patients, 35 patients (52.23%) had distal tibial fracture without distal articular involvement and 32/67 (47.76%) patients had articular involvement. The mean time lapse before surgery, mean operation time, mean hospital stay, and mean duration of external applicator were recorded and analyzed are shown in Table 2. There

was no significant difference in the mean times between the extra- and intra-articular involvement cases of tibial fractures at lower ends in this study. The similarity was no significant difference in the mean times between the extra- and intra-articular involvement cases of Tibial fractures at lower ends in this study $p < 0.05$ (P taken as statistically significant at <0.05).

At the end of 1 year, the range of ankle joint movements was analyzed in all the patients using standard clinical methods. It was observed that there was no significant difference between the two types of Tibial fractures (with either intra- or extra-articular involvement), with Ilizarov method of external fixators application; $p < 0.05$ (P taken as significant at <0.05) [Table 3].

DISCUSSION

The present study is a clinical analysis of 67 patients who had lower end tibial fracture with or without joint involvement. The study was found to be satisfactory with Ilizarov method of treatment independent of the fracture pattern. The surgical protocol used was identical for both intra- and extra-articular fractures. All the patients were operated without delay irrespective of the status of soft tissues, bone defect, the size of the distal fragment, and the intra-articular fracture lines, whether a staged protocol should be used. There was the absence of clinically important differences in the present study in terms of the results between the intra- and extra-articular fractures. Among the 67 patients, 35 (52.23%) patients had distal tibial fracture without distal articular involvement and 32/67 (47.76%) patients had articular involvement. The mean time lapse before surgery, mean operation time, mean hospital stay, and mean duration of external applicator were recorded and analyzed as shown in Table 2. There was no significant difference in the mean times between the extra- and intra-articular involvements in this study. There was no significant difference in the mean times between the extra- and intra-articular involvements in this study. The similarity was statistically proved with $p < 0.05$ (P taken as significant at <0.05). The extra-articular fractures observed were 35/67 (52.23%) of the patients could possibly have been treated with open reduction and internal fixation using intra-medullary nails or plates. The use of intramedullary nails in extra-articular distal tibial fractures is technically correct because of the widening medullary canal in the metaphysis, but it raises the concern regarding the biomechanical stability and the subsequent increased risk of malunion.[15] Review of literature shows that early aggressive debridement of non-viable tissues, stabilization with Ilizarov external fixators, and either primary or delayed primary closure followed by early mobilization and weight bearing is a sound treatment method for tibial shaft injuries.[16] Acute shortening, using the Ilizarov technique followed by progressive lengthening, is one of the methods used to deal with complex fractures combined with severe soft tissue injuries.[17] The most frequent complication was pin-tract infections.[18] In the present study, the pin-tract infection was observed in 4/67 (5.97%) patients. Review of literature shows that the incidence of pin site infections varies from 4.5% to 7.1%.[19] Parameswaran *et al.*[20] found

Table 1: The observations made on the study group (*n*=67)

Observation	Number (%)
Age	
18–24	15 (22.38)
25–40	34 (50.74)
41–55	10 (14.92)
56–75	8 (11.94)
Injury	
Traffic	49 (73.13)
Work	7 (10.4)
Riding	6 (08.95)
Fall	5 (07.46)
Energy	
High	48 (71.64)
Low	19 (28.35)
Extension from the joint/mm	
55–95	11 (16.41)
95–135	23 (34.32)
135–175	19 (28.35)
175–215	14 (20.89)
Bone defect/mm	
15–35	21 (31.34)
35–55	29 (43.28)
55–75	17 (25.37)
Ilizarov rings	
3	13 (19.40)
4	38 (56.71)
5	26 (38.80)
Foot extension	
Good	55 (82.08)
Fair	11 (16.41)
Bad	1 (01.49)
Pin infection	4 (05.97)

Table 2: The timing of the Ilizarov applicator (*n*=67)

Type of fracture tibia	Extra articular 35	Intra articular 32	*P* value
Mean time lapse before surgery	6.5±1.32	4.8±0.96	0.342
Mean operation time (min)	154±7.40	179±6.32	0.410
Mean hospital stay (days)	8.37±2.10	7.50±1.70	0.215
Mean duration of external applicator (weeks)	16.35±1.10	18.73±1.40	0.389

Table 3: The range of movements at ankle at the end of 1 year (*n*=67)

Range of movement	Extra articular-35	Intra articular-32	*P* value
Ankle dorsiflexion	18–20°	17–22°	0.210
Ankle plantar flexion	30–37°	29–38°	0.351

that ring fixators had the lowest incidence of infection compared with unilateral and hybrid fixators. Functional results were better in upper fourth and distal fourth tibial fractures and in Type VI tibial plateau fractures only. Kumar and Whittle compared with other series, and they believed that it is appropriate for the treatment of these complex tibial fractures (Schatzker Type VI), especially those with a poor soft-tissue envelope.[21] In the present study, the range of ankle joint movements was good in 55/67 and fair in 11/67 (16.41%) patients. At the end of 1 year, the range of ankle joint movements was analyzed in all the patients using standard methods. It was observed that there was no significant difference between the two types of tibial fracture (with either intra- or extra-articular involvement), with Ilizarov method of external fixators application. It was observed that there was no significant difference between the two types of Tibial fracture (with either intra- or extra-articular involvement), with Ilizarov method of external fixators application; $p < 0.05$ (P taken as significant at <0.05), [Table 3]. The present study had patients with clinical features of complications of fracture such as soft-tissue injuries and diaphyseal fracture extension [Table 1].

CONCLUSIONS

A satisfactory outcome was possible in lower end metaphyseal tibial fractures with the Ilizarov technique allowing early definitive treatment and good allowing early definitive treatment and good functional recovery in the ankle joint. This was irrespective of the nature of injury, soft-tissue damage, and articular involvement. The complication rate was low in both the extra-articular and the intra-articular fractures. The entire period of treatment was compliant with all the patients.

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Original Article

Outcome Analysis of Tracheobronchial Injuries at a Large Service Hospital

Pawan Sharma[1], Abhishek Sharma[2], K M Mehdi[3], Zenith Mohanty[2], Usha Kumari[4], Sanya Chikara[5]

[1]Associate Professor, Department of Surgery, Army College of Medical Sciences, Delhi Cantt, New Delhi, [2]Final year Surg Resident, Army College of Medical Sciences, Delhi Cantt, New Delhi, [3]Second year Surg resident, Army College of Medical Sciences, Delhi Cantt, New Delhi, [4]Final Year MBBS student, Army College of Medical Sciences, Delhi Cantt, New Delhi, [5]Second year MBBS Student, Army College of Medical Sciences, Delhi Cantt, New Delhi

Abstract

Background: Tracheobronchial injuries, although uncommon, are potentially fatal injuries consequent to both blunt and penetrating neck and chest trauma. Majority of the patients die at the scene before reaching definitive care centers. Moreover, the diagnosis and treatment of these unusual injuries is often missed or delayed, resulting in a significant number of preventable deaths or marked morbidity.

Methodology: All patients with tracheobronchialinjuries presenting at a large service hospital in New Delhi between January 2014 and December 2018 were studied prospectively to determine the current pattern, presentation, and associated injuries along with modalities for diagnosis, treatment, and outcome of these injuries. Only those patients with tracheobronchial injuries who were alive at presentation and consented to be a part of the study were included in the study. Results were analyzed with the currently available literature on the subject.

Results: A total of 52 patients were enrolled for the study during the above-mentioned duration. Injuries were consequent to both blunt and penetrating trauma in almost equal proportions. The most common presentation was found to be surgical emphysema in 21 patients. The injurywas detected within 3 cm of the carina in 65% of the patients with blunt tracheal trauma, whereas cervical trachea was injured in majority (81%) of the penetrating injuries of the neck. Theproximity of the injury to the carina had no detectable effecton mortality. Overall, mortality from tracheobronchial injury was 17%, mainly consequent to multiple neck or chest traumas or other significant associated injuries.

Conclusion: To the best of our knowledge, this study represents one of the most comprehensive cohorts of patients with tracheobronchial injuries evaluated and managed at a service hospital till date. These injuries are potentially life threatening and warrant quick assessment and management. The associated morbidity and mortality continue to be significant enough to highlight the importance of high index of suspicion, early detection, and appropriate management of these serious and often missed injuries.

Key words: Carina, Pneumothorax, Tracheobronchial injury

INTRODUCTION

Injury to the trachea or either of the mainstem bronchus is an unusual and potentially fatal condition which is often overlooked on initial assessment. Although 15–25% of all trauma deaths are due to thoracic trauma, little information is available concerning theincidence of injuries specifically to the trachea or the bronchus as a result of neck or chest trauma. It has been reported that tracheal injury occurs in <1% of trauma patients.[1,2] This may be attributed to the fact that as high as 80–90% of the patients with tracheobronchial injuries go unreported as they die before arriving at any medical facility.[3,4] Trachea is most commonly injured either in the cervical portion or within 2.5 cm of the carina[5] following blunt trauma, whereas penetrating injuries can occur anywhere along the course of the trachea or bronchi. Despite the change in the mechanism of injury, the nature of injuries encountered has remained essentially the same. The immediate effect may include death from asphyxiation, whereas lack of recognition or incorrect management may result in life threatening or disabling airway stricture, bronchopleural fistula, pneumonitis, and acute respiratory distress syndrome (ARDS). Although the awareness of existence of such uncommon and lethal

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Corresponding Author: Pawan Sharma, 58/12, Baird Place, Delhi Cantt, New Delhi - 110010. E-mail: drpawansharma55@gmail.com

injuries has increased over the past few decades, delayed recognition of this injury is not uncommon even today.

PATIENTS AND METHODS

This was a prospective observational study over a period of 4 years beginning January 2014, conducted at a large service hospital at New Delhi. All patients with tracheobronchial injuries admitted during the study period at this center were included in the study. All those subjects who were dead on arrival and those who did not give consent were excluded from the study. A thorough review of the literature related to these injuries was carried out. This included all reports listed in Medline and PubMed (using key words: Trachea, bronchus, tracheobronchial injury, bronchopleural fistula, and chest injury) as well as all other cases that could be identified from listed references in published articles on the subject. Collected information included mechanism of injury, time until diagnosis and treatment, anatomic location of injury, method of diagnosis, type of treatment, and the final outcome. Outcome was reported as survival or death during hospital stay or within 30 days of discharge.

Statistics

Statistical analysis of the data collected was done using descriptive statistics such as mean, median, and mode and multivariate analysis for study of outcome. Quantitative data were analyzed using Student's *t*-test. Qualitative data were analyzed using Chi-square test. Confidence interval of 95% with $P < 0.05$ was taken as statistically significant. Associations between death from tracheobronchial injury and injury location, treatment, and mechanism of injury were assessed using an ordinary χ^2 statistic. To explore the relationship between the variables in a manner that controls for confounding, we fit a multivariable logistic regression model using death from trachea bronchial injury as the outcome. SPSS Version 17 was used for analysis of data.

RESULTS

A total of 1550 patients presented with neck and chest trauma at our hospital during the study period, out of which tracheobronchial injury was present in 52 (3.3%) patients. Complete tracheobronchial transaction was present in 13 (25%) patients (12 tracheal and 1 bronchial) while partial transaction or rent in the tracheal or bronchial wall was present in 39 (75%) cases (37 tracheal and 2 bronchial). 32 (62%) cases were brought directly to our trauma center while 20 (38%) were referred from various other smaller hospitals. Mechanism of injury was blunt trauma in 25 (48%) and penetrating trauma in 27 (52%) patients. Tracheobronchial injury was present in 30 (58%) patients of isolated neck and chest trauma and in 22 (42%) patients with polytrauma. The predominant mode of injury [Figure 1] was found to be vehicular accidents in 21 (41%) patients, wherein pedestrians were involved in 12 cases, while 5 were four-wheeler related and another 4 were two-wheeler related.

Airway was threatened and needed emergent tracheal tube placement in 40 cases either through the wound in trachea in 6 of the 13 cases of complete tracheal transaction or by conventional endotracheal intubation in the remaining 32 cases. 12 patients with a rent in trachea had a patent airway. These injuries were associated with polytrauma or presented as single or multiple neck or chest injuries, most commonly, subcutaneous emphysema in 40% of the patients [Figure 2]. 38 (73%) patients underwent surgical repair of the tracheal injury with tracheostomy in 32 of them, two underwent pneumonectomy for bronchial and other hilar injuries and another one with partial bronchial tear and extensive lung lacerations was managed with bronchial repair and lobectomy. The remaining 11 (21%) cases were managed non-operatively [Figure 3], out of which bronchoscopic-guided tissue glue repair was carried out in two patients.

Intensive Care Unit management was required in 26 (50%) patients. The mean hospital stay was 10.05±8.27 days with a median of 8 days (range - 4–19 days). 43 patients survived and were discharged in a stable condition while nine patients died either in emergency department (ED) or during the course of treatment.

DISCUSSION

The true incidence of tracheal and bronchial injury is difficult to establish, but it has been estimated that only 0.5% of all patients with multiple injuries managed in modern trauma centers suffer from tracheobronchial injury.[5] The vast majority of these injuries is found within 2.5 cm of the carina and is associated with a high mortality due to difficulty in ventilation and maintenance of adequate oxygenation combined with delay in diagnosis.[3,6] Most injuries related to blunt trauma involve the intrathoracic trachea and mainstem bronchi, with only 4% of these injuries reported in the cervical trachea.[4] In penetrating injuries, the cervical trachea is involved in up to 75–80% cases. These injuries are rarely isolated. The associated injuries, especially to the great vessels, coupled with delay in early recognition and prompt intervention, usually results in fatality.

The incidence of tracheobronchial injuries in our series was 3.3% of all neck and chest trauma, mainly as a consequence of right to information, whereas self-inflicted cut throat injuries mainly involved the cervical trachea with exposed

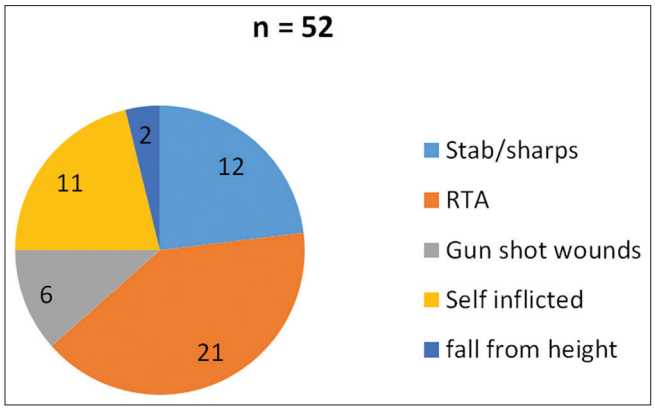

Figure 1: Modes of injury

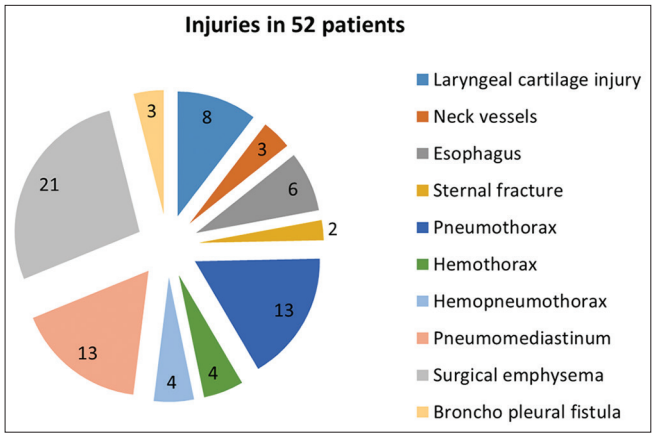

Figure 2: Associated isolated or multiple neck or chest injuries

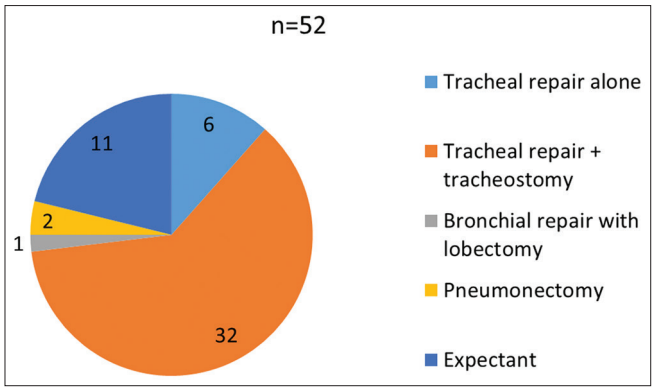

Figure 3: Surgical procedures

airway. Blunt trauma was mainly associated with injury to the intrathoracic trachea, bronchial or parenchymal injuries. All penetrating injuries were explored and major airway injuries were repaired along with repair of other associated injured structures [Figure 4]. Five cases of blunt tracheal injuries were missed on initial ED evaluation but were subsequently picked up either during secondary or tertiary survey. None of the isolated tracheal injury resulted in any fatality. It was rather other neck or chest injuries, mainly major vascular, esophageal, cervical spine, cardiac, or lung injuries including ARDS and hemorrhagic shock which resulted in death in 6 of the 9 cases that included two of the three bronchial injury cases who did not survive. The cause of death in the remaining three was severe traumatic brain injury, coagulopathy consequent to Grade 5 liver trauma and sepsis as a result of bowel injury with pelvic fracture.

The most important reason for delay in diagnosis for these injuries is their subtle presentation. At times, the only presentation is gradually increasing subcutaneous emphysema or a persistent air leak in the underwater seal drain for chest tube. Dyspnea and respiratory distress are frequent symptoms, occurring in 76–100% of patients.[7-9] The other common symptom is hoarseness or dysphonia, which occurred in 46% of the patients in a series published by Reece and Shatney.[10] Deep cervical emphysema and pneumomediastinum are seen in 60% and pneumothorax occurs in 70% of patients with tracheobronchial injuries.[11,12]

Occasionally, complete or near-complete transaction of mainstem bronchus results in the "absent hilum" or "fallen lung" sign of Kumpe on chest radiographs [Figure 5]. Contrast-enhanced computed tomography (CT) may show pneumomediastinum. In fact, the presence of this ominous finding should prompt us to look for tracheal or esophageal injury. CT scan may also show disruption in the continuity of the tracheobronchial air column [Figure 6]. Flexible bronchoscopy has proved to be an important diagnostic as well as an occasional therapeutic tool in the management of these injuries and should be performed in all the patients with suspected tracheobronchial injury after initial resuscitation and stabilization.[13,14] It can delineate the site and extent of injuries but at the same time, it may create larger defects and very small defects may go unnoticed if it is done by an unexperienced person. Therapeutic utility of bronchoscopy lies in sealing small, mainly blunt trauma defects of the major airways with glue or a sealing agent. Patients with small injuries without appreciable air leaks can be treated non-operatively; however, most patients with larger defect and significant air leak require urgent repair. Surgical management is dictated by the extent, location and size of the injury, amount and pattern of air leak, and the presence of associated injuries.[15] Delay or lack of recognition is common, and subsequent complications of stenosis and obstruction are the rule in missed tracheobronchial injuries.

In a review of 1178 trauma autopsy reports, only 33 patients (2.8%) of tracheobronchial rupture were identified and 81% of these patients died before reaching the hospital.[16] Another study of 585 patients who died from motor vehicle accidents over a 10-year period identified only 5 patients with tracheobronchial injuries, or <1%.[17] Four of these five patients died at the scene. In 1873, Seuvre[17] describeda 74-year-old woman with the right main bronchus avulsion discovered at autopsy. In 1931, Nissen[18] described a successful

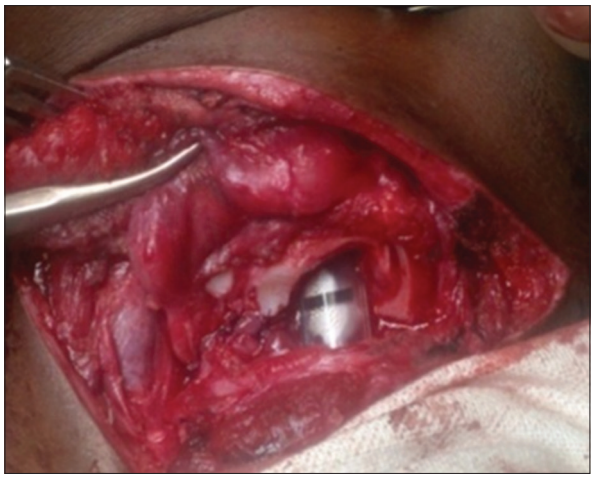

Figure 4: Tracheal injury with endotracheal tube *in situ*

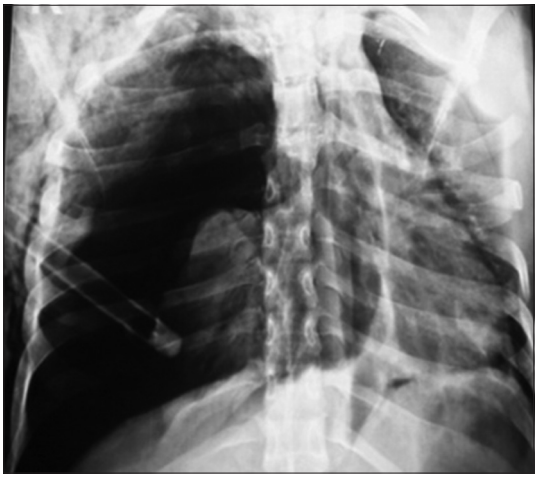

Figure 5: Chest radiograph showing the right bronchial injury with lung collapse and tension pneumothorax - Fallen lung sign

pneumonectomyin a 12-year-old girl with a post-traumatic stricture of the left main bronchus. Later, in 1949, Griffith[19] reported a patient with primary sleeve resection and repair of a post-traumatic stricture of the left main bronchus.

Various theories have been suggested regarding mechanism of injury to the tracheobronchial tree.[20,21] One theory associates tracheobronchial disruption with a sudden, forceful compression of the chest wall, decreasing its anteroposterior diameter, and pulling lungs apart at the carina. This may be the likely mechanism involved in crush injuries. Another theory suggests compression of the chest and trachea on a closed glottis increasing the airway pressure, leading to rupture of the airway at the membranous portion, which has been demonstrated experimentally in a canine model.[20,21] The most logical third theory is applicable in blunt trauma consequent to rapid deceleration, producing shearing force, such as the one experienced in motor vehicle crash, causing rupture of the trachea and bronchi.

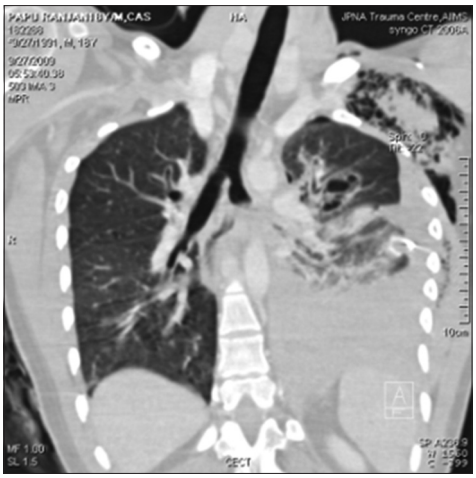

Figure 6: Left mainstem bronchus injury seen on coronal section of computed tomography chest

Although some investigators have found equal frequency of the right-sided and left-sided injuries,[22,23] others also have noticed an increased frequency of the right mainstem injuries.[4,18] In our study, out of three bronchial injuries, two were on the right side and one was on the left side [Figure 7]. The acuity of the presentation of a patient with a right-sided injury may be related to a higher incidence of associated injuries.

Some authors have suggested that the high early mortality in blunt tracheobronchial trauma is from other associated injuries.[16,24] For patients with blunt tracheobronchial injuries, Jones *et al*.[25] reported an average of five associated injuries in patients who died compared with three associated injuries in patients who survived. The survivors experienced less severe injuries such as bony fractures and closed head injuries.[25] The increased early mortality appears to result from coexisting fatal injuries and not necessarily the tracheobronchial injury. During our study period, nine patients died consequent to either multiple (>3) neck or chest injuries or other associated significant injuries with a median ISS of 22 (range 16–34).

Tracheobronchial injuries are not diagnosed immediately in 25–68% of patients.[26,27] Taskinen *et al*.[28] described a surrounding layer of peribronchial tissue, especially on the left, which may be adequate to allow continued ventilation past an area of bronchial injury. However, in 2–6 weeks, the bronchus can become obstructed by granulation tissue, preventing air exchange. Those bronchi that do not completely obstruct but remain stenotic tend to develop post-obstructive pneumonia and bronchiectasis. This development usually leads to non-functional lung tissue distal to the area of stenosis, even if the airway is restored. However, when the airway is completely obstructed, the distal lung is often filled with mucus and protected

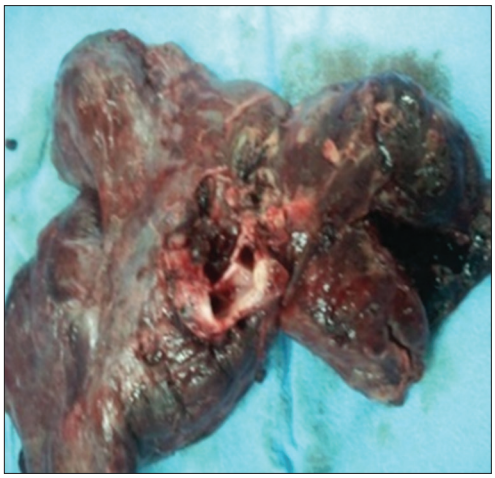

Figure 7: Extensive bronchial and parenchymal lung injury seen on pneumonectomy specimen

from infection.[29] Experimentally occluded bronchi for 5–7 months can be repaired and reairated with return of physiological functions. Patients with chronic but complete bronchial obstruction do not have parenchymal destruction but instead, maintain functional pulmonary tissue beyond the point of obstruction.[4,30]

Chest radiography is the standard initial imaging modality for evaluation of all chest injuries including tracheobronchial injury, but CT is preferred if a tracheobronchial tear is suspected.[31] Apart from imaging, a suspected airway injury should undergo fiberoptic bronchoscopy for detection and localization of the injury. Both surgical incision and intraoperative ventilation are dictated by the location of the injury and the surgical approach. Surgical debridement of the area of acute injury and excision of scarred, narrowed segments of chronic tracheobronchial injuries should be performed to create healthy edges that can be repaired successfully. Often the airway distal to the chronic obstruction will be filled with mucus, which must be removed to allow adequate ventilation of the atelectatic segment. The choice of suture material is absorbable suture. In our study, we used 3-0 polydioxanone interrupted sutures. Follow-up bronchoscopy to evaluate the airway anastomosis is recommended at 1–2 weeks following surgery.

Summary

Road traffic accidents with high-speed deceleration have become more common over the past few decades and have accounted for majority of the life-threatening tracheobronchial injuries occurring today. Both deceleration and crush injuries occur near the carina and most commonly involve the distal 3 cm of trachea or right main bronchus. Penetrating injuries involve proximal trachea more often than distal trachea and bronchi. The significant mortality rate appears to be related to coexisting injuries rather than the tracheobronchial injury per se. Immediate recognition of these injuries is often difficult and is based on the mechanism of injury, and a high index of suspicion should be exercised to diagnose these potentially fatal injuries. Instead of an acute presentation with a large air leak, tracheobronchial injuries may often run an indolent course involving retained secretions, poor lung expansion, residual or recurrent pneumothorax, and eventually high-grade bronchial obstruc

Our experience has been mainly in treating both blunt and penetrating tracheal injuries. Although early diagnosis is becoming more common now, a significant delay is still seen in a large number of patients even today. This study supports active search and early repair of these injuries to prevent potential pulmonary complications and long-term morbidity associated with missed tracheobronchial injuries.

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Original Article

A Comparison of Intrathecal Neostigmine and Clonidine for Post-operative Analgesia in Total Abdominal Hysterectomies

Manjulata Shakya[1], Hansraj Baghel[1], Avtar Singh Yadav[2]

[1]Assistant Professor, Department of Anaesthesia, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, [2]Professor, Department of Anaesthesia, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

Abstract

Background: Intrathecal neostigmine 5 μg and clonidine 30 μg with bupivacaine produce substantial antinociception and potentiate analgesia of bupivacaine.

Aims: The aim was to investigate the effect of intrathecal neostigmine and clonidine on post-operative analgesia and hemodynamic when added to 0.5% hyperbaric bupivacaine.

Subjects and Methods: In this prospective, randomized, and double-blind study, we took 90 patients of ASA Grade I and II adult female patients posted for total abdominal hysterectomies.patients were assigned into three groups of 30 patients each. Patients of Group 1 received neostigmine 5 μg, Group 2 received clonidine 30 μg, and Group 3 received normal saline as an adjuvant to 3 ml of hyperbaric bupivacaine. Onset, duration of analgesia, heart rate, mean arterial pressure, and adverse effects were recorded. Recorded data were statistically analyzed. $P < 0.05$ was statistically significant.

Results: The mean duration of analgesia was significantly longer in Group 2 followed by Group 1 and lowest in Group 3. Additional analgesic requirement was significantly less in Group 2 followed by Group 1 and Group 3. The pain score was significantly less in Group 2. The incidence of hypotension and bradycardia was the lowest in Group 1.

Conclusion: Neostigmine and clonidine both provide longer post-operative analgesia and neostigmine also provides better hemodynamic stability with fewer side effects.

Key words: Neostigmine, Clonidine, Postoperative analgesia

INTRODUCTION

Anesthesiologists succeed to a greater extent by rendering the patient absolutely pain free during surgery, but despite advances, many patients continue to experience considerable discomfort in the post-operative period. Inadequate post-operative analgesia may result in significant morbidity which may delay recovery and increase hospital stay.[1]

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Spinal anesthesia is routinely performed for lower abdominal surgeries and lower limb procedures. Local anesthetic (LA) alone provides the short duration of its effects. To increase the quality and duration of spinal analgesia, a number of adjuvant is added to LAs, i.e. opioids (morphine, fentanyl, sufentanil, etc.), neostigmine, clonidine, dexmedetomidine, and midazolam, etc., are add intrathecally. These adjutants not only reduce the dose of LAs but also provide prolonged post-operative analgesia with reduced incidence of side effects such as central nervous system depression, motor effects, or hypotension.

Neostigmine is anticholinesterase agent which increases the acetylcholine (Ach) concentration at the cholinergic synapse by blocking the activity of true and pseudocholinesterase.[2] In post-operative period descending noradrenergic or cholinergic antinociceptive spinal system

Corresponding Author: Dr. Hansraj Baghel, New Doctors Colony, Rewa, Madhya Pradesh, India. Phone: +91-8989094694.
E-mail: dr.hansrajbaghel@gmail.com

is activated by ongoing pain causing an increase in the release of Ach, which in the presence of neostigmine results in augmented analgesia. It has no untoward side effects such as respiratory depression, pruritis, and drowsiness as experienced with intrathecal narcotics.[3]

Clonidine is an alpha-2 receptor agonist which has gained popularity in recent times as an adjuvant in spinal anesthesia. Analgesic effect of clonidine mediated by α2-adrenoceptors situated in the dorsal horn of spinal cord. The antinociceptive properties of clonidine indicate that it might be useful as an alternative to intrathecal opioids for postoperative analgesia,[4] thus also avoiding the adverse effect of opioids.

Aims and Objectives

1. To study and compare the effect of intrathecal neostigmine and intrathecal clonidine on post-operative analgesia.
2. To study and compare the hemodynamic parameters and side effects.

MATERIAL AND METHODS

The present study was randomized prospective study, conducted in the Department of Anesthesiology S.S. Medical College, Rewa, Madhya Pradesh, India. After getting approval from Institutional Ethics Committee, 90 female patients of ASA Grade I and II, aged between 30 and 50 years scheduled for total abdominal hysterectomy were included in this study. Informed consent was taken from all the patients.

Patients fulfilling the selection criteria were randomly divided into 3 groups of 30 patients each:

Group 1: Injection bupivacaine hydrochloride heavy 0.5% 15 mg (3 ml) intrathecal
Injection neostigmine 5 μg (1 ml) intrathecal

Group 2: Injection bupivacaine hydrochloride heavy 0.5% 15 mg (3 ml) intrathecal
Injection clonidine 30 μg (1 ml) intrathecal

Group 3: Injection bupivacaine hydrochloride heavy 0.5% 15 mg (3 ml) intrathecal
Injection normal saline 1 ml intrathecal.

Patient taking any medication (ace inhibitors, calcium channel blockers, adrenergic agonist, or any contraindication to subarachnoid block were excluded from the study.

Pre-anesthetic examination was done a day before surgery. All the patients were kept nil by mouth for at least 6 h. The patient was shifted to the operating room; an IV line was secured. All patients were premedicated with injection ondensetron 4 mg 30 min before surgery. All the monitoring equipments (non-invasive blood pressure, pulse oximetry, and electrocardiography) were attached, and baseline values of heart rate, blood pressure, SPO_2, and respiratory rate were recorded. All patients were preloaded with 15 ml/kg ringer lactate's solution.

The patients were placed in sitting position. Under all aseptic precautions, lumbar puncture was performed through midline approach in between L3 and L4 intervertebral spaces using 25 G Quincke's spinal needle. After the free flow of cerebrospinal fluid (CSF) study drugs which were prepared by another resident and provided in coded syringes were injected into the subarachnoid space.

Level of sensory blockade was assessed using a 23 G hypodermic needle (pinprick analgesia extending cranially at least to the T8 dermatome). Duration of effective analgesia was measured as the time from intrathecal drug administration to the patient's first complain of pain.

The level of motor blockade was assessed by modified Bromage scale [Table 1]. Duration of motor blockade was recorded as the time from onset of motor block to the time when the patient was able to raise his limb.

Hemodynamic parameters, i.e. heart rate, systolic blood pressure, diastolic blood pressure, and SPO_2 were recorded at different time intervals. Side effects, i.e. bradycardia, hypotension, nausea, vomiting, sedation, desaturation or hypoxemia (SPO_2 < 90%), and any other were also recorded.

Bradycardia (heart rate <60/min) treated with injection atropine 0.6 mg IV, hypotension (fall of systolic blood pressure >20% OR systolic blood pressure <90 mm hg) was treated with IV fluids and/or injection mephentermine 6 mg IV.

Pain was assessed by visual analog scale score at 2 h, 4 h, 6 h, and 24 h after surgery.

All recorded data were decoded, tabulated and statistically analyzed by Student's *t*-test, Chi-square test. $P < 0.05$ was taken as statistically significant.

RESULTS

All patients were demographically similar in regards to age, weight, height, and duration of surgery and it can be

Table 1: Modified Bromage scale

1	No paralysis
2	Inability to lift outstretched leg
3	Inability to flex the knee
4	Total paralysis of lower limb

Table 2: Patient's characteristics

Patient's characteristics	Group 1	Group 2	Group 3	*P* value
Age in years (mean±SD)	31.7±4.8	29.6±3.7	30.5±2.8	>0.05
Weight in kg (mean±SD)	55.67±4.21	55.17±6.22	56.04±1.77	>0.05
Height in cm (mean±SD)	153.93±4.03	153.77±3.40	153.67±3.57	>0.05
Duration of surgery in minutes	106.33±12.994	107.87±10.954	106.55±11.757	>0.05

SD: Standard deviation

Table 3: Comparison of sensory and motor block

Criteria	Group 1	Group 2	Group 3	*P* value
Onset of sensory block (in seconds)	90.57±15.5	107.60±14.79	110.00±11.54	<0.05
Onset of motor block (in seconds)	107.10±14.7	192±34.00	193.83±34.33	<0.05
Duration of analgesia (in minutes)	314.67±15.11	387.07±83.17	244.90±35.05	<0.05

Table 4: Side effects

Complication	Group 1	Group 2	Group 3
Hypotension	0	3	2
Bradycardia	0	2	3
Nausea	2	0	1
Vomiting	0	0	0
Sedation	0	0	0
Cardiac arrest	0	0	0
Resp. depression	0	0	0

presumed that the groups were comparable for the purpose of the study [Table 2].

All the patients in each group have achieved complete sensory block up to T8 and complete motor block (Bromage scale grade 3).

Onset of sensory block was earlier (90.57 ± 15.5 s) in Group 1 than Group 2 (107.60 ± 14.79 s) and Group 3 (110.00 ± 11.54 s). The difference was statistically significant between Group 1 and Group 2 ($P < 0.05$).

Onset of motor block was 107.10 ± 14.7 in Group 1 compared to 192 ± 34.00 in Group 2 and 193.83 ± 34 in Group 3. Early onset of motor block in Group 1 is also clinically significant ($P < 0.05$).

Duration of analgesia was longer in Group 2 (387.07 ± 83.19) than Group 1, (314.67 ± 15.11), and Group 3 (244.90 ± 35.05) minutes Group 2. This difference was statistically significant between all three groups ($P < 0.05$) [Table 3].

The differences in mean pulse rate mean systolic and diastolic blood pressure at different time intervals were almost similar in all the groups.

Most common side effects found in our study were hypotension, bradycardia, nausea, and sedation. Mild hypotension was found in three patients of Group 2 and two patients of Group 3 it was easily corrected with crystalloid infusion and 6 mg IV mephentermine. Bradycardia observed in two patients in Group 2 and three patients in Group 3 and corrected with IV atropine 0.6 mg. Complained of nausea was in two patients of Group 1 and one patient of Group 3. Other side effect was minimal, i.e., sedation, Shivering etc [Table 4].

DISCUSSION

Recent research has focused on non-opioid spinal receptors that inhibit transmission of pain signals. A number of adjuvant has been added to the intrathecal LAs for supplementation of intraoperative anesthesia and post-operative analgesia.

Neostigmine and clonidine both are widely available at a very affordable price. Absence of neurotoxicity, respiratory depression, etc., has been established in several studies when administered intrathecally.[5,6] It has encouraged us to compare the effectiveness and adverse effects of these two drugs when used as an adjuvant with intrathecal bupivacaine.

Spinal administration of neostigmine block the activity of true and pseudocholinesterase thus inhibits the breakdown of endogenous neurotransmitter Ach that has intrinsic analgesic properties.[7-9] High density of muscarinic cholinergic receptor binding sites has been demonstrated in substantia gelatinosa and Lamina III and V of dorsal grey matter of spinal cord.[10,11] The concentration of Ach in CSF increases with painful stimulus and remains at a plateau for 4–6 h.[12] The concentration of neostigmine in CSF even after the lowest dose was adequate to significantly inhibit cholinesterase in CSF.[13,14] Pain itself activates a pain inhibitory system at the level of spinal cord. This effect is due to spinal-supraspinal spinal loop and descending inhibitory system.[11]

Clonidine is an imidazoline derivative with selective partial α2-adrenergic receptor agonistic activity which has analgesic effect at spinal level mediated by postsynaptically situated α2-adrenoceptors in the dorsal horn of spinal cord in substantia gelatinosa. Cholinergic interaction in spinal α2-adrenergic receptors which are located on descending noradrenergic pathways produces noradrenaline release that causes analgesia directly, and also it releases Ach to produce analgesia clonidine also blocks A and C-fibers at Lamina V, thereby producing analgesia.[15-17]

Clonidine was used in different doses from 15 μg to 450 μg, and many previous studies concluded that minimum 30 μg dose of clonidine provide a significant increase in the duration of sensory block, motor block, and spinal analgesia without increasing the incidence of side effects.[15,18] On the other hand, neostigmine was used in different dose ranges from 5 μg to 750 mg by intrathecally but a low dose of 5 μg sufficient to cause early onset of sensory and motor block.[19] With higher doses (>150 μg)[6,20] it has more pronounced side effect such as nausea and vomiting due to rostral spread, but in our study, we used only 5 μg to alleviate these side effects.

In our study, we noticed that neostigmine cause early onset for sensory and motor blockade then clonidine, also mean time taken for maximum motor blockade was significantly faster in neostigmine group than clonidine. Similar results were obtained in a study by Klamt *et al*.[15] Due to the potential direct inhibition of motor activity by administration of neostigmine; it was speculated that increased spinal levels of Ach may augment motor block as a result of axonal conduction block from spinal bupivacaine.

We also noted that duration of analgesia was prolonged with the addition of clonidine compared to neostigmine because it produces local vasoconstriction by acting on vascular smooth muscle (receptors), which decreases absorption of LAs from subarachnoid space.[21-23]

Sedation and hypotension are the central effects of α2-adrenergic receptors may occur after clonidine administered by any route. Higher doses of (50-450 mcg) clonidine have been associated with hypotension, bradycardia, and higher degree of sedation.[18,24,25] In our study, as we use clonidine 30 mcg is usually not associated with such effects.

The incidence of hypotension and bradycardia was less with neostigmine as compared to clonidine suggested the more hemodynamic stable property of neostigmine as reported by Carp *et al*. and Pan.[26,27]

CONCLUSION

From our study, it was concluded that both intrathecal neostigmine and clonidine can provide longer post-operative analgesia, but neostigmine causes better hemodynamic stability with less side effects.

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Original Article

Screening for Acanthosis Nigricans in Type 2 Diabetes Mellitus - It's Time for Reinforcement

Swathy Moorthy[1], M K Sudhakar[2]

[1]Associate Professor, Department of General Medicine, Sri Ramachandra Medical College, Porur, Chennai, Tamil Nadu, India, [2]Former Professor and Head, Department of General Medicine, Sri Ramachandra Medical College, Porur, Chennai, Tamil Nadu, India

Abstract

Background: Acanthosis nigricans is a well-known external marker for insulin resistance, obesity and type 2 diabetes mellitus (T2DM). The prevalence of acanthosis varies among different ethnic groups.

Aim: The aim of the study was to study the prevalence and relationship of acanthosis nigricans with age, body mass index (BMI), and other risk factors in T2DM.

Methods: A total of 300 patients with T2DM attending the medical outpatient department in a tertiary care teaching hospital were included in the study. Their demographic and clinical parameters were recorded. The presence of acanthosis nigricans, its severity and relationship with other diabetic risk factors were assessed.

Results: Among the 300 patients enrolled in study 187 patients had evidence of acanthosis of varied severity. 172 were female patients. The mean BMI was 28.8 kg/sq m and mean waist circumference was 97.5 cm. Significant association ($P < 0.005$) of acanthosis nigricans was noted with younger age, female sex, overweight, and obesity. Similar significance was also noted with hypertension and dyslipidemia. However, the duration of T2DM, previous history of CVA or coronary artery disease, family history of T2DM did not bear a significant association with the presence of acanthosis.

Conclusion: The high prevalence of acanthosis nigricans in T2DM patients favors it as a potential screening tool in the T2DM risk assessment.

Key words: Acanthosis nigricans, Insulin resistance, Obesity, Type 2 diabetes mellitus

INTRODUCTION

India is turning a diabetic capital in incidence and prevalence of diabetes and its related adverse health issues are causing resource wastage.[1,2] Having such a huge burden of the disease, the availability of screening tests that are affordable, safe and sensitive are the need of the hour. Acanthosis nigricans (AN) is one such recommended screening tool.[3] Its association with hyperinsulinemia, insulin resistance, Type 2 diabetes mellitus (T2DM), and obesity is well established.[4-6] Various studies have shown varying prevalence of AN among different ethnic groups, darker races have higher incidences than the whites.[7] In a study by Grandhe *et al.*, AN was seen in up to two-thirds of T2DM patients in North India.[8]

This study aims to know the prevalence of AN among T2DM patients and its relationship with anthropometric measurements and other risk factors for T2DM.

METHODS

A total of 300 T2DM as per the WHO criteria[9] attending the medical outpatient department were enrolled in the study. People with other known conditions associated with AN such as internal malignancies and autoimmune diseases such as systemic lupus erythematosus, scleroderma, Sjogren's syndrome, Hashimoto's thyroiditis, history of intake of oral contraceptive pills, and usage of topical Fusidic acid[5,7] were excluded from the study.

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Corresponding Author: Dr. Swathy Moorthy, Department of Medicine, Sri Ramachandra Medical College, Porur, Chennai, Tamil Nadu, India. Phone: +91-9444016401. E-mail: swathy.murali@gmail.com

Demographic and clinical parameters including anthropometric measurements were recorded in a pre-structured pro forma. Apart from demographic data, history of dyslipidemia, systemic hypertension, coronary artery disease and/or cerebrovascular accident, duration and treatment of T2DM, and family history of T2DM were recorded. Anthropometric measurements such as weight, height, body mass index (BMI), waist and hip circumference, and waist-hip ratio were measured. Waist circumference was recorded midway between iliac crest and lower margins of ribs. Hip circumference was measured at the maximum circumference of the buttocks. Body mass index was measured by Quetelet's index (weight in kilograms divided by height in meters squared). BMI of ≥23 kg/m^2 was considered overweight for both men and women in the study population.[6] All the study group subjects were examined for the presence of AN at the neck and other sites. Its severity and texture were graded as described by Burke *et al.*[10] According to this scale, Grade 0 - not visible on close inspection, Grade 1 - clearly present on close visual inspection, Grade 2 - limited to base of skull but does not extend to the lateral margins of the neck, Grade 3 - extending to the lateral margins of the neck but not visible from the front, and Grade 4 - extending to the anterior aspect of the neck. The texture of AN is graded from 0 to 3 as Grade 0 - smooth to touch with no differentiation from normal skin on palpation, Grade 1 - rough to touch, clearly differentiated from normal skin, Grade 2 - coarseness can be observed visually with portions of skin clearly raised above other areas, and Grade 3 - extremely coarse, hills and valleys appearance on examination. Other sites where AN can appear such as the knuckles, elbows, axillae, and knees were also examined and documented. The presence and severity of AN were assessed by a single trained observer.

The recent HbA1c was taken as a surrogate marker for glycemic control.

Statistical Analysis

Descriptive statistical analysis has been carried out in the present study. The proportion is computed for categorical data. Chi-square test has been used to find the statistical significance between two groups of proportions. The mean and standard deviation is computed for continuous data. The independent *t*-test was used to find statistical significance between the groups of mean. Correlation coefficient was computed to assess the linear relationship between continuous variables. All analyses were two-tailed, and $P \leq 0.05$ was considered significant. SPSS version 16.0 was used for data analysis.

RESULTS

Acanthosis nigricans was observed among 62.33% of the study patients. Table 1 shows the demographic characteristics of the study group. 33.67% of female patients had AN as compared to 28.67% of male patients. The prevalence of AN was inversely proportional to the age group. AN was seen in 96.15% (25 out of 26) in the age group 25–30 years while 31.48% (17 out of 54) of patients in the age group of >70 years had AN. The prevalence of AN was directly proportional to the BMI of the patients. It was seen in 56.56%, 61.85%, and 68.26% among the normal BMI, overweight, and obese patients, respectively. 69.56% of patients with central obesity had evidence of AN as compared to 50.86% of patients without central obesity. Similarity higher prevalence of AN was seen in patients with a history of systemic hypertension and dyslipidemia as compared to their absence (64.95% and 65.48% vs. 55.81% and 56.31%). The incidence of acanthosis nigricans was higher among uncontrolled diabetic patients than those with well-controlled diabetic patients (78.87% vs. 21.83%).

Table 2 shows the severity of acanthosis at the nape of the neck and other sites.

The nape of the neck was involved among all the patients with evidence of acantosis nigricans (100%) followed by axilla (71.65%), cubital fossa (32.62%), popliteal fossa (24.06%), knuckles (18.18%), and other areas (6.95%) being groin, and dorsum of toes and flanks. Table 3 shows the comparison of anthropometric parameters and comorbid conditions in subjects with or without AN. Although females seemed to have a higher incidence of AN, the values were not statistically significant. Higher levels of BMI, waist circumference, hip circumference, and waist-to-hip ratio were noticed among the AN group. The incidence of AN was significantly higher among uncontrolled diabetic patients with long-standing history of diabetes mellitus. The presence of comorbidities such as dyslipidemia and systemic hypertension was also higher among the patients with AN. Table 4 shows the comparison of the anthropometric variables with varying severity of acanthosis nigricans. There is a steady increase in the severity of acanthosis as the anthropometric variables increased, which was statistically significant.

DISCUSSION

The burden of diabetes is increasing exponentially, so is obesity. Hence, adjuvant sensitive screening tools for patients with T2DM for early identification are essential. As most of the T2DM patients are obese, BMI forms a major confounder in the association of AN with T2DM. This study highlights the presence of AN as a sensitive screening tool for T2DM.

AN is "a symmetric eruption characterized by hyperpigmented, velvety cutaneous thickening that can

Table 1: Demographic and clinical characteristics

Characteristics	Subgroup	Frequency of characteristics *n*=300 (%)	Prevalence in AN group *n*=187 (%)
Age in years	25–39	26 (8.67)	25 (13.37)
	40–49	41 (13.67)	41 (21.93)
	50–59	91 (30.33)	62 (33.15)
	60–69	88 (29.33)	42 (22.46)
	≥70	54 (18)	17 (9.09)
Sex	Males	128 (42.67)	76 (40.64)
	Females	172 (57.33)	111 (59.35)
Body mass index (kg/sq.m)	Normal	99 (33)	56 (29.95)
	Overweight	97 (32.33)	60 (32.09)
	Obese	104 (34.67)	71 (37.97)
Waist circumference (cm)	Normal	116 (38.67)	59 (31.55)
	Central obesity	184 (61.33)	128 (68.45)
Waist-hip ratio	Normal	122 (40.67)	64 (34.22)
	Increased	178 (59.33)	123 (65.77)
Duration of T2DM	<5 years	57 (19)	24 (12.83)
	5–10 years	138 (46)	95 (50.80)
	>10 years	105 (35)	68 (36.36)
Family history of T2DM	Yes	248 (82.67)	149 (79.68)
	No	52 (17.33)	38 (20.32)
Systemic hypertension	Yes	214 (71.33)	139 (74.33)
	No	86 (28.67)	48 (25.67)
Dyslipidemia	Yes	197 (65.67)	129 (68.98)
	No	103 (34.33)	58 (31.01)
CAD/CVA	Yes	188 (62.67)	92 (49.19)
	No	112 (37.33)	95 (50.80)
Treatment modality	OHAS	174 (58)	92 (49.19)
	Insulin	36 (12)	31 (16.57)
	OHAS and insulin	90 (30)	64 (34.22)
Glycemic control	Uncontrolled	213 (71)	168 (89.83)
	Good control	87 (29)	19 (10.16)

T2DM: Type 2 diabetes mellitus, CAD: Coronary artery disease

Table 2: Acanthosis nigricans severity at the nape of neck and other sites

Severity of AN	No. at nape of neck *n*=187 (%)	No. of AN at other sites (%)
Grade 1	71 (37.96)	31 (16.57)
Grade 2	56 (29.94)	29 (11.76)
Grade 3	52 (27.80)	25 (13.36)
Grade 4	8 (4.27)	3 (1.60)

Table 3: Comparison of anthropometric and comorbid characteristics among diabetic patients with or without acanthosis nigricans

Parameter	AN no. *n*=187 (%)	No AN no. *n*=113 (%)	*P* value
Sex			
Male	76 (40.64)	52 (46.01)	0.068
Female	111 (59.36)	61 (53.98)	
Duration of T2DM	9.2±3.18	5.6±2.42	0.04
BMI	28.3±2.04	23.4±1.74	0.000
Waist circumference	96.4±5.6	86.6±5.3	0.000
Waist-hip ratio	0.99±0.074	0.92±0.052	0.002
Glycemic control			
Uncontrolled	168 (89.83)	77 (68.14)	<0.000
Good	19 (10.16)	68 (60.17)	
Dyslipidemia			
Present	129 (68.98)	68 (60.17)	0.063
Absent	58 (31.01)	46 (40.707)	
SHT			
Present	139 (74.33)	75 (66.37)	0.004
Absent	48 (25.67)	38 (33.62)	

occur on any part of the body."[5] It can develop anywhere on the skin most frequently involving the neck, axilla, cubital and popliteal fossae, knuckles, and inner aspects of thighs. Traditionally, AN can be sub-grouped as three forms. They are:

i. Idiopathic form - in healthy children
ii. Paraneoplastic form - in patients with internal malignancy
iii. In obese patients with or without endocrine disorders - this was previously known as pseudoacanthosis nigricans.

It is considered a marker of insulin resistance and hyperinsulinemia and a risk factor for T2DM.[3,4,11] The pathogenesis could be explained by high levels of insulin activating the dermal and epidermal cells - the fibroblasts and keratinocytes, respectively, through the insulin-like growth factor receptors present on these cells. This, in turn, results in increased glycosaminoglycan deposition in the

Table 4: Comparison of anthropometric variables with the severity of AN

Variable	Grade 1 AN no.	Grade 2 AN no.	Grade 3 AN no.	*P* value
BMI	27.4±2.58	28.5±2.14	32.7±1.687	0.000
Waist circumference	93.5±5.6	98.2±4.82	102.8±3.78	0.001
Waist-hip ratio	0.98±0.032	0.99±0.027	1.01±0.0198	0.002

BMI: Body mass index

dermis leading to papillomatosis mediated by fibroblasts and keratinocyte proliferation causing hyperkeratosis and acanthosis.[8]

ADA recommends AN as part of T2DM risk assessment criteria for children and adolescents.[12] Our study throws light on AN as a good marker of T2DM even for the adult population. However, despite decreasing prevalence with age, AN was still prevalent in older groups. The higher prevalence of AN in younger diabetic patients could be explained by the fact that obesity was more prevalent among the younger patients. Previous studies showed BMI and fasting insulin levels correlated with AN severity at the nape of the neck.

The AN prevalence was higher among both males and females with 59.37% and 64.53%, respectively. The slight female predominance could be explained by the fact that polycystic ovarian syndrome (PCOS), an established insulin resistant state could have accounted for some of the higher prevalence of AN among diabetic women.[13]

In the present study, 34.67% and 32.33% of the diabetic population were obese and overweight, respectively. Among them, 68.26% and 61.85% demonstrated the presence of AN. Normal weight patients were 33%, and AN was noticed in 56.56% of these patients. These percentages show greater insulin resistance with patients having AN and obesity in combination than with obesity alone,[14] so the presence of AN in an obese patient should prompt the suspicion of T2DM. The mere fact that 56.56% of normal weight patients had evidence of AN tells that AN could be a valuable marker of T2DM even in the low-risk groups.

Among the study population 62.33% had evidence of AN at the neck with or without AN at other sites, which were similar to the observations made in the previous studies.[10,15] In addition to a significant association between AN and BMI, other anthropometric measurements such as waist circumference and waist-hip ratio also showed significant association with AN prevalence. This was also observed with progressing severity of AN. Higher prevalence of AN was also found among patients with hypertension and dyslipidemia.

Thus, AN can serve as a valuable tool for improved detection of not just undiagnosed T2DM but also a significant predictor of future T2DM. This was also described by Stuart *et al*.[16] Therefore presence of AN, mandates early lifestyle modifications to prevent T2DM and its complications.

Limitations

The specificity of AN as a valuable tool to predict T2DM could not be ascertained in the present study as it was conducted among diabetic patients. We did not include a screening of acanthosis among prediabetic patients which could have answered this question. The study population was sampled from tertiary care teaching hospital which could be representing more severe forms of T2DM.

CONCLUSION

Acanthosis nigricans is highly prevalent across age groups and both sexes among the diabetic patients. The simplicity and convenience in assessing acanthosis nigricans favors its implementation as a valuable screening and risk assessment tool for T2DM. Therefore, proactive screening for AN in clinical practice should be strongly recommended, and the presence of AN should prompt a clinical suspicion of T2DM.

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Original Article

Comparing Two Different Doses of Clonidine as an Adjuvant to Bupivacaine in Blind Fascia Iliaca Compartment Block Preoperatively in Patients Posted for Femur Fractures

Meena Singh[1], Vandana Pandey[2], Mamta Mahobia[3]

[1]Assistant Professor, Department of Anaesthesia and Critical Care, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India, [2]Assistant Professor, Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Bhopal, Madhya Pradesh, India, [3]Associate Professor, Department of Anaesthesia and Critical Care, Netaji Subhash Chandra Bose Government Medical College, Jabalpur, Madhya Pradesh, India

Abstract

Background: Femur fractures occur commonly due to trauma and cause excruciating pain causing difficulty in the positioning of a patient during spinal anesthesia. Fascia iliaca compartment block is an easy, bedside procedure for pain relief of such a patient. Addition of clonidine to local anesthetic agent improves the quality of analgesia.

Aims: The aim of the study was to study the effect of two different doses, 50 μg and 100 μg of clonidine as an adjuvant to bupivacaine in blind fascia iliaca compartment block orthopedic patients with a femur fracture.

Methods: A total of 120 adult patients of either sex, belonging to American Society of Anesthesiologists (ASA) physical status Class I and II, admitted in an orthopedic ward with femur fractures were randomly divided into three groups. The patients in Group I (control) received 39ml of 0.25% bupivacaine + 1 ml of normal saline, in Group II received 39 ml of 0.25% bupivacaine + 50 μg of clonidine diluted to 1 ml, and in Group III received 39 ml of 0.25% bupivacaine + 100 μg clonidine diluted to 1 ml. The demographic characteristics, hemodynamic parameters, ASA physical status, visual analog scale (VAS) scores, onset of analgesia, duration of analgesia, number of rescue analgesics, and any side effects and patient satisfaction during positioning for spinal anesthesia were noted.

Results: VAS scores till 24 h were lower in clonidine groups. The onset of analgesia was also reduced in clonidine groups. The mean duration of analgesia in Group I was 5.4 ± 0.6 h, 11.5 ± 0.3 h in Group II, and 16 ± 0.4 in Group III. The total number of rescue analgesics consumed in Group I was 4.5 ± 0.5, 3.2 ± 0.8 in Group II, and 2.8 ± 0.7 in Group III. The patient satisfaction during positioning for spinal anesthesia after the fascia iliaca compartment block was satisfactory in 30 patients in Group I, 34 patients in Group II, and 35 patients in Group III.

Conclusions: We conclude that the use of 50 μg clonidine as an adjuvant to bupivacaine in fascia iliaca compartment block for femoral fracture patients as a component to multimodal analgesic approach for effective pain relief.

Key words: Bupivacaine, Clonidine, Fascia iliaca compartment block

INTRODUCTION

Femur fractures occur commonly due to trauma and cause acute pain in the perioperative period. Patient presents with pain, swelling, and restricted movements.[1] The patient may require surgical intervention such as closed reduction, open reduction and internal fixation, dynamic hip screw fixation or hip arthroplasty, and among others.[2] These procedures require neuraxial anesthesia for which optimum positioning is critical in the pre-operative period, but the presence of pain makes the management difficult.

Fascia iliaca compartment block is a simple, bedside, blind underrated procedure used to provide analgesia in the perioperative period for patients with a femur fracture. It

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Corresponding Author: Dr. Vandana Pandey, B-79, Rajved Colony, Nayapura, Kolar Road, Bhopal – 462 042, Madhya Pradesh, India. Phone: +91-7898169898/0755-2416697. E-mail: pandeyvandana92@gmail.com

blocks the femoral, lateral cutaneous nerve of thigh and obturator nerve in a single shot.[3] It was first performed by Dalen *et al.*, in 1989, where he compared it with 3 in 1 block in pediatric patients.[4]

Clonidine, an α_2 agonist is a widely used adjuvant with local anesthetics to prolong the duration of analgesia. It acts by sympatholysis and direct inhibitory effect on peripheral nerve conduction by A and C fibers.[5]

We intended to evaluate the efficacy of clonidine as an adjuvant to bupivacaine in fascia iliaca compartment block specifically for femur surgeries.

MATERIALS AND METHODS

The present study was undertaken in a tertiary care hospital as a prospective, randomized, double-blind study after approval by hospital ethics committee. A written informed consent was taken from all the patients participating in the study. A total of 120 adult patients of either sex, aged between 18 and 60 years, belonging to American Society of Anesthesiologists (ASA) physical status Class I and II, admitted in an orthopedic ward with femur fractures were randomly divided into three groups. The patients in Group I (control) received 39ml of 0.25% bupivacaine + 1 ml of normal saline, in Group II received 39 ml of 0.25% bupivacaine + 50 μg of clonidine diluted to 1 ml, and in Group III received 39 ml of 0.25% bupivacaine + 100 μg clonidine diluted to 1 ml. The total volume of drug used in all the three groups was 40 ml. Clonidine was measured in an insulin syringe. The anesthesiologist preparing the drug was not involved in patient care, and the patients were also blinded to the group they were in. Patients having an allergy to local anesthetics, infection at the injection site, bleeding diathesis, having systemic coexisting diseases predisposing to altered sensation such as diabetes mellitus and neuropathies and having any contraindication to regional anesthesia were excluded from the study.

A thorough preanesthetic evaluation including baseline relevant investigations was done before surgery. During preanesthetic evaluation, patients were explained about visual analog scale (VAS) and about its use as a tool for measuring pain which consisted of 100 millimeters line with "0" equaling no pain at all and, "10" being worst pain. Patients were also explained about the procedure of fascia iliaca compartment block, the drugs being used and the possible side effects. Patients were kept nil orally 6 h before surgery. Patients were not premedicated to avoid any bias. After being shifted to operation theater baseline, vital parameters comprising heart rate (HR), systolic and diastolic blood pressure (SBP/DBP), peripheral oxygen saturation (SpO_2), and respiratory rate (RR) were recorded. Intravenous access was secured with 18G cannula and patient was preloaded with 10 ml/kg of ringer lactate. The patient was placed supine on the OT table under proper illumination. Under all aseptic precautions, fascia iliaca compartment block was performed using landmark technique as described by Dalens *et al.*[4]

The landmark of this technique was a line drawn between the anterior superior iliac spine and the pubic tubercle along the deep inguinal ligament. The site of needle insertion is 1 cm below the junction of lateral one-third and medial two-third of this line. 23 G short beveled needle was inserted vertically till 2 pops were appreciated - the first pop and the second pop occurred when fascia iliaca and fascia lata were pierced, respectively. After negative aspiration, 40 ml of the prepared drug was injected, and the injected area massaged to ensure adequate spread.

After the block, vital parameters such as HR, SBP, DBP, RR, and SpO_2 were monitored every 5 min for initial 20 min and then every 30 min intraoperatively and later at 4 h, 8 h, 12 h, and 16 h. Analgesia was assessed by VAS scale at 1 h, 2 h, 6 h, 12 h, and 24 h. The onset of analgesia was defined as the time taken from injecting drug for fascia iliaca compartment block to VAS <3 to pinprick sensation at the cutaneous distribution of femoral nerve and lateral cutaneous nerve of thigh. The duration of analgesia was defined from time of giving block to the first request for rescue analgesic. For rescue analgesia, tramadol 100 mg was given intravenously. The patient satisfaction during positioning for spinal anesthesia was graded as satisfactory or non-satisfactory.

Patients were observed for any possible side effects such as nausea, vomiting, hypotension (defined as SBP <90 mm of Hg), sedation, bradycardia (defined as HR <50/min), and local anesthetic toxicity. All observations were collected by an anesthesiologist who was blinded to group allocation.

The collected data were analyzed using Statistical Package of the Social Sciences software version 20. The normally distributed variables were analyzed using student's *t*-test, categorical variable using Fischer's exact *t*-test, or Chi-square test. Analysis of variance was used to determine any statistically significant difference in means of two or more groups. $P < 0.05$ was considered statistically significant.

For sample size calculation, we assumed an alpha error of 5% and dropout rate at 10%. The power of the study was kept at 90%. Therefore, to achieve an effect size of at least 30% in VAS scores, the sample size was selected as 40 in each group.

The primary outcome of our study was to see the effect of the combination of clonidine and bupivacaine on duration and quality of analgesia. The secondary outcomes were pain scores, hemodynamic parameters, patient satisfaction during positioning for spinal anesthesia and adverse effects.

RESULTS

There are no significant differences in the demographic profile of patients in three groups. [Table 1].

The mean age of patients in Group I was 52 ± 11.1, Group II was 50 ± 13.2, and Group III was 49 ± 12.4 years. There were 28 males and 12 females in Group I, 30 males and 10 females in Group II, and 26 males and 14 females in Group III. The mean height of patients in Group I was 165 ± 4.8, in Group II was 163 ± 5.1, and in Group III was 166 ± 4.2 cm. The mean weight of patients in three groups was also comparable - 66 ± 6.2 kg in Group I, 68 ± 5.9 kg in Group II, and 65 ± 7.7 kg in Group III. There was no significant intergroup variation regarding ASA physical status.

The baseline VAS scores in the three groups were comparable. At 12 h, the mean VAS score of Group I was 6.8 ± 0.26, Group II was 4.2 ± 0.32, and 4.0 ± 0.28 Group III. At 24 h, the mean VAS score was 8.12 ± 0.30 in Group I, 5.8 ± 0.12 in Group II, and 5.6 ± 0.9 in Group III. The difference in mean VAS score between Group I and rest of the groups was highly significant ($P < 0.05$), while there was no statistically significant difference between Group II and Group III [Table 2].

The time for onset of analgesia in Group I was 20.5 ± 2.2, 16.8 ± 2.6 in Group II, and 15.9 ± 2.0 in Group III. The difference in onset of analgesia between Group II and Group III was not significant. The mean duration of analgesia in Group I was 5.4 ± 0.6 h, 11.5 ± 0.3 h in Group II, and 16 ± 0.4 in Group III. The difference between the groups was statistically significant. The total number of rescue analgesics consumed in Group I was 4.5 ± 0.5, 3.2 ± 0.8 in Group II, and 2.8 ± 0.7 in Group III. The difference between Group I and the clonidine groups was statistically significant while the difference in Group II and Group III was not statistically significant [Table 3].

The patient satisfaction during positioning for spinal anesthesia after the fascia iliaca compartment block was satisfactory in 30 patients in Group I, 34 patients in Group II, and 35 patients in Group III which was not significant statistically [Table 4].

There was no statistically significant difference among hemodynamic parameters, RR, and oxygen saturation.

The side effects were noted in all the three groups. No patient reported nausea/vomiting or respiratory depression or local anesthetic toxicity. Hypotension occurred in 1 patient in Group I, 2 patients in Group II, and 4 patients in Group III which was statistically not significant. Bradycardia occurred in 3 patients in Group III which was statistically significant, 2 patients in Group II and 3 patients in Group III were sedated which was statistically significant when compared between Group I and Group III [Table 5].

Table 1: Demographic profile

Parameter	Group I	Group II	Group III
Age (years)	52±11.1	50±13.2	49±12.4
Sex (M/F)	28/12	30/10	26/14
Height (cm)	165±4.8	163±5.1	166±4.2
Weight (kg)	66±6.2	68±5.9	65±7.7

Table 2: VAS score

Time (h)	Group 1	Group II	Group III
Baseline	7.9±1.2	8.32±0.9	8.0±1.4
2	4.6±2.0	3.5±1.0	3.3±0.42
4	4.5±0.4	3.62±0.29	3.56±0.32
6	4.5±0.39	3.8±0.34	3.6±0.22
12	6.8±0.26	4.2±0.32	4.0±0.28
24	8.12±0.30	5.8±0.12	5.6±0.9

VAS: Visual analog scale

Table 3: Analgesia assessment

Parameters	Group I	Group II	Group III
Onset of analgesia (min)	20.5±2.2	16.8±2.6	15.9±2.0
Duration of analgesia (h)	5.4±0.6	11.5±0.3	16±0.4
No. of rescue analgesics in 24 h	4.5±0.5	3.2±0.8	2.8±0.7

Table 4: Patient satisfaction during positioning for spinal anesthesia

Parameters	Group I	Group II	Group III
Satisfactory	30	34	35
Non satisfactory	10	06	05

Table 5: Adverse effects

Parameters	Group I	Group II	Group III
Nausea/vomiting	0	0	0
Hypotension	1	2	4
Bradycardia	0	0	3
Sedation	0	2	5
Respiratory depression	0	0	0
Local anesthetic toxicity	0	0	0

DISCUSSION

Fascia iliaca compartment block was first described by Dalen *et al.*, in children for hip surgeries, femur fractures, and treatment of burns on thigh.[4] It has been found to be a very easy, safe bedside procedure as the site of injection is far from the neurovascular bundle.[6]

Femoral fractures are extremely painful, and analgesia is mainly by systemic administration of nonsteroidal anti-inflammatory drugs or opioids as per the local institutional protocol. A study demonstrated that of all patients presenting to the emergency department of a hospital, 36% received no analgesia, 7% received nonopioids, and rest 57% received opioids.[7]

We intended to use fascia iliaca compartment block by anatomical landmark technique to such patients and assess pain relief with bupivacaine alone or bupivacaine with clonidine in two different doses. Clonidine, a centrally acting α2 agonist, causes peripheral effects through inhibition of the hyperpolarization-activated cation current (I_h current) especially on C-fibers (pain fibers) than A∝-fibers (motor fibers), resulting in more sensory blockade.[8]

The baseline VAS scores in all the groups were similar. There was a significant reduction in VAS scores in patients receiving fascia iliaca compartment block. The reduction was more significant in the clonidine groups (mean VAS score was 4.2 ± 0.32 in Group II and 4.0 ± 0.28 in Group III) where VAS scores remained <5 even at 12 h of giving block. Similar results were documented in a study done by Tomar *et al.* where they found lower VAS scores till 24 h in clonidine groups.[9] We conducted this study with same doses and drug composition but the sample size was doubled, and the block was given specifically to femur fracture patients.

The onset of analgesia was significantly reduced in clonidine groups as compared to the control group. The difference in onset time between Group II and Group III was not statistically significant. Clonidine is known to shorten the onset of action of local anesthetic by its effect on descending noradrenergic tract in the spinal cord which plays an important role in pain modulation.[10]

The duration of analgesia was also prolonged in clonidine groups. Group I patients who received only bupivacaine were pain-free for 5.4 ± 0.6 h. Patients who received clonidine had a significant extended duration of analgesia - 11.5 ± 0.3 h in Group II and 16 ± 0.4 h in Group III. The average number of rescue analgesics used in 24 h in Group I was 5.5 ± 0.5 which was significantly higher than that consumed in clonidine groups (3.2 ± 0.8 in Group II and 2.8 ± 0.7 in Group III). This shows that clonidine prolongs the duration of analgesia and hence consumption of rescue analgesics was also reduced. Monzon *et al.* also found prolongation of the duration of analgesia up to 8 h after single shot fascia iliaca compartment block.[11] The analgesic action of clonidine in combination with local anesthetic agents for the peripheral neuraxial block has been widely accepted.[12,13]

We also evaluated patient satisfaction during positioning for spinal anesthesia and found that there was no intergroup statistically significant difference among all the groups signifying that fascia iliaca compartment block significantly reduces pain during positioning. Candal-cauto *et al.* also demonstrated that fascia iliaca compartment block causes femoral neck fracture patients to tolerate sitting position which they assessed using an objective sitting score.[14]

Patients were observed for any side effects. None of the patients in any group had any nausea and vomiting or respiratory depression or any features of local anesthetic toxicity. Patients in Group III demonstrated increased incidence of hypotension, bradycardia, and sedation. This can be attributed to a higher dose of clonidine used.

A major limitation of our study was that we did not use ultrasound-guided block technique as there was no availability of ultrasound machine at our center. We also did not study dose-response relationship of clonidine to find out the lowest possible dose of clonidine which would increase the duration of analgesia without causing any systemic side effects.

CONCLUSION

We conclude that fascia iliaca compartment block is a very safe, easy to perform bedside pre-operative block for femur fracture patients. Addition of even a small dose of 50 μg clonidine increased the duration of analgesia without significant side effects while 100 μg clonidine was associated with increased sedation and bradycardia. We recommend the use of 50 μg clonidine as an adjuvant to bupivacaine in fascia iliaca compartment block for femoral fracture patients as a component to multimodal analgesic approach for effective pain relief.

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Original Article

Comparative Study of Serum Ferritin and Lipid Profiles (Serum Cholesterol, High-density Lipoprotein, and Low-density Lipoprotein) Between Normal Population and Patients Suffering from Cholelithiasis

Renuka Sharma[1], R KSharma[1], Money Gupta [1], Vishal Mandial[1], K S Jaswal [1], Harpreet Kaur[2]

[1]Associate Professor, Department of General Surgery, Maharishi Markandeshwar Medical College and Hospital, Kumarhatti, Solan, Himachal Pradesh, India, [2]Assistant Professor, Department of Biochemistry, Maharishi Markandeshwar Medical College and Hospital, Kumarhatti, Solan, Himachal Pradesh, India

Abstract

Background: Calculous biliary disease by far, the most common pathology involving the gallbladder (GB) and biliary tree. The basic pathophysiology of gallstone (GS) formation is a complex interplay of supersaturation of secreted bile, concentration of bile in the gallbladder, crystal nucleation, and GB dysmotility. Thus, high concentrations of cholesterol and lipid in bile secretions from the liver predispose to cholesterol stone formation, whereas increased hemoglobin catabolism leads to pigment stone formation. The lipid profiles of patients with GS disease its implication have already been reported in the literature; however, the effect of patient iron profile and its association with GS disease has not been much evaluated so far; thus, we planned this prospective study to assess the iron status of patients of GS disease and compare it with normal population.

Aims and Objectives: The objective of the study was to compare the levels of serum ferritin and serum cholesterol, low-density lipoprotein, and high-density lipoprotein between normal population and patients suffering from GS disease.

Materials and Methods: The prospective study was conducted over a period of 12 months in the Department of General Surgery, Maharishi Markandeshwar Medical College and Hospital, Kumarhatti, Solan, Himachal Pradesh, India. A total of 100 subjects, 50 patients suffering from cholelithiasis admitted and confirmed by ultrasonography and 50 healthy volunteers as the control group, were included in this study.

Summary and Conclusion: Low serum iron level in one or the other way was leading to bile supersaturation with respect to cholesterol, which leads to GS formation. Serum ferritin levels were significantly lower in iron-deficient patient; however, as its value can vary due to other causes such as iron therapy, hepatocellular disease, and inflammations (since cholecystitis is an inflammatory condition, this could be the reason for the high level of serum ferritin) hence cannot be taken as sole diagnostic marker for iron deficiency anemia and indicator of GS disease.

Key words: Biliary tree, Cholelithiasis, Hemoglobin

INTRODUCTION

Calculous biliary disease by far, the most common pathology[1-3] involving the gallbladder (GB) and biliary tree. GB concentrates bile; however, the concentration of solutes in the GB differs from that in the rest of the biliary tree. This increase in solute concentration[4] combined with stasis in the GB between meals predisposes to stone formation in the gallbladder. GS can be subclassified into two major subtypes, based on the major solute component of the stone. Majority of >70% of GSs in the United States of America[5] are reported as combination of cholesterol and calcium, whereas pure cholesterol stones are only found in a small fraction of <10% patients. Pigment stones can be further subclassified as black or brownstones due to

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Corresponding Author: Dr. Renuka Sharma, Department of General Surgery, Maharishi Markandeshwar Medical College and Hospital, Kumarhatti, Solan, Himachal Pradesh, India. Phone: +91-8350800452. E-mail: rerrsdoc@gmail.com

precipitation of concentrated bile pigments, the breakdown products of hemoglobin. The basic pathophysiology of GS formation[6,7] is a complex interplay of supersaturation of secreted bile, concentration of bile in the gallbladder, crystal nucleation, and GB dysmotility. Thus, high concentrations of cholesterol and lipid in bile secretions from the liver predispose to cholesterol stone formation, whereas increased hemoglobin catabolism leads to pigment stone formation. The lipid profiles of patients with GS disease its implication have already been reported in the literature; however, the effect of patient iron profile[8,9] and its association with GS disease has not been much evaluated so far; thus, we planned this prospective study to assess the iron status of patients of GS disease and compare it with normal population. Since serum ferritin is a good marker of body iron stores, hence, we included it along with lipid profile of the study subjects and controls for our study.

Aims and Objectives

The objective of the study was to compare the levels of serum ferritin and serum cholesterol, low-density lipoprotein (LDL), and high-density lipoprotein (HDL) between normal population and patients suffering from GS disease.

MATERIALS AND METHODS

The prospective study was conducted over a period of 1 year (January 2017–December 2017) in the Department of General Surgery, Maharishi Markandeshwar Medical College and Hospital, Kumarhatti, Solan, Himachal Pradesh, India. A total of 100 subjects, 50 patients suffering from cholelithiasis admitted and confirmed by ultrasonography and 50 healthy volunteers as the control group, were included in this study after obtaining a written and informed consent. The Normal reference values in our lab are shown in Table 2.

Inclusion Criteria

All patients suffering from cholelithiasis confirmed by ultrasonography were included in this study and willing to participate in the study.

Exclusion Criteria

Patients not willing to participate and having following disorders/disease were not included: Hematological disorders, cirrhosis of liver, and pregnant females.

Based on the hemoglobin of the patients, all cases were divided into two groups: Non-anemic (i.e., hemoglobin >13 g% in males and >12 g% in females) and anemic (i.e., hemoglobin ≤13 in males and <12 in females). Serum cholesterol, LDL, HDL, and ferritin contents of both groups were compared with each other and the control group.

Observations

Out of fifty patients of GS disease during the Study period from April 2017 to March 2018, 40 (80%) were female and 10 (20%) were male patients. The mean age in the study group (GS s present) was 37.5 years (range 22–57 years) for males and 33.5 (range 25–65 years) for females. It was 33.5 years (18–65) for the control group of healthy volunteers. Both groups were comparable as far as age distribution was considered. 12% males and 48% females in the study group were anemic, whereas 32% of the control group subjects were anemic, of which two-third was female. The overall serum ferritin was low in female patients, both in anemic (n = 24.17 ± 5 [9–55]) and non-anemic (n = 16, 27 ± 5 [19–135]) subjects as compared to their male counterparts as shown in Table 1. Serum ferritin in control group anemic subjects was comparable (15 ± 4 [10–66]) to the study group; however, it was higher in non-anemic males (57 ± 18 [25–260]) in study group and non-anemic (52 ± 16 [26–272]) control group subjects. The serum ferritin levels were lowest in anemic female patients and significantly lower than (P < 0.05; Table 1) the other two groups (non-anemic patients and controls). The lipid profile of anemic female patients (serum cholesterol - 219 ± 28 [163–369]; serum LDL - 128 ± 23 [102–267]; and serum HDL - 28 ± 9 [27–63]) was significantly (P < 0.05) higher than the non-anemic female patients and the male patients in Table 1.

Table 1: Lipid and serum ferritin profile of study and control groups

Patient and Lab parameters	Males=10	Non-anemic *n*=4	Females *n*=40	Non-anemic *n*=16	Controls *n*=50	Anemic *n*=16 (Hb<12 g/dl) M=4, F=12
	Anemic *n*=6 (Hb<13 g/dl)		Anemic *n*=24 Hb<12 g/dl)		Non-anemic *n*=34 M=30, F=4	
Age range (in years)	40±10 (30–55)	35±12 (22–57)	40±15 (25–45)	45±12 (35–65)	39±20 (32–67)	28±12 (18–40)
Serum ferritin (ng/ml)	37±15 (20–160)¥	57±18 (25–260)	17±5 (9–55)¥	27±5 (19–135)	52±16 (26–272)¥	15±4 (10–66)
Serum cholesterol (mg/dl)	195±25 (180–279)§	185±35 (160–236)	219±28 (163–369)§	205±17 (180–279)	176±42 (163–212)§	201±25 (174–320)
Serum LDL (mg/dl)	98±25 (72–167)§	108±18 (92–197)	128±23 (102–267)§	115±21 (84–193)	103±17 (77–172)§	124±24 (101–256)
Serum HDL (mg/dl)	38±5 (28–76)	26±8 (22–67)	28±9 (27–63)	35±12 (27–98)	52±15 (35–82)	38±9 (24–69)

¥P≤0.05, §P≤0.05. HDL: High-density lipoprotein, LDL: Low-density lipoprotein

Table 2: Normal laboratory values for the assessed parameters are as below

Lab parameter	Males	Females
Hemoglobin (g/dl)	13	12
Ferritin (ng/ml)	22–322	10–29
Cholesterol (mg/dl)	0–200	0–200
LDL (mg/dl)	60–130	60–130
HDL (mg/dl)	30–80	30–80

HDL: High-density lipoprotein, LDL: Low-density lipoprotein

DISCUSSION

Our results revealed a higher frequency of GSs in female patients with iron deficiency anemia (IDA) than in the control subjects. In animal studies, it has been observed that iron-deficient diets alter hepatic enzyme metabolism which results in a higher level of GB bile cholesterol levels, thereby promoting the formation of cholesterol crystals.[4,5] We were unable to analyze the biochemical constituents of GS in our patients. Nevertheless, studies[8,9] from our country reported that the most frequent type of GS was cholesterol GS which is similar to the situation in western countries. The three main factors which play roles in the formation of cholesterol GS are supersaturation of bile with cholesterol, hypersecretion of mucin from GB mucosa and crystal nucleation, and GB hypomotility.[6,7] In many studies, GSs were found to be more prevalent in females.[10,11] Our study, similarly, found a higher frequency of GS in female IDA patients, although this was not significant (11.4%). Various studies claimed that this condition was mediated through the effects of estrogens and/or progesterone on bile saturation.[1,5] Pregnancy is one of the factors which is held responsible for GS formation in females.[2] Nevertheless, the number of pregnancies in our IDA and control groups was similar. There was a trend toward a higher frequency of GS in male IDA subjects (12%). However, the number of male IDA patients was not high enough. Studies about the prevalence of GS in the normal population reported that age was an important risk factor for GS development.[1,2] The median age of our IDA patients with GS was higher. It was also claimed that diabetes and chronic liver disease were associated with GS. The results of our study did not reveal a significant role for diabetes in GS formation in IDA patients. Elevated serum triglyceride and decreased HDL levels are also risk factors for GS formation.[12-14] Obesity is another well-known risk factor for the formation of GS.[2] In our study, we found a statistically significant association between lipids, obesity, and GS formation as the levels were significantly higher in females as compared to the males and control population. The innervation of the GB is mainly supplied by the autonomic nervous system; and parasympathetic innervation from the vagus nerve and sympathetic innervation from the splanchnic nerves are also provided to the GB.[15] GB stasis and difficulty in emptying are factors gaining increasing importance because they might predispose to GS formation.[16] This mechanism is probably responsible in conditions such as diabetes mellitus, hyperglycemia, pregnancy, progesterone usage, and total parenteral nutrition.[17,18] Iron is known to have an important role in hepatic enzyme metabolism.[19] Iron-containing cofactors are fundamental components of the nitric oxide (NO) synthase complex.[20] NO acts as a putative inhibitory neurotransmitter and it is present throughout the gastrointestinal system.[21] In addition, it has been demonstrated in prairie dogs that NO is an important for maintenance of basal GB tone and that it acted as an inhibitor of the contractile response of the GB to physiologic stimulators.[15] In iron deficiency, there is diminished GB neuronal NO synthase which results in altered biliary motility without affecting the hepatic metabolism of cholesterol[4] and contributes to GB stasis.[5] In addition, the motilities of GB and sphincter of Oddi are suppressed acutely in iron deficiency because of decreased neuronal NO synthase levels, and compensatory mechanisms return neuronal NO synthase to baseline levels while cholesterol crystal formation increases over time.[6] NO synthase was demonstrated to be present in neurons of the GB in humans.[20] Nevertheless, the effect of iron deficiency on NO synthase in humans has not been studied yet. In our study, we found that the GB dysmotility observed in iron-deficient animals was present also in humans. Although it is difficult to explain the mechanism exactly, the higher frequency of GS in our IDA patients might be a result of the tendency to impaired GB motility. One of the limitations of our study was that the number of patients, especially that of males, was not much. Another limitation of our study was that we were unable to perform the biochemical analysis of the constituents of GS. The design of our study was cross-sectional; therefore, cholecystectomy and analysis of GS were not undertaken in our IDA patients with GS. As a result, we found a significantly increased prevalence of GS in our IDA patients. Impaired GB emptying in these patients might have contributed to the higher frequency of GS in IDA.

CONCLUSION

In the present prospective study of 100 cases, the following conclusions were drawn. Serum lipid profile of female patients with cholelithiasis was significantly higher and lower ferritin levels than the males and general population. The low serum iron level in one or the other way could have contributed to bile supersaturation with respect to cholesterol and GS formation. However, serum ferritin cannot be taken as a sole diagnostic tool in the diagnosis of

IDA as its value can vary due to other causes such as iron therapy, hepatocellular disease, and inflammations (since cholecystitis is an inflammatory condition, this could be the reason for the high level of serum ferritin).

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Original Article

Evaluation of the Efficacy of Endoscopic Hemostasis with Argon Plasma Coagulation Plus Injection Sclerotherapy and Injection Sclerotherapy Alone in Acute Non-variceal Upper Gastrointestinal Bleeding

Arshied Hussain Bhat[1], T Masood[2], Bilal Ahmad Khan[3], Showkat A Kadla[4]

[1]Clinical Registrar, Department of Medicine, Government Medical College, Srinagar, Jammu and Kashmir, India, [2]Professor, Department of Medicine, Government Medical College, Srinagar, Jammu and Kashmir, India, [3]Consultant, Department of Gastroenterology and Hepatology, Government Medical College, Srinagar, Jammu and Kashmir, India, [4]Professor and Head, Department of Gastroenterology and Hepatology, Government Medical College, Srinagar, Jammu and Kashmir, India

Abstract

Background: This study aims to evaluate the efficacy of endoscopic hemostasis with argon plasma coagulation (APC) plus injection sclerotherapy and injection sclerotherapy alone in acute non-variceal upper gastrointestinal (UGI) bleeding.

Materials and Methods: A prospective, randomized, hospital-based study of 100 subjects divided into two groups of A and B of 50 each, comprising those who received injection sclerotherapy alone and those who received APC in addition.

Results: About 94% patients in Group B had no rebleeding, compared to 76% in Group A carrying high statistical significance (Chi-square 5.563 and p 0.135). Majority of cases (6%) with rebleeding belonged to Forrest Class Ib from Group A. Mortality was more in Group A (4%) compared to Group B (2%). There were 11 (22%) patients in our study who rebled in the 1st week, 3 (6%) rebled in the 2nd week, and 1 (2%) rebled in the 3rd week. In our study, the patients who died had Rockall risk scoring system >6.

Conclusion: Injection sclerotherapy supplemented with APC is superior to injection therapy alone in the endoscopic treatments of non-variceal bleeding.

Key words: Argon plasma coagulation, Endoscopy, Hemostasis, Non-variceal bleeding, Sclerotherapy

INTRODUCTION

Upper gastrointestinal (UGI) bleeding represents a substantial clinical and economic burden, with reported incidence ranging from 48 to 160 cases/100,000 per year[1,2] with mortality of 10–14%.[3] The efficacy and safety of commonly used endoscopic hemostatic techniques have been reported, and early endoscopic intervention reduces the chances of rebleeding and has become the treatment of choice.[4-7] The injection therapy is easy to use, safe, and cheap but carries potential risk of perforation.[8,9] This has a transient effect and may have cardiovascular risk when large volume is increased.[10] Argon plasma coagulation (APC) is a special procedure of contact-free electrocoagulation in which energy is transmitted to the tissue through ionized conductive argon gas.[11-16] There is little evidence that addition of other agents like sclerosants reduce the rate of rebleeding, and the use of these agents may cause life-threatening necrosis of the infectious sites.[17,18] A single-center study from Srinagar showed that ulcer bleeding patients receiving high dose oral omeprazole therapy rebled less often and required less blood transfusions compared to controls.[19]

We conducted the present study with the aim of evaluating efficacy of endoscopic hemostasis with APC plus injection

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Corresponding Author: Dr. Arshied Hussain Bhat, Department of Medicine, Government Medical College, Srinagar – 190 010, Jammu and Kashmir, India. E-mail: drarshidbhat2014@gmail.com

sclerotherapy and injection sclerotherapy alone in acute non-variceal UGI bleeding.

MATERIALS AND METHODS

This prospective, randomized, and controlled trial was conducted in the Postgraduate Department of Medicine at the Government Medical College, Srinagar - a tertiary center of Jammu and Kashmir. The study included 100 patients. They were categorized into two groups of 50 subjects each: Those who received injection sclerotherapy and APC. All the patients admitted to the emergency department presenting with hematemesis, melena, or both were taken up for UGI endoscopy with 24 h of presentation/admission. Informed consent was obtained from each study subject for the therapeutic endoscopic intervention. Patients having variceal bleed, clearly malignant ulcers, Dieulafoy's lesion, or Mallory-Weiss tear were excluded from the study. Randomization of patients with two groups of A and B of 50 subjects each was done by sealed number envelopes. Group A received injectable epinephrine, 4–10 ml of 1:10,000 dilution around the ulcer. Subjects of the Group B received epinephrine injection as in Group A plus APC around the ulcer. Forrest classification[20] was used for the endoscopic grading of lesions and also Rockall risk scoring system was applied.

Patients were followed weekly for next 4 weeks after initial hemostasis to monitor the bleeding. During stay at home, patients were contacted telephonically for rebleeding in the form of hematemesis, melena, or both and were advised to contact the nearest hospital for immediate resuscitation, preferable our center. The efficacy of endoscopic hemostasis in both groups was assessed.

Statistical Analysis

The analysis was conducted by experienced statistician using Statistical Package for the Social Sciences (SPSS, Ver. 20). Continuous data were expressed as mean ± standard deviation and categorical data as percentage. Chi-square test was used wherever necessary and $P < 0.05$ was considered statistically significant.

RESULTS

Of 100 study subjects, 88% were male. Among the subjects of Group A, 20% had comorbid illness such as chronic obstructive pulmonary disease (5%), hypertension and chronic kidney disease (5%), cardiovascular disease (7%), and hypertension (16%) and subjects of Group B had comorbid illnesses. Majority of subjects belonged to Forrest Class IIa [Table 1] carrying high statistical significance (Chi-square 2.938; $P = 0.401$). Duodenal ulcer was the most common site (Group A, 74%; Group B, 66%), followed by gastric (20% and 28%) and prepyloric ulcer (2% vs. 4%) among the two groups. In our study, in Group A, 39 (78%) patients were having Rockall's score of 3, 1 (2%) having Rockall's score of 5, 7 (14%) having Rockall's score of 6, 2 (4%) having 7 Rockall's score, 1 (2%) having 8 Rockall's score Table 3. In Group B, 40 (80%) were having Rockall's score of 3, 2 (4%) having Rockall's score of 5, 5 (10%) were having Rockall's score of 6, 1 (2%) having Rockall's score of 7, 2 (4%) having Rockall's score of 8 Figure 1. Mortality was more in Group A compared to Group B (8% vs. 2%) that was statistically high significant ($P < 0.0001$). Mortality was more observed in subjects belonging to Forrest Ib. In both groups, patients who underwent surgery had Rockall score of 3.

Table 1: Forrest classification of the study population

Forrest classification		Group		Total
		Injection sclerotherapy	Injection sclerotherapy+APC	
I a	*n* (%)	1 (2.0)	2 (4.0)	3 (3.0)
I b	*n* (%)	20 (40.0)	21 (42.0)	41 (41.0)
II a	*n* (%)	19 (38.0)	12 (24.0)	31 (31.0)
II b	*n* (%)	10 (20.0)	15 (30.0)	25 (25.0)
Total	*n* (%)	50 (100.0)	50 (100.0)	100 (100.0)

Chi-square=2.938; *P*=0.401. APC: Argon plasma coagulation

Table 2: Mortality with respect to Forrest classification in both groups

Forrest classification		Mortality			
		Group A		Group B	
		Yes	No	Yes	No
I a	*n* (%)	0 (0)	1 (2)	0 (0)	2 (4)
I b	*n* (%)	2 (4)	18 (36)	1 (2)	20 (40)
II a	*n* (%)	1 (2)	18 (36)	0 (0)	12 (24)
II b	*n* (%)	1 (2)	9 (18)	0 (0)	15 (30)
		Chi-square = 0.443; *P*=0.931		Chi-square = 1.409; *P*=0.703	

Table 2 in group A, the patients who died, 2 (4%) patients were having Forrest Ib classification, 1 (2%) patients was having Forrest IIa, 1 (2%) patient was having Forrest IIb classification. In group B, the patient who died was having Forrest Ib classification.

Table 4 in group A, the patients who died, 1 (2%) patient was having Rockall's score of 6, 2 (4%) patients were having Rockall's score of 7 and 1 (2%) patient was having Rockall's score of 8. In group B, the patient who died was having Rockall's score of 8.

Table 5 in group A, 10 (20%) patients were having comorbid illness and out of which 4 died. In group B, 8 (16%) patients were having comorbid illness out of which 1 patient died.

Table 6 in our study, 11 (22%) patients rebled in first week, 3 (6%) patients rebled in second week and 1 (2%) rebled in third week.

DISCUSSION

Up to 80% of duodenal ulcers and 50% gastric ulcers are due to *Helicobacter pylori*.[21] Nonsteroidal anti-inflammatory agents are next in order. Although bleeding stops spontaneously in 80% of cases, 20% will still have

Table 3: Rockall score of the study population

Rockall score		Group		Total
		Injection sclerotherapy	Injection sclerotherapy+APC	
3	*n* (%)	39 (78.0)	40 (80.0)	79 (79.0)
5	*n* (%)	1 (2.0)	2 (4.0)	3 (3.0)
6	*n* (%)	7 (14.0)	5 (10.0)	12 (12.0)
7	*n* (%)	2 (4.0)	1 (2.0)	3 (3.0)
8	*n* (%)	1 (2.0)	2 (4.0)	3 (3.0)
Total	*n* (%)	50 (100.0)	50 (100.0)	100 (100.0)

Chi-square = 1.346; *P*=0.854. APC: Argon plasma coagulation

Table 4: Mortality with respect to Rockall score in studied subjects

Rockall score		Mortality			
		Group A		Group B	
		Yes	No	Yes	No.
3	*n* (%)	0 (0%)	39 (78)	0 (0)	40 (80)
5	*n* (%)	0 (0)	1 (2)	0 (0)	2 (4)
6	*n* (%)	1 (2)	6 (2)	0 (0)	5 (10)
7	*n* (%)	2 (4)	0 (0)	0 (0)	1 (2)
8	*n* (%)	1 (2)	0 (0)	1 (2)	1 (2)
		Chi-square = 6.42; *P*=0.040		Chi-square = 3.42; *P*=0.180	

Table 5: Mortality of patients in the studied groups with relation to comorbid illness

Group	Comorbid illness		Mortality	
			Yes	No
A	Yes (%)	10 (20)	4 (8)	6 (12)
	No (%)	40 (80)	0 (0)	40 (80)
B	Yes (%)	8 (16)	1 (2)	7 (14)
	No (%)	42 (84)	0 (0)	42 (84)

Chi-square = 17.39; *P* ≤ 0.0001 (Group A); Chi-square = 5.35; *P* = 0.021 (Group B)

Table 6: Profile of rebleeding

Follow-up		Group		Total
		Injection sclerotherapy	Injection sclerotherapy+APC	
Rebleeding	Number rebleeding (%)	38 (76.0)	47 (94)	85 (85.0)
Bleeding 1st week	*n* (%)	8 (16.0)	3 (6.0)	11 (11.0)
Bleeding 2nd week	*n* (%)	3 (6.0)	0 (0.0)	3 (3.0)
Bleeding 3rd week	*n* (%)	1 (2.0)	0 (0.0)	1 (1.0)
Total	*n* (%)	50 (100.0)	50 (100.0)	100 (100.0)

Chi-square=5.563; *P*=0.135. APC: Argon plasma coagulation

continuous bleeding.[22] Early endoscopic intervention reduces rebleeding and has become the treatment of choice.[7] Injection is easy to use, is cheaper but carries the risk of perforation.[8,9,23] Majority of our cases were males, in a similar way to observations of Longstretch and Feitelberg, where they found the UGI bleeding occurs more frequently with advanced age.[24] Data suggest that early endoscopy is safe and effective for all risk groups. A systemic review by Spiegel *et al.* observed no major complications in patients triaged to outpatient care after early endoscopy.[25] Previously, it was found that although pre-endoscopic proton-pump inhibitor therapy has not been shown to affect rebleeding surgery or mortality and has been found useful in those suspected of having high-risk stigmata.[26]

In our study, less chances of rebleeding and mortality were found in cases of Group B; however, opposites were the findings of Skok *et al.*[27] Chau *et al.* found that epinephrine injection plus APC is safe and effective in the treatment of patients with high risk of bleeding peptic ulcers.[28] In a similar way, previous studies have found APC a safe, quick, and effective method of treating non-variceal UGI bleeding and concluded that it can be a powerful tool for endoscopic hemostasis.[13,29,30] However, large sample studies are needed in future to widen the spectrum of these therapeutic modalities.

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Original Article

Smartphone Use among Healthcare Providers in Saudi Arabia: A Cross-sectional Study

Khalid A. Aljohani

Head of Community Health Nursing Faculty of Nursing, Taibah University, Prince Naïf Road, Madinah, Saudi Arabia

Abstract

Introduction: Distraction due to smartphone use in healthcare settings is a threat to patient safety. There are growing concerns regarding its negative impacts on health providers' performance and image.

Purpose: The aim of this study was to explore smartphone usage among healthcare providers in Saudi public hospitals with a focus on potential distractions and risks to patient safety.

Materials and Methods: A cross-sectional study using an electronic version of a validated instrument conducted in four hospitals of Al Madinah Region, Saudi Arabia. The study sample included nurses, physicians, and other healthcare providers working in main medical departments. Descriptive and bivariate analysis using SPSS (V.20) was applied.

Results: The response rate was acceptable at 86% (1290). A total of 56.20% of respondents used their smartphone during working hours. Respondents who received e-mails, sent e-mails, chatted, or watched video clips 20 times or less in the previous working day were 19.40%, 14.10%, 25%, and 13.70%, respectively. A total of 43.80% of respondents agreed that smartphone use distracted them from patient care, while 42.20% believed that these distractions harmed patients. The belief that smartphone use could harm patients was significantly associated with age (P = 0.001), nationality (P = 0.000), length of experience (P = 0.000), and current position (P = 0.032).

Conclusions: The patterns of smartphone utilization identified in this study pose a significant challenge to patient safety. Initiatives to reduce the negative consequences of smartphone use on patients' outcomes and health professionals' image are needed. Such efforts should not underestimate the role of smartphones in facilitating access of health professionals to updated medical knowledge and international clinical guidelines.

Key words: Distractions, Patient safety, Smartphone

INTRODUCTION

Distraction due to smartphone use is one of the top ten technology hazards in healthcare settings, as it may distract healthcare providers attention while performing medical procedures.[1] Regardless of the cause of healthcare providers' distraction, the consequences could bring serious harm to the patient.[2] For instance, using smartphones was found to decrease peripheral vision, which may lead to missing important medical signs.[3] Furthermore, the improper use of smartphones by healthcare providers during duty could raise professional concerns such as poor professional image due to using the phone in patient rooms.[4]

The literature reveals a growing concern with smartphone negative effects. Previous studies reported that almost 43% of nurses were distracted by their colleagues' smartphones, while 70% believed that using mobile phones during duty had consequences for patient care.[5] Furthermore, using smartphones contributed to nurses' inability to recognize critical patient and a higher probability of medical errors, which raises significant concerns regarding patient safety.[6,7] Additional concerns include breaching patients' confidentiality and microbial contamination.[8,9]

In general, healthcare providers use smartphones during duty hours to send text messages, read news, check social

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Corresponding Author: Faculty of Nursing, Taibah University, Prince Naïf Road, Madinah, Saudi Arabia. Phone: +96-6555313015. E-mail: kajohani@taibahu.edu.sa

networking sites, shop online, and play games; in addition, physicians also text orders to nurses.[4,5,7,10,11] A literature review revealed few studies investigating smartphone use in Saudi Arabia. Two studies examined smartphone adoption and utilization among university students.[12,13] From a healthcare perspective, smartphone usage among medical residents was investigated in one study on work-related smartphone usage.[14] To the best of the researcher knowledge, no studies have examined possible distractions and patient safety issues in relation to smartphone usage in the Saudi public healthcare system. Therefore, this study examined smartphone usage among healthcare providers in four hospitals of Al Madinah Region, Saudi Arabia.

MATERIALS AND METHODS

Study Design

This was a cross-sectional study.

Setting and Sample

The study was conducted in four hospitals in Al Madinah Region, Saudi Arabia. Health professionals, predominantly nurses, and physicians working in main departments (ER, critical areas, medical, and surgical) were included in the study sample. Interns and temporary staff were excluded from the study. The estimated target population in all study locations was about 3,422 healthcare providers.

Ethical Considerations

Ethical approval was granted by the health directorate of Al Madinah Province.

Measurement/Instruments

The study instrument was adapted from the tool developed by McBride, LeVasseur, and Dongmei.[10] The instrument included two parts: First, demographic data, and second, six questions investigating participant's smartphone utilization and potential risks to patient safety.

Data Collection/Procedures

Following ethical approval, the researcher conducted data collection in the four locations sequentially. Invitation posters explaining the study aim and providing a brief explanation of the previous literature and the link to the electronic questionnaire were posted in nurses' stations. Since there was no personal information collected on the electronic form and no traceable data, responding to the questionnaire was considered as participants' consent to participate in the study.

Data Analysis

Data were analyzed using SPSS (version 20). Descriptive statistics including frequencies and percentages were calculated, and bivariate analyses were performed to identify associations between the study variables.

RESULTS

A total of 1,290 healthcare providers were responded to the study questionnaire, resulting in a response rate of 86%. Table 1 presents the distribution of the respondents' characteristics. It was observed that most of the respondents were working at study location A, with 31.20%, followed by location B, with 26.20%, and only 16.90% at location C. The majority of the respondents were female (74.30%). In addition, most of the respondents were aged between 26 and 30 years (43%). Nurses, physicians, and other healthcare providers represented 79.50%, 10.50, and 10%, respectively.

A total of 56.20% of respondents used their smartphone during working hours [Table 2]. Regarding frequency of use, participants were asked to identify how many times they used their mobile phone during the last working day. Those who received e-mails, sent e-mails, chatted, and watched video clips 20 times or less were 19.40%, 14.10%, 25%, and 13.70%, respectively. A total of 43.80% of the respondents agreed that smartphone use distracted from patient care, while 42.20% believed that these distractions harmed patients. Participants were asked to identify the purpose of their daily use of smartphone [Figure 1]. Talking and listening to music were the most frequent

Table 1: Percentage distribution of the respondents' profile

Profile variables	*n* (%)
Workplace	
Study location A	403 (31.20)
Study location B	331 (25.70)
Study location C	218 (16.90)
Study location D	338 (26.20)
Gender	
Male	331 (25.70)
Female	959 (74.30)
Age (years)	
≤25	321 (24.90)
26–30	555 (43.00)
≥30	414 (32.10)
Nationality	
Saudi	721 (55.90)
Non-Saudi (Arab)	179 (13.90)
Non-Saudi (non-Arab)	390 (30.20)
Length of experience	
<2	319 (24.70)
2–5	413 (32.00)
>5	558 (43.30)
Current position	
Physician	135 (10.50)
Nurse	1026 (79.50)
Others	129 (10.00)

Table 2: Percentage distribution of the respondents' profile regarding smartphone

Variables	Frequency (%)
Have smartphone	
Yes	1079 (83.60)
No	211 (16.40)
Use smartphone during work	
Yes	841 (65.20)
No	449 (34.80)
During the last working shift, how many times did you: Received email	
1–20	250 (19.40)
≥21	1 (0.10)
Send email	
1–20	182 (14.10)
≥21	4 (0.40)
Received calls	
1–20	686 (53.20)
≥21	12 (1.00)
Initiate calls	
1–20	638 (49.50)
≥21	28 (2.2)
Send text/chat	
1–20	322 (25.00)
≥21	14 (1.00)
Watch video clips	
1–20	177 (13.70)
≥21	10 (0.80)
Smartphone distracted patient care	
Yes	565 (43.80)
No	725 (56.20)
Using smartphone harming patient	
Yes	545 (42.20)
No	745 (57.80)

with 33% and 24%, respectively. Searching, which could be explained as the need for medical related information, was identified as a purpose for 4%.

There were statistically significant associations between demographic and work characteristics and the belief that smartphone use caused distraction from patient care [Table 3]. However, workplace was not significantly associated with this belief. On the other hand, the belief that smartphone use could harm patients was significantly associated with age ($P = 0.001$), nationality ($P = 0.000$), length of experience ($P = 0.000$), and current position ($P = 0.032$).

DISCUSSION

There is no doubt that smartphones have become life essentials; however, their negative effects on healthcare services should be minimized. In the current study, a wide proportion of participants reported using their personal smartphone during working hours. E-mail was the dominant use of a smartphone during participants' last working day (30%), which may have various explanations. On the one hand, e-mails could have been work related, and on the other hand, they could have been personal. Regarding work e-mails, several studies showed a steady increase in smartphone applications in healthcare settings for clinical purposes, such as referrals and consultations,

Table 3: Association between the demographic profiles and smartphone distracted or harm patients' care

Demographic profile	Smartphone distracted patients' care		Smartphone somehow harming patient	
	X^2	*P*	X^2	*P*
Workplace	2.343	0.504	2.041	0.564
Gender	5.333	0.021	0.390	0.532
Age	9.703	0.008	15.168	0.001
Nationality	14.719	0.001	19.377	0.000
Length of experience	13.046	0.001	20.058	0.000
Current position	11.373	0.003	6.856	0.032

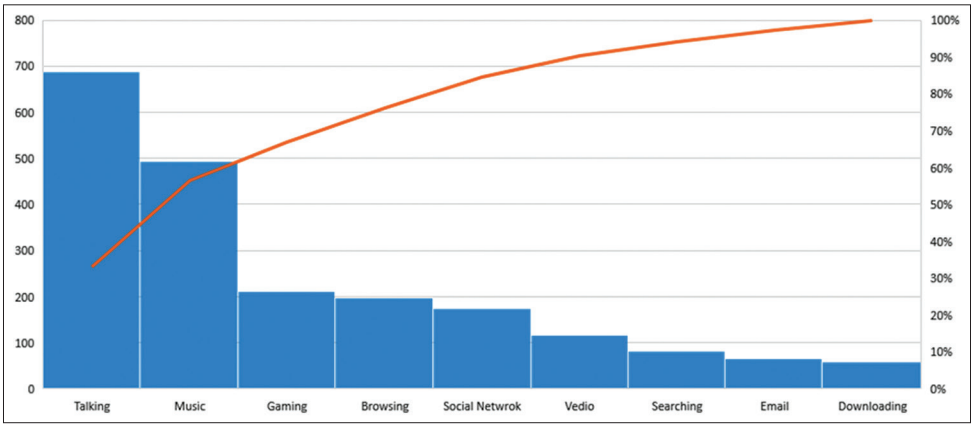

Figure 1: Rationales for daily use of smartphone during working hours

telemedicine, and requesting information.[10,14,15] The study instrument did not allow the researcher to identify the reason for sending/receiving e-mails during working hours, which is a limitation to be avoided in future studies.

As indicated in Figure 1, the main reason for everyday smartphone utilization during working hours was searching, which may suggest the role of smartphones in developing health professionals' knowledge and consulting clinical guidelines.[13] Health professionals in Saudi Arabia have the privilege to access several data engines supported by the Ministry of Health and Saudi Commission for Healthcare Specialties.

On the other hand, there was improper utilization of smartphones during working hours in activities such as social networking and gaming. These activities were evident in this study, which raises concerns about patient safety and an increased risk of distractions in clinical settings.[1,4] The proportion of gaming activities in the current study was identical to a study in the United States (6.50%). Therefore, this seems to be an international trend that healthcare organizations should manage by implementing international recommendations related to smartphone use during working hours.[10]

An important finding from the current study was that 43.80% of the respondents agreed that smartphone use distracted from patient care and 42.20% believed that these distractions harmed patients. These percentages were more than triple of those reported in an earlier study in the United States.[7] Moreover, this raised the alarm regarding the urgent need for smartphone use policies in healthcare organizations. Training to increase health professionals' awareness and compliance was positively associated with lower improper smartphone utilization.[11] In addition, future health professionals should gain awareness of and complete training on the negative consequences of smartphone utilization during patient care as part of the university curriculum.[16,17]

CONCLUSION

The patterns of smartphone utilization in Saudi public hospitals pose a significant challenge to patient safety. Policy and decision-makers and healthcare organizations should work together to reduce the negative consequences of smartphone use on patients' outcomes and health professionals' image. Such efforts should not underestimate the role of smartphones to facilitate the access of health professionals to updated medical knowledge and international clinical guidelines. Further studies are needed to explore the best use of smartphones and evidence-based interventions to decrease their potential harm to patients' outcomes.

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Original Article

Comparative Evaluation of Intrathecal Administration of Plain Ropivacaine and Bupivacaine in Patients Undergoing Lower Limb Surgeries

Hansraj Baghel[1], Arvind Kumar Rathiya[2], Avtar Singh Yadav[3]

[1]Assistant Professor, Department of Anaesthesia, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, [2]Associate Professor, Department of Anaesthesia, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, [3]Professor, Department of Anaesthesia, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

Abstract

Background: Central neuraxial blockade techniques are the most common and popular ones among various regional anesthetic techniques.

Aim: The aim of the study was to assess the efficacy of Bupivacaine 0.5% plain and Ropivacaine 0.5% plain through subarachnoid block for lower limb orthopedic surgeries.

Objectives: The objectives of the study were to compare the quality and duration of anesthesia and analgesia provided by Bupivacaine 0.5% plain and Ropivacaine 0.5% plain for subarachnoid block in lower limb orthopedic surgeries.

Materials and Methods: The present study was conducted in a prospective randomized manner on 50 patients of ASA Grade I and II patients in the age group of 20–50 years scheduled to undergo elective lower limb orthopedic surgeries.

Result: In our study, we found that no significant difference was found in onset and duration of sensory blockade between two groups. However, motor blockade was found of lesser duration with ropivacaine as compared to bupivacaine when used intrathecally. Furthermore, ropivacaine provided better hemodynamic stability.

Conclusion: We conclude that ropivacaine is a better alternative to bupivacaine when used intrathecally as it provides less duration of motor blockade and more hemodynamic stability.

Key words: Bupivacaine, Hemodynamic, Ropivacaine, Subarachanoid block

INTRODUCTION

There has been rapid improvement in the field of regional anesthesia in past few decades. The advantages of regional anesthetic techniques have been extensively studied with better anatomical understanding and rapid advances in local anesthetic pharmacology. Regional anesthesia has less side effects and fewer complications as compared to general anesthesia, so it is more popular for below umbilical surgeries nowadays.

Regional anesthesia can provide adequate anesthesia neither impairing the consciousness level of the patient nor abolishing the protective airway reflexes in contrast to general anesthetic techniques. Patients can also communicate with the anesthesiologist regarding their problems.

Central neuraxial blockade techniques are the most common and popular ones among various regional anesthetic techniques. It includes the subarachnoid block, the epidural block, and the caudal block.

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Corresponding Author: Dr. Arvind Kumar Rathiya, Department of Anaesthesiology, New Doctors Colony, Arjun Nagar, PTS Chouk Road, Rewa – 486 001, Madhya Pradesh, India. Phone: +91-8959949669. E-mail: arvind.rathiya@gmail.com

Subarachnoid block is probably the most widely used regional anesthetic procedure for below umbilical surgeries in routine clinical anesthesiology (Hinnerk FWW 1998). It provides rapid onset, consistent sensory blockade and adequate muscle relaxation for all types of surgery below the level of the umbilicus. This procedure is relatively easier, requires less equipment and very cost effective. Main disadvantages of the subarachnoid block are hypotension, lack of ability in precisely controlling the level and duration of block and risk of introduction of infection directly into the cerebrospinal fluid (Ronald D. Miller) Table 2.

Epidural block has the advantage to extend the block to desired level and duration. It causes lesser hypotension which is gradual in onset and easier to control. Patients remain hemodynamically more stable with this technique. This procedure is somewhat less popular compared to subarachnoid block due to some limitations with this procedure. More technical expertise is needed for this procedure, and the onset of block is somewhat slow and time consuming. Occasional patchy effect and sacral sparing can also occur. Inadvertent dura puncture with its own consequent problems may result.

Combined spinal epidural block is a time-tested regional anesthetic technique by which advantages of both subarachnoid block and epidural block can be summated, and disadvantages can be attenuated.

Newly introduced long-acting amide local anesthetics like Ropivacaine which is a pure "S" enantiomer of ropivacaine and levobupivacaine which is a levorotatory isomer of bupivacaine have been clinically used for various regional anesthetic procedures. The claimed benefits of reduced cardiovascular toxicity (Markham A, Faulds D [1996], McClellan K.J., Faulds D. [2000], McClellan K.J., Spencer C.M. [1998], Milligan K.R. [2004], Feldman HS, Arthur GR [1989] Gristwood RW *et al.* [2002] Susan E. Copeland *et al.* [2005] Stefania Leone *et al.* [2008]) has received differential comments from various workers. The advantages do not appear clinically significant when the single shot subarachnoid block is considered.

The difference in densities of the two available preparations is believed to affect their diffusion patterns and distribution after injection into the CSF in the subarachnoid space. The diffusion pattern determines the effectiveness, spread (dermatome height or block height), and side effect profile of bupivacaine.[1]

Hence, this study was designed to determine if ropivacaine really offered any added advantage over the time-tested drug Bupivacaine when used in the subarachnoid block in patients undergoing surgeries below the level of the umbilicus. Their quality of anesthesia, duration of onset of sensory and motor block, total duration of motor block, regression of sensory block, and associated hemodynamic parameters were recorded and analyzed.

Aims and Objectives

The objectives of the study are as follows:

1. To compare the quality and duration of anesthesia provided by Bupivacaine 0.5% plain and Ropivacaine 0.5% plain for subarachnoid block in lower limb orthopedic surgeries.
2. To compare the duration of post-operative analgesia among the two groups.
3. To evaluate and compare the side effects and complications associated among two groups.

MATERIALS AND METHODS

The present study was conducted in a prospective randomized manner on 50 patients of ASA Grade I and II patients in the age group of 20–50 years in the Department of Anaesthesiology, Shyam Shah Medical College and associated Sanjay Gandhi Memorial Hospital, Rewa, Madhya Pradhesh, India, scheduled to undergo elective lower limb orthopedic surgeries.

Selection Criteria

- Patients of age group 20–50 years of ASA I and II physical status.
- Patients of severe stenotic valvular heart disease or ventricular outflow obstruction, severe hypovolemia, severe hypotension, increased intracranial tension, coagulopathy or any other bleeding disorder, infection at the site of injection, and patient refusal for consent were excluded from our study.
- All patients were administered 500 ml ringer lactate solution. Baseline pulse rate, blood pressure, respiratory rate, SPO_2, and electrocardiogram (ECG) were recorded.
- The patients were randomly divided using envelope method into two groups of 25 each:

Group I: Received intrathecal 3 ml 0.5% isobaric Bupivacaine (15 mg).

Group II: Received intrathecal 3 ml 0.5% isobaric Ropivacaine (15 mg).

Continuous monitoring of HR, NIBP (Non invasive blood pressure Non invasive blood pressure), R/R, SPO_2, and ECG was done during intraoperative period and readings noted at regular intervals of 0, 5, 10, 15, 20, 25, 30, 45, 60, 120, 150, 180, 240, 300, 360, and 420 min. Onset of sensory blockade and motor blockade was noted in all the

patients. Determination of onset of sensory block was done by pinprick technique; while assessment of motor blockade was done using Bromage Scale.

Grade 0 - Able to raise the lower limb straight (straight leg raising test).

Grade I - Able to perform knee joint movement but not at the hip joint movement.

Grade II - Able to perform movement at ankle joint but neither at hip joint nor at the knee joint.

Grade III - Able to perform the movement, but unable to perform ankle, knee, and hip joint movement.

Grade IV - No movement at lower limb.

Post-operative H.R, NIBP, R/R, spO2, and ECG were observed till the requirement of first rescue analgesic dose. Duration of sensory and motor blockade was observed postoperatively, and duration of first rescue analgesia was noted in all the patients.

Patients were observed for side effects such as hypotension, bradycardia, respiratory depression, nausea/vomiting, tightness in chest, respiratory difficulty, and convulsions.

All statistical analysis was done using IBM SPSS ver.20. Observations were duly recorded, tabulated and then statistically analyzed by paired *t*-test between the groups. $P < 0.05$ was considered statistically significant.

RESULTS

All patients were demographically similar in regards to age, sex, and duration of surgery and it can be presumed that the groups were comparable for the purpose of the study.

In our present study, onset of sensory block took 6.36 ± 1.76 for 0.5% bupivacaine and 6.16 ± 1.72 for 0.5% ropivacaine and there was no intergroup significance ($P < 0.05$).

The time to achieve complete motor blockade (Modified Bromage Scale 1) was shorter in the bupivacaine group (11.50 ± 3.272) than the ropivacaine group (15.39 ± 3.166), and the difference was statistically significant ($P < 0.05$).

The duration of sensory block was less in ropivacaine group (200 min) than in bupivacaine (237 min). The duration of motor block was also less in ropivacaine group (170 min) as compared to bupivacaine (218 min).

The decrease in systolic blood pressure in relation to baseline levels was more pronounced in Group I which was consistent with the higher maximum level of sensory blockade in their group.

No significant changes were reported in pulse rate, respiratory rate, and SpO_2 in the present study.

Duration of analgesia was longer in Group I (234.76 ± 11.16) than Group II (202.40 ± 12.64) and was statistically significant ($P < 0.05$).

Most common side effects found in our study were hypotension, bradycardia, and nausea.

DISCUSSION

Regional anesthesia has many advantages over general anesthesia for below umbilical surgeries and is associated with lower incidence of pulmonary and cardiovascular complications, better post-operative pain management, lower incidence of deep vein thrombosis, and pulmonary embolism.[2]

Subarachnoid block provides rapid onset, consistent sensory blockade and adequate muscle relaxation for all types of surgery below the level of the umbilicus. It is relatively easier, requires less equipment and very cost effective. Main disadvantages of the subarachnoid block are hypotension, lack of ability in precisely controlling the level and duration of block and risk of introduction of infection directly into the cerebrospinal fluid.

In the present study, we used plain 0.5% of bupivacaine and plain 0.5% ropivacaine intrathecally for lower limb orthopedic surgeries.

All patients were demographically similar in regards to age, sex, and duration of surgery and it can be presumed that the groups were comparable for the purpose of the study.

In our study, there was a slight reduction in mean arterial pressure (MAP) after the spinal block in both the groups, however, was significant only in bupivacaine group. In addition, there was a decrease in heart rate after spinal block in both the groups. However, there were no significant intergroup differences. Mantouvalou *et al.* also reported the same observation in their study.[3] Shesky *et al.* also reported an average maximum decrease in MAP of 9–17% with isobaric bupivacaine within 30 min after the induction of spinal anesthesia, a maximum decrease in heart rate of approximately 8–17% was also observed by them.[4]

In our present study, onset of sensory block took 6.36 ± 1.76 for 0.5% bupivacaine and 6.16 ± 1.72 for 0.5% ropivacaine and there was no intergroup significance [Table 1].

The time to achieve complete motor blockade (Modified Bromage Scale 1) was shorter in the bupivacaine group (11.50 ± 3.272) than the ropivacaine group (15.39 ± 3.166), and the difference was statistically significant ($P < 0.05$) which is shown in Table 1. Same observation was made by Mantouvalou *et al.*[3] and Luck *et al.*[5]

The duration of sensory block was less in ropivacaine group (200 min) than in bupivacaine (237 min). The duration of motor block was also less in ropivacaine group (179 min) as compared to bupivacaine (225 min). Luck *et al.* observed sensory block duration of 210 min, 270 min, and 255 min in ropivacaine, bupivacaine, and levobupivacaine groups, respectively. In their study motor block regression started at 90 min in ropivacaine and 180 min in bupivacaine and levobupivacaine group.[5] Mantouvalou *et al.* observed sensory block time of 220, 237, and 230 min in ropivacaine, bupivacaine, and levobupivacaine groups, respectively. McNamee *et al.* compared ropivacaine and bupivacaine at a dose of 17.5 mg and they also found faster recovery from sensory and motor block in ropivacaine group.[6]

Intraoperative hypotension requiring treatment with I.V. ephedrine occurred more often in the Bupivacaine group (4 patients) than in the Ropivacaine (1 patient). The decrease in systolic blood pressure in relation to baseline levels was more pronounced in Group I which was consistent with the higher maximum level of sensory blockade in their group. Ephedrine which was given when physical signs of low blood pressure were apparent or when systolic blood pressure fell below 90 mmHg was administered in 4 patients in Group I, compared to 1 patient in Group II. No significant changes were reported in pulse rate, respiratory rate, and SpO_2 in the present study. Adverse events such as nausea/vomiting, rigor, and itching were equally distributed in all the groups and statistically insignificant Table 3.

Thus, our results are consistent and coincides with the various studies conducted by Kallio *et al.*,[7] McNamee *et al.*,[12] and McClelland *et al.*,[8] Veering *et al.*,[9] Mantouvalou *et al.*, Luck *et al.*,[7] and Gautier *et al.*,[10] in past. Their conclusions were similar to our current study that intrathecal Ropivacaine 0.5% has shorter sensory and motor block duration than equipotent doses of bupivacaine. Hypotension was more common in bupivacaine group.

Table 1: Onset of sensory and motor block and duration of motor block

Criteria	Mean±SD		*P* value
	I	II	
Sensory block, onset (min)	6.36±1.38	6.16±1.10	0.6737
Sensory block, duration (min)	237±15.2	200±11.3	0.001
Motor block onset (min)	12.84±2.06	12.16±2.23	0.2768
Motor block duration (min)	225.20±19.17	179.20±32.14	0.0001

SD: Standard deviation

Table 2: Duration of analgesia

Criteria	Mean±SD		*P* value
	Group I	Group II	
Duration of analgesia (min)	234.76±11.16	202.40±12.64	0.0001

SD: Standard deviation

CONCLUSION

We conclude that intrathecal 0.5% ropivacaine is a good alternative to intrathecal 0.5% bupivacaine as it provides shorter duration of motor and sensory block and provides more hemodynamic stability than Bupivacaine 0.5% intrathecally.

Thus, ropivacaine merits use as a day case anesthesia agent as it produces rapid onset of reliable block providing adequate surgical anesthesia of appropriate duration followed by rapid regression of motor and sensory blocks with minimal side effects.

Table 3: Comparison of incidence of adverse effects

Adverse effects	Number of patients in Group I	Number of patients in Group II
Nausea/vomiting	1	0
Rigor	1	1
Hypotension requiring Vasopressor (>1 bolus of injection ephedrine, 5 mg)	4	1
Itching	0	0
PDPH	0	0

PDPH: Postdural puncture headache, NIBP: Non invasive blood pressure

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Original Article

A Clinical Analysis of Pre-operative Tranexamic Acid and Wound Closure without Suction Drain in Decreasing the Blood Loss in Surgical Treatment of Fractures of Hip

Sathis Chandran[1], Sasikumar Sasidharan[2]

[1]Associate Professor, Department of Orthopaedics, Kannur Medical College, Anjarakandy, Kannur, Kerala, India, [2]Assistant Professor, Department of Orthopaedics, Kannur Medical College, Anjarakandy, Kannur, Kerala, India

Abstract

Background: Fractures of the hip region are very common in the elderly population and include fracture neck of femur, intertrochanteric fractures, and subtrochanteric fractures. All of these are routinely treated by surgery to make the patient ambulant early. Most of these elderly people are anemic with poor blood reserve, and many of them need pre-operative blood transfusion to improve their hemoglobin concentration to make them fit for surgery. Hence, an additional blood loss during surgery and in the immediate post-operative period is to be avoided as much as possible. A common practice is to use suction drains in fracture surgery to decrease the incidence of post-operative blood collection (hematoma inside the wound). Tranexamic acid is a drug which reduces blood loss during surgery and post-operative period.

Materials and Methods: Kindly provide text part: A total of 210 patients with fracture hip joint were divided into three groups of 70 each. Group A consisted of patients with fracture hip joint undergoing surgery, treated pre-operatively with tranexamic acid but no suction drain. Group B consisted of patients with fracture hip joint undergoing surgery in which only suction drain was used (no tranexamic acid). Group C consisted of patients with fracture hip joint undergoing surgery without tranexamic acid and suction drain. Both pre-operative and post-operative hemoglobin concentration estimations were done. All surgeries were done under epidural/spinal anaesthesia. In Group A, tranexamic acid intravenous (I.V.) injection of tranexamic acid 1 g was given 10 min before incision and repeated as 500 mg I.V after 6 h in the post-operative period. The post-operative hemoglobin was compared with pre-operative hemoglobin value.

Conclusions: It was found that average fall of hemoglobin in the group with pre-operative intravenous tranexamic acid with drain less wound closure was less compared to other groups and to known standard loss after hip surgery.

Key words: Arthroplasty, Closed wound, Fractures, Hemoglobin, Hip, Suction drain, Tranexamic acid

INTRODUCTION

Hip fracture surgeries are the most common semi-emergency orthopedic procedure conducted at Kannur Medical College Hospital. Most of the patients are the elderly with comorbidities and low hemoglobin concentration. Blood loss during and in the post-operative period adds up an additional insult to these patients. One of the accepted methods of preventing blood loss is using tourniquets which are not possible in fractures of the hip. Hidden blood loss in hip fractures, in addition to intraoperative blood loss, may be as high as 1500 cc.[1,2] The rate of blood transfusion in the Intra-operative period for hip fracture patients is reported between 20% and 60%.[3,4] Total blood loss and thus rate of transfusion are greater for extracapsular hip fractures compared to intracapsular hip fractures.[1] A meta-analysis of 20 studies found a significantly increased risk of post-operative bacterial infection in patients who

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Corresponding Author: Dr. Sasikumar Sasidharan, Assistant Professor, Kannur Medical College, Anjarakandy, Kannur, Kerala, India. Phone: +91-7558833386 E-mail: drssasikumar@yahoo.com

receive an allogeneic blood transfusion in the peri-operative period.[5] In addition to the increased risk of infection, patients who require blood transfusion following hip fracture have an increased hospital length of stay.[6] Closed-suction drainage has been widely used in many orthopedic surgical procedures, including total hip arthroplasty (THA), based on the theory of effectively decreasing hematoma formation, which is theoretically associated with decreasing post-operative pain and limb swelling, accelerating wound healing, and prevention of infection.[7,8] However, some authors have advocated that not using drainage would have more benefits in THA[9,10] because closed drainage leads to blood loss after THA by eliminating the tamponade effect and potentially allows retrograde infection. Tranexamic acid is a lysine analog which is also an inhibitor of fibrinolysis. It acts by competitively inhibiting the conversion of plasminogen to plasmin. It also matures fibrin clots, to be maintained and coagulation to continue uninhibited. Most orthopedic surgeons use closed suction drains to decrease hematoma collection and chances of infection. However, suction drains leads to increased blood loss in the post-operative period. Furthermore, drain may even act as a portal for the bacteria to enter the wound increasing the chances of post-operative infection. In this context, a study was conducted in this tertiary teaching hospital to analyze the roles of tranexamic acid and drain less wound closure in fractures of hip surgeries.

Period of Study

The duration of this study was from January 2012 to December 2014.

Institute of Study

The study was conducted at Kannur Medical College hospital, Anjarakandy, Kannur, Kerala.

Type of Study

This was a prospective, randomized cross-sectional, and comparative study.

MATERIALS AND METHODS

A total of 210 patients with fracture hip joint, attending the Department of Orthopaedics, Kannur Medical College Hospital, Anjarakandy, Kannur, Kerala, a tertiary teaching hospital were included in the present study. They were divided into three groups of 70 each. Group A consisted of patients with fracture hip joint undergoing surgery, treated pre-operatively with tranexamic acid but no suction drain. Group B consisted of patients with fracture hip joint undergoing surgery in which only suction drain was used (no tranexamic acid). Group C consisted of patients with fracture hip joint undergoing surgery without tranexamic acid and suction drain.

Inclusion Criteria

Patients admitted through the emergency department or transferred to our institution who meet the following criteria were included in the study:

- Adults over the age of 18.
- Acute intertrochanteric or femoral neck hip fracture.
- Patients treated surgically with cephalomedullary nail, hemiarthroplasty, or THA.

Exclusion Criteria

Patients who meet any one or more of the following criteria were excluded from the study:

- Use of any anticoagulant at the time of admission (e.g., Vitamin K antagonists, antithrombin agents, antiplatelet agents, or factor IIa and Xa inhibitors).
- Documented allergy to tranexamic acid.
- History of deep vein thrombosis (DVT) or pulmonary embolus.
- Hepatic dysfunction (aspartate transaminase/alanine transaminase >60).
- Renal dysfunction (Cr >1.5 of glomerular filtration rate >30).
- Active coronary artery disease (event in the past 12 months).
- History of cerebrovascular accident (CVA) in the past 12 months.
- Presence of a drug-eluting stent.
- Color blindness.
- Leukemia or any active cancer.
- Coagulopathy based on admission laboratory values (international normalized ratio >1.4, partial thromboplastin time >1.4× normal, and platelets <50 000).
- Non-displaced femoral neck fractures treated percutaneously.

Randomization of patient selection was done using method available on online randomization.com. The surgical team, anesthesia team, and patients were blinded to the details of the patient in regard to the stud. The incidence of blood transfusion, total calculated blood loss, and acute adverse events (transfusion reaction, CVA, myocardial infarction, pulmonary embolism, symptomatic DVT, surgical site infection, and death) was observed and recorded. Patients were also assessed at 2 weeks, 6 weeks, and 3 months postoperatively to understand the long-term adverse events as well as determine mortality rate. The patients underwent appropriate pre-operative investigations and necessary specialist consultations to assess fitness for undergo surgery. Both pre-operative and post-operative hemoglobin concentration estimations were done in all the patients. All cases were done under epidural/spinal anesthesia. In Group A, tranexamic acid intravenous (I.V.) injection of tranexamic acid 1 g was given 10 min before incision and

Table 1: The analysis observations made in the study (*n*=210) (BN: number of blood bags used, BA: Amount of blood transfused in ml)

Analysis Observation	Group A-70	Group B-70	Group C-70	*P* value
Mean pre-operative hemoglobin g%	12.2±1.05	11.8±0.98	12.06±1.10	0.045
Mean post-operative hemoglobin g%	11.23±0.78	10.10±0.90	10.75±1.02	0.037
Wound infection	11	12	10	0.021
Blood loss	03	04	02	0.041
BN	19	18	17	0.031
BA (Mean)	2.5±0.45	3.0±0.34	2.7±0.20	0.047
Wound hematomas	3	4	6	0.029
Limb swelling	3	5	4	0.026
Reinforcement	3	5	3	0.030
Oozing	4	3	6	0.029
Reoperation for wound healing	07	09	10	0.019
Thromboembolic complications (DVT)	02	01	03	0.021
Thromboembolic complications (PE)	03	02	05	0.017
Pain	02	03	03	0.018

DVT: Deep vein thrombosis, PE: Pulmonary Embolism

repeated as 500 mg I.V after 6 h in the post-operative period. The post-operative hemoglobin was compared with pre-operative hemoglobin value. The fall in hemoglobin values was compared with other Group B and C. All the values were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

A total of 210 patients were included in the present study and divided into three groups. In Group A, there were 45 males (64.28%) and 25 females (35.71%) with a male-to-female ratio of 1.8:1. In Group B, there were 47 males and 23 females with a male-to-female ratio of 2.04:1. In Group C, there were 48 males and 22 females with a male-to-female ratio of 2.18:1. The mean age in group A was 78.4 ± 4.56 years. In Group B, it was 77.56 ± 5.41 years, and in Group C, it was 79.10 ± 3.85 years. All the observations noted in the three groups are analyzed and tabulated in Table 1.

DISCUSSION

Surgery for the hip joint fractures is one of the most common surgeries undertaken in this tertiary teaching hospital. There is clinical uncertainty and a lack of high-quality evidence regarding the use of tranexamic acid in hip fracture patients. Despite its proven efficacy in elective orthopedic surgery,[11,12] the optimal dosing and timing of tranexamic acid administration are still debated.[13] Furthermore, the efficacy and side effect profile of tranexamic acid in patients with fractures remain unclear. A larger percentage of hip fracture patients have significant medical comorbidities, and many have a history of cardiac disease.[8] While tranexamic acid has demonstrated safety and efficacy in patients without significant cardiac disease undergoing elective surgery, there is still debate if tranexamic acid will have the same effect in patients with significant comorbidities.[14] The potential benefit of decreasing blood loss and decreasing the number of transfusions following hip fracture surgery is overwhelming and will likely result in improved patient outcomes, shorter length of stay, and lower cost.[9] Since the closed suction drainage system was first reported in the 19th century,[15,16] it has been used postoperatively for more than 100 years. The original aim of drainage system is to reduce hematoma formation and post-operative edema, decrease the possibility of infection, and minimize the probability of external contamination of the surgical site. The use of post-operative drainage has been increasingly questioned since the end of the 20th century. A series of RCTs comparing closed-suction drainage and no drainage have been published.[17-19] Most of the patients in the present study were old-aged poor nutrition and blood reserves, and they cannot afford to also have blood loss during surgery. Pre-operative tranexamic acid definitely reduced blood loss during surgery and in the immediate post-operative period in Group A of this study when compared to other groups. The use of suction drains allows the blood loss due to negative pressure in the wound which is also present constantly. The suction drain also acts as a portal of entry for bacteria to the operative wound. As is evident in this study when I.V tranexamic acid was used, there was a decrease in post-operative blood ooze and therefore no recommendation of suction drain also. There was no hematoma formation following hip surgery in this study.

CONCLUSIONS

The study suggests I.V tranexamic acid combined with drain less wound closure which was proved to be safe and effective. It reduced blood loss during hip surgeries following trauma.

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Original Article

Comparing Efficacy of Plain Bupivacaine, Bupivacaine with Fentanyl, and Bupivacaine with Dexmedetomidine Intrathecally in Lower Abdominal Surgical Procedures: A Double-blind Randomized Control Study

R Srinivasan[1], R Selvarajan[2], Heber Anandan[3]

[1]Assistant Professor, Department of Anaesthesiology, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India, [2]Associate Professor, Department of Anaesthesiology, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India, [3]Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Healthcare Limited, Chennai, Tamil Nadu, India

Abstract

Introduction: The potentiating effect of short-acting lipophilic opioid fentanyl and a more selective α2 agonist dexmedetomidine is used to reduce the dose requirement of bupivacaine and its adverse effects and also to prolong analgesia.

Aim: The aim of this study is to compare the effect of plain bupivacaine versus bupivacaine with fentanyl versus bupivacaine with dexmedetomidine administered intrathecally for lower abdominal surgeries.

Methods: Group B (n = 30): Patients in this group received 3 ml of 0.5% hyperbaric bupivacaine of total volume of 3.0 ml. Group F (n = 30): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 25 μg (0.5 cc) of fentanyl to a total volume of 3.0 ml intrathecally. Group D (n = 30): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 5 μg (0.5cc) of preservative-free dexmedetomidine to a total volume of 3.0 ml intrathecally.

Results: The time taken to achieve a sensory level of T10 and T6 was statistically insignificant among 3 groups. There was a statistically significant difference among three groups in the mean duration of motor block $P < 0.0001$. There was a statistically significant difference among three groups in the duration of time for demand analgesia $P < 0.002$.

Conclusion: Intrathecal dexmedetomidine supplementation of spinal block seems to be a good alternative to intrathecal fentanyl since it produces prolonged sensory block and motor block.

Key words: Bupivacaine, Dexmedetomidine, Fentanyl, Spinal anesthesia

INTRODUCTION

Spinal anesthesia is used extensively for lower abdominal and lower extremity surgeries because it has distinct advantages over general anesthesia.[1,2] Lignocaine and bupivacaine are the commonly used local anesthetic agents for spinal anesthesia. The adjuvants such as opioids and α2 agonist are sometimes combined with local anesthetic for spinal anesthesia. The rationale for combining adjuvants to local anesthetic drugs is to lower the dose of each agent and maintaining analgesic efficacy while reducing the incidence and severity of side effects. Surgery on the bowel, uterus, and other genital organs performed under spinal or epidural block is often accompanied by visceral pain, nausea, and vomiting.[3-5] Fentanyl in various doses when added to spinal bupivacaine increases the duration of analgesia and reduces intraoperative nausea and vomiting. Dexmedetomidine is an α2-agonist that is approved as an intravenous sedative and co-analgesic drug. Most of the clinical studies about intrathecal α2 adrenoreceptor agonist

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Corresponding Author: Dr. R Selvarajan, Department of Anaesthesiology, Tirunelveli Medical College Hospital, Tirunelveli, Tamil Nadu, India. E-mail: jaymichella@gmail.com

are related to clonidine. The present study was designed to evaluate the efficacy and adverse effects of plain bupivacaine, bupivacaine with fentanyl, and bupivacaine with dexmedetomidine intrathecally in lower abdominal surgical procedures.[6-9]

Aim

The aim of this study is to compare the effect of plain bupivacaine versus bupivacaine with fentanyl versus bupivacainewith dexmedetomidine administered intrathecally for lower abdominal surgeries.

MATERIALS AND METHODS

This study was done in prospective double-blinded randomized manner. It was conducted at our institute between March 2017 and August 2017 after approval from the ethical committee of the institution and written informed consent. 90 American Society of Anesthesiology (ASA) I patients undergoing elective lower abdominal surgeries under spinal anesthesia were recruited.

Inclusion Criteria

Patients in the age group of 30 and above, both sexes, and ASA I were included in the study.

Exclusion Criteria

Hypersensitivity to the study drug, renal or hepatic dysfunction, uncontrolled labile hypertension, and diabetes mellitus were excluded from the study.

Group B (n = 30): Patients in this group received 3 ml of 0.5% hyperbaric bupivacaine of total volume of 3.0 ml. Group F (n = 30): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 25 μg (0.5 cc) of fentanyl to a total volume of 3.0 ml intrathecally. Group D (n = 30): Patients in this group received 2.5 ml of 0.5% hyperbaric bupivacaine + 5 μg (0.5 cc) of preservative-free dexmedetomidine to a total volume of 3.0 ml intrathecally. In this study, 0.5% hyperbaric bupivacaine in 8% dextrose, dexmedetomidine hydrochloride 50 mics/0.5 ml, and preservative free fentanyl 50 mics/1 ml were used. Intrathecal drugs were prepared by an anesthesiologist not involved in the study and were administered by another anesthesiologist who was blinded and performed spinal anesthesia. The volume of the drug, size of the syringe, and color of the drug of interest were similar in three groups. The final volume of injected solutions was 3.0ml in three groups. Surgical anesthesia was graded as excellent if there was no complaint of pain at any time during surgery. Good if there was minimal pain or discomfort which was relieved by a small dose of intravenous pentazocine 0.5 mg/kg and poor if GA has to be administered.

In post-anesthesia care unit (PACU), pain was assessed every 15 min. When the patient reaches the pain score 2, diclofenac 75 mg injection was given. Duration of effective analgesia was defined as the time interval between onset of SAB and the time to reach pain score 2. Patients were shifted to the post-operative ward after complete resolution of motor blockade.

RESULTS

The three groups were comparable with respect to their age, height, and weight. There was no statistically significant difference among three groups in demographic aspects [Table 1].

Three groups were similar in respect of diagnosis and ASA. (P = 0.99) which is not statistically significant. Three groups were similar in types of surgeries and statistically no significant difference among three groups P = 0.72.

The time taken to achieve a sensory level of T10 from the time of SAB was tested by alcohol swab (loss of cold sensation). The mean time taken in Group B was 2.83 ± 0.53 min, in Group F was 2.93 ± 0.58 min, and in Group D, was 2.67 ± 0.48 min. There was statistically no significant difference among three groups (P = 0.153).

The time taken to achieve a peak sensory level of T6 from the time of SAB was tested by alcohol swab. The mean time taken in Group B was 4.80 ± 0.76 min, in Group F was 5.03 ± 0.85 min, and in Group D was 4.77 ± 0.68 min. There was no statistically significant difference among three groups P = 0.345 [Table 2].

The time taken to achieve Bromage 3 from the time of SAB was tested by modified Bromage scale. The mean time

Table 1: Distribution of mean duration of surgery (in min) by groups

Group	*n*	Mean±SD	*P* value
Group B	30	70.83±22.40	0.841
Group F	30	69.07±25.16	
Group D	30	72.01±20.50	

SD: Standard deviation

Table 2: Distribution of mean onset of sensory block (T10 and T6) in min by groups

Onset of sensory block	Group	Mean±SD	*P* value
T10	Group B	2.83±0.53	0.153
	Group F	2.93±0.58	
	Group D	2.67±0.48	
T6	Group B	4.8±0.76	0.345
	Group F	5.03±0.85	
	Group D	4.77±0.68	

SD: Standard deviation

taken in Group B was 6.63 ± 0.56 min, in Group F was 6.67 ± 0.55 min, and in Group D was 6.53 ± 0.68 min. There was statistically no significant difference among three groups $P = 0.669$ [Table 3].

The mean time taken for return of cold sensation to S1 level was 305.63 ± 44.50 min in Group B, 358.97 ± 46.74 min in Group F, and 457.30 ± 54.28 min in Group D. There was a statistically significant difference among three groups in the duration of sensory block $P < 0.0001$ [Table 4].

The mean duration of return of motor block to Bromage scale zero (0) was 231.33 ± 40.77 min in Group F, 279.43 ± 56.01 in Group D, and 171.83 ± 39.98 min in Group B. There was statistically significant difference among three groups in the mean duration of motor block $P < 0.0001$[Table 5].

The mean time for demand analgesia (defined as the time at which patient demands some mode of pain relief) was 215.67 ± 42.39 min in Group F, 276.87 ± 49.32 min in Group D, and 159.33 ± 36.79 min in Group B. There was statistically significant difference among three groups in the duration of time for demand analgesia $P < 0.002$ [Table 6].

The maximum degree of motor block in both groups was Grade 3. There was no statistically significant difference among three groups in the maximum Grade of motor block $P > 1$ [Table 7].

The range of maximum level of sensory block was T4–T6 in three groups. The median of the onset of sensory block was T6 in three groups. T4 was 13.3% in Group F, 10% in Group D, and 16.6% in Group B. T6 was 86.6% in Group F, 90% in Group D, and 80% in Group B which was statistically not significant >1 [Table 8].

Quality of surgical anesthesia was excellent in all patients. There was no statistically significant difference among three groups $P > 1$ [Table 9].

The incidence of hypotension in Group F was 30%, 3.33% in Group D, and 33.3% in Group B which was significant statistically $P = 0.029$ [Table 10].

The incidence of bradycardia in Group F was 3.33%, 10% in Group D, and 3.33% in Group B, and there was statistically significant difference in three Groups $P = 0.30$. The incidence of pruritus in Group F was 26.66%, and in Groups D and B, no case of pruritus was observed. There was statistically significant difference in three groups $P = 0.002$. The incidence of vomiting was13.3%% in Group F, 3.33% in Group D, and 13.3% in Group B which was statistically not significant $P = 0.44$ [Table 11].

The incidence of sedation score 2 was 100% in three groups which was statistically not significant $P > 1$ [Table 12].

Table 3: Distribution of mean time to reach motor block (Bromage 3) min by groups

Group	Mean±SD	*P* value
Group B	6.63±0.56	0.669
Group F	6.67±0.55	
Group D	6.53±0.68	

SD: Standard deviation

Table 4: Distribution of mean time for regression of sensory block (S1) in min by groups

Group	Mean±SD	*P* value
Group B	305.63±44.50	<0.0001
Group F	358.97±46.74	
Group D	457.30±54.28	

SD: Standard deviation

Table 5: Distribution of mean time for regression of motor blockade (Bromage 0) in min by groups

Group	Mean±SD	*P* value
Group B	171.83±39.98	<0.0001
Group F	231.33±40.77	
Group D	279.43±56.01	

SD: Standard deviation

Table 6: Distribution of mean time for rescue analgesia in min by groups

Group	Mean±SD	*P* value
Group B	159.33±36.79	<0.0001
Group F	215.67±42.39	
Group D	276.87±49.32	

SD: Standard deviation

Table 7: Maximum grade of motor block by groups

Group	B1	B2	B3
Group B	0	8	22
Group F	0	8	22
Group D	1	1	28

Table 8: Maximum level of the sensory block by T4–T6 groups

Group	T6	T8	T10	T11	T12	*P* value
Group B	14	10	3	1	2	0.303
Group F	14	10	3	1	2	
Group D	24	5	1			

Table 9: Distribution of cases by groups and quality of surgical anesthesia

Group	Excellent	Good
Group B	30	0
Group F	30	0
Group D	30	0

Table 10: Distribution of cases by hypotension in both groups

Group	No	Yes	*P* value
Group B	20	10	0.029
Group F	21	9	
Group D	29	1	

Table 11: Distribution of cases by groups and side effects

Group	Group B	Group D	Group F	*P* value
Bradycardia	1	3	1	0.3
Pruritus	0	0	8	0.002
Vomiting	4	1	4	0.44

Table 12: Distributions of cases by sedation score

Group	Score 1	Score 2	Score 3
Group B	0	30	0
Group F	0	30	0
Group D	0	30	0

DISCUSSION

Subarachnoid block is a commonly used anesthetic technique for lower abdominal surgeries. There has been a growing interest in the use of analgesic additives to spinal local anesthetics. Alpha-2 agonist like dexmedetomidine has been shown to prolong the duration of both sensory and motor blockade and to provide extended post-operative analgesia. In this study, 5 μg of dexmedetomidine was added to 12.5 mg (2.5 ml) of 0.5% hyperbaric bupivacaine or 25 μg of fentanyl added to 12.5 mg (2.5ml) of 0.5% hyperbaric bupivacaine, and its efficacy as an adjuvant to subarachnoid bupivacaine was studied in 90 patients undergoing elective open appendicectomy and hernioplasty surgeries. Al-Ghanem[10] who compared the effect of 5 μg dexmedetomidine versus fentanyl 25 μg in intraoperative analgesia and the duration of sensory and motor block when added to 10 mg intrathecal plain bupivacaine and observed that there is no statistically significant difference between the two groups as regard to the onset time of sensory block at T10 level. Benha *et al.*[11] did a comparative study of adding intrathecal 5 μg dexmedetomidine and 5 μg of sufentanil to 10 mg of heavy bupivacaine and found that there is no statistically significant difference in the onset of sensory block T10 level Group D = 5.5 ± 3.7, where Group 57 = 6.2 ± 1.3 $P = 0.69$. In our study, the mean time to onset of sensory block (T10 level) was 2.93 ± 0.58 min in Group F, 2.67 ± 0.48 min in Group D, and 2.83 ± 0.53 min in Group B. There is no statistically significant difference among the three groups in the onset of sensory level $P = 0.153$. The addition of 5 μg of dexmedetomidine to hyperbaric bupivacaine did not shorten the onset of sensory block (T10 level) when compared to the addition of 25 μg of fentanyl to hyperbaric bupivacaine. The onset of sensory block (T10 level) was similar in three groups.

Kanazi[12] found that there is statistically no significant difference for the maximal sensory block for 12 mg bupivacaine 0.5% alone or combined 3 μg of dexmedetomidine or 30 μg of clonidine ($P = 0.3$). Al-Mustafq[13] found that addition of intrathecal dexmedetomidine in increasing doses 5 μg (10 mg) of dexmedetomidine with 12.5 mg of spinal bupivacaine increased the level of sensory block as the dose of dexmedetomidine increases.

Benha *et al.*[11] found that there is statistically no significant difference for the maximal sensory block when compared with 5 μg of dexmedetomidine and 5 μg of sufentanil to 10 mg of heavy bupivacaine. In our study, the median of the upper limit block was T6 in Group B, Group D, and Group F. There was no statistically significant difference among the three groups in the maximum level of sensory block. The addition of dexmedetomidine to hyperbaric bupivacaine did not increase the speed of sensory level when compared with 25 μg of fentanyl to hyperbaric bupivacaine.

Al-Ghanem[10] who found that addition of 5 μg of dexmedetomidine and 25 μg of fentanyl with 10 mg of isobaric bupivacaine intrathecally had no significant difference on the mean time to reach peak sensory level 19.34 ± 2.87 in Group D and 18.39 ± 2.46 in Group F, $P = 0.12$. In our study, the mean time to reach T6 level was 5.03 ± 0.85 min in Group F, 4.77 ± 0.68 min in Group D, and 4.80 ± 0.76 min in Group B. There is no statistically significant difference among the three groups to reach peak level T6. Benha *et al.*[11] found that there is statistically no significant difference with 5 μg of dexmedetomidine and 5 μg of sufentanil to 10 mg of heavy bupivacaine on the mean time to achieve Bromage 3 score. In our study, the mean time to achieve Bromage 3 score was 6.67 ± 0.55 min in Group F, 6.53 ± 0.68 min in Group D, and 6.63 ± 0.56 min in Group B. There is no statistically significant difference among the three groups. The addition of 25 μg fentanyl or 5 μg dexmedetomidine to 12.5 mg of bupivacaine has no effect on the onset of motor block.

Al-Ghanem[10] found that the addition of 5 μg of dexmedetomidine to 10 mg of isobaric bupivacaine 274.83 ± 73.4 significantly prolongs the duration of sensory blockade while 25 μg of fentanyl to 10 mg of isobaric bupivacaine was 179.5 ± 47.4. There was statistically significant difference among the two groups, $P < 0.001$ (intrathecal dexmedetomidine when combined with spinal bupivacaine prolongs the sensory block by depressing the release of c-fibers transmitters and by hyperpolarization of post-synaptic dorsal horn neurons). Kanazi[12] found that the addition of 3 μg of dexmedetomidine to 12 mg of intrathecal bupivacaine or 30 μg of clonidine significantly prolonged the sensory block. Al-Mustafq[13] studied that there is a significant difference in the duration of sensory block among three groups who received spinal bupivacaine 12.5 mg alone or combined with 5 μg of dexmedetomidine or with 10 μg of dexmedetomidine. He concluded that dexmedetomidine has a dose-dependent effect on the onset and regression of sensory and motor block when used in SAB. In our study, the duration of sensory block was 358.97 ± 46.74 min in Group F, 457.30 ± 54.28 min in Group D, and 305.63 ± 44.5 min in Group B. There is statistically significant difference among the three groups $P < 0.0001$. The addition of 5 μg of dexmedetomidine to hyperbaric bupivacaine significantly prolonged the duration of sensory block. (Intrathecal dexmedetomidine when combined with spinal bupivacaine prolongs the sensory block by depressing the release of c-fibers transmitters and by hyperpolarization of post-synaptic dorsal horn neurons).

Al-Ghanem[10] found in their study that 5 μg of dexmedetomidine to 0.5% hyperbaric bupivacaine prolonged effect of motor blockade that 25 μg of fentanyl to 0.5% hyperbaric bupivacaine intrathecally. Kanazi[12] observed that addition of 12 mg of bupivacaine supplemented with dexmedetomidine and 12 mg of bupivacaine with 30 μg of clonidine intrathecally produces similar prolongation in the duration of motor block when compared 12 mg of bupivacaine alone. (The prolongation of motor block produced by subarachnoid hyperbaric bupivacaine combined with 5 μg of dexmedetomidine results from binding this agonist to motor neurons in the dorsal horn of the spinal cord). Benha *et al.*[11] found that the addition of 5 μg of dexmedetomidine to 2 ml of heavy bupivacaine and 5 μg of sufentanil to 2 ml of heavy bupivacaine produces a significant difference in the duration of motor blockade. In our study, the mean duration of motor block was 231.33 ± 40.77 min in Group F, 279.643 ± 56.01 min in Group D, and 171.83 ± 39.98 min in Group B. There is a statistically significant difference among the three groups, $P < 0.0001$. The addition of 5 μg of dexmedetomidine to 0.5% bupivacaine significantly prolonged the duration of motor block.

Benha *et al.*[11] found that the quality of surgical anesthesia was better in patients received 5 μg sufentanil to 2 ml of heavy bupivacaine when compared to 5 μg of dexmedetomidine to 2 ml of heavy bupivacaine. In our study, the quality of surgical anesthesia was excellent in three groups. There is no statistically significant difference among the three groups, $P > 1$.

Benha *et al.*[11] found that the addition of 5 μg of dexmedetomidine to 10 mg of hyperbaric bupivacaine and 5 μg of sufentanil to 10 mg of hyperbaric bupivacaine intrathecally produces no significant difference in the duration of pain relief Group SF = 265.8 ± 112.3 and Group D = 240. 2±77.3 min ($P = 0.8$). In our study, the mean time for rescue analgesia is 215.67 ± 42.39 min in Group F, 276.87 ± 49.321 min in Group D, and 159.33 ± 36.79 min in Group B ($P < 0.0001$) which was statistically significant difference in the duration of analgesia by three groups.

Kanazi[12] studied that the addition of dexmedetomidine or clonidine to bupivacaine did not cause a significant decrease in the blood pressure intraoperatively or postoperatively. Intrathecal local anesthetics block the sympathetic outflow and reduce the blood pressure. The sympathetic block is usually near maximal with the doses used for spinal anesthesia. The addition of a low dose of α2 agonist to a high dose of local anesthetics does not further affect the near maximal sympatholysis.

Ibrahim *et al.*[11] found that the addition of 5 μg of dexmedetomidine to spinal bupivacaine and 5 μg of sufentanil to spinal bupivacaine did not produce a significant difference in the incidence of hypotension.

Al-Ghanem[10] found that hypotension was more in fentanyl group than in the dexmedetomidine group, but it did not reach a significant difference. Meanwhile, hypotension occurred 25–30 min after spinal injection in 2 patients in the dexmedetomidine group and one patient in fentanyl group had mild episodes of hypotension in PACU.

In our study, the incidence of hypotension was 30% in Group F, 3.3% in Group D, and 33.3% in Group B. Hypotension was mild to moderate in three groups which was statistically significant difference, $P = 0.029$. The most significant side effects reported about the use of intrathecal α2 adrenoreceptor agonists is bradycardia. However, in the present study, these side effects were not significant because small dose of intrathecal dexmedetomidine was used.

Benha *et al.*[11] found that there is statistically no significant difference in the incidence of bradycardia in both the groups with 5 μg of sufentanil to 10 mg

of 0.5% bupivacaine and 5 μg of dexmedetomidine to 10 mg of 0.5% bupivacaine. Al-Ghanem[10] found that there is statistically no significant difference in the incidence of bradycardia among two groups of 5 μg of dexmedetomidine to 10 mg of isobaric bupivacaine and 25 μg of fentanyl to 10 mg of isobaric bupivacaine intrathecally. In our study, the incidence of bradycardia was 10% in Group D, 3.33% in Group F, and 3.33% in Group B ($P = 0.3$) which is a statistically significant difference among three groups.

Benha *et al.* found that there is a significant difference in the incidence of pruritus in the sufentanil group. Al-Ghanem[10] found that there is statistically significant difference in the incidence of pruritus. Pruritus after intrathecal fentanyl is reported to be 40–70%, but it was only 13% in the present study which can be explained by the fact that pruritus is a benign subjective symptom which is under reporting and usually needs to treatment. Bogra *et al.*[14] found that there is statistically significant difference in the incidence of pruritus with 10 mg of fentanyl, 12.5 mg of fentanyl, added to hyperbaric bupivacaine. In our study, the incidence of pruritus was 26.67% in Group F, 0% in Group D, and 0% in Group B. There is a statistically significant difference among three groups, $P = 0.002$.

Kanazi[12] found that intrathecally administrated α2 agonist has a dose-dependent sedative effect. The doses of clonidine and dexmedetomidine selected in their study were at the lower end of the dosing spectrum. This explains the lack of sedative effects between the study Groups B and C and the intraoperative anxiety one patient in Group D. In our study, sedation was not statistically significant in three groups $P > 1$.

CONCLUSION

Intrathecal dexmedetomidine supplementation of spinal block seems to be a good alternative to intrathecal fentanyl since it produces prolonged sensory block and motor block. It is evident that this type of block may be more suitable for lower abdomen and lower extremities surgeries with prolonged duration.

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Original Article

Diversion in Posterior Urethral Valves: Needs and Results

Ramdhani Yadav[1], Sandip Kumar Rahul[1], Vinit Kumar Thakur[2]

[1]Assistant Professor, Department of Paediatric Surgery, Indira Gandhi Institute of Medical Sciences, Patna – 800 014, Bihar, India, [2]Additional Professor, Department of Paediatric Surgery, Indira Gandhi Institute of Medical Sciences, Patna -800014, Bihar, India

Abstract

Objective: The objective is to evaluate the outcome of diversion procedures done for posterior urethral valves (PUV).

Materials and Methods: A retrospective study was done on 29 patients out of 203 patients of PUV treated in the Department of Paediatric surgery at a tertiary care center from January 2011 to December 2016. Data regarding clinical history, examination findings, investigation results, and treatment given were collected from their case records. Data collected were analyzed.

Results: A total of 203 patients with a mean age of 31.78 ± 9.11 months presented to the Paediatric Surgery Department with dribbling, poor urinary stream (55.17%), and urinary tract infection (36.94%) as the major symptoms. Vesicoureteric reflux was found in 55.66% cases. While 71.92% patients had cystoscopic fulguration, in 13.79% patients, we had to use Chooramani hook to ablate the valves and 28 (14.29%) patients had to be diverted to treat urosepsis. Valve bladder syndrome occurred in 60.59% cases. Of the 28 diverted patients, 21 had vesicostomy and 8 had ureterostomy. Of the 12 patients with vesicostomy, 7 showed lessening of serum creatinine and lessening of reflux with age; two patients showed high pressure, small capacity bladder. Two patients showed poor voiding and are on chronic kidney disease medications as advised by the nephrologist. One patient had bilateral ureteric reimplant after optimization of bladder function. Rest 12 patients are still on vesicostomy. Of the eight patients with ureterostomy, 2 had ureterostomy closure and are doing well on follow-up; 2 had bilateral ureteric reimplant, of which 1 died and the other is doing well; other 4 are still on ureterostomy. Urodynamic evaluation could be done in only two patients after vesicostomy closure and one after ureterostomy closure. Closed vesicostomy patients showed small capacity, high-pressure bladder, while closed ureterostomy patient showed normal capacity and normal pressure bladder. Other patients are awaiting urodynamic evaluation. Mean follow-up in our series was 2.6 ± 1.1 years.

Key words: Children, Posterior urethral valves, Ureterostomy, Urinary diversion, Urinary drainage, Valve ablation, Vesicostomy

INTRODUCTION

Being the most common cause of bladder outlet obstruction in male children, posterior urethral valves (PUV) are notorious for their heterogeneous and variable presentation and outcome.[1] PUV has devastating effects on bladder dynamics resulting in significant morbidity and mortality in pediatric patients. Repeated urinary tract infection (UTI), chronic renal failure, urinary incontinence, urinary ascites, and urosepsis represent the spectrum of manifestations of this anomaly. A subset of these patients present with bladder characteristics which do not revert by simple valve fulguration and bladder dynamics have a significant role in determining the extent of damage to the kidneys in such patients. It is these patients who benefit from diversion. We present the results of a retrospective study conducted at our center to share the results of urinary diversion in PUV patients.

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MATERIALS AND METHODS

A retrospective study was conducted on patients presenting with poor urinary stream, UTI and fever and diagnosed to have PUV on investigation in the Department of Pediatric Surgery, Indira Gandhi Institute of Medical Sciences

Corresponding Author: Dr. Ramdhani Yadav, C/O Shri Lala Prasad, Village + Post – Bari Pahari, Agamkuan, Gulzarbag, Patna – 800 007, Bihar, India. Phone: +91-7250285072. E- mail: drrdyadav1@gmail.com

(IGIMS), Patna. All patients of PUV managed by urinary diversion in the department from January 2011 to December 2016 constituted the study group. A total of 203 patients of PUV were managed during this period, of which 29 patients who were diverted constituted the study group. These patients were managed according to the standard protocol for management of PUV patients in our department. Details of each patient were collected from their case records, investigation sheets, and operative records. Patients who turned up for follow-up in the outpatients department gave an opportunity to include their follow-up details in this study. The collected data were analyzed.

Protocol for Management of PUV in our Department

PUV patients represent a heterogeneous group depending on the age of presentation, symptoms at the time of presentation, and extent of damage to the urinary tract.

Neonates may present with difficulty non-passage of urine, urosepsis with raised serum creatinine, and altered electrolytes; some of them may have an antenatally-diagnosed PUV, and some may present with urinary ascites or other pop-off mechanisms. After general assessment, management at our center begins with urethral catheterization, fluid and electrolyte resuscitation with intravenous antibiotics after initial evaluation of blood counts, serum electrolytes and creatinine, blood gas, and urine culture. Once patient's condition stabilizes and his counts and culture normalizes, ultrasonography (USG) and micturating cystourethrogram (MCUG) are done. Due to lack of small-sized resectoscopes in our department, we use Chooramani hook for valve ablation with constant monitoring of the urinary stream on suprapubic pressure in the operation theater. Children who have difficulty in accommodating this instrument or have persistent UTI or urosepsis are diverted with either vesicostomy or ureterostomy depending on the findings on MCUG and normalization of serum creatinine level on catheterization. Periodic evaluations are done by USG, serum creatinine, routine urine examination, and renograms if needed on follow-up visits to the hospital. Follow-ups are initially advised monthly and also at the time of any febrile UTI.

We routinely come across older children who present with chronic kidney disease (CKD), valve-bladder syndrome, and renal rickets. They are very difficult to manage despite adequate valve management and need periodic urodynamic evaluation to guide bladder management and CKD medications. Due to cost constraints and ease of performance, we have now begun bedside cystometry to assess the bladder dynamics. Some of these patients ultimately need renal replacement therapy in the form of dialysis or renal transplantation. Two of our patients were had to be referred to higher centers excelling in pediatric renal transplantation.

Vesicoureteric reflux (VUR) in patients of PUV is very commonly seen; it is initially managed on prophylactic antibiotics after valve fulguration with circumcision. In case, recurrent UTI occurs or there is evidence of renal scarring on dimercaptosuccinic acid scan, diversion is done for the protection of kidneys.

The RIFLE system criteria were used to define acute renal failure[2,3] and estimated glomerular filtration rate[4] and persistent proteinuria are used to define CKD.

RESULTS

Table 1 shows the demographic data of all 203 PUV patients treated in our department during this period. Maximum patients were late presenters.

Table 2 shows the symptoms of all PUV patients at the time of their presentation to the Department. Dribbling and poor stream and UTI are the common complains at the time of presentation.

VUR in PUV Patients

A total of 113 (55.66%) of PUV patients in this study had VUR. While 82 (40.39%) had bilateral reflux, 31 (15.27%) had unilateral reflux.

PUV-associated VURD (Unilateral VUR and Renal Dysplasia)

VURD was found in 8 patients; 5 on the left side and 3 on the right side.

Table 3 depicts the results of patients who underwent diversion procedures.

Results of Diversion Procedure in PUV

Figure 1 shows the results of patients of PUV who were diverted for proper management.

Long-term Follow-up

Mean follow-up time in our series is 2.6 ± 1.1 years. Table 4 summarizes the long-term results in our PUV patients.

Urodynamic evaluation could be done in only two patients after vesicostomy closure and one after ureterostomy closure. Closed vesicostomy patients showed small capacity, high-pressure bladder; while closed ureterostomy patient showed normal capacity and normal pressure bladder. Other patients are awaiting urodynamic evaluation.

DISCUSSION

Valve fulguration and diversion procedures are the twin ways to relieve the obstructed system in PUV patients. However, whether these methods optimize the bladder

Table 1: Demographic details

Age at presentation	Frequency (%)
Neonates	25 (12.31)
1–12 months	55 (27.09)
12 months	123 (60.59)
Total	203

Table 2: Presenting symptoms

Symptoms at presentation	Frequency (%)
Dribbling and poor stream	112 (55.17)
UTI	75 (36.94)
Fever	6 (2.96)
Hematuria	2 (0.98)
Hypertension	2 (0.98)
Renal rickets	2 (0.98)
Abdomnal distension (urinary ascites)	2 (0.98)
Seizures	2 (0.98)
Total	203

UTI: Urinary tract infection

Table 3: Diversion results

Blocksom's vesicostomy	21 (10.34%)
Ureterostomy	8 (3.94%)
Subsequent surgery following diversion procedures – (e.g., fulguration+vesicostomy closure/ ureterostomy closure)	15(7.39%)
Ureteric reimplantation for VUR patients after bladder management	3 (1.48%)

VUR: Vesicoureteric reflux

Table 4: Long-term results in PUV

Outcome	No. of patients (%)
ARF	62 (30.54)
Residual valve on repeat MCUG	32 (15.76)
CKD	13 (6.40)
VBS	123 (60.59)
Stricture	1 (0.49)
Mortality	7 (3.45)
Hypertension	2 (0.98)
Dialysis	2 (0.98)

PUV: Posterior urethral valves, ARF: Acute renal failure, MCUG: Micturating cystourethrogram, CKD: Chronic kidney disease, VBS: Valve bladder syndrome

dynamics is questionable. Whether simple fulguration of valves is adequate in itself for appropriate management has been addressed by many researchers and thereafter arose the need and concept of "valve bladder syndrome (VBS) management."[5,6] Furthermore, it is now evident that diversion also does not in itself correct the bladder changes but by diverting urine, further damage to upper tracts is limited and sepsis gets controlled. This is at the cost of continuous passage of urine from stoma site, its complications, and the need for subsequent corrective surgeries. Analysis of the outcomes of these diversions is important to establish them as treatment options.

That distal obstruction to the bladder has significant effects on bladder muscle cell, extracellular matrix, and nerves in the bladder muscle wall resulting in clinical effects as seen in the spectrum of the VBS.[7-9] Furthermore, early treatment of obstruction by adequate valve fulguration helps in alleviating and normalization of these changes.[10,11] This is in contrast to bladders which have changes secondary to neurogenic affection.[11] Since diversion procedures do not correct the obstruction distal to the bladder and also limit the urinary volume in the bladder, they are less likely to correct the altered bladder dynamics.

Diversion in PUV is indicated in cases where urosepsis does not settle after fulguration of PUV or fulguration is not possible due to non-availability of adequate sized cystoscopic instruments for neonates. Both these conditions are very common in clinical practice. With the improvement in cystoscopic instruments, it has now become possible to fulgurate valves in small children also. In addition to this, we use Chooramani's hook in case cystoscopy is not possible in small children. This is the reason for fewer numbers of diversions in our study compared to other similar studies.

The urodynamic patterns of PUV bladders managed by fulguration were compared with those which were diverted using vesicostomy or ureterostomy in a study by Puri *et al.*[12] While fulgurated and ureterostomy groups showed good capacity and compliant bladder, vesicostomy group showed small capacity and hyperreflexic bladder. Primary fulguration was, therefore, found to be better than vesicostomy and also vesicostomy and ureterostomy had different effects on the bladder and its dynamics. We also, at our center, prefer doing valve fulguration and divert only when urosepsis does not settle. In case both ureters are tortuous, we prefer to do bilateral ureterostomy instead of vesicostomy due to this reason.

In their series on PUV, Smith *et al.* concluded that by avoiding diversion in most cases, bladder function is preserved and the need for bladder augmentation decreases.[13] Podestá *et al.* reported better bladder functional outcome in patients who had valve ablation compared to patients who had diversion, on conducting urodynamic study.[14] Farhat *et al.* observed that the severity of hydronephrosis and reflux downgraded more in ablated patients and also renal function normalized more in ablated patients compared to diverted patients.[15] In their series of 26 patients with supravesical urinary diversion, Tietjan *et al.*[16] concluded that on biopsy of the diverted kidneys, progression to end-stage renal disease was not prevented and so questioned the benefits of supravesical diversion. Although modern-day Western literature leans strongly toward non-diversion, diversion in select groups of complicated patients in PUV

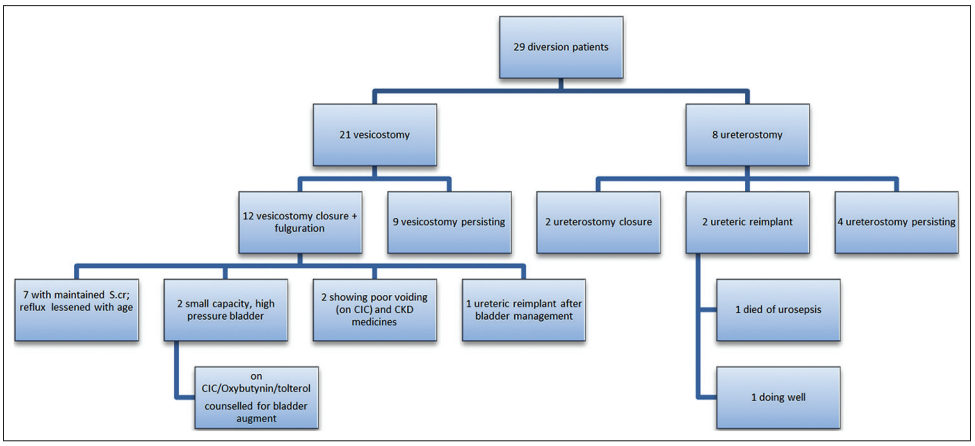

Figure 1: Results of Diversion in PUV patients

presenting late in developing countries need diversion to allow recovery of renal function and correct urosepsis.[16]

In contrast, Ghanem *et al.* in their analysis of patients managed by bilateral Sober's ureterostomy,[17] inferred that high diversion does not have negative influence on bladder dynamics and immediately releases high intrarenal pressures but only improves renal function temporarily. Liard *et al.* advocated that for severe cases of PUV, one should not hesitate in doing temporary high diversion and that Sober's ureterostomy does not damage the bladder.[18] Jaureguizar *et al.* reported that supravesical diversion did not affect the long-term bladder dysfunction adversely.[19] Kim *et al.* found that temporary diversion does not damage the bladder and actually improved the bladder function in the long run by putting the detrusor of the damaged bladder at rest.[20] Parag *et al.*, in their series, had 26 bilateal loop ureterostomy and found them effective in optimizing renal function and serum creatinine in these patients.[21]

Of the 21 patients with vesicostomy in our study, 12 patients had valve fulguration with vesicostomy closure, while in 9 patients, vesicostomy has not yet been closed. Of the 12 patients with vesicostomy, 7 showed lessening of serum creatinine and lessening of reflux with age; two showed high pressure, small capacity bladder with high-pressure bladder. These children were kept on clean intermittent catheterization and anticholinergic medications. They have been counseled for bladder augmentation and are awaiting bladder augment. Two patients showed poor voiding and are on CKD medications as advised by the nephrologist. One patient had bilateral ureteric reimplant after optimization of bladder function.

Of the 8 patients with ureterostomy, 2 had ureterostomy closure and are doing well on follow-up; 2 had bilateral ureteric reimplant, of which 1 died and the other is doing well; and 4 patients are still on bilateral ureterostomy.

In comparison to other studies, urodynamic evaluation, in our study, was done in fewer number of patients as most of the patients either did not have their stoma closed or had not attained a comfortable age for this procedure to be done. Urodynamic evaluation could be done in only two patients after vesicostomy closure and one after ureterostomy closure. Closed vesicostomy patients showed small capacity, high-pressure bladder; while closed ureterostomy patient showed normal capacity, normal-pressure bladder. Other patients are awaiting urodynamic evaluation.

CONCLUSION

Although the use of diversion in PUV patients has lessened in the developed world, it still is important in patients in developing world where patients have uncontrolled sepsis, persistent dilatation of the upper tracts following valve ablation and valve ablation is not possible due to non-availability of small-sized cystourethroscopes. Periodic follow-up and monitoring of bladder function and dynamics are equally important in patients with urinary diversion.

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Original Article

A Hospital Based Study on Empirical Use of Antibiotics in the Treatment of Lower Respiratory Tract Infections

Sabir Cholas[1], Iftekhar Ahmed Nazeer[2]

[1]Associate Professor, Department of T.B and Chest diseases, Kannur Medical College, Kannur, Kerala, India, [2]Associate Professor, Department of Pharmacology, Kannur Medical College, Kannur, Kerala, India

Abstract

Background: Improving the care of adult patients with lower respiratory tract infections (LRTI) especially community-acquired pneumonia (CAP) has been the focus of many different organizations, and several have developed guidelines for management of CAP. The guidelines are mainly for emergency medicine physicians, hospitalists, and primary care practitioners. Every hospital should conduct an audit of the treatment protocols followed by their physicians at regular intervals.

Aim of the Study: The aim of the study was to analyze the current trends in the selection of antibiotic empirically and their effectiveness in the treatment of LRTI in a tertiary teaching hospital.

Materials and Methods: A total of 86 patients with the diagnosis of LRTI were included in this study. The severity of LRTI was assessed using the confusion, oxygen saturation, respiratory rate, and blood pressure (CORB) score. A point was given for each parameter to compute the total score. A CORB score of 0, 1, and >2 indicates mild, moderate, and severe CAP, respectively. Investigations done were Chest "X" ray, antibiotics received: (1) Antibiotics prescribed on admission, (2) route of AB administration, and (3) duration of ABs given. (4) If there is a switch from parenteral to oral therapy. (5) If there is a change of ABs group or not. (6) If yes to which group? (7) Duration and cause of such change were noted.

Observations and Results: Among the 86 patients included in the study there were 51 (59.30%) males and 35 (40.69%) female patients. The mean age was 47.90 ± 9.48 years. The mean age among the males was 53.78 ± 6.45, and in females, the mean age was 49.85 ± 4.70 years. History of active smoking was present in 23/86 (26.74%), passive smoking in 14 (16.27%), and ex-smoker in 19 (22.09%) patients. The frequent antibiotic prescription used was broad-spectrum penicillins and cephalosporins (21) in all the LRTI patients amounting to 14/58 of CAP, 4/14 of chronic obstructive pulmonary disease, and 3/14 of bronchiectasis in this study.

Conclusions: Empirical antibiotic prescription practices need to be well evaluated in a hospital to formulate an acceptable rationale aiming at improving the antibiotic usage. Awareness among the physicians about different widely accepted guidelines is necessary. The pharmacological audit should include patient compliance, patient demand, combination antibiotic therapy, and cost of treatment.

Key words: Antibiotic, Bacteria, Infection, Lower respiratory tract infections, Pneumonia

INTRODUCTION

Lower respiratory tract infections (LRTI) are a broad terminology which includes different diseases including acute bronchitis, pneumonia, and acute exacerbation of chronic lung diseases such as chronic obstructive pulmonary disease (COPD) or bronchiectasis. Annual incidence of pneumonia, one of the most important LRTIs, is reported to be 24.8/10,000 adults. The rates differ based on the age, with higher incidence observed in patients between 65 and 79 years of age (63.0/10,000 adults) and >80 years of age (164.3/10,000 adults).[1] Pneumococcal pneumonia is the most common cause of mortality due to the lower respiratory infections. According to the global burden of disease 2015 study,[2] pneumococcal pneumonia is the most common cause of pneumonia responsible for

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Corresponding Author: Dr. Iftekhar Ahmed Nazeer, Department of Pharmacology, Kannur Medical College, P.O. Anjarakandy, Kannur – 670 612, Kerala, India. Phone: +91-8129476372. E-mail: driftekhar@gmail.com

over 15 lakhs deaths across the world in 2015. Community-acquired pneumonia (CAP) and acute exacerbation of chronic bronchitis are the two commonly encountered acute LRTIs in outpatient setting. The annual incidence of CAP is about 5–11/1,000 population with higher rates reported in the elderly population.[3] LRTI account for large-scale morbidity and mortality in India. They are among the top six causes of death in low-income, middle-income, and high-income countries[4-6] and impose a huge economic burden on the health services of a country. LRTI can present in adults and children in a variety of community based and hospital settings with variable complex, clinical presentations from the minimally symptomatic to the rapidly fulminant. Current standard diagnostic tests for acute and chronic bacterial and viral infections are laborious and time consuming. Currently, all ill patients presenting with any form of respiratory tract infections community-acquired pneumonias (CAP), hospital-acquired pneumonias, ventilator-assisted pneumonia, or respiratory tract infections in the immunosuppressed are treated empirically without an accurate diagnosis of the causative microorganism and their antibiotic sensitivity patterns.[7] Correctly identifying the exact microorganism causing respiratory tract infections and treating with appropriate antibiotics they are susceptible to is essential, as morbidity and mortality rates are high.[8] Carroll,[9] in 2002, reported, LRTIs as the most frequently reported infectious diseases of human in worldwide. Panda *et al.* showed that LRTIs are responsible for 4.4% of all hospital admissions and 6% of all general practitioner consultations.[10] As bacterial etiology may vary in different geographical regions and even over time in the same location and population, Tripathi suggested routine surveillance of microbial etiology of LRTI in their management.[11] Gram-positive bacteria such as *Staphylococcus aureus* and *Streptococcus pneumonia* and Gram-negative bacteria, for example, *Pseudomonas* spp., *Escherichia coli*, and *Klebsiella* spp. were identified in the LRTI patients in the study conducted by Mishra *et al.*[12] and Kollef *et al.* opined that unnecessary and inappropriate initial antibiotic therapy is a potential risk factor that has been associated with increased mortality in patients with serious infections.[13] When the etiologic agents causing LRTI and their antibiotic susceptibility patterns are known, the choice of antimicrobial therapy for bacterial LRTIs is relatively straightforward; however, the clinical presentation is usually not specific enough to make a firm etiologic diagnosis whether in the community or hospital setting.[14] In almost all cases, eradication of causative agents requires initiation of antimicrobial therapy before obtaining culture report; however, during the past few years, the increase in antibiotic resistance has compromised the selection of empirical treatment[15] and how to choose an effective antimicrobial agent is a new challenge to the clinicians, as the composition and the resistance to antimicrobial agents of infection pathogens was changing frequently. The practices of using antibiotics empirically without culture reports, transmission of resistant bacteria from patient to patient and from health-care practitioners to patients and vice versa[13] are some of the factors for the development of resistance to the antibiotics. Therefore, the clinicians and microbiologists worldwide are focusing on knowledge and strategies to limit the development of antimicrobial resistance. The present study was conducted with the aim of analyzing the current trends in the selection of antibiotic empirically and their effectiveness in the treatment of LRTI in a tertiary teaching hospital.

Period of Study

This study was from February 2014 to January 2016.

Institution of Study

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

Type of Study

This was a prospective, cross-sectional hospital-based study.

MATERIALS AND METHODS

The present study was a prospective cross-sectional one conducted in a tertiary teaching Hospital. Ethical Committee Clearance was obtained before the study was undertaken. 86 patients with the diagnosis of LRTI were included in this study using ICD 10 coding (codes 09–J18) from the medical records section of the hospital. Inclusion criteria: (1) Patients aged above 20 years were included in the study. (2) Patients with LRTI were defined by acute onset of respiratory symptoms (cough, fever, expectoration, chills, and sweating) with a latest chest X-ray infiltrate were included. (3) Patients with history of cough, expectoration, Pneumonias lasting for more than 48 h were included. Exclusion criteria: (1) Patients aged below 20 years were excluded. (2) Patients with pneumonias of hospital-acquired or aspiration pneumonia; patients with chronic lung disease such as interstitial lung disease, bronchiectasis or advanced COPD on home oxygen therapy or with known bacterial colonization were excluded. (3) Patients who were prescribed antibiotics before admission were excluded. (4) Patients diagnosed as having; patients receiving immunosuppressive treatments (defined as receiving a daily average Prednisolone dose ≥7.5 mg or other immunosuppressive medications); and patients who were considered for palliative treatment within 48 h of admission. The severity of pneumonia was assessed using the confusion, oxygen saturation, respiratory rate, and blood pressure (CORB) score. The CORB assessment parameters include the following: Confusion; oxygen saturation <90% on room air; respiratory rate

>30/min; and systolic blood pressure <90 mmHg. A point was given for each parameter to compute the total score. A CORB score of 0, 1, and >2 indicates mild, moderate, and severe CAP, respectively. All the patients were subjected to the following: (1) Full medical history and examination, (2) chest "X" ray, and (3) antibiotics received: (1) Antibiotics prescribed on admission, (2) route of AB administration, and (3) duration of ABs given. (4) If there is a switch from parenteral to oral therapy. (5) If there is a change of ABs group or not. (6) If yes to which group? (7) Duration and cause of such change. The relevant demographic, clinical, and laboratory and outcome data were extracted by the review of medical records. The following information was collected: Age, gender, usual residence (home vs. residential care), usual comorbidities, usual medications, history of allergy (particularly penicillin allergy), information on personal activities of daily living (PADL) (PADLs- transferring, walking, toileting, bathing, dressing, and feeding), antibiotics prescribed within 24 h of admission, the parameters required for computing the CORB score, relevant laboratory data, admission to high-dependency unit or intensive care unit (ICU), and admission outcomes such as length of stay and death. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

Among the 86 patients included in the study there were 51 (59.30%) males and 35 (40.69%) female patients. The mean age was 47.90 ± 9.48 years. The mean age among the males was 53.78 ± 6.45 and, in females, the mean age was 49.85 ± 4.70 years. History of active smoking was present in 23/86 (26.74%), passive smoking in 14 (16.27%), and ex-smoker in 19 (22.09%) patients. The positive clinical manifestations were tabulated in Table 1.

The trends of empirical antibiotic prescriptions to the patients with LRTI among the treating physicians of the hospital were tabulated in Table 2. The frequent antibiotic prescription used was broad-spectrum penicillins and cephalosporins 21/86 (24.41%) in all the LRTI patients amounting to 14/58 (24.13%) of CAP, 4/14 (28.57%) of COPD, and 3/14 (21.42%) of bronchiectasis in this study. This was followed by cephalosporins 11/58 in CAP, 4/14 (28.57%) in COPD, and 3/14 (21.42%) in bronchiectasis. Cephalosporins and macrolides were used in 9/58 (15.51%) of CAP patients, 2/14 (14.28%) of COPD, and 2/14 (14.28%) of bronchiectasis patients [Table 2].

The number of days these prescriptions were used by the patients was observed and found that 53/86 (61.62%) were for 5–7 days and the remaining 33/86 (38.37%) for 7–10days. The frequency of changing the antibiotics was observed and found that more than 3 times were found in 43% of the patients and <3 times were observed in 57% of the patients.

DISCUSSION

The present study was on prescribing pattern of antibiotics in LRTI, is a component of the medical audit, which seeks monitoring, evaluation, and necessary modification in the prescribing practice of prescribers to achieve rational and cost-effective medical care. It is necessary to define prescribing habits to drive a remedial message to the prescribers. Most people will develop an acute LRTI almost

Table 1: The incidence of clinical manifestations of LRTI (*n*-86)

Observations	Community-acquired pneumonia 58 (%)	COPD 14 (%)	Bronchiectasis 14 (%)
Fever	50 (86.20)	10 (71.42)	07 (50.0)
Cough/expectoration	43 (74.13)	09 (64.28)	13 (92.85)
Hemoptysis	31 (53.44)	06 (42.85)	12 (85.71)
Worsening of dyspnea	12 (20.68)	10 (71.42)	11 (78.57)
Comorbid diseases	00 (00)	00 (00)	00 (00)
Increased temperature	46 (79.31)	12 (85.71)	09 (64.28)
High respiratory rate	45 (77.58)	09 (64.28)	07 (50.0)
Antibiotics in the past 3 months	07 (12.06)	03 (21.42)	08 (57.14)
Consolidation	22 (37.93)	02 (14.28)	05 (35.71)
Sonorous rhonchi	37 (63.79)	08 (57.14)	13 (92.85)
Coarse crepitation	18 (31.03)	11 (78.57)	13 (92.85)
X-ray			
Patchy infiltration	20 (34.48)	03 (21.42)	02 (14.28)
Cavity	07 (12.06)	05 (35.71)	03 (21.42)
Emphysema	11 (18.96)	03 (21.42)	02 (14.28)
Leukocytosis	37 (63.79)	06 (42.85)	07 (50.0)
ESR	33 (56.89)	07 (50.0)	08 (57.14)
Sputum Gram stain	29 (50.0)	09 (64.28)	11 (78.57)
Sputum C and S	53 (91.37)	06 (42.85)	06 (42.85)

LRTI: Lower respiratory tract infections, COPD: Chronic obstructive pulmonary disease

Table 2: The antibiotics prescribed for admission (*n*-86)

Antibiotics used empirically total patients- 86	Community-acquired pneumonia 58 (%)	COPD 14 (%)	Bronchiectasis 14 (%)
Broad-spectrum penicillins and cephalosporins - 21	14 (%)	04 (28.57)	03 (21.42)
Cephalosporins - 18	11 (18.96)	04 (28.57)	03 (21.42)
Cephalosporins and macrolides - 13	09 (15.51)	02 (14.28)	02 (14.28)
Broad-spectrum penicillins and Aminoglycosides - 10	07 (12.06)	01 (07.14)	02 (14.28)
Broad-spectrum penicillins, aminoglycosides and metronidazole - 09	06 (10.34)	01 (07.14)	02 (14.28)
Cephalosporins and metronidazole - 08	06 (12.06)	01 (07.14)	01 (07.14)
Ciprofloxacin and metronidazole - 07	05 (08.62)	01 (07.14)	01 (07.14)

COPD: Chronic obstructive pulmonary disease

every year. LRTI are the common problems encountered in the primary health-care centers. The treating physician starts an antibiotic empirically based on presumptive bacterial infections of the area and season. However, in the modern times, the rates of major complications are now low because of the higher rate of empirical prescription of antibiotics. In addition, there is no convincing evidence, either from international comparisons or evidence within countries, that lower rates of prescribing are associated with higher rates of complications. In this study based on the clinical diagnosis and laboratory diagnosis of LRTI was made (CAP, COPD, and bronchiectasis). Depending on the physicians started with broad-spectrum penicillins and cephalosporins in 21/86 (24.41%) of CAP patients. These patients had no complications, and during the course of treatment, no complications developed. Cephalosporins alone without combination were started in 18/86 patients (20.93%). Cephalosporins and macrolides were started in 3/86 (03.48%) of the patients. In the present study, 16 physicians were depended to collect the prescription pattern. All of them were using their textbook knowledge as the main source of information. Whereas in a study by Vancelik *et al*.[16] found that the 73.7% of the physicians got the information from pharmaceutical companies and 26.31% from medical textbooks. In the present study, there were no comorbid diseases associated with LRTI; hence, the change of prescriptions noted was <10%. Review of Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines[17] show that the presence of comorbid diseases should influence the choice of AB group. Furthermore, this result matched with the study done by Abbas *et al*.[18] who found that (97%) of physicians took into consideration the presence of comorbid diseases during AB prescription. Empirical antibiotics have to be started in LRTI especially in cases of CAP because earlier an antibiotic is started better would be the chances of recovery and lesser complications. In this study, all the patients were given antibiotics within 6 h after their clinical diagnosis. Time to first antibiotic dose for CAP has recently received significant attention from a quality of care perspective. This emphasis is based on 2 retrospective studies of Medicare beneficiaries that demonstrated statistically significantly lower mortality among patients who received early antibiotic therapy.[19,20] The initial study suggested a breakpoint of 8 h,[19] whereas the subsequent analysis found that 4 h was associated with lower mortality.[20] In the present study, all the patients received antibiotics by parenteral route initially later on changed to the oral route of administration. The switchover took place between 3rd and 7th day. With the use of a potent, highly bio-available antibiotic, the ability to eat and drink is the major consideration for switching from intravenous to oral antibiotic therapy for non-ICU patients. Initially, Ramirez *et al*.[21] defined a set of criteria for an early switch from intravenous to oral therapy. The duration of treatment in this study was for 3–10 days. IN case of macrolides it was 3–5 days. Most patients with CAP were treated for 7–10 days or long. Few well-controlled studies have evaluated the optimal duration of therapy for patients with CAP. Available data on short-course treatment do not suggest any difference in outcome with appropriate therapy in either inpatients or outpatients.[22] All the patients in this study responded to empirical antibiotic treatment in the hospital. Although difficult to define, non-response is not uncommon. Overall, 6–15% of hospitalized patients with CAP do not respond to the initial antibiotic treatment.[23-25] The incidence of treatment failure among patients with CAP.

CONCLUSIONS

Empirical antibiotic prescription practices need to be well evaluated in a hospital to formulate an acceptable rationale aiming at improving the antibiotic usage. Awareness among the physicians about different widely accepted guidelines is necessary. The pharmacological audit should include patient compliance, patient demand, combination antibiotic therapy, and cost of treatment.

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Original Article

Scientific Study on Morbidity and Mortality in Late-preterm Infants in Neonatal Intensive Care Unit in Kanyakumari Government Medical College Hospital

R Nagalekshmi[1], P M Suresh[2], Heber Anandan[3]

[1]Assistant Professor, Department of Paediatrics, Kanyakumari Government Medical College, Asaripallam, Tamil Nadu, India,
[2]Professor, Department of Paediatrics, Kanyakumari Government Medical College, Asaripallam, Tamil Nadu, India,
[3]Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Healthcare Limited, Chennai, Tamil Nadu, India

Abstract

Introduction: Late-preterm infants are infants born between 34 and 37 weeks. The morbidities are more common among these infants. They constitute around 9% of neonates. The various morbidities are due to physiological and metabolic immaturity.

Aim: This study aims to study the morbidities and mortalities in late-preterm infants admitted in our neonatal intensive care unit (NICU).

Materials and Methods: This is a retrospective analysis of all late-preterm infants admitted in our NICU during January 2016–December 2016.

Results: A total of 206 late-preterm infants were analyzed in this study. Among the morbidities, 30% of infants had neonatal hyperbilirubinemia (NNH), 30% had sepsis, 17% of infants had respiratory distress syndrome (RDS), 10% were intrauterine growth retardation (IUGR), meconium-stained amniotic fluid (MSAF) 4%, tachypnea of the newborn (TTN) 6%, and 3% had congenital anomalies mortality of 3%.

Conclusion: The most common morbidity among the infants analyzed is NNH, 30% had sepsis, 17% of infants had RDS, 10% were IUGR, MSAF 4%, TTN 6%, 3% had congenital anomalies, and mortality is about 3%.

Key words: Meconium-stained amniotic fluid, Morbidity, Neonatal hyperbilirubinemia, Preterm infants, Respiratory distress syndrome, Tachypnea of the newborn

INTRODUCTION

Late-preterm infants - The American Academy of Paediatrics, define late-preterm birth as the delivery of an infant from 34 weeks to 36 weeks and 6 days of gestation.[1] They account for 9.1% of all births and three-quarter of all preterm births.[2] The morbidity and mortality pattern in late-preterm infants is higher than term infants (gestational age ≥37 weeks). The main reason behind that is the relative physiologic and metabolic immaturity. The late-preterm infants are at twice to thrice increased risk of morbidities such as hypoglycemia, poor feeding, jaundice, infection, and readmission rates after initial hospital discharge.[3] The infant mortality rate during 1st year of life for late-preterm infants is on an average 4-fold higher than that for term infant. Apnea occurs more frequently among late-preterm infants than term infants. The incidence of apnea in late-preterm infants is reported to be between 4% and 7%. Immature liver glycogenolysis, hormonal dysregulation, and inefficient hepatic glycogenesis and ketogenesis predispose preterm's for developing symptomatic hypoglycemia.[4-6] Furthermore, late-preterm infants have increased chances of developing hyperbilirubinemia because feeding difficulties that predispose them to an increase in enterohepatic circulation, decreased stool frequency, and dehydration.[7,8] Late-

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Corresponding Author: Dr. P M Suresh, Department of Paediatrics, Kanyakumari Government Medical College, Asaripallam, Tamil Nadu, India. E-mail: drpmsuresh@gmail.com

preterm infants are also more vulnerable to develop various respiratory morbidities including transient tachypnea of the newborn, respiratory distress syndrome (RDS), pneumonia, and pulmonary hypertension.

Aim

This study aims to study the morbidities and mortalities in late-preterm infants admitted in our neonatal intensive care unit (NICU).

MATERIALS AND METHODS

This is a retrospective analysis done in late-preterm infants admitted in NICU. All data regarding gestation age, sex, birth weight, and morbidities were taken and analyzed. Inclusion criteria: All preterm infants admitted during January 2016–December 2016. All babies blood count, C-reactive protein, blood culture, serum bilirubin, and X-ray chest were done. Babies with increased respiratory rate, retractions, and grunting as RDS. Statistical analysis: All data of the late-preterm babies were collected and analyzed by SPSS. Among the morbidities, 30% of infants had neonatal hyperbilirubinem (NNH), 30% had sepsis, 17% of infants had RDS, 10% were intrauterine growth retardation (IUGR), meconium-stained amniotic fluid (MSAF) 4%, tachypnea of the newborn (TTN) 6%, and 3% had congenital anomalies mortality of 3%.

RESULTS

A total of 206 infants were analyzed, 127 were male babies (62%) and 79 were female babies (38%) Table 1.

Babies were further subgrouped based on birth weight, babies <2 kg were 61 (30%) and 2–2.5 kg were 91% and those >2–5 kg were 54 (26%) Table 2.

About 30% of babies had NNH and sepsis, 17% had RDS, 10% were IUGR, 7% had perinatal hypoxia, 4% had meconium aspiration amniotic fluid and distress, 3% had anomalies, and 3% mortality Table 3.

Among the various morbidities RDS, PNH, TTN, IUCR were statistical significant on birth weight.

DISCUSSION

A total of 206 late-preterm infants admitted in KKGMCH, Asaripallam, NICU were analyzed in this study. Among the total 206 babies, 127 were male babies (62%) and 79 were female babies (38%). The babies <2 kg were 61 (30%) and 2–2.5 kg were 91% and those >2–5 kg were 54 (26%). Late-preterm infants have increased chances of developing hyperbilirubinemia because feeding difficulties that predispose them to an increase in enterohepatic circulation, decreased stool frequency, and dehydration.[7-9]

Among the morbidities analyzed, most of babies had NNH and sepsis, 30% of infants had NNH, 30% had sepsis, and preterm infants are at increased risk of developing hypoglycemia after birth because they have immature hepatic glycogenolysis and adipose tissue lipolysis, hormonal dysregulation, and deficient hepatic gluconeogenesis and ketogenesis.[4-6] Statistically, respiratory morbidities were found significantly higher in late-preterm

Table 1: Distribution of gender

Gender	Number of cases (%)
Male	127 (62)
Female	79 (38)

Table 2: Distribution of birth weight

Birth weight	Number of cases (%)
<2	61 (30)
2-2.5	91 (44)
>2.5	54 (26)

Table 3: Distribution of neonatal complications

Complication	Percentage
RDS	17
NNH	30
Sepsis	30
PNH	7
MSAF	4
TTN	6
IUGR	10
Anomalies	3
Mortality	3

RDS: Respiratory distress syndrome, NNH: Neonatal hyperbilirubinemia, MSAF: Meconium-stained amniotic fluid, TTN: Tachypnea of the newborn, IUGR: Intrauterine growth retardation

Table 4: Distribution of neonatal complications in birth weight

Complication	Birth weight			*P*
	<2.5 (%)	2–2.5 (%)	>2.5 (%)	
RDS	28	15	7	0.012
NNH	30	27	33	0.756
Sepsis	31	32	24	0.581
PNH	2	5	17	0.006
MSAF	2	5	6	0.462
TTN	2	5	13	0.041
IUCR	16	12	0	0.011
Anomalies	2	4	4	0.649
Mortality	3	3	2	0.864

RDS: Respiratory distress syndrome, NNH: Neonatal hyperbilirubinemia, MSAF: Meconium-stained amniotic fluid, TTN: Tachypnea of the newborn, IUGR: Intrauterine growth retardation

neonates as compared to term neonates. Due to immaturity of respiratory system, 17% of infants had RDS, 10% were IUGR, MSAF 4%, TTN 6%, and 3% had congenital anomalies mortality of 3%.

CONCLUSION

In late-preterm neonates analyzed in our center, NNH is the most common morbidity it our institutes about 30% and 30% had sepsis, 17% had RDS, 10% had IUGR, and MSAF 4%.

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Original Article

A Comparative Study of Conventional Versus Mass Closure in Management of Generalized Peritonitis

Mohammed Ibrahim[1], T Ravi Mohan[2], K D B S Tanuja[3]

[1]Assistant Professor, Department of General Surgery, Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India, [2]Associate Professor, Department of General Surgery, Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India, [3]Postgraduate, Department of General Surgery, Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India

Abstract

Introduction: Many of the operations performed by the general surgeons take place within the abdomen and consequently incision and suturing of the abdominal layers are the most common exercises in operative surgery. The present study is taken up to evaluate the advantages of mass closure in comparison with the conventional layered closure on the basis of operative time, healing time, and post-operative morbidity such as wound infection, burst abdomen, and incisional hernia.

Aim and Objectives: The aim of the study was to compare the techniques of mass closure and conventional layered closure of laparotomy wounds.

Materials and Methods: This study includes 100 patients who were admitted to the Department of General Surgery, Mahatma Gandhi Memorial Hospital, Warangal, during the period of June 2015–October 2017, for acute abdominal surgical problems needing emergency surgery. Stratified randomized sampling was done. The patients were chosen randomly, irrespective of their age, sex, and nature of disease.

Results: The results of this study of 100 patients who underwent laparotomy for acute abdominal surgical problems at Mahatma Gandhi Memorial Hospital, Warangal.

Key words: Burst abdomen, Incisional hernia, Laparotomy wound, Wound infection

INTRODUCTION

Many of the operations performed by the general surgeons take place within the abdomen and consequently incision and suturing of the abdominal layers are the most common exercises in operative surgery. Abdominal closure is very important as regards to incision, technique of repair and use of newer suture material, and has created a great interest to surgeons.[1,2]

Recent data suggests that technical factors are crucial and can be manipulated by the surgeon. Different suture techniques are used for closure of laparotomy wounds, and each has its strong proponents. However, the ideal method of abdominal wound closure is modified frequently. Commonly followed methods of abdominal closure are conventional layered closure and single layer closure.[3]

Since 1973, different workers have carried out comparative studies of these two methods with encouraging results and single layer closure was found to have definite advantages over conventional closure as regards to operating time, cost, feasibility, ease, and post-operative morbidity.[4]

The present study is taken up to evaluate the advantages of mass closure in comparison with the conventional layered closure on the basis of operative time, healing time, and post-operative morbidity such as wound infection, burst abdomen, and incisional hernia.

Aim and Objectives

Aim

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Corresponding Author: Dr.Mohammed Ibrahim, H.No: 7-2-26, Subhash nagar, Sirsilla post, Rajanna siricilla- District, Telangana, India pincode: 505301. E-mail: ibrahim.gmc@gmail.com

Objectives

The objectives of the study are as follows Table 1:

1. To compare the operative time and healing time for mass closure and conventional layered closure of laparotomy wounds Table 2.
2. To compare the post-operative complications after performing mass closure and conventional layered closure of laparotomy wounds such as seroma Table 3, wound infection, wound gaping, burst abdomen, and incisional hernia Table 4.

MATERIALS AND METHODS

Material

This study includes 100 patients who were admitted to the Department of General Surgery, Mahatma Gandhi Memorial Hospital, Warangal, during the period of June 2015–October 2017 Table 5, for acute abdominal surgical problems needing emergency surgery. Stratified randomized sampling was done. The patients were chosen randomly, irrespective of their age, sex, and nature of disease (cause of peritonitis).

Of these 100 patients, 50 were randomized to have the abdominal wall closed by mass closure technique and remaining 50 by the conventional layered closure, and they were grouped as Group 1 and Group 2, respectively Table 6.

Inclusion Criteria

The following criteria were included in this study:

1. Patients aged 15–75 years.
2. Patients posted for laparotomy, on an emergency basis.
3. Patients who underwent surgery with midline, paramedian, and subcostal incisions Table 7.

Exclusion Criteria

The following criteria were excluded from this study:

1. Patients with comorbid conditions such as diabetes mellitus, seropositive patients, patients on cancer chemotherapy, immunotherapy, and on long-term steroids.
2. Patients who died within 7 days after surgery.
3. Patients who underwent surgery by Grid-iron and Transverse abdominal incisions.
4. Patients who underwent second laparotomy or re-laparotomy.

RESULTS

The results of this study of 100 patients who underwent laparotomy for acute abdominal surgical problems at Mahatma Gandhi Memorial Hospital, Warangal, are as follows:

In our study, age of the patients ranged from 15 to 71 years in Group 1 and 23 to 73 years in Group 2, with a mean age of 49.9 years in Group 1 and 47.6 in Group 2.

Male:Female ratio in our study undergoing laparotomy was 3:1.

In our study, 50 patients underwent emergency surgery in Group 1 and 50 patients in Group 2.

In our study, 65% of patients had midline abdominal incision and 33% had a right paramedian incision. 84% of patients in mass closure technique had midline incision and 12% had right paramedian. Whereas only 46% of patients had midline incision and 54% had right paramedian incision in conventional layered closure group.

In our study, 28% of patients had surgery done for intestinal obstruction, and 14% of patients had surgery done for enteric perforation, and 45% of patients underwent surgery for gastroduodenal perforation. Other surgeries included splenectomies, drainage of intraabdominal abscesses, gallbladder perforation, and hemoperitoneum.

In our study, the mean time taken for the closure of laparotomy wounds, by single layer closure technique was 19.6 min, and by conventional layered closure, technique was 27.9 min. There was a difference of about 8 min in the mean time between the two techniques used which was statistically significant ($P = 0.001$), indicating that the time needed for mass closure technique was significantly less than that needed for conventional layered technique.

In our study, 53% of patients undergoing laparotomy had suture removal done on the 7th post-operative day and 25% on the 8th post-operative day. The mean time taken was 7.74 days for mass closure method and 7.75 days for conventional layered closure method. There was no significant difference in the time taken for suture removal between the mass closure technique and the conventional layered technique.

DISCUSSION

The present study aimed at comparing the techniques of laparotomy wound closure. The technique of laparotomy wound closure is one of the important factors in preventing post-operative complications such as wound infection, burst abdomen, and incisional hernia. Prevention of herniation of abdominal contents through the incisional wound, resulting in burst abdomen or herniation through a weak scar resulting in an incisional hernia is the main aims of a surgeon closing laparotomy wounds.

Although different closure techniques exist for the closure of laparotomy wounds, the ideal method of closure is yet to be finalized. Hence, the present study was taken up by us at Mahatma Gandhi Memorial Hospital, Warangal, to compare the mass closure and the conventional layered closure of laparotomy wounds on the basis of operative time and post-operative complications.

The ideal fascial closure should maintain tensile strength throughout the healing process. The dynamic process of wound healing can be divided into three phases. The first exudative phase (days 1–4) does not provide any holding strength to the wound. It is followed by the proliferative phase (days 5–20), in which the tissue regains approximately 15–30% while up to 80% of its original tensile strength is regained in the third or remodeling phase (days 21 onward). It was demonstrated in the early 1950s that the healing process of abdominal fascia after surgical incision continues for 9–12 months. Abdominal fascia regains only 51%–59% of its original tensile strength at 42 days, 70%–80% at 120 days, and 73%–93% by 140 days. It has been shown experimentally by Jenkins that the length of a midline laparotomy incision can increase up to 30% in the post-operative period in association with several factors that increase the intra-abdominal pressure and determined that a suture length to wound length ratio should be 4:1.

The term wound dehiscence includes partial or total separation of layers of wound closure. Evisceration indicates protrusion of bowel through the separate edges of abdominal wound closure, an emergency situation. Despite the arguments for and against different suture materials, the sitting of incisions and the insistence on meticulous surgical techniques in the closure of wound, better pre-operative and post-operative care, control of infection with antibiotics, the cases of wound disruption still occur.

Many clinical studies have attested to a continuing steady incidence of wound disruption to be 1%–3% regardless of the type of suture used. It is the dreaded complication that increases the hospital stay and cost wound disruption is associated with a mortality rate of 10%–20% despite the most sophisticated intensive care these patients receive today. The problem remains accordingly a real one, although individual "runs" have been reported in which disruption has never occurred. Wound disruption has been known to occur following the used of every type of suture material, whether natural or synthetic. This is understandable.

The surgeon is upset because of an unfortunate occurrence, and an inanimate piece of suture material has the advantage that is cannot answer back. Although a number of systemic and local factors have been associated with an increased incidence of burst abdomen, attention to the technique and materials for closure is associated with low rates of wound complications. It was found that the cause of wound dehiscence is not the poor tissues but the poor technique, too small bites, suture placed too far apart or tied too tightly predispose to disruption.

A maximum zone inflammatory reaction with edema and a resultant weak area was recognized to lie in the 0.5 cm adjacent to the wound edge. From the review of literature, no difference in dehiscence has been noted between various absorbable sutures or the various monofilament sutures, be absorbable or nonabsorbable, In the opinion of inflammatory reaction with edema and a resultant weak area was recognized to lie in the 0.5cm adjacent to the wound edge.

Therefore, it seems logical that the use of nonabsorbable sutures in laparotomy closure is a better choice and is favored in most of the resent studies. Wound dehiscence usually occurs within 2 weeks postoperatively, often following local serosanguinous discharge. At this time, most of the wound strength is provided by sutures and not by wound healing; it seems logical that the type of closure has an important role in fascial disruption. Burst abdomen or post-operative evisceration may be partial or complete, depending on whether all the layers of the abdominal wall have separated or either skin or peritoneum remain intact. It may occur up to 3% of laparotomy wounds, with mortality as high as 49%. It was pointed out that about 50% of dehisced wound healed primarily, finish with a late incisional hernia, a serosanguineous (pink) discharge from wound is a forerunner or disruption in burst abdomen.

The hernia may occur through a small portion of scar. Most cases of an incisional hernia are asymptomatic and broad necked and do not need treatment. Late incisional hernia is not always innocent. It can lead to potentially fatal complication of intestinal obstruction and strangulation. It has been found that incidence of an incisional hernia continues to rise with the passage of time; thus long-term (10–12 years) follow-up is required to determine its true incidence. The reported incidence of a such hernia varies from 1.6 to 10.8%.

A midline incision is regularly used for exploratory laparotomy in patients with abdominal trauma and does not endanger the abdominal muscle, blood supply or nerve supply or damage aponeurosis. In mesogastric and hypogastric incisions a greater portion of wound dehiscence occurred after paramedian incision than midline incisions. However, low incidence of wound dehiscence and incisional hernia with paramedian incision has been reported.

Table 1: Age distribution of patients undergoing laparotomy

Age group	Type of closure		Total
	Mass closure	Conventional layered	
<20	4	0	4
20–30	3	9	12
30–40	7	7	14
40–50	8	13	21
50–60	16	11	27
60–70	10	8	18
>70	2	2	4
Total	50	50	100

Table 2: Sex distribution of patients undergoing laparotomy

Sex	Type of closure		Total
	Mass closure	Conventional	
Male	38	34	72
Female	12	16	28
Total	50	50	100

Table 3: Type of surgery in patients undergoing laparotomy

Type of surgery	Type of closure		Total
	Mass closure	Conventional	
Emergency	50	50	100

Table 4: Type of abdominal incision used in patients undergoing laparotomy

Type incision	Type of closure		Total
	Mass closure	Conventional	
Midline	42	23	65
Right paramedian	6	27	33
Right kocher's	2	0	2
Total	50	50	10000

Asymptomatic bulge develop in up to 10% of abdominal incisions and requires surgical intervention. Incisional hernia occurs after 3–5% of all abdominal operations. The management is by two techniques. One is an anatomical approach (Keel method). The other is implantation of prosthetic materials such as marlex or mersilene. Incisional hernia although a less serious complication than acute disruption, but is not always innocent. Full-length incisional hernia probably represents covert dehiscence and usually starts as a symptomless partial disruption of the deep layer of abdominal wound, while the superficial layers remain intact, and skin is only to heal.

Consequently, the hernia appears immediately, although it may not be recognized until some month. These large

Table 5: Nature of abdominal surgeries performed in patients undergoing laparotomy

Nature of surgery	Type of closure		Total
	Mass closure	Conventional	
Intestinal obstruction	16	12	28
Enteric perforation	7	7	14
Gastro duodenal perforation	19	26	45
Others	8	5	13
Total	50	50	100

Table 6: Time taken for closure of laparotomy wounds

Time taken (min)	Type of closure		Total
	Mass closure	Conventional layered	
10–15	7	0	7
15–20	26	1	27
20–25	16	10	26
25–30	1	26	27
30–35	0	11	11
35–40	0	2	2
Total	50	50	100

Table 7: Time taken for suture removal after laparotomy

Time taken for suture removal (days)	Type of closure		Total
	Mass closure	Conventional	
7	27	26	53
8	12	13	25
9	8	7	15
10	3	4	7
Total	50	50	100

incisional hernias are caused by the failure of technique (broken sutures, knot slippage, or a suture cutting out of the tissues following an inadequate bite). The smaller incisional hernia probably results from wound sepsis or may follow the placement of a drain through the wound.

The majority of incisional hernias develops in the 1st year after the operation and is the result of the interaction of a number of factors including the method of closure. The early hernia is attributable to mechanical wound failure. The combined strength of the healing wound, a function of the extrinsic strength dependent on the mechanical aspect of wound closure, and the slowly increasing intrinsic strength is inadequate to withstand the forces applied and a diffuse hernia results.

In our study, the mean age of patients taken up for the study was 49.9 years in mass closure group and 47.6 years in conventional layered closure group, showing no significant difference between the two groups.

In our study, 65% of patients had midline abdominal incision and 33% had right paramedian abdominal incision, for the approach into the abdomen. 65.63% of midline incisions were closed by mass closure technique, and 82% of paramedian incisions were closed by conventional layered technique, showing that mass closure technique was used significantly more in midline incisions and significantly less in paramedian incisions and preferring conventional layered closure for paramedian incisions.

This was due to the fact that we found in paramedian incisions, closing the peritoneum separately and then suturing the anterior rectus sheath only was more technically easier than taking a single bite through the peritoneum, posterior rectus sheath, rectus muscle, and anterior rectus sheath, which was bulkier and had high chance of injuring the bowel at the end of the closure.

A meta-analysis on 23 randomized trials showed that odds of the burst are reduced to half with the interrupted method of closure compared to the continuous method. In emergency surgery, interrupted sutures are better than continuous method as they have "Gigli saw" or "hacksaw" effect. In conventional abdominal closure, the primary advantage of layered closure is that as the individual fascial layer is sequentially closed, the multiple strands exist,

so that if a break, the incision is held intact by the remaining sutures. Whereas, continuous fascial mass closure with a single closure allows the even tension distribution across the entire length of the suture which results in minimization of tissue strangulation.

However, excessive tension if applied in layered closure, leads to tissue necrosis and resultant failure of closure. Agrawak *et al.* have concluded that interrupted abdominal wall closure prevents burst abdomen, in his randomized controlled trial comparing interrupted X and conventional continuous closures in surgical and gynecological patients.

Many larger earlier studies, and Weiland *et al.*[1] study advocated the use of monofilament nonabsorbable suture material for closure of laparotomy wounds. Weiland *et al.*, from their meta-analysis study suggested that continuous closure with nonabsorbable suture should be used to close most abdominal wounds; however, if infection or distension is anticipated, interrupted absorbable sutures are preferred. Rucinski *et al.*[2] in their meta-analysis of an optimal technique for closure of abdominal midline fascia compared absorbable and nonabsorbable sutures. They found no statistically significant difference between nonabsorbable and monofilament absorbable sutures with regard to post-operative wound infection, dehiscence, and incisional hernia. There was, however, a higher incidence of wound infection and incisional hernia formation when braided absorbable suture material was used. There was a higher incidence of incision area pain and suture sinus formation when nonabsorbable suture material was used. They advocated a continuous mass closure with absorbable monofilament suture material for laparotomy wounds. However, results of larger studies showing the advantages of absorbable sutures over nonabsorbable sutures are still awaited. Hence, in our study, we used monofilament, nonabsorbable continuous interlocking sutures (Prolene No.1) for the closure of laparotomy wounds.

In our study, the mean time taken for the closure of laparotomy wounds by mass closure was 19.6 min and by conventional layered closure was 27.9 min. Mass closure took about 8 min lesser time than conventional layered closure. In Banerjee and Chatterjee[3] study, mass closure took about 10 min lesser time than conventional layered closure. Our study was inconsistent with the study of Banerjee and Chatterjee. Reduction in operative time prevents anesthetic hazards, reduces the cost of anesthetic agent and saves the time of the surgeon.

Different studies have reported post-operative complication rates which are definitely less in mass closure than in conventional layered closure. Irvin *et al.*[4] found that wound infection was responsible for ten-fold rise in the incidence of burst abdomen and incisional hernia. Tearing through the weak infected tissues with intact suture is the main cause for wound dehiscence.

The incidence of post-operative seroma formation in our study was 6% in single layer closure group and 10% in conventional layered closure group, showing a higher incidence in conventional layered closure group.

CONCLUSION

In our study, mass closure of laparotomy wounds took less operative time than conventional layered closure. Furthermore, the incidence of post-operative complications such as seroma, wound infection, wound gaping, burst abdomen, and incisional hernia was less in mass closure. Hence, we conclude that mass closure technique is better than the conventional layered closure of laparotomy wounds in terms of operative time and post-operative complications. However, longer study period is required to know the exact incidence of an incisional hernia.

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Original Article

Effect of Middle Meatal Spacer in Prevention of Post Functional Endoscopic Sinus Surgery Synechiae - A Prospective Study

K Semmanaselvan

Assistant Professor, Department of Otorhinolaryngology, Upgraded Institute of Otorhinolaryngology, Madras Medical College, Chennai, Tamil Nadu, India

Abstract

Introduction: Middle meatal (MM) scarring is reported as being one of the most common post-operative complications of endoscopic sinus surgery. The incidence of post-operative synechia ranges between 4% and 27%. The severity of scarring varies widely from mild, significant synechia to clinically obstructive disease requiring further surgical intervention. In an attempt to decrease the frequency of this complication, various surgical techniques and MM stents have been designed and used.

Aim: The aim of the study was to study the effect of MM spacer in preventing post-operative complications of endoscopic sinus surgery.

Methods: A non-randomized single-center prospective study was conducted at Rajiv Gandhi Government General Hospital, Madras Medical College among 30 patients undergoing endoscopic sinus surgery. Diagnostic nasal endoscopy was done preoperatively to evaluate the anatomy and pathology of the nasal cavity. Polyvinyl acetate a highly absorbent inert material was used to stent the middle meatus, and it was removed on the 6th post-operative day. Diagnostic nasal endoscopy was done postoperatively to look for any synechiae and other complications. All details of the patient were collected using a pro forma, and the data were analyzed.

Results: Synechiae were present in only 6% of the study population in the 2nd visit, i.e. 1 week after pack removal. These adhesions too were clinically insignificant during the follow-up period. Hence using the bioinert spacer and retaining it for a week is effective in preventing synechiae and the few synechiae that do occur have been clinically silent.

Conclusion: Using the bioinert spacer and retaining it for a week is effective in preventing synechiae and the few synechiae that do occur have been clinically silent.

Key words: Middle meatal spacer, Middle meatal stent, Post functional endoscopic sinus surgery synechiae, Polyvinyl acetate spacer

INTRODUCTION

Middle meatal (MM) scarring is reported as being one of the most common post-operative complications of endoscopic sinus surgery.[1] The incidence of post-operative synechia ranges between 4% and 27%. The severity of scarring varies widely from mild, significant synechia to clinically obstructive disease requiring further surgical intervention. In an attempt to decrease the frequency of this complication, various surgical techniques and MM stents have been designed and used. Some authors advocate suture medialization or controlled synechia medialization of the middle turbinate. Others believe partial middle turbinate resection to be beneficial in decreasing the rate of synechia formation.[2-4] Some advocate placing stents within the ostiomeatal complex. Others place synthetic sponges (i.e. Merocel). However, many questions linger regarding stenting of the MM: Are stents truly beneficial? What is their exact purpose or function? Are they to be used solely as MM spacers? Can

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Corresponding Author: Dr. K Semmanaselvan, Department of Otorhinolaryngology, Upgraded Institute of Otorhinolaryngology, Madras Medical College, Chennai, Tamil Nadu, India. Phone: +91-9840068082. E-mail: erodekottivakkam@yahoo.co.in

they catalyze or delay wound healing? Do they promote hemostasis? Other questions pertain to the stent shape and size, whether the stent biomaterial is important, and whether surgical technique influences synechia formation. The purpose of this report is to explore some of these questions.[5-7]

Aim

The aim of the study was to study the effect of MM spacer in preventing post-operative complications of endoscopic sinus surgery.

MATERIALS AND METHODS

This nonrandomized single-center prospective observational study was conducted at Rajiv Gandhi Government General Hospital, Madras Medical College. 30 consecutive patients operated for chronic sinusitis by functional endoscopic sinus surgery (FESS) using local or general anesthesia. The patients underwent FES Surgery for chronic sinus infections were included.

Procedures

Step 1: Pre-operative plain computed tomography scan of the paranasal sinuses and pre-operative nasal endoscopy.
Step 2: Per-operative nasal endoscopy followed by FESS.
Step 3: MM spacer kept at the end of the surgery.
Step 4: MM spacer removed on the 6th post-operative day followed by nasal endoscopy.
Step 5: Nasal endoscopy 1 week and 1 month after pack removal.

Post-operative Video Nasal Endoscopy

- On the day of pack removal, 6th post-operative day.
- 1 week after pack removal.
- 1 month after pack removal.

Surgery was only decided on if patient's signs and symptoms failed to respond to an aggressive trial of medical therapy (>3 weeks of antibiotics in addition to mucolytics, decongestants). Polyvinyl acetate (PVAc) stent was placed in the middle meatus. During each post-operative visit patients were evaluated through nasal endoscopy for the presence of synechia and or granulation tissue between the middle turbinate and lateral nasal wall. Patients were assessed as well for possible stent-related morbidity, specifically nasal obstruction, headache, and infection. Such symptoms and signs were only considered to be stent-related if present before the first post-operative visit. Patients were required to attend at least 2 of the 3 post-operative visits to be included in the study.

RESULTS

About 40 % of the beneficiaries were in the age group of 21–30 years. No difference in male and female prompt attendance to the post-operative visits noticed. For the 2 patients, with adhesion, it was clinically insignificant during the follow-up period and therefore not lysed. Post-operative infection developed in patients, missing few doses of oral antibiotics and self-administered nasal douching. One patient developed temporary granulation tissue in the middle meatus. One patient developed temporary granulation tissue in the middle meatus [Tables 1-2].

DISCUSSION

Synechiae, or scarring, of the sinonasal cavity, has traditionally been considered a complication of sinus surgery, or at least a poor outcome which should be avoided. This belief is evidenced by the numerous spacers and stents designed and marketed to prevent synechiae formation after sinus surgery, as well as the many studies which include synechiae formation as a primary outcome measure.[8] Gaskins reported a synechia rate of 10.0% for the nonstented side and 6.7% for the stented side.[9] MM spacers have shown benefit in decreasing MM adhesions. Data from our study support the literature consensus that MM stents seem to be efficacious.[3] Synechiae rate of 6.6% was observed in our study. Post-operative nasal edema will enlarge the middle turbinate beyond its normal size, therefore, requiring that the stent extend past it's anterior and inferior edges for best functional results. The anteroinferior aspect of the middle turbinate and the lateral nasal wall form an anatomic bottleneck to the MM, which during the period of postsurgical edema, is prone to synechia formation due to contact of de-epithelialized mucosal edges. In addition, the surgical technique may play a significant role in reducing the rate of synechia. Minimally Invasive Sinus Technique (MIST), a surgical model that is effective in treating all stages of chronic sinus disease, does not disturb the maxillary birth ostium.[3] No maxillary antrostomy is performed, and nasal mucosa and nasal turbinates are always preserved. Furthermore, the powered microdebrider tends to result in a more delicate and precise dissection within the nasal cavity. These procedural modifications minimize surgical trauma in the MM. No previous study has reported the incidence of synechia following MIST. It is also noted that synechia, when present following MIST, is rarely clinically significant. This observation may directly relate to the natural position/orientation of the maxillary birth ostium. In most patients, the maxillary birth ostium is oriented either obliquely or horizontally, thereby minimizing the risk of a lateralized middle turbinate causing obstruction. An MM antrostomy,

Table 1: Distribution of post-operative findings

Post-operative findings	Visit 1, 6th post-operative day, pack removal	Visit 2 1 week after pack removal	Visit 3 1 month after pack removal
Packing injury	Absent	Absent	Absent
Edema	3	Absent	Absent
Post-operative reactionary hemorrhage	Absent	-	-
Post-operative secondary hemorrhage	Absent	Absent	Absent
Blood clot in the middle meatus	Absent	Absent	Absent
Granulation	Absent	1	Absent
Post-operative infection	Absent	2	Absent
Crusting	Absent	2	Absent
Middle Meatus/turbinate collapse	Absent	Absent	Absent
Stenosis of a surgically enlarged maxillary antrostomy	Absent	Absent	Absent
Lateralization of the middle turbinate	Absent	Absent	Absent
Adhesion/synechiae	Absent	2	Absent
Contracture	Absent	Absent	Absent
Scar formation	Absent	Absent	Absent

Table 2: Distribution of morbidity

Stent-related morbidity	Number of patients
Nasal obstruction	3
Headache	3
Infection	0

however, creates a parasagittal opening, which is favorably positioned to become occluded from a lateralized middle turbinate or edematous middle meatus. The granulation tissue, post-operative infection, and adhesion resolved by the time of subsequent visit. Many factors contribute to nasal obstruction in the immediate post-operative period, including postsurgical edema, atopy, and infection.

CONCLUSION

The ideal FESS should include preservation of the middle turbinate with a minimal rate of lateral synechiae formation. Using the spacer is not a substitute for meticulous technique while performing the operation. Using the bioinert spacer and retaining it for a week is effective in preventing synechiae. Few synechiae that do occur have been clinically silent. Minimal scarring and granulation help prevent impairment of mucociliary flow patterns. Compressed small compact shape allows quick and easy insertion into the middle meatus. PVAc nasal spacer has porous outer surface and interconnected cell structure producing a packing that is highly absorbent and prevents blood clot formation. Quickly expands on exposure to fluids to fill the contours of the middle meatus to provide gentle pressure and stop bleeding. Extremely soft when hydrated making removal less traumatic. Drawstrings help retention and easy removal. Normal post-operative regeneration of the mucosa is not affected by the spacer because physiological nasal secretory functions recover.

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Original Article

Laparoscopic Evaluation of Female Infertility

Syeed Masuma Rizvi[1], Shaheera Ajaz[2], Farhat Ali[2], Shazia Rashid[3], Tashaffi Qayoom[2], Lubna Rashid[2]

[1]Associate Professor, Department of Gynaecology and Obstetrics, Government Medical College, Srinagar, Jammu and Kashmir, India, [2]Senior Resident, Department of Gynaecology and Obstetrics, SKIMS Soura, Srinagar, Jammu and Kashmir, India, [3]Senior Resident Department of Gynaecology and Obstetrics, Government Medical College, Srinagar, Jammu and Kashmir, India

Abstract

Background: Infertility, one of the most common disorders confronting gynecologists, has multifactorial etiology and none of the laboratory findings alone is conclusive in diagnosis. Laparoscopy helps in finding the etiology and planning further management.

Objectives: The objectives of this study were to study the role of diagnostic laparoscopy in evaluation of female infertility and analyze the comparative frequencies of different etiologies in primary and secondary infertility.

Methodology: A total of 60 infertile patients underwent diagnostic laparoscopy after basic infertility work up in the Department of Gynaecology and Obstetrics, Government Medical College, Srinagar, from April 2013 to September 2014. Frequencies were calculated for laparoscopic findings regarding primary and secondary infertility.

Results: Of the 60 infertile patients, 41 (68.33%) had primary and 19 (31.67%) had secondary infertility. Mean duration of infertility was 4.08 years in primary and 5.15 years in secondary infertility. Of the secondary infertility patients, 47% had previous history of abortion. On laparoscopy, the most common finding was tubal blockade accounting for 26.8%, 57.9%, and 36.7% of primary, secondary, and total infertility patients, respectively. The difference in tubal factors in primary and secondary infertility was statistically significant ($P < 0.02$). Ovarian factors contributed to 24.5%, 15.9%, and 21.7% of primary, secondary, and total infertility patients, respectively. Uterine factors were implicated in 17%, 10.5%, and 15% of primary, secondary, and total infertility patients, respectively. Peritoneal factors were implicated in 22%, 5.2%, and 16.7% of primary, secondary, and total infertility patients, respectively. No cause was found in 9.7%, 10.5%, and 10% of primary, secondary, and total infertility patients, respectively, which were included in unexplained infertility.

Conclusion: Laparoscopy plays a valuable role in the complete evaluation of infertility. It helps to find those causes which are unrevealed by other investigations and thus helps to guide appropriate therapy.

Key words: Laparoscopic, Female, Infertility

INTRODUCTION

Infertility, one of the most common conditions confronting gynecologists, is defined as inability to conceive after 1 year of regular unprotected sexual intercourse.[1]

Infertility is a problem of global proportion. The World Health Organization (WHO) estimates 60–80 million couples worldwide suffer from infertility.[2] Infertility varies across regions of the world and is estimated to affect 8–12% of couples worldwide.[3,4] The WHO estimates the overall prevalence of primary infertility in India to be between 3.9 and 16.8%.[2] Estimates of infertility varies widely among Indian states from 3.7% in Uttar Pradesh, Himachal Pradesh, and Maharashtra[5] to 5% in Andhra Pradeshand 15% in Kashmir.[6]

Infertility can be divided into primary and secondary infertility. In primary infertility, no previous pregnancies have occurred, and in secondary infertility, a prior pregnancy although not necessarily a live birth has occurred.[7] Globally, most infertile couples suffer from primary infertility.[8]

The female factors contribute most (40–55%) in the etiologies of infertility followed by malefactors (30–40%), both partners (10%), and unexplained (10%).[9]

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Corresponding Author: Dr Shaheera Ajaz, House Number 8, Lal ded colony, Goripora, Rawalpora, Srinagar, Jammu and Kashmir, India. Phone: +91-9419522226. E-mail: shaheeraajaz900@gmail.com

Laparoscopy is an essential step and a standard procedure in the evaluation of infertile patients before initiating infertility treatment.[10,11] Laparoscopy is the gold standard for diagnosing tubal and peritoneal disease, endometriosis and adhesions because no other imaging technique provides same degree of sensitivity and specificity. Laparoscopy with direct visual examination of the pelvic reproductive anatomy is the only method available for specific diagnosis of peritoneal factors that may impair fertility. It is also helpful in diagnosing uterine and ovarian factors. The practice committee of American Society of Reproductive Medicine suggests that laparoscopy should be seriously considered before applying aggressive empirical treatments involving significant costs and/or potential risks.[12]

This study was conducted in Government Lalla Ded Hospital - a 500-bedded tertiary care center which is the only referral hospital which caters to the whole of Kashmir Valley and, therefore, reflects the whole scenario of Kashmir. Kashmir has low literacy rate of just 68%[13] and about 20% of the people are living below poverty line.[14] Thus, many people are illiterate and belong to low socioeconomic status. They go to untrained health practitioners for infertility treatment which leads to delay in proper management. Further, infertility, being highest in Kashmir among various states of India,[6] needs an appropriate diagnosis and proper treatment at appropriate time.

Aims and Objectives

1. To study the utility of diagnostic laparoscopy in the evaluation of female infertility.
2. To analyze the comparative frequencies of different etiologies in primary and secondary infertility.

MATERIALS AND METHODS

This study was carried from April 2013 to September 2014 in the Department of Obstetrics and Gynaecology at Government Lalla Ded Hospital in Srinagar, Jammu and Kashmir. This was a cross-sectional study involving 60 patients. The inclusion and exclusion criteria were as follows:.

Inclusion Criteria

The following criteria are included in the study:

1. Patients with primary or secondary infertility after excluding the exclusion criteria reporting to the hospital.
2. Normal semen analysis of the male partner.
3. Patients of polycystic ovarian syndrome not responding to treatment.

Exclusion Criteria

The following criteria are excluded from the study:

1. Couples with male factor infertility.
2. Couples who had not lived together for 12 months.
3. Patients with absolute or relative contraindications for laparoscopy.
4. Hyperprolactinemia or thyroid function abnormalities.
5. Vaginal causes for infertility.

All patients underwent standard infertility evaluation including complete history, physical examination with special reference to secondary sexual characters, thyroid examination, abdominal, per speculum, and per vaginal examination.

All baseline investigations, male semen analysis, and hormonal analysis including follicle-stimulating hormone (FSH), luteinizing hormone (LH), thyroid-stimulating hormone, serum progesterone day 21, anti-Mullerian hormone (AMH), and serum prolactin were done. TVS with antral follicle count (AFC) and hysterosalpingography were also done. Laparoscopic evaluation was done as per standard guidelines.

The data were collected on a pro forma and various laparoscopic findings in primary, secondary, and total cases of infertility were noted. SPSS (Version 20.0) and Microsoft Excel were used to carry out the statistical analysis of data. Data were analyzed with the help of descriptive statistics, namely percentages, means, and standard deviations and presented by means of bar and pie diagrams. Student's *t*-test was employed for parametric data, and for non-parametric data, Chi-square test or Fisher's exact test, whichever appropriate was applied. $P < 0.05$ was considered statistically significant.

OBSERVATION AND RESULTS

In the present study, out of 60 cases, 41 (68.33%) presented with primary infertility and 19 (31.67%) with secondary infertility. The age distribution is shown in Table 1. In our study, majority of patients of primary (58.5%) and secondary (52.6%) infertility belonged to the age group of 31–35 years. Minimum and maximum age for primary infertility was 21 years and 38 years, respectively.

In our study, majority of patients of primary infertility (78%) and that of secondary infertility (63%) had duration of infertility of 1–5 years. Longest duration of infertility in primary infertility group was 10 years and in secondary infertility group was 15 years. Mean duration of infertility for primary infertility group was 4.08 years and secondary infertility was 5.15 years. The mean duration of infertility

Table 1: Age distribution in cases of primary and secondary infertility

Age (years)	*n* (%)		
	Primary (*n*=41)	Secondary (*n*=19)	Total (*n*=60)
21–25	3 (7.4)	0 (0)	3 (5)
26–30	9 (21.9)	4 (21.1)	13 (21.67)
31–35	24 (58.5)	10 (52.6)	34 (56.66)
36–40	5 (12.2)	5 (26.3)	10 (16.67)
Total	41 (100)	19 (100)	60 (100)
Mean±SD	31.9±3.73	33.9±2.86	*P*=0.041 (Student's *t*-test)

SD: Standard deviation

Table 2: Obstetric histories in secondary infertility

Obstetric category	*n* (%)
Previous uneventful delivery	8 (42.2)
Previous abortion	9 (47)
Previous IUD	2 (10.5)
Total	19 (100)

IUD: Intrauterine device

between primary and secondary infertility groups was not statistically significant ($P = 0.174$).

The obstetrical history is shown in Table 2. In the present study, majority of the patients of secondary infertility - 9 cases (47.3%) had previous history of abortion. Out of nine cases, seven had spontaneous and two had medically induced abortion. Out of seven spontaneous abortions, there was a history of check curettage in three patients. Out of two medically induced abortions, one case gave a history of dilatation and curettage.

Out of eight uneventful deliveries, only two had delivered at home and six patients had a history of previous institutional delivery. Two patients with previous history of intrauterine device of fetus had institutional delivery at that time. The hysterosalpingogram findings are shown in Table 3. The causes of infertility are shown in Table 4. In our study, overall, uterine factors accounted for 15% of infertility patients. Fibroid uterus was the most common cause both in primary (14.6%) and secondary infertility (13.3%) group. Mullerian anomaly was found in one case (2.4%) of primary infertility who had unicornuate uterus. The difference in uterine factors in infertility on laparoscopy in primary and secondary infertility groups was not statistically significant ($P = 0.705$).

Bald ovaries (anovulation) were the most common ovarian cause (10%) in both primary (9.7%) and secondary infertility (10.5%). Of the six patients with bald ovaries, two patients had atrophic ovaries, with high FSH and LH and low AMH and AFC suggestive of premature ovarian failure. Polycystic Ovary Syndrome (PCOD) was present in only primary infertility group. It accounted for 7.4% of the cases of primary infertility and 5% of the total cases of infertility. Ovarian cyst accounted for 5% of infertility patients. The difference in ovarian factors in primary and secondary infertility groups was not statistically significant ($P = 0.522$).

Peritoneal factors accounted for 16.7% of the cases of infertility. Pelvic endometriosis was seen in 8 patients (13.3%). All of these were in primary infertility group. Active pelvic infection was seen in one patient in primary infertility group (2.5%) and one in secondary infertility group (5.25%).

The difference in total cases with peritoneal factor in primary and secondary infertility groups was not statistically significant ($P = 0.148$). When endometriosis was compared between primary and secondary infertility patients, the difference was statistically significant ($P = 0.047$).

In some cases, more than one factor was detected on laparoscopy. The most important and significant one was considered. However, despite thorough laparoscopic evaluation, no factor was revealed in 6 cases (10%) and was, therefore, included in unexplained infertility.

Although tubal factor was more common in secondary infertility (57.9%) than primary infertility (26.8%), the difference being statistically significant ($P = 0.020$), it was the most common factor in both groups on laparoscopy. This was followed by ovarian, peritoneal, uterine, and unexplained (in that order) in both groups. Thus, there was no statistically significant difference in the distribution of causes among primary and secondary infertility ($P = 0.171$).

DISCUSSION

Diagnostic laparoscopy is an essential part in the complete evaluation of infertile couple. Direct visualization of abdominal and pelvic organs allows definitive diagnosis to be made in cases where clinical evaluation and imaging techniques have failed.

In the present study, laparoscopy was done to study its utility in the evaluation of female infertility, and comparative frequencies of different etiologies in primary and secondary infertility were analyzed. Of the 60 infertile patients, studied over a period of 18 months, 41 (68.3%) presented with primary infertility and 19 (31.7%) presented with secondary infertility. It was comparable to Naz *et al.* study,[15] Shetty and Shetty study,[16] Boricha *et al.* study,[17] and Saini *et al.* study.[18] 35 years is considered as the limit in fertility terms for advanced reproductive age (American Society of Reproductive Medicine,

Table 3: HSG findings in infertile women

HSG Finding	*n* (%)		
	Primary infertility (*n*=41)	Secondary infertility (*n*=19)	Total (*n*=60)
Normal	15 (36.6)	7 (36.9)	22 (36.7)
B/L blocked tubes*	16 (39)	10 (52.6)	26 (43.3)
U/L blocked tube	8 (19.5)	2 (10.5)	10 (16.6)
Hydrosalpinx	1 (2.45)	-	1 (1.7)
Mullerian anomaly	1 (2.45)	-	1 (1.7)
Total	41 (100)	19 (100)	60 (100)

*In 1 patient with secondary infertility with b/l blocked tubes endometrial cavity also was not delineated suggestive of Asherman's syndrome. 2 patients in secondary infertility with b/l blocked tubes had hydrosalpinx associated with blocked tubes. #Fisher's exact test

Table 4: Causes of infertility at laparoscopy

Causes of infertility	*n* (%)			
	Primary (*n*=41)	Secondary (*n*=19)	Total (*n*=60)	p
Uterine	7 (17)	2 (10.5)	9 (15)	0.705#
Tubal	11 (26.8)	11 (57.9)	22 (36.7)	0.020*
Ovarian	10 (24.5)	3 (15.9)	13 (21.7)	0.522#
Peritoneal	9 (22)	1 (5.2)	10 (16.6)	0.148#
Unexplained	4 (9.7)	2 (10.5)	6 (10)	1.000#
Total	41 (100)	19 (100)	60 (100)	

Distribution of causes in primary and secondary infertility group. *P*=0.171*, Not significant. #Fisher's exact test, *Chi-square test

2013).[19] In our study, 5 (12.2%) of women in primary infertility group and 5 (26.3%) of women in secondary infertility group were of age more than 35 years. As recommended by American Society of Reproductive Medicine, these women should be referred after 6 months of trying to conceive for infertility workup because of decline in fertility and increased time to conception after 35 years of age.[19,20]

The mean duration of infertility for primary infertility was 4.08 years and that for secondary infertility was 5.15 years, which is comparable with Boricha *et al.*,[17] Shetty and Shetty study,[16] and Wani *et al.*[21] study.

In our study, tubal factors were responsible for infertility in 22 (36.7%) cases, which were comparable with Shetty and Shetty,[16] Samal *et al.*,[22] and Agarwal and Anand[23] study. It was accounted for 11 (26.8%) of primary and 16 (57.9%) of secondary infertility. Tubal factor was the most common cause of both primary and secondary infertility in our study which was comparable with Samal *et al.* study[22] but differed from other studies.[16,18,23] Tubal occlusion usually represents past pelvic infection or surgery. Incidence of subsequent tubal infertility is 8%, 19.5%, and 40% after one, two, and three episodes of pelvic inflammatory disorder (PID).[24]

In secondary infertility patients, 75% of the previous uneventful deliveries and 100% of dilatation and evacuations had been done in hospital settings. Thus, 100% institutional deliveries and aseptic precautions during abortion and delivery in these hospital settings can prevent PID and hence tubal block in these patients.

As tubal factor is the most common factor in primary infertility also, it may be because of subclinical PIDs in young women and adolescents because of poor perineal hygiene, particularly during menstrual periods. Thus, proper education and counseling of adolescent girls are an important preventive measure for infertility.

Ovarian factor was the second most common cause of infertility in our study. It accounted for 13 (21.7%) of total infertility patients, 10 (24.5%) cases of primary infertility, and 3 (15.9%) cases of secondary infertility which correlates with study from Samal *et al.*[22] and Shetty and Shetty.[16]

According to ASRM-sponsored consensus workshop group, polycystic ovary syndrome (PCOS) is the most common cause of anovulation or oligoovulation in women presenting with infertility.[25] In our study, polycystic ovaries were present in 3 cases (5%) of infertility and were the second most common cause of ovarian factor for infertility. This is because only those cases of PCOS were included in the study, who did not respond to medical treatment. All 3 of these cases belonged to primary infertility group (7.4%). There was no case of PCOD in secondary infertility which may be because of small study group of 60 patients in our study.

In our study, peritoneal factors accounted for 10 (16.7%) of the total cases of infertility - 9 (22%) of primary infertility cases and 1 (5.2%) of secondary infertility. These findings were comparable with Agarwal and Anand study[23] and Saini *et al.* study.[18]

Endometriosis was found in 8 (13.3%) of the total cases of infertility which was comparable with Agarwal and Anand

study.[23] All the 8 cases belonged to primary infertility group (19.5%). There was no case of endometriosis among secondary infertility patients. The incidence of endometriosis has been found more in primary infertility as noticed in other studies.[26,27] Finding of no case of endometriosis in secondary infertility may be because of small study group of 60 patients in our study.

In developing countries, PID is a common cause of infertility. Tubal occlusion usually represents past pelvic infection or surgery. A single episode of PID causes up to 8% of future tubal factor for infertility.[24] In our study, active pelvic infection was present in 1 case of primary infertility (2.5%) and 1 case of secondary infertility (5.2%).

Despite thorough laparoscopic evaluation, no cause (unexplained infertility) was detected in 6 (10%) cases - 4 patients (9.7%) were primary infertility and 2 (10.5%) of secondary infertility which was comparable with Saini *et al.* study.[18]

Thus, diagnostic laparoscopy by direct visualization of the pelvic organs facilitates the exact identification of the pelvic etiology in majority of the patients and thus helps to guide appropriate therapy. In some patients, it alters treatment plans, including earlier utilization of assisted reproductive technology, thus avoiding unnecessary medical treatment. It also helps in giving definitive diagnosis so that couples who have no chance of conception can plan earlier for adoption.

CONCLUSION

Laparoscopy plays a valuable role in the evaluation of infertility. In our study, laparoscopy helped to detect a cause in 90% of the infertile patients. Furthermore, keeping in view, the high rates of infertility and illiteracy in our region and large number of patients having tuboperitoneal factor for infertility, for which laparoscopy is the gold standard, laparoscopy is a very effective procedure in evaluating these infertile women and thus to plan appropriate management.

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Original Article

A Comparison between Conjunctival Autograft with Bare Sclera Technique in Pterygium Excision and Its Recurrence

Abhijeet Jain

Assistant Professor, Department of Ophthalmology, Government Medical College, Ambikapur, Surguja, Chhattisgarh, India

Abstract

Background: Pterygium is a fibrovascular growth that originates from conjunctiva encroaching onto the cornea. This study deals with the comparison between conjunctival autograft with bare sclera technique in pterygium excision and its recurrence. Several surgical and adjunctive medical therapies have been tried to reduce the fibrovascular activity and recurrence rate but none of its where universally accepted. This study might take an important role during treatment of pterygium.

Methods: This study was done in the Kamlesh Netralaya Hospital, Ambikapur, Surguja, Chhattisgarh, between the periods of 2016 and 2018. A total of 120 eyes diagnosed with pterygium, of which 70 eyes operated with conjunctival autograft technique and 50 eyes were operated with bare sclera technique selected for this study. The patients with hypertension, diabetes mellitus, cataracts, dry eye syndrome, and pseudopterygium were excluded, and every patient has to fill a consent form. Slit-lamp examinations and routine investigation were done before the procedure. Post-operative follow-up visits of patients were scheduled and during follow-up visit operated eye was examined under slit lamp, and complication was recorded in tabulated form.

Results: The present study was done on 120 eyes diagnosed with pterygium, of which 70 eyes (42 males and 28 females) operated with conjunctival autograft technique and 50 eyes (28 males and 22 Females) were operated with bare sclera technique selected for the study. Mean age in conjunctival autograft technique was 45.05, maximum age was 65, and minimum age was 30 wherein bare sclera technique mean age was 53.76, maximum age was 60, and minimum age was 45. The recurrence rate in conjunctival autograft technique was nil and recurrence rate in bare sclera technique was 4 (8%). In this study, 96 (80%) eyes (patients) are having an outdoor occupation and 24 (20%) eyes (patients) having indoor occupation, respectively.

Conclusion: The present study revealed that conjunctival autograft technique having a minimum or nil recurrence rate of pterygium compared with bare sclera technique. Incidence of pterygium was more in male compared to female and pterygium was common inpatient having outdoor occupation compare to indoor. Hence, this studies useful for an ophthalmologist, clinicians for proper clinical diagnosis and treatment of disease.

Key words: Bare sclera technique, Conjunctival autograft technique, Occupation, Pterygium, Recurrence rate

INTRODUCTION

Pterygium was derived from Greek word Pterygos = little wing. 3000 years ago pterygium was recognized. Susrutha describes pterygium way back in 1000 B.C. in India, and it was also distinguished by Hippocrates, Galen, Celsius, etc. Pterygium defined as a wing-shaped, benign condition characterized by fibrovascular growth that originates from conjunctiva encroaching onto the cornea. This is showing with high ultraviolet radiation (UVR) and some other environmental pathogenesis such as dry eye, wind, dust, heat, infection, smoke, chemicals, and pollens play an important role.[1] The risk of pterygium is higher with an occupation such as salt workers, postmen, policemen, and limited health service due to long exposure of sunlight.[2] The exact cause or pathogenesis of pterygium is still not completely unstated.[3] Asia and other countries around the world located between 37° north and 37° south of the

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Corresponding Author: Dr. Abhijeet Jain, Kamlesh Netralaya hospital Ambikapur, Surguja – 497 001, Chhattisgarh, India.
Phone: +91-9826408811. E-mail: abhichetna.2008@gmail.com

equator is known as extends of pterygium belt. Pterygium disease is common in this equatorial belt.[4] Pterygium is a common disease in Indian rural areas because India is located in a "within a peri-equatorial 'pterygium belt' of latitudes."[5] The incidence of pterygium is more in male compared to female.[6] Morphology pterygium having three parts: The cap (flat zone on the cornea that consists mainly of fibroblasts that occupy and obliterate Bowman's membrane), the head (vascular region that lies behind the cap and attached to the cornea), and the body/tail (the movable region of the bulbar conjunctiva, which can be dissected from the underlying tissue).[7]

Surgical techniques which have been commonly used for the excision of pterygium are bare sclera, conjunctival autograft, and amniotic membrane transplantation, but none of its where universally accepted because of variable recurrence rates. Thus, the adjunctive medical therapies have been included into the management of pterygium and they are conjunctival flaps, lamellar keratoplasty, mucous membrane grafts, chemotherapy by Thiotepa, radiation therapy by radon bulbs, radium plaques, beta irradiation ablation with erbium YAG laser, smoothening the corneal surface with excimer laser, and antimetabolite such as 5-fluorouracil and Mitomycin c but all these adjunctive medical therapies have their own potential side effects.[8]

The aim of present study was to a comparison between conjunctival autograft with bare sclera technique in pterygium excision and its recurrence.

MATERIALS AND METHODS

The present study was conducted in the Kamlesh Netralaya Hospital Ambikapur, Surguja, Chhattisgarh, between the period of 2016 and 2018. A total of 120 eyes diagnosed with pterygium, of which 70 eyes (42 males and 28 females) operated with conjunctival autograft technique and 50 eyes (28 males and 22 females) were operated with bare sclera technique selected for the study. All patients, i.e. male and female patients in the age group of 20–70 years were included in this study. The patients having hypertension, diabetes mellitus, cataracts, dry eye syndrome, pseudo pterygium were excluded from the study. Every patient have to fill a standard proforma consent form which included Name, age, sex, address etc., after explaining the procedure. Occupation (Outdoor, Indoor) and family history of Pterygium taken from hospital record.

Pre-operative Procedure

Xylocaine sensitive test is done, routine investigations such as blood pressure, complete blood count, random blood sugar, and detailed slit-lamp examinations were done before the operation. Intramuscular in gluteal region tetanus toxoid vaccine was given to the patients before procedure shown in Figures 1 and 2.

Operative Procedure

The patient was shifted to the operation theater placed in supine position in operation table. Thorough cleaning of eye to be operated was done with betadine 7.5% solution i.e. povidone iodine solution. Peribulbar block 5 ml local anesthesia was administered which 2% lidocaine, adrenaline, and 01% bupivacaine. Now lid wire speculum placed in the eyelid for proper viewing of the operation site. The pterygium body was hold with tooth forceps and separated gently including the adjacent tenon's capsule with the help of crescent knives (D-Blade), and after separation of mass, it was dissected with corneoscleral scissors without damage to medial rectus muscle and surrounding area this technique is known as Bare sclera technique shown in Figure 3. Now the bare sclera of the eye was cleaned with normal saline and measured with a Vernier Caliper. The graft tissue was taken from superior

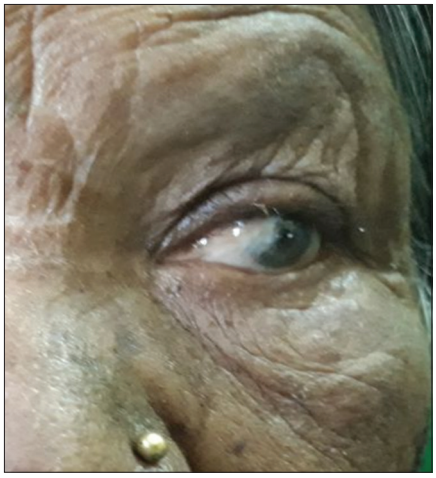

Figure 1: Pre-operative pterygium

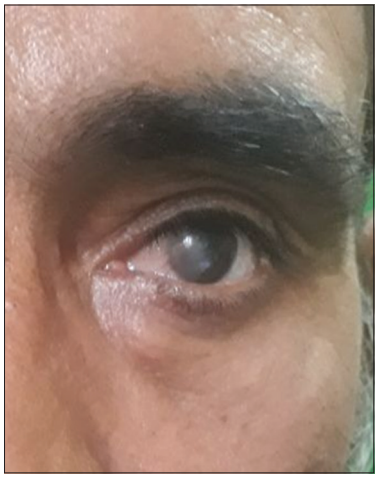

Figure 2: Pre-operative pterygium

sclera according to the measurement of caliper 0.5 mm additional. Then this graft tissue was placed on bare area of sclera and it was sutured using 10.0 silk and fix by applying 4–5 suture in the autograft tissue this procedure is known as conjunctival autograft technique shown in Figure 4. Now the antibiotic ointment was applied and pad bandage done.

Post-operative Procedure

Bandage opened after 12 h of surgery. Antibiotic and prednisolone eye drop was prescribed 6 times per day for 1 month in tapering dose. Oral tablets such as Diclofenac and serratiopeptidase were given B.D for 3 days from the day of surgery. Post-operative follow-up visits of patients were scheduled 1st day, 1st week, 1st month, 3rd month, and 6th month. During follow-up operated eye was examined under slit lamp, and complication such as pterygium recurrence, visual acuity, and corneal perforation was recorded. All the data were recorded in tabulated form.

Figure 3: Bare sclera technique post-operative

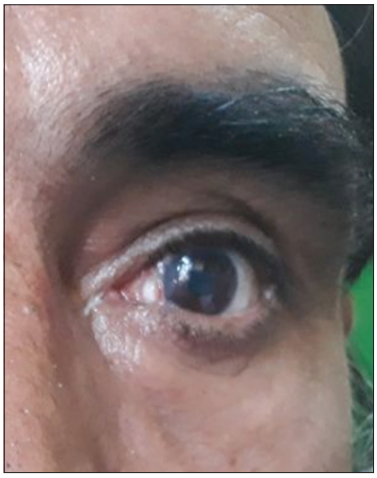

Figure 4: Conjunctival autograft technique post-operative

RESULTS

The present study was done on 120 eyes diagnosed with pterygium, of which 70 eyes (42 males and 28 females) operated with conjunctival autograft technique and 50 eyes (28 males and 22 females) were operated with bare sclera technique selected for the study. All patient lies in the age group of 20–70 years were included in this study. Mean age in conjunctival autograft technique was 45.05, maximum age was 65, and minimum age was 30 wherein bare sclera technique mean age was 53.76, maximum age was 60, and minimum age was 45 shown in Table 1. The recurrence rate in conjunctival autograft technique was nil and recurrence rate in bare sclera technique was 4 (8%) in this study. In this study, 96 (80%) eyes (patients) are having an outdoor occupation and 24 (20%) eyes (patients) having indoor occupation shown in Table 2.

DISCUSSION

Pterygium is a fibrovascular wing-shaped encroachment from conjunctiva onto the cornea. It is a common disease in India because India located "within a peri-equatorial 'pterygium belt' of latitudes."[5] UVR especially UVR-A and UVR-B (290–400 nm), hot and dusty climate is a frequent environmental risk factor for the development of

Table 1: Distribution of pterygium based on age and gender

Age (year)	Conjunctival autograft technique		Bare sclera technique	
	Male	Female	Male	Female
20–30	0	01	0	0
31–40	11	14	0	0
41–50	13	10	05	04
51–60	17	01	23	18
61–70	01	02	0	0
Number of eye	42	28	28	22
Total number of eye	70		50	
Mean age	45.05		53.76	
Maximum	65		60	
Minimum	30		45	

Table 2: Classification based on occupation

Technique	Number of eye	Occupation	
		Outdoor	Indoor
Conjunctival autograft technique	70	55	15
Bare sclera technique	50	41	09
Total (%)	120 (100)	96 (80)	24 (20)

Table 3: Comparative studies of recurrence rate among the various study of world.

Studied by	Conjunctival autograft technique		Bare sclera technique	
	Number of Patients	Recurrence rate	Number of patients	Recurrence rate
Alpay *et al*. 2009[10]	18	3 (16.6%)	21	8 (38.09%)
Khan *et al*. 2010[8]	34	03 (8.80)	30	11 (36.6)
Ahmed *et al*. 2012[11]	15	01 (6%)	15	06 (40%)
Kompalli 2016[12]	25	2 (8%)	25	6 (24%)
Present study	70	0	50	04 (8%)

pterygium.[3] The excision of pterygium with bare sclera was commonly used technique but recurrence rate was more compared to conjunctival autograft technique and operation time is less in bare sclera technique. Conjunctival autograft technique was first describe in 1985.[8]

This study reveals the comparison between conjunctival autograft with bare sclera technique in pterygium excision and its recurrence. The present study was done on 120 eyes diagnosed with pterygium, of which 70 eyes (42 males and 28 females) operated with conjunctival autograft technique and 50 eyes (28 males and 22 females) were operated with bare sclera technique selected for the study. All patient lies in the age group of 20–70 years were included in this study. Mean age in conjunctival autograft technique was 45.05, maximum age was 65, and minimum age was 30 wherein bare sclera technique mean age was 53.76, maximum age was 60, and minimum age was 45 shown in Table 1.

In this study, incidence of pterygium is more common in male than female which correlates with the study of Shah *et al*.[9] and Khan *et al*.[8]

In this study, recurrence rate in conjunctival autograft technique was nil and recurrence rate in bare sclera technique was 4 (8%) which correlates with the study of Khan *et al*.,[8] Alpay *et al*.,[10] Ahmed *et al*. 2012,[11] and Kompalli 2016[12] shown in Table 3.

In this study, 96 (80%) eyes (patients) having an outdoor occupation and 24 (20%) eyes (patients) having indoor occupation which correlates with the study of Salagar and Biradar[13] shown in Table 2.

CONCLUSION

The present study exposed that conjunctival autograft technique having a minimum or nil recurrence rate of pterygium compared with Bare Sclera Technique. Incidence of pterygium was more in male compared to female and pterygium was common inpatient having outdoor occupation compare to indoor.

Hence, this studies useful for an ophthalmologist, clinicians for proper clinical diagnosis and treatment of disease.

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Original Article

Prevalence of Signs and Symptoms of Temporomandibular Joint Disorders among Saudi Population - A Cross-sectional Study

Mohamed Fadul A Elagib[1], Saad Al-Qahtani[1], N Raghavendra Reddy[1], Sara M H Baldo[2], Rania A Sharif[3], Shankar T Gokhale[1]

[1]Asssistant Professor, Department of Periodontics and Community Dental Sciences, College of Dentistry, King Khalid University, Abha, Kingdom of Saudi Arabia, [2]Public Health Dentist, Abha, Kingdom of Saudi Arabia, [3]Assistant Professor, Department of SDS, College of Dentistry, King Khalid University, Abha, Kingdom of Saudi Arabia

Abstract

Background: This cross-sectional study evaluated the prevalence of the signs and symptoms of temporomandibular joint (TMJ) disorder (TMD) among Saudi patients with TMD symptoms.

AQ1 **Methods:** A total of 300 patients were screened; and of which 243 patients, 116 were males and 127 were females, with the age group of 15–30 years and above, who were randomly picked from the different school and colleges and also patients visiting the college of dentistry, King Khalid University, Abha, Saudi Arabia. A detailed questionnaire was distributed among the subjects asking about the presence of TMJ pain and related habits. The data obtained were compiled and statistically analyzed using Statistical Package for the Social Sciences software version 16.0. The *P* value was analyzed using the Pearson Chi-square test.

Results: About 20 patients (7 male and 13 female, i.e., 8.23%) had pain in TMJ or related or facial region, with a $P = 0.0015$ which is statistically significant.

Conclusion: Females with age group above 30 years had TMD signs and symptoms more frequently than males in the study population. The most common problem in both genders was pain.

Key words: Chewing habit, Headache, Pain

INTRODUCTION

Temporomandibular joint (TMJ) disorders (TMD) are one of the common conditions which affect the orofacial region. The American Dental Association in 1983 has suggested a broader term TMD refers to a group of disorders characterized by pain in TMJ, the periauricular area, or the muscles of mastication based on various risk factors[1] In the past few years, the risk factors underlying the etiology of TMJ is subject of debate.[2,3] In general, the risk factors such as parafunctional habits, emotional stress, genetic and psychosocial factors, age, and gender have gained an important role in the etiology of TMD.[4,5] The most common signs are noises during opening and closing of mandible and deviation or restriction in mandibular range of motion. Most common symptom of TMD is pain during mandibular movements, at rest, or on palpation of the muscles. Pain results from the changes in muscle activity that limits the movements of the mandible and protects it from further damage while trying to promote healing.[6] TMD can also occur as a consequence of pain of non-dental origin in the orofacial region, including the head, face, and related structures. TMD is a possible cause of headache and vice versa as a positive correlation was found between TMD and the prevalence of headaches.[7] The prevalence of TMD varies from 9.8 to 80% from published data, according to epidemiological studies in different population age group based on risk factors. Few studies have been reported on the prevalence of TMD in

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Corresponding Author: Dr. Shankar T Gokhale, Department of Periodontics and Community Dental Sciences, College of Dentistry, King Khalid University, Abha, Kingdom of Saudi Arabia. Phone: +966581573072. E-mail: sgokhale@kku.edu.sa

Saudi Arabia in normal children, during the primary, mixed, and permanent dentition population group.[8-10] Other Saudi reports were on signs and symptoms of TMD in a specific patient and non-patient subjects such as military students, female patients seeking orthodontic treatment, and dental students.[11] The prevalence of TMD is still not well known, and more studies and comparisons are necessary to allow better understanding of the pathological aspects so as to address effective preventive and therapeutic measures. The aim of this questionnaire study is to assess the common predisposing or risk factors for TMJ pain in Saudi population.

MATERIALS AND METHODOLOGY

The present study followed a cross-sectional design. Ethical clearance was obtained from the Institutional Review Board (SRC ETH/2012-13/022). The study sample consists of 300 subjects, Saudi nationals (both male and female) who were randomly picked from the different school and colleges and also patients visiting the College of Dentistry, King Khalid University, Abha, Saudi Arabia. A detailed questionnaire was distributed among the subjects asking about the presence of TMJ pain and related habits. All the subjects were informed regarding the purpose of the study, and written consent was obtained from participants. The subject sample that did not complete the questionnaire was excluded from the study. The final sample size was 243 (116 males and 127 females).

DATA AND STATISTICAL ANALYSIS

Data were collected by questionnaire and were entered into a spreadsheet (Excel 2000; Microsoft, US) and analyzed subsequently using Statistical Package for the Social Sciences version 16.0. The *P* value was analyzed using the Pearson Chi-square test.

RESULTS

A total of 243 subjects were questioned regarding the presence of TMJ pain, and about 20 patients (7 male and 13 female [8.23%]) had pain in TMJ or related or facial region, with $P = 0.0015$ which is statistically significant. In age group between 15 and 30 years, 5 females and 7 males were suffering from the TMJ pain. In age group above 30 years, no males had TMJ problem, but eight females had pain [Table 1].

Of 243 subjects, about 40% had regular headache from time to time, and among them, male subjects in the age group of 15–30 years had higher prevalence followed by female subjects. About 11.5% of patients had TMJ noise (clicking) while opening or closing the mouth, whereas 7.7% of patients had pain on the wide opening of the mouth. Moreover, 10% of the population were suffering from arthritis, 5.5% had a previous history of blow to the jaws, 6.8% had pain while chewing food, while 13% of the patients expressed pain while eating a big meal. Rest of the subjects, i.e., 10.7% felt pain in the jaw joint when they visited the dentist [Table 2].

Regarding the habits as recorded by the questionnaire, about 26% had chewing on one side, of which males of 15–30 years had higher prevalence making about 46.6%. Moreover, 41% of the subjects had a habit of using chewing gum more than an hour per day, of which female students had a higher incidence of 69%, whereas 23% of subjects had the habit of biting their nails, of which female population was more (25%). The prevalence of biting some article like pen or pencil with their teeth was 28%. A large number of samples about 52% of subjects had the habit of supporting their hand on TMJ area while relaxing or watching television. Bruxism accounted for 4% and stress biting for 3.4% [Table 3].

DISCUSSION

Risk factors are pathophysiologic, psychological, or structural processes that alter the masticatory system sufficiently to increase the risk of development of TMD.[12,13] "We have been taught that pain is a symptom and the way to relieve a symptom is to remove the cause. If no somatic cause can be found, we may give up and abandon the patient else we may hypothesize a cause and treat it, either conservatively or less conservatively. If the treatment fails, we may try something else or tell the patient to learn to live with the pain."

The present study examined 243 subjects by questionnaire consisting of risk factors and 20 subjects, both male and AQ2

Table 1: Age group

Age	Sample	TMJ complaint (%)
15–30	Males - 78	7 (8.9)
	Female - 106	5 (4.7)
30 and above	Male - 38	0
	Females - 21	8 (38.9)

TMJ: Temporomandibular joint

Chi-square tests

	Value	df	Asymptotic significant (two-sided) (P value)
Pearson Chi-square	9.88 (a)	6	0.003

Table 2: TMJ symptoms

S. No.	Symptoms	Males		Females		Total (%)
		15–30 (a)	30 ab (b)	15–30 (a)	30 ab (b)	
1	Head ache	46	4	38	5	93 (40)
2	Rheumatoid arthritis	18	2	2	1	23 (10)
3	Accident or a blow on the jaw	11	0	2	0	13 (5.5)
4	Clicking	18	3	3	3	27 (11.5)
5	Pain on opening mouth widely	10	2	5	1	18 (7.7)
6	Pain when chewing	4	5	2	5	16 (6.8)
7	Feel pain while eating a big meal	12	4	12	3	31 (13)
8	Pain in the jaw joint when you visit the dentist	10	4	8	3	25 (10.7)

TMJ: Temporomandibular joint

Chi-square tests

	Value	df	Asymptotic significant (two-sided)
Pearson Chi-square	13.518 (a)	9	0.141

Table 3: Habits

S. No.	Habits	Males		Females		Total (%)
		15-30 year (a)	30 ab (b)	15–30 (a)	30 ab (b)	
1	Chewing on one side	26	10	18	7	61 (26)
2	Bruxism	3	1	5	1	10 (4)
3	Use of chewing gum	23	2	65	4	94 (41)
4	Nail biting	25	4	18	6	53 (23)
5	Biting articles	33	2	27	4	66 (28)
6	Jaw enforcement	49	3	65	6	123 (52)
7	Stress biting	3	1	3	1	8 (3.4)

Chi-square tests

	Value	df	Asymptotic significant (two-sided)
Pearson Chi-square	8.735 (a)	9	0.462 (non-significant)

female, had the complaint of pain in TMJ or orofacial region, broken down by age and by gender. 14.5% of the subjects experienced pain in periauricular region which were in contrary to the previous study.[14]

Headache is one of the common symptoms seen with TMD. In the present study, 40% of the subjects experienced headache. The younger age groups had higher prevalence rate compared to older age group. 40% of male and female subjects in the age group of 15–30 years had higher when compared to above 30 years of age. This was at higher rate when compared to previous studies.[15] The prevalence of TMJ pain in younger age group is due to parafunctional habits such as chewing on one side and jaw enforcement, and the results were correlating with previous studies and possible causative mechanism for head ache, namely, TMD and TMD-induced sensitization in the central and peripheral nervous systems.[16] Clicking while opening and closing of the mouth was prevalent in 11.5% of population where the higher prevalent group was males under 30 years of age, with 66% which was contrary to the study conducted on adults in West Bothnia.[17] A history of rheumatoid arthritis was found in 10% of population, but a strange finding was more number of sufferers who were below 30 years' male, and this may not be clinical finding instead it was a questionnaire which sample group might have mistaken for other pain. 13% of population had pain in temporomandibular area after a big meal where both males and females under 30 years had similar prevalence rate. 10% of population had pain after long dentist appointments. Questionnaire on the personal habits we found that 52% of population (123 out of 243) had a habit of placing their palm on TMJ area and supporting on elbow while relaxing or watching television. 41% of population, 94 patients, had a habit of chewing gums for longer period affecting the masticatory system. Female below 30 years were more compared to other groups. 28% of population had a habit of biting articles such as pen and pencil, which was more common among males below 30 years of age. In a study conducted in Jeddah, Saudi Arabia, the prevalence of parafunctional habits like nail biting was 41%. 26% of population had a habit of chewing

AQ3

on one side of the jaw which had led to unilateral pain on temporomandibular areas in this group. A common habit of biting nail or trimming the nail with the teeth was found in 23% of population. Other habits such as bruxism and stress biting or psychological stress lead to bit the upper and lower teeth which were found in few patients about 4% and 3.4% of population, respectively.[18]

SUMMARY AND CONCLUSION

The prevalence of TMD among Saudi population in Asir region Abha females were comparatively more affected than the males. Females with age group above 30 years were found to have more prevalence when compared to 15–30 years age group. Common symptoms in these patients were headache, pain after a big meal, clicking of joints, and pain in the preauricular area after prolonged dentist appointment. To some extent, these patients also had symptoms like pain on opening wide and chewing. The most common etiological factors for TMD in descending order were found to be pressure on TMJ while relaxing or watching television, use of chewing gum for longer period, biting articles such as pen or pencil, unilateral chewing, nail biting, bruxism, and psychological stress for lesser extent.

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Original Article

Clinical Study of Splenic Trauma in Blunt Injury Abdomen

Madipeddi Venkanna[1], Budida Sharada[2], Doolam Srinivas[1]

[1]Associate Professor, Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India, [2]Assistant Professor, Mahatma Gandhi Memorial Hospital, Warangal Telangana, India

Abstract

Introduction: Motor vehicle accidents account for most of the cases of splenic injury. Although protected under the bony ribcage, the spleen remains the most commonly affected organ in blunt injury to the abdomen in all age groups.

Aims and Objectives: The aim of the study is to evaluate the incidence of blunt injury abdomen, clinical presentation, mortality, and morbidity.

Materials and Methods: This study is conducted at Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India. After admission, data for the study were collected by detailed history, thorough clinical examination, and relevant diagnostic investigations performed over the patient.

Results: In our study, total abdominal injuries from June 2015 to November 2017, total injuries of splenic trauma 50, incidence of splenic trauma 25.2%.

Conclusion: Spleen is most commonly injured organ in intra-abdominal injuries age and sex has no association with the outcome of management. Mean age group involved in splenic trauma 28.45 years.

Key words: Blunt injury abdomen, Mortality, Road traffic accidents

INTRODUCTION

Although protected under the bony ribcage, the spleen remains the most commonly affected organ in blunt injury to the abdomen in all age groups. Due to the rapid industrialization and urbanization spleen are at the top of the solid organ lists injured in blunt trauma abdomen. Motor vehicle accidents account for most of the cases of splenic injury. Although protected under the bony ribcage, the spleen remains the most commonly affected organ in blunt injury to the abdomen in all age groups. Majority of cases with splenic injury are observed in the second and third decade of life, this being the most active period of life when movements in motor vehicles and outdoor works result in increased risk of trauma. These injuries are common in both rural and urban environments and result from motor vehicle crashes, domestic violence, sporting events, and accidents involving bicycle handlebars.

A quarter of a century ago, removing an injured spleen was routine surgical practice. In fact, the thought of saving a torn spleen with even a minor tear was considered quite preposterous. With the advancement of medical knowledge, conservative management has received worldwide acceptance, especially in the lesser grades of splenic injury.

All surgeons involved in emergency care, especially, whether rural or urban, must keep up-to-date on issues regarding splenic injury diagnosis, splenic salvage techniques, indications for both non-operative treatment and potential complications arising from both operative splenectomy and non-operative management of this important organ. Associated injuries to other organs, uncontrolled hemorrhage contribute significantly to morbidity and mortality.

This dissertation with analysis of 50 patients with splenic trauma attempts to put forward the observations and data

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Corresponding Author: Dr. Madipeddi Venkanna, H. no: 1-8-52, Abhaya Nest Apartment, Balasamudram, Hanamkonda, Warangal – 506 002, Telangana, India. Phone: +91-9949750169. E-mail: venkannadr@gmail.com

pertaining to the comprehensive picture of recent concepts in assessment and management of splenic injuries with specific reference to non-operative management. The objective of the dissertation will be fulfilled if it can guide a general surgeon for a right decision when facing problem in management of splenic trauma.

Aims and Objectives

The aim of the study was to know the incidence of splenic trauma, means of presentation, and grade them. To present a comprehensive picture of recent concepts in assessment and management of splenic injuries with specific reference to non-operative management. To asses the failure rate of nonoperative management of splenic trauma. To asses the factors responsible for mortality and morbidity.

MATERIALS AND METHODS

This study is conducted at Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India. 50 patients of splenic trauma of 252 patients of blunt injury abdomen who are admitted to Mahatma Gandhi Memorial Hospital and who underwent non-operative (13 patients), non-operative converted to operative (2 patients), and operative management (35 patients) for abdominal trauma and having splenic injury forms the material of the study. This study is conducted over a span of June 2015–November 2017.

All the patients were first received at casualty department and general surgery of the patient is done to identify emergency treatment conditions. After securing the airway and breathing an intravenous line are secured, and blood is drawn and sent for blood grouping and typing, crossmatching, urea and sugar, hemoglobin percentage. Initially, Ringer's lactate is infused for resuscitation. Depending on the severity of injury if the patient is not responding to initial crystalloids, compatible whole blood transfusion is given which are brought after cross matching from our blood bank. A brief history about the date and time of injury, mode of injury and complaints with special reference to pain abdomen, vomiting, and distension of abdomen is taken, and site size, shape, and character of wounds are noted. Specific examination of the abdomen is done with special reference to tenderness, guarding and rigidity and bowel sounds. In all cases of blunt injury plain X-ray erect abdomen, chest X-ray and if necessary, plain X-ray of other parts of the body is taken. Emergency ultrasound of the abdomen and pelvic cavity of the patient is done using ultrasound machine 3.5 Mhz curvilinear transducers with the patient in the supine position by a radiologist. Unstable patients are not subjected to ultrasound. Computed tomography (CT) scan of the abdomen (with and without contrast) done for those patients who are stable, who have no free peritoneal tap, and who are planned to be managed by the non-operative procedure.

If the patient is having chest injury with or without fracture ribs and with hemothorax or pneumothorax, intercostal drainage tube is inserted in the 4th or 5th intercostal space in midaxillary line using a 32F or 28F intercostal drainage tube underwater seal kit, under local anesthesia with strict aseptic precautions.

Other associated injuries are treated by the concerned specialists of our hospital. Those patients (15) who are stable, no free diagnostic peritoneal tap, minimal free fluid on ultrasound are subjected to CT scan of abdomen and pelvis graded accordingly by grading system given by American, Association for the surgery of trauma splenic injury scale (1994 revision) and recorded and managed nonoperatively by continuous monitoring, two of them are converted to operative procedure after deterioration of the condition and contrast blush on CT scan. Rest of the patients are taken up for surgery (splenectomy) after a reasonable time of resuscitation. All the patients are operated under general anesthesia with endotracheal intubation.

Laparotomy

Incision and procedure: All the patients were operated by midline incision and incision extended when necessary. Hemoperitoneum evacuated by suction apparatus and injury evacuated. Grading of spleen injury assessed according to grading system given by American Association for the surgery of trauma splenic injury scale (1994 revision) and recorded. Spleen is mobilized after incising all ligamentous attachments (splenophrenic ligament at the superior pole and the splenocolic and splenorenal ligaments at inferior pole), then short gastric vessels are ligated splenic artery and vein are double ligated, hemostasis secured well, peritoneal cavity washed with normal saline, drain kept in the splenic bed and abdomen closed after examining liver, stomach, small, and large bowel and mesentery. Induction doses of intravenous Ceftriaxone 1 g I.V. B.D, Gentamicin 80 mg I.V. B.D, and metronidazole 500 mg I.V., T.I.D, are given to the patients. In high-risk patients cephalosporins such as cefotaxim and piperacilline with Amikacin and Metronidazole are used. The antibiotics were continued in the post-operative period and are used until the patients are discharged. Pneumococcal vaccine administered to all the patients postoperatively. Patients are allowed on an oral diet from 2nd or 3rd post-operative day if uncomplicated. Abdominal drain removed whenever the collection is <25 m1 or whenever there is no drainage. In our series, most of the drains are removed on the 3rd or 4th post-operative day.

RESULTS

Total abdominal injuries from June 2015 to November 2017 total injuries of splenic trauma 50 incidence of splenic trauma 25.2%

It is clear from above data that a maximum number of patients are in the age group of 21–30 years (38%). Mean age of presentation is 28.45 years (8–60 years). There is no single patient aged >60 years [Table 1].

Sex incidence [Table 2]

Table 2 shows 88% of patients (44) are males and 12% of patients (6/50) are females. So the male female ratio is 7.38 : 1.

Lapse Time of Injury and Admission

Lapse time of injury and admission varied from 30 min to 78 h and the patient ho injured after 78 h following injury does not remember the incidence of injury. It is clear that 58% of patients (29/50) presented within 8 h after injury.

Lapse Time of Admission and Surgery

The lapse time of surgery after the admission of the patient is varying from 30 min to 11 h 25 min. 4% of patients (2/50) are operated within 1 h that was in 30 min. One patient, who is operated after 11 h and 25 min after admission, did not respond to resuscitation.

Mode of injury [Table 3]

The Table 3 shows The maximum number of patients presented with injury are due to road traffic accidents 74% (37/50).

Vital Parameters at Admission

Nearly 75% of patients (35/50) present with stable vital data, i.e. pulse rate from 60 to 100 min and blood pressure ranging from >100 mm Hg of systolic to 70–90 mm Hg diastolic blood pressure. 24% of patients (12/50) presented with unstable vitals and were resuscitated, 3 patients presented with thread pulse and low blood pressure (shock) of which only one patient died without responding on resuscitation.

Associated Injuries

Of 27 patients, 15 patients had fractures to various bones of the body. Associated bony injuries and head injuries were managed by orthopedician and neurosurgeon accordingly. In the rest 12 patients who had associated injuries, 5 patients had laceration to the skin where suturing under aseptic conditions is done at the time of admission. The rest 7 patients had hemothorax and pneumothorax, which was confirmed with the intercoastal drainage tube was inserted for, immediately at the time of admission [Table 4].

Table 1: Age

Age of patients (years)	Number of patients (%)
0–10	5 (10)
11–20	8 (16)
21–30	19 (38)
31–40	11 (22)
41–50	4 (8)
51–60	3 (6)
>60	0 (0)

Table 2: Sex incidence

Sex	Number of patients (%)
Male	44 (88)
Female	6 (12)

Table 3: Mode of injury

Mode of injury	Number of patients (%)
Road traffic accidents	37 (74)
Wall collapse	4 (8)
Bullock cart injury	5 (10)
Fall from height (tree)	4 (8)

Table 4: Associated injuries

Associated bony injuries	Number of patients
Fracture clavicle	1
Fracture femur	5
Fracture both bone legs	2
Colles fracture	2
Fracture ribs	5
Fracture pelvis	2
Fracture both bone forearm	1
Other abdominal injuries	5
Head injuries	4
Total	27

Ultrasound Scan of Abdomen and Pelvic Cavity

In our series 88% of patients were scanned with ultrasound scan abdomen and pelvis preoperatively. The sensitivity of ultrasound scan in our series is 81.81%. Of these 44 patients, the pre-operative ultrasound scanning of the abdomen and pelvic cavity of was consistent with CT scan and laparotomy findings in 36 patients. Sensitivity in our series is 81.81%.

Incidence of Grade of Spleen Injury

The most common grade of splenic trauma is both Grade II and Grade III. These two grade constituting 78% of splenic injuries [Table 5].

Management Procedure

Of 50 patients, 13 patients are nonoperatively managed, 35 patients are operatively managed, 2 patients are initially managed, and nonoperatively then converted to operative management [Table 6].

Table 5: Incidence of grade of spleen injury

Grade of spleen injury	Number of patients (%)
I	9 (18)
II	20 (40)
III	19 (38)
IV	2 (1)
V	0 (0)

Table 6: Management procedure

Total number of patients	50
Non-operative	13
Operative	35
Non-operative converted to operative	2

Cause of Death

Nearly 8% of patients (4/50) expired. One patient died of primary hemorrhage from open fracture right femur and both bone of both legs. One patient died of acute respiratory distress syndrome following septicemia. One patient died of subdural hemorrhage. One patient died of hemorrhagic shock from pelvic fracture.

DISCUSSION

This is a prospective study of 50 patients done during a time span of June 2015–November 2017.

Splenic Trauma Incidence

Nearly 25.2% of abdominal trauma resulted in splenic injury.

Age Incidence

About 38% of patients (19/50) presented to us are in the age group of 21–30 years and 22% of patients (11/50) are in the age group of 31–40 years. Only 10% of patients (5/50) are <10 years old. There are no patients above 60 years. The most affected population is in the age group of 21–30 years (19 patients). In our series, mean age of presentation is 28.45 years (8–60). This data tally with the report of Wilson and Loris who found the greatest number of patient in the age group between 20 and 40 years, Shackford *et al.* found patient between 4 and 82 years, mean age 27.5 years and Akio and Toshibumi between 6 and 80 years with mean age of 33 years.[1,2] Brasel *et al.* found patient between 6 and 84 years with mean age of 31.4 years. Ahmed *et al.* studied mean age of presentation is 15–25 years with the incidence of 40%.[3]

Sex Incidence

In our series, 88% of patients (44/50) are males and only 12% of patients (6/50) are females. In Cocanour 11 *et al.* series 90% of patients are males and 10% of patients are females. Males are more affected with spleen injury. Hussain *et al.* studied males grossly outnumbered the females, with male-female relative percentages being 86.66% and 13.33%, respectively., Elmo *et al.* found incidence between male and female as 84.98% and 15.01%. Fuchs *et al.* found the male-female incidence of 80% and 20%. Peter *et al.*, in 1986, found the male-female incidence of 69.69% and 30.0%.[1] Akio and Toshibumi found the incidence of 81.91% and 18.8%.[2] Arlet *et al.* found the male-female incidence of 77.02% and 22.08%, respectively.

Time Interval Between Injury and Admission

The minimum lapse time was 30 min in our series and the maximum period was 78 h. 18% of patients presented within 24 h of injury. The patients who presented early within 2 h have good outcome ($P < 0.01$). 58% of patients (29/50) presented within 8 h. The patients who presented late (>24 h) had higher complication rates (52%).

Time Interval Between Admission and Surgery

About 26°/o of patients (13/50) managed nonoperatively and 70% (35/50) are managed operatively. 4% of patients 2 (50) are initially managed nonoperatively and then converted to operative procedure after 16 h, 80% of patients (28/35) are taken to laparotomy within 8 h, and 3% of patients (1/35) are taken for laparotomy within 1 h. This time duration is utilized for resuscitation and investigations whenever the patient is hemodynamically stable. If they are not stable, they are taken immediately within 1 h as we have done in 3% of patients (1/35).

Mode of Injury

In our series of road traffic accidents causing blunt trauma accounted for 74% of patients (37/50). 8% of patients (4/50) presented with injury due to wall collapse and 8% of patients (4/50) presented with injury due to fall from height (such as tree and building roof). Bullock cart as a cause of injury is seen in 10% of patients (5/50). This figure correlates with studies shown by Ahmed 46.66%,[3] Ellis and Paterson-Brown 60%,[4] Goins, Rodriguez, Manjari, Joshi and Jacob 53%, Satish and Changlani 40%, Powel *et al.* 67%, and Khanna *et al.* 52%.

Vital Data at Admission

About 76% of patients (38/50) presented with stable vitals. 24% (12/50) presented with unstable vitals. The patients were resuscitated thoroughly before taking for laparotomy with crystalloids and whole blood transfusion.

Patient Clinical Presentation

In our series, 94% of patients (47/50) presented with pain abdomen. Some of them have association with distension of abdomen and very few patients have associated vomiting (18%). 92% of patients (46/50) on examination had

tenderness and guarding and rigidity, bowel sound is present in only 56% of patients (28/50). Loris (1948) reported it to be the most common symptoms of abdominal trauma. Whiteshell reported that pain constantly dominated the symptomatology of splenic laceration. Tripathi *et al.* reported pain in 91.4% of cases. Vomiting was found in 3 patients (10%) in Ahmed study.[3]

Griswold and Collier noted that vomiting was a common symptom in 88% of abdominal injury cases.[5] Griswold and Collier stated that the splenic injury was always associated with vertigo, nausea, and vomiting.[5] Arlet *et al.* found 28% of the patient with blunt trauma abdomen presenting with vomiting.[6] Ahmed *et al.* studied that the rigidity was observed in 3 cases (10%) and mainly to the left side of the upper abdomen. Jervis *et al.* observed that the rigidity was a reliable finding in a patient with blunt trauma abdomen. 17 Fixed splenic dullness (Ballance sign) was found in 2 cases. Cope stated that demonstration of shifting dullness in the flank is sufficient to indicate bleeding from solid viscera. However, in splenic injury frequently the dullness on the left side cannot be shifted (Ballance sign).

The most common symptom is pain abdomen and clinical sign in the tenderness of abdomen associated with guarding and rigidity.

Associated Injuries

About 54% of patients (27/50) had associated injuries. 30% of patients (15/50) presented with injuries and fractures of limb bone both upper limb and lower limb. 6% of mortality (3/50) is due to associated injuries. In one patient hemorrhage from fracture femur and both bones legs lead to the death of the patient. In one patient hemorrhagic shock from pelvic fracture lead to death of patient. In one patient subdural hematoma lead to respiratory arrest and death.

Ultrasound Scan of Abdomen and Pelvis (FAST)

In our series, 88% of patients were scanned with ultrasound scan abdomen and pelvis preoperatively. The sensitivity of ultrasound scan in our series is 81.81%.

Ultrasound scan sensitivity study group 63% Bode *et al*.[7] 82% Golleti *et al*.[8] 81.81% Mahatma Gandhi Memorial Hospital. Rozycki *et al.* stated that specificity of 99.7% and sensitivity of 81.5%. Kuehnert stated that ultrasonography was able to detect abnormal fluid including hemoperitoneum in 25 of 25 patients and isolated splenic parenchymal injuries in 22 of 25 patients.

Diagnostic peritoneal tap (aspiration), either four quadrant or bilateral flank tap was performed in all 50 cases showing positive tap in 30 cases and negative tap in 20 cases. Any quantity of fluid aspirated was considered to be positive tap. Negative tap was one which did not reflect any aspirate. The entire positive tap correlated with operative findings.

CT Scan of Abdomen

CT scan was performed in a limited number of patients (21 cases). The cases which did not merit immediate laparotomy on the clinical ground or other investigation findings were subsequently subjected to CT scan whole abdomen for further evaluation. It was done in 21 patients and was found to be accurate in distinguishing subcapsular hematoma from a splenic laceration with free intraperitoneal blood and helps to diagnose accurately associated injury to other intraperitoneal and retroperitoneal structures which are of great clinical importance in the conservative management of splenic rupture. Federle *et al.* reported 99% accuracy of CT scan in 200 patients with blunt trauma abdomen. Kuehnert stated CT specificity of 99.5 % and sensitivity of 74.3%. Sutyak *et al.*stated that CT in 49 patients with 43 splenic injuries correlated surgically with CT findings.

Incision for Laparotomy

All most all patients managed by the operation, midline incision were taken.

Operative Findings

On laparotomy blood in peritoneal cavity was found in all cases. The splenic injuries varied from large subcapsular hematoma, intraparenchymal laceration. Ahmed *et al.* studied group 36.66% underwent operation. All are operated by splenectomy.[3] Satish *et al.* performed splenectomy in 111 of 150 patients, Brasel *et al.* performed splenectomy in 69 of 164 patients, Khanna *et al.* did splenectomy in 5 patients of 19 patients of splenic trauma. Dr. Stuart Thompson reported splenectomy in 30 patients of 52 patients with splenic trauma.

Incidence Grade of Spleen Injury:(Intraoperarive)

In Zucker *et al.* series Grade-I and Grade-II injuries are commonly involved accounting for 70% of patients. In our series, Grade-II and Grade-III injuries are more commonly involved accounting for 78% of patients.

Management Procedure

In Myers *et al.* series 68 of 204 were nonoperatively managed, and success rate of non-operative management is 93%, and the failure rate is 7%.

In Cocanour *et al.* series 57 of 311 patients were nonoperatively managed success rate of non-operative management is 86%, and the failure rate is 4%.

In Zucker *et al.* series 24 of 68 were nonoperatively managed, and success rate of non-operative management is 95%, and the failure rate is 5%.

In our series, 15 of 50 were nonoperatively managed, and success rate of non-operative management is 86.66%, and the failure rate is 13.34%.

All the patients were administered injection *pneumococcal* and *Hemophilus influenzae* vaccine postoperatively.

MORTALITY

Mortality rate is 8% in our series (4 patients). One patient died of a primary hemorrhage from open fracture right femur and both bone of both legs. One patient died of acute respiratory distress syndrome following septicemia. One patient died of subdural hemorrhage. One patient died of hemorrhagic shock from pelvic fracture. None of our patients are died due to non-operative management.

CONCLUSIONS

Spleen is most commonly injured organ in intra-abdominal injuries (25.2%). Age and sex have no association with the outcome of management. Males are commonly involved than females. Mean age group involved in splenic trauma 28.45 years. Time lapse between injury and treatment has a significant association with outcome. Patients who present with <2 h of injury are having a better prognosis with less morbidity and mortality ($P < 0.005$). Grade of splenic injury, continuous monitoring of the patient and associated injuries have a direct bearing on the outcome. Pre-operative ultrasound scan of the abdomen and the pelvic cavity is diagnostic of splenic with a sensitivity rate of 81.81%. Overall, splenic injuries of Grade I, II, have good outcome with non-operative management when not associated with other injuries ($P < 0.001$). Prophylactic antibiotics will prevent post-operative complications. *Pneumococcal*, *H. influenza* vaccine prevents overwhelming post splenectomy infections. Respiratory complications are common in post-operative patients. Associated injuries add to morbidity and mortality of splenic trauma patient.

Failure of non-operative management is due to hemodynamic instability age older than 55 years contrast blush vascular blush on CT scan.

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Original Article

Clinical, Diagnostic, and Operative Correlation of Acute Abdomen

Madipeddi Venkanna[1], Doolam Srinivas[2], Budida Sharada[1]

[1]Associate Professor, Department of General Surgery, Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India, [2]Assistant Professor, Department of General Surgery, Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India

Abstract

Introduction: The term acute abdomen refers to signs and symptoms of abdominal pain and tenderness, a clinical presentation that often requires emergency surgical therapy. The correct interpretation of abdominal pain is one of the most challenging demands to any surgeon. Since proper therapy often requires surgent action, the luxury of the leisurely approach suitable for the study of other conditions is frequently denied.

Aims and Objectives: This study aims to compare the preoperative diagnosis based on clinical examination and investigation with the operative diagnosis in non-traumatic acute abdomen.

Materials and Methods: The study was conducted from August 2015 to September 2017 over a period of 23 months conducted at Mahatma Gandhi Memorial Hospital, Warangal, Telangana, 100 patients with various causes of acute abdomen were included in the study. All the patients attending the emergency department (causality) with the clinical feature suggestive of non-traumatic acute abdomen within the study period were included in the study.

Results: A total number of 100 patients were included in this study. All these patients underwent emergency laparotomy (surgery) with the provisional diagnosis of acute abdomen. 66% of the patients were male and 34% were female.

Conclusion: Total leukocytes count and differential leukocytes count were most sensitive in evaluating patients with acute appendicitis and peritonitis while plain X-ray abdomen had highest sensitivity in evaluating patients with bowel obstruction and acute peritonitis as well. Acute appendicitis was the most common cause (60%) of patient presenting to emergency and casualty as acute abdomen.

Key words: Acute abdomen, Laparotomy, Diagnosis

INTRODUCTION

The term acute abdomen refers to signs and symptoms of abdominal pain and tenderness, a clinical presentation that often requires emergency surgical therapy. Acute abdominal pain generally refers to previously undiagnosed pain that arises suddenly and is of <7 days' (usually <48 h) duration = 3.1. The correct interpretation of abdominal pain is one of the most challenging demands to any surgeon. Since proper therapy often requires surgent action, the luxury of the leisurely approach suitable for the study of other conditions is frequently denied. The complexity of situation is enhanced by the various types of intra- and extra-abdominal pathology that contributes to the complaint of abdominal pain.

Abdominal pain that persists for 6 h or longer is usually caused by disorders of surgical significance.[1] The primary goals in the management of patients with acute abdominal pain are[2] to establish a differential diagnosis and a plan for confirming the diagnosis through appropriate imaging studies, to determine whether operative intervention is necessary, and[3] to prepare the patient for operation in a manner that minimizes perioperative morbidity and mortality.

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Corresponding Author: Dr. Madipeddi Venkanna, H. No: 1-8-52, Abhaya Nest Apartment, Balasamudram, Hanamkonda, Warangal – 506 002, Telangana, India. Mobile: +91-9949750169. E-mail: venkannadr@gmail.com

The proper management of patients with acute abdominal pain requires a timely decision about the need for surgical operation. This decision requires evaluation of the patient's history and physical findings, laboratory data, and imaging tests. Many diseases, some of which do not require surgical treatment, produce abdominal pain, so the evaluation of patients with abdominal pain must be methodical and careful. All patients with abdominal pain should undergo evaluation to establish a diagnosis so that timely treatment can minimize morbidity and mortality.[3-5]

Correct pre-operative diagnosis of acute abdomen with limited resources is very crucial to minimize the morbidity and mortality in the developing countries like ours, where the facilities of diagnosis are limited and not economical, the clinical skills play a pivotal role in the diagnosis and management of acute abdomen.[6,7] Thus, the surgeon in the developing countries needs to improve the diagnostic acumen and the decision-making, in the management of acute abdomen.

Aims and Objectives

This study aims to compare the pre-operative diagnosis based on clinical examination and investigation with the operative diagnosis in non-traumatic acute abdomen.

Measurement

At the end of the study, following variables were measured: Sensitivity, specificity, positive predictive value, and negative predictive value of different investigations results. Diagnostic accuracy of acute abdomen is confirmed by operative findings, rate of negative laparotomy.

MATERIALS AND METHODS

All the patients attending the emergency department (casualty) with the clinical feature suggestive of non-traumatic acute abdomen within the study period were included in the study. A well-designed pro forma had been used that recorded all the detailed history, including present complaint, history, drug and treatment history, and another relevant history. A detail in clinical findings and investigation results were also included in the study. At that time, the pre-operative diagnosis is made which is recorded, and subsequently, the operative finding also recorded after performing surgery.

Methodology

All the patients attending the emergency department with the clinical features suggestive of non-traumatic acute abdomen within the period will be included. A pro forma form would be designed to record detailed history, clinical examination findings, and investigation results.

Study Design

This is a prospective observational study conducted in the General Surgery Department of Surgery, M.G.M. Hospital, Warangal.

Inclusion Criteria

All the patient with clinical diagnosis of acute abdomen, Patient with no history of recent trauma, Patient requiring surgery for acute abdomen, Age group from above13 years.

Exclusion Criteria

Traumatic acute abdomen will be excluded from the study. Although laparoscopy which is of both diagnostic and therapeutic, best tool with approximately no mortality and least morbidity, we are not provided with equipment in emergency operation theater, so it was excluded from the study.

Clinical examination of the patient was done thoroughly at the emergency and casualty department and investigated appropriately. Final diagnosis was then confirmed, the decision to operate was made, and the operative findings were recorded.

The study was conducted from August 2015 to September 2017 over a period of 23 months. 100 patients with various causes of acute abdomen were included in the study.

Statistical Analysis

Pre-operative diagnosis based on clinical examination and investigations were compared with the operative diagnosis based on operative findings.

Specificity, sensitivity, positive predictive value, and negative predictive value of the investigations were calculated. Statistical analysis was done using SPSS11.5, Version.

$P < 0.05$ was considered statistically significant.

RESULTS

A total number of 100 patients were included in this study. All these patients underwent emergency laparotomy (surgery) with the provisional diagnosis of acute abdomen. 66% of the patients were male and 34% were female [Table 1].

Table 1: Showing sex distribution of the patient

Sex	Frequency (%)
Male	66 (66.0)
Female	34 (34.0)

60% of the total patients of acute abdomen comprised acute appendicitis, 26% peritonitis due to hollow viscus perforation, and 14% of the cases were due to bowel obstruction.

All the patients were subjected to total leukocytes count (TLC), differential leukocytes count (DLC), urine analysis, serum amylase, and plain X-ray abdomen examination. Selected patients were subjected to abdominal ultrasonography (USG) and computed tomography (CT) of abdomen.

TLC was found raised in 78% of patients and DLC in 92%. Serum amylase was significant in 30% of the patient of acute abdomen, whereas plain X-ray abdomen was positive in 43% of patients [Table 2].

Abdominal USG was performed in 84 patients and 62% of reports had positive findings. CT of abdomen was done in only 26 patients, of which 22 reported with positive finding comprising 84% of the patients.

Among the 60 patients diagnosed as acute appendicitis, seven turned out to be negative in which were later diagnosed as urinary tract infection, pelvic inflammatory diseases (PID), and non-specific abdominal pain and ovarian cyst [Table 3].

Similarly, in five patients with acute pancreatitis, psoas abscess and bilateral basal pneumonia presented with features of peritonitis where laparotomy was not actually necessary.

In two patients with abdominal tuberculosis who presented with features of bowel obstruction where no sites of obstruction were found, laparotomy was not actually necessary. Thus, the percentage of negative laparotomies in the study group was 14%.

Highest diagnostic accuracy of 85% was seen with the patient of acute intestinal obstruction with no statistically significant difference ($P = 0.65$). Lowest diagnostic accuracy of 65% was observed with causes of peritonitis. Acute appendicitis had the diagnostic accuracy was of 80%.

Overall, diagnostic accuracy was 77%. There was statistically significant difference between the pre-operative and operative diagnosis ($P = 0.00032$) [Tables 4 and 5].

12 of 60 patients were not confirmed as an acute appendicitis but were made highly suspicious among which five were absolutely normal with no other diagnosis could make out among other two patients had PID while two had ureteric stone, one twisted ovarian cyst, one urinary tract infection, and one Meckel's diverticulitis as the cause of acute abdomen. In one patient, no cause of acute abdomen was established and was thus diagnosed as having non-specific abdominal pain.

Similarly, in nine patients, the causes of peritonitis were pancreatitis,[4] Meckel's diverticulum perforation,[2] bilateral basal pneumonia,[3] and appendicular perforation[6] which were not diagnosed accurately preoperatively.

In two patients, the causes of acute bowel obstruction were carcinoma colon[1] and abdominal tuberculosis[1] that were not accurately diagnosed preoperatively.

Table 2: Investigation performed to diagnose causes of acute abdomen

Investigation	Positive finding	Percentage value
TLC (100)	78	78
Differential leukocytes count (100)	92	92
Urine analysis (100)	22	22
Serum amylase(100)	30	30
Plain X-ray abdomen (100)	43	43
Ultrasonogram (84)	52	62
CT scan (26)	22	84
DLC (100)	92	92

DLC: Differential leukocyte count, TLC: Total leukocyte count

Table 3: Total number of negative laparotomy and their percentage

Cases	Negative laparotomy	Percentage value	*P*
Appendicitis (60)	7	11.6	0.0018203
Peritonitis (26)	5	19.2	0.033281
Obstruction (14)	2	14.3	0.3297645
Total (100)	14	14	0.0010062

Table 4: Total number of cases with correct pre-operative diagnosis (% of correct diagnosis)

Pre-operative diagnosis	Correct diagnosis	Percentage value
Acute appendicitis (60)	48	80
Acute peritonitis (26)	17	65
Intestinal obstruction (14)	12	85
Total (100)	77	77

Table 5: *P* significance of different etiology with acute abdomen

Cases	Mean±SD	*P*
Acute appendicitis	1.40±0.492	0.0049
Peritonitis	1.74±0.441	0.0044
Intestinal obstruction	1.86±0.349	0.065

SD: Standard deviation

Of 100 patients studied, 60 patients presented with diagnosis of appendicitis. Male-to-female ratio was 2:1.90% of patients were of 13–39 years. Highest incidence of acute appendicitis was seen in the age of 20–29 years (43.3%).

Operative finding of the patients with the provisional diagnosis of appendicitis showed that acutely inflamed appendix was found in 31, phlegmonous in 7, gangrenous in 7, and perforated appendix in 3. 12 patients operated with the provisional diagnosis of appendicitis had other causes 12 of 60 patients operated with provisional diagnosis of acute appendicitis. Among of them, five were absolutely normal with no other diagnosis could make out. In other seven members, two patients had PID while two had ureteric stone, and one each had twisted ovarian cyst, Meckel's diverticulitis. In one patient, no cause of acute abdomen was established and was thus diagnosed as having non-specific abdominal pain.

Table 6: Investigation performed to diagnose acute appendicitis

Investigation	Positive finding	Percent positive
TLC (60)	44	73
DLC (60)	51	85
Urine analysis (60)	6	10
Plain X-ray abdomen (60)	6	10
Serum amylase (60)	12	20
USG abdomen (53)	24	45
CT scan abdomen (15)	13	86

DLC: Differential leukocyte count, USG: Ultrasonography, CT: Computed tomography, TLC: Total leukocyte count

Table 7: *P*-value of different test to diagnose acute appendicitis

Investigation	Mean±SD	95% Confidence interval of the difference		*P*
		Lower	Upper	
TLC	0.11±0.650	−0.02	0.24	0.044
Ultrasound abdomen	−0.42±0.819	−0.58	−0.26	0.000
DLC	0.25±0.609	0.13	0.37	0.000
Plain X-ray abdomen	−0.24±0.889	−0.42	−0.06	0.008
Urine analysis	−0.46±0.642	−0.59	−0.33	0.000
Serum amylase	−0.31±0.748	−0.46	−0.16	0.000
CT scan abdomen	0.61±0.92	0.62	0.38	0.001

DLC: Differential leukocyte count, SD: Standard deviation, CT: Computed tomography, TLC: Total leukocyte count

TLC and DLC were raised in 73% and 85% of patients, respectively, while urine analysis had positive findings in only 10% of the patients. In 10% of patients, plain abdominal X-ray had positive finding while in 45% of patients, abdominal USG had positive result. However, CT scan was diagnostic in 86% of the patients Tables 6-8.

DLC had the highest sensitivity of 90.55 while USG abdomen had the highest specificity in evaluating patients with acute appendicitis. USG abdomen had the highest positive predictive value as well as negative predictive values, but if available CT scan is the best of all modalities with highest sensitivity and specificity as well as reproducible in diagnosis of acute appendicitis.

Acute Peritonitis

Of 100 patients, 26 patients presented with clinical features suggestive of peritonitis. Males were 62% and females were 38% comprising the sex ratio 1.4:1. Highest incidence of peritonitis was observed in the age of 30–39 years (34.6%), while15% each in the age groups of 13–19 years and 20–29 years and 19% in the age range of 40–49 years. Duodenal perforation was the cause of peritonitis in 33% of patients while in 28% and 20% of patients the causes of peritonitis were gastric ulcer perforation and ileal perforation, respectively.

Other less common causes of peritonitis were appendicular perforation 6% and Meckel's diverticulum perforation 2%.

Acute pancreatitis 4%, pelvic abscess 4%, and others (3%) also presented with features of peritonitis.

Investigations to Diagnose Cases of Peritonitis

TLC was raised in 73% while DLC was raised in 88% of the patients. Urine analysis showed positive findings in 30.7% and plain abdominal X-ray had positive finding in 69.2% of patients. Serum amylase was suggestive in 50% of patients. USG abdomen was done in 17 patients and in 58.8% it showed abnormality while CT scan was not done in any cases diagnosed as peritonitis [Table 9].

Predictive Values of Investigations for Peritonitis

DLC had the highest sensitivity and negative predictive value while plain X-ray abdomen had highest specificity

Table 8: Predictive values of investigations to diagnose acute appendicitis

Investigation	TLC	DLC	Urinalysis	PAX	Amylase	USG	CT scan
Sensitivity	84.2	90.5	52.2	52.2	71.3	71.3	92
Specificity	68.2	83.6	32.2	32.2	54.7	90.4	88.4
Positive predictive value	66.7	61.3	30.18	30.18	30.7	78.6	91.2
Negative predictive value	69.8	64.5	60.8	60.18	69	80.5	95

TLC: Total leukocyte count, DLC: Differential leukocyte count, USG: Ultrasonography, CT: Computed tomography

Table 9: *P*-value of different investigations to diagnose cases of peritonitis

Investigation	Paired differences					*P*
	Mean	SD	SE	95% Confidence interval of the difference		
				Lower	Upper	
Peritonitis -total leukocytes count	0.45	0.642	0.064	0.32	0.58	0.000
Peritonitis differential leukocytes count	0.59	0.552	0.055	0.48	0.70	0.000
Peritonitis -urine analysis	−0.12	0.477	0.048	−0.21	−0.03	0.014
Peritonitis serum amylase	0.03	0.540	0.054	−0.08	0.14	0.580
Peritonitis -plain X-ray abdomen	0.10	0.503	0.050	0.00	0.20	0.049
Peritonitis -ultrasound abdomen	−0.08	0.907	0.091	−0.26	0.10	0.380

SD: Standard deviation, SE: Standard error

Table 10: Investigations to diagnose cases of acute intestinal obstruction

Investigation	Number of positive cases	Percentage positive
TLC (14)]	9	64.2
DLC (14)	11	78.45
Urine analysis (14)	0	0
Plain X-ray abdomen (14)	12	85.7
Serum amylase (14)	4	28.5
USG abdomen (10)	4	40
CT abdomen (11)	9	81

P-value of different investigations to diagnose cases of acute intestinal obstruction. TLC: Total leukocyte count, DLC: Differential leukocyte count, USG: Ultrasonography, CT: Computed tomography

and positive predictive value in evaluating patients with causes of peritonitis.

Acute Intestinal Obstruction

Fourteen patients presented with features of bowel obstruction with male constituting 60% and females 40%. Patients presenting with features of bowel obstruction were widely distributed in relation to age with highest numbers of patients in the age range of 4th–5th decade of life.

Distribution of different causes for acute intestinal obstruction: Band adhesion and groin hernia were the most common causes of obstruction constituting 54% and 30%, respectively. Other causes were malignant growth and intussusceptions, which constituted 5% each. TB abdominal so manifested with acute abdomen in 2% of patients, whereas sigmoid volvulus constitutes 4% of patients.

In 78.45% of patients with bowel obstruction, DLC and plain abdominal X-ray showed positive finding while in 64.25% of patients TLC was raised. Ultrasound abdomen was done in 10 patients and had positive finding in 40%. Serum amylase was raised only in 28.5% of patients with acute intestinal obstruction [Table 10].

Predictive Values of Investigation for Acute Intestinal Obstruction

Plain X-ray abdomen had the highest sensitivity, specificity, and CT scan had highest negative predictive value.

CONCLUSION

Following Conclusions were drawn from this Study

- Diagnostic accuracy was 77%. Highest diagnostic accuracy was seen with bowel obstruction (85%) and lowest with peritonitis due to hollow viscous perforation (65%). Thus, clinical and preoperative diagnostic difference was statistically significant ($P = 0.003712$).
- Overall, negative laparotomy rate was 14%. Highest negative laparotomy rate was seen with acute peritonitis (19.2%), while the least is with acute appendicitis (11.6%).
- TLC and DLC were most sensitive in evaluating patients with acute appendicitis and peritonitis while plain X-ray abdomen had highest sensitivity in evaluating patients with bowel obstruction and acute peritonitis as well.
- USG abdomen had high specificity as well as positive and negative predictive values in evaluating patients with acute appendicitis. However, if feasible CT scan abdomen has the highest sensitivity (95%) and specificity (92%), in diagnosis of acute abdomen and acute intestinal obstruction. Further study with large sample is necessary to evaluate its importance in diagnosis of cause of acute abdomen.
- Acute appendicitis was the most common cause (60%) of patient presenting to emergency and casualty as acute abdomen.

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Original Article

Evaluating the Role of Serological Testing Versus Rapid Urease Test for Planning *Helicobacter pylori* Eradication

K Y Santosh Kumar[1], Milind H Iddalagi[2]

[1]Associate Professor, Department of General Surgery, Kannur Medical College, Anjarakandy, Kannur, Kerala, India, [2]Assistant Professor, Department of General Surgery, Kannur Medical College, Anjarakandy, Kannur, Kerala, India

Abstract

Introduction: The prevalence of *Helicobacter pylori* infection is high in India. The testing of *H. pylori* has a significant role to play in evaluating patients presenting with upper abdominal symptoms. There is a wide variety of tests available for detecting *H. pylori* infection including invasive and non-invasive tests. In this study, authors have attempted to evaluate the role of serological testing for planning *H. pylori* eradication in the era where the upper gastrointestinal (GI) endoscopy is widely available at an affordable cost.

Material and Methods: In our hospital, we selected patients with chronic upper abdominal symptoms who were evaluated for *H. pylori* infection with both serological testing and rapid urease test (RUT) after their consent.

Results: It was found that serological positivity (70%) was significantly higher than RUT positivity (18%).

Conclusion: In the era, where upper GI endoscopy is widely available at an affordable cost we feel that RUT needs to be considered before planning *H. pylori* eradication based on the serological results alone thereby avoiding unnecessary treatment. Such an approach seems to be cost-effective in the long run and also avoids exposure of patients to significant side effects of the therapy.

Key words: Eradication, *Helicobacter pylori*, Rapid urease test, Serology

INTRODUCTION

H. pylori, a Gram-negative microaerophilic fastidious human pathogen has colonized humans for at least 1000 of years.[1] Since its discovery by Marshall and Warren in 1983, there has been a significant change in our understanding of acid peptic diseases. It is now believed that 90% of duodenal ulcers and roughly 75% of gastric ulcers are associated with *H. pylori* infection.[2,3] When this organism is eradicated as part of ulcer treatment, ulcer recurrence is extremely rare. Warren and Marshall were the first to identify and isolate the organism and note its close relationship with inflammatory gastritis that occurred in the stomach. *H. pylori* testing should also be done in all patients with the suspected acid peptic disease. Diagnostic tests for *H. pylori* are divided between tests that do or do not require a sample of gastric mucosa. The non-invasive tests available are serology and the carbon-labeled urea breath test. The invasive tests available are the rapid urease test (RUT), polymerase chain reaction (PCR), histology, and culture. Non-invasive tests do not require endoscopy, whereas invasive tests done. As each test has its own advantages and disadvantages, none of these tests can be considered as gold standard.[4] However, as detection of *H. pylori* infection is part of the evaluation of cases in whom peptic ulcer disease is suspected, patients should be offered one or more of these tests for planning eradication therapy. In this article, we intend to review the two most common tests performed for detection of *H. pylori*.

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Urease test or RUT

This test is based on the ability of *H. pylori* to hydrolyze urea. The enzyme urease catalyzes the degradation of

Corresponding Author: H I Milind, Department of General Surgery, Kannur Medical College, Anjarakandy, Kannur, Kerala, India.
E-mail: milindvimsms@gmail.com

urea to ammonia and bicarbonate, creating an alkaline environment that can be detected by a pH indicator. Consequently, endoscopy is performed and gastric mucosal tissue biopsied. Mucosal biopsy samples are placed into a liquid or solid medium containing urea and a pH indicator. Sensitivity is about 90% and specificity 98%, and the results are available within hours.[5-7] The test can also be performed per endoscopically by using pH-sensitive biosensor within minute, giving sensitivity and specificity of 92% and 95%, respectively.[8] The low cost, ease, and speed of diagnosis of *H. pylori* infection give RUT upper hand on culture and histology.[9]

Serological Test

Due to the fact that *H. pylori* infection elicits a local as well as a systemic immunoglobulin G -mediated immune response, serology can be used to diagnose *H. pylori*. There are a variety of enzyme-linked immunosorbent assay laboratory-based tests available as well as some rapid office-based immunoassays. The studies have shown the sensitivity and specificity ranging between 80% and 90%.[10,11] As the host immune response varies from person to person and also the duration of exposure, nutritional status, and cross antigenicity with related bacteria, for example, campylobacter, etc. serological testing cannot be fully reliable.[12] In addition, the most importantly serological test cannot differentiate between active and cured infection as antibody titers can remain high for a year or more, and consequently, this test cannot be used to assess eradication after therapy.[12,13]

MATERIALS AND METHODS

In our institution, we evaluated 100 patients who presented to us with chronic upper abdominal symptoms. All patients were enrolled in the study after their consent. All the patients were instructed to discontinue antacids or proton pump inhibitors 30 days before evaluation. They were evaluated with a serological test for *H. pylori* and upper gastrointestinal (GI) endoscopy with RUT.

Upper GI endoscopy was done using Pentax gastroscope, and biopsies taken from antrum and tissues were tested with RUT kits, and results were interpreted as positive, negative, or equivocal as per manufacturer's instructions.

About 5–10 ml of blood was drawn from the patients and tested for *H. pylori* antibody using commercially available kits, and results were interpreted as per manufacturer's guidelines.

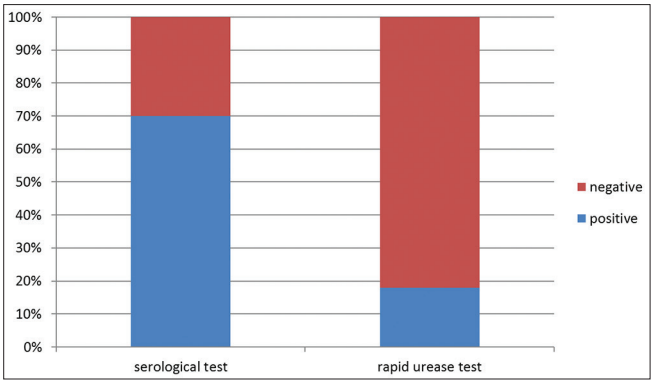

Figure 1: comparison of serological testing and RUT results.

RESULTS

In our study, 75 out of 100 patients were found to be positive for *H. pylori* serologically, whereas only 18 out of 100 patients were positive for RUT [Figure 1].

This means 57 patients who were positive for *H. pylori* as per serological test were *H. pylori* negative according to RUT, and therefore, were not candidates for eradication.

DISCUSSION

The test to diagnose *H. pylori* infection should preferably be rapid and reasonably accurate so as not to delay the eradication therapy. A variety of methods are available including both invasive and non-invasive tests.

Even though histopathological diagnosis is considered to be accurate and is one of the earliest investigations, it suffers interobserver variation.[14,15]

RUT has been reported to have high sensitivity and specificity in many clinical studies.[16-18] It is easy to perform, and results are reproducible and rapidly available.

Serological tests are inexpensive, and results are available rapidly. However, some studies have showed that the results are less accurate and less specific. This low accuracy may be attributable to the inability of these tests to differentiate between present and past infections.

One clinical study found the accuracy of the tests for *H. pylori* diagnosis in order as follows: RUT > PCR > histology > stool antigen test > serology.[19] None of the tests can be considered as gold standard. However, in general, like most of the studies conclude biopsy-based tests are preferable to non-invasive tests especially when upper GI endoscopy is available in a large number of centers.[19,20] We, therefore, conclude that instead of considering *H. pylori* eradication solely on the basis of serological test RUT or a combined approach is preferable.

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Review Article

Human Papilloma Virus Vaccine: Choice or Necessity?

Haritha Vardhini Katragadda[1,2], Ashmini Persuad[1,3], Jay Krishna Katragadda[4]

[1]MPH, Department of Public Health, St. John's University, Queens, New York, USA, [2]MBBS, Bachelor of Medicine and Bachelor of Surgery, SRM Medical College Hospital and Research Center, Tamil Nadu, India, [3]BA, Bachelor of Arts in Psychology, CUNY Hunter College, NY, USA, [4]CRRI, Bachelor of Medicine and Bachelor of Surgery, Shri Sathya Sai Medical College and Research Institute, Tamil Nadu, India

Abstract

Human papilloma Virus affects sexually active individuals at some point in their life. There is no effective screening or means to prevent the spread of infection. Hence, vaccination could be a very useful tool to combat this issue. A health education intervention using posters in college can help educate adolescents about vaccinations and its benefits reinforce their decision to get vaccinated. Ultimately, we are trying to promote better health among individuals by convincing them to get vaccinated. The designed poster covers important facts from center of disease control and prevention, World Health Organization and U.S department of health and human services.

Key words: Cervical cancer, DNA virus, Genital warts, Health education, Human papillomavirus, Poster, Vaccination

INTRODUCTION

One of the most common preventable sexually transmitted diseases among adolescents is human papillomavirus (HPV) infection.[1] Every sexually active individual at some point of time in life is affected with HPV. Based on the recent studies, HPV infection and its long-term consequences can be prevented with vaccination.[1] Most HPV infections are cleared by the immune system, but few results in clinical sequelae. To answer the burning question on the necessity of vaccination, it should be noted that – 1 - there are no effective screening tests, 2 - there are no effective means to prevent the spread of HPV infection, 3 - individuals can spread the infection without showing any signs and symptoms of the infection, and 4 - available treatment options are not curative.[1]

Currently, there are about 79 million individuals infected with HPV infection in the United States, 14 million adds to the total annually.[2] Annually 11,000 women are diagnosed with cervical cancer in the United States. At any given point of time in the United States, 10% of the population has an active HPV infection. The infection with cytological abnormalities is found in 4% individuals and 1% with genital warts.[2] There are more than 40 types of HPV strains, and all of them are sexually transmitted. Two strains of HPV- 16 and 18 are associated with 99.7% of cervical cancers.[3] An estimated 1.7 billion is spent annually in direct medical costs associated with HPV infections and sequelae.[1]

The first vaccine for HPV infection was introduced in 2006. By early 2017, 71 countries have included HPV vaccination in their routine list of vaccination for girls. According to recommendations from the center of disease control and prevention (CDC) and the American Academy of Pediatrics, boys and girls at ages 11–12 should be given the HPV vaccine. Usually, two doses 6–12 months apart are given. In the case of teens starting the vaccine late around 15 years, three doses are recommended, the second dose after 1–2 months after the first dose, and third dose after 6–12 months. They are most effective when given at young age, before sexual activity and exposure to HPV. It is important to note that the vaccine is ineffective when given to those already infected. At the least, the vaccine provides protection for 5–10 years depending on the type of vaccine. 33.4% have completed the three-dose schedule of the HPV vaccine in the USA compared to the 71.2%

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Corresponding Author: Dr. Haritha Vardhini Katragadda, 200/1, Vellala Street, Pursaiwalkam, Chennai – 600 084. Phone: +91-9962061359. E-mail: harithavardhinichowdary@gmail.com

in Australia and 60.4% in the United Kingdom.[4-6] The causes for low vaccination rates of HPV vaccination in America include missed opportunities for simultaneous administration of HPV vaccine with Tdap, concern about side effects, moral or religious grounds, objection to a large number of needles, lack of access, lack of information, and language barrier.

Goal

Our goal is to plan an intervention for the protection the students from the HPV infection and its long-term effects.

LITERATURE REVIEW

In spite of being a developed country, United States still has the majority of the population who continue to get vaccine-preventable diseases. According to the CDC, 79 million women are affected with HPV. The World Health Organization (WHO) estimates that 265,673 deaths occur annually due to cervical cancer in the world. The 4th leading cause of female cancer death in the world is cervical cancer associated with HPV. Among women aged 15–44 years, cervical cancer associated with HPV is the second most common.

Virology

HPV is a double-stranded DNA virus from Papillomaviridae family. They are non-enveloped and double-stranded genome.[7] There are 170 different types, of which 40 types are associated with common genital infections, and two types are associated with cervical cancer.[7] International Agency for cancer research has broadly divided HPV into two types: High risk and low risk. With the link to different types of cancers (cervical, penile, anal, and throat), HPV strains 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, and 59 are termed as high-risk type. The remaining strains are generally associated with common benign conditions like genital warts and termed as low-risk type.

Transmission

Most people are affected by HPV infection at some point in their life.[8] Risk factors for HPV infection among women include young age, risky sexual behavior (e.g., multiple sexual partners and early age of the first encounter), immune status, oral contraceptives, smoking, and poor nutrition. Most common risk factors among males include multiple sexual partners, unsafe sexual practice and being uncircumcised. Transmission of infection requires contact with a viable HPV and microtrauma to skin or mucous membrane. Few strains of HPV cross the placental barrier during the delivery to cause juvenile-onset recurrent respiratory papillomatosis.

Signs and Symptoms

Most of the individuals infected with HPV are asymptomatic. Skin infection with HPV presents itself as warts. Of the infection individuals, 10% are present with warts. Common warts are found in soles of the feet, under the fingernails, arms, face, and forehead. Genital warts are the classical sign of HPV infection. Another common occurrence with HPV strains 6 and 11 is warts in the larynx termed as laryngeal papillomatosis. These interfere with regular respiration and recur frequently.

HPV Associated Cancers

High-risk strains are associated with cancers. 5.2% of all the cancers are believed to be associated with HPV infection.[9] Cancer of cervix, vagina, vulva, penis, anus, oropharynx, and lung is linked to persistent HPV infection.[10] HPV associated cancers result in 27,000 deaths in the United States alone every year.[8] Cervical cancer associated with HPV infection resulted in 266,000 deaths and 528,000 new cases was recorded in 2012; majority have these been in the developing nations.[11]

Vaccination

The WHO recommends HPV vaccines as a part of routine vaccine schedule along with additional cancer screenings in place. In the United States, HPV vaccines are recommended by CDC for boys ages 11–12. The main aim here is to decrease the virus prevalence within the population. It is important to note that a cost of HPV vaccine is $200 in the United States, while it is $40 in a developing nation.[12] Vaccines of three types are available in the market today - bivalent, quadrivalent, and nonavalent.

Bivalent HPV vaccine

It is mainly used for HPV strains 16 and 18. The route of administration is intramuscular, containing 0.5 ml dose. It is available in 1 dose or 2 dose vials. This vaccine is indicated for girls especially for protection against cancers of cervix, vagina, vulva, and anus.

Quadrivalent HPV vaccine

It is mainly for HPV strains 6, 11, 16, and 18. The route of administration is intramuscular, containing 0.5 ml dose. It is available in 1 dose vial. It is indicated in both males and females for protection from associated cancers.

Nonavalent HPV vaccine

It is mainly used for HPV strains 6, 11, 16, 18, 31, 33, 45, 52, and 58. The route of administration is intramuscular, containing 0.5 ml dose. It is available in 1 dose vial. It is indicated in both males and females for protection from associated cancers and against benign conditions like warts.

Naud *et al.* concluded that the three available vaccines have similar effectiveness in preventing cancer.[13] There is also evidence from the literature suggesting the success of vaccination programs. There is established evidence that there is a reduction in cervical abnormalities in females.[14,15]

There has been reduction in viral loads recorded among males who have had the quadrivalent vaccine.[16]

Previous Efforts Related to HPV Vaccination

Various educational measures for HPV vaccination has been put out by the CDC and American Medical Association in the recent years.[17] For the success of any vaccine uptake understanding two important perspectives are important, physicians, and the parents. 78% of family physicians and pediatricians preferred CDC's factsheet as their medium for information for HPV vaccination.[17] Based on recent studies factors influencing the decision-making for HPV vaccination have been identified. They include perception and beliefs of peers, physicians recommendations, communication about sexual practices.[18] One of the efforts by the Congress to ensure protection against HPV is to pass law 106–554, which includes specific provisions for HPV vaccination.[19] According to the Law, " the CDC should

- Conduct sentinel surveillance and special studies to determine the prevalence of HPV in the United States.[19]
- Conduct behavioral and other research on the impact of HPV-related diagnosis on individuals; formative research to assist with the development of educational messages; surveys of physician and public knowledge, attitudes, and practices about genital HPV infection.[19]
- On the completion of formative research, develop and disseminate educational materials for the public and health-care providers regarding HPV and its impact and prevention." [18,19]

APPLICATION OF THEORETICAL FRAMEWORK

The socio-ecological model would be applied to our focus on HPV prevention and education by determining the

Figure 1: Poster educating students about HPV vaccination

environmental and personal factors that influence one's behavior. In this case specifically, we are focusing on the intention to get the HPV vaccination done after being provided with all necessary information. By determining behavioral factors at multiple levels, we can promote healthier choices and bring awareness to the young population from a community level specifically.

This model is based on a multilevel intervention. Since we are targeting college students we are focusing on how providing the knowledge on HPV will initiate them to get the vaccination done and/or find out more to ensure they are making a correct decision. This intervention originally has five levels including individual, interpersonal, institutional, community, and policy. We will now cover how each of these levels can be applied to this program intervention [Figure 1].

Individual Level

Educate college students, ideally students who did not get vaccinated at the target age of 11–12 years old. These individuals will have the ability to gain the information needed through posters to carry out their decision to get vaccinated. The effectiveness can be affected by demographic factors such as age and gender, social determinants, and more.

Interpersonal Level

At this level, students will need to be reassured to complete the vaccine or see the benefits of getting the vaccine done to eliminate preventable HPV related illnesses. The need for the vaccine is most important in this level. The vaccine will eliminate future diseases as well as certain cancers related to the HPV infection. Individuals can obtain this information from their PCPs, on-campus medical center or available clinics in the area.

Institutional/Organizational Level

At this level, the providers will need to carry out the vaccination and follow-up to ensure the entire series is completed. Providers can educate individuals more thoroughly on medical facts regarding HPV that was not mentioned in detail on the posters.

Community level

Public education campaigns on HPV long-term consequences, highlighting prevention through the use of vaccines and guiding the importance of completing vaccines even after target age and/or is already sexually active. The health message will be provided through posters on the campus for a 1 month period. Other modes of communication may include the radio, television, newspapers, and social media. These young individuals may not have any previous knowledge of this topic, therefore, leading to low vaccination rates.

Public Policy Level

Federal Legislation will ensure providers are meeting the criteria to share this information as well as carry out process of vaccinations. Managing resources should also be a main priority. Providing individuals with free health clinics or insurance coverage will allow teenagers or those who are not as financially stable to not make the cost of the vaccine a negative factor. The government can also provide funds to schools to increase health education on HPV as well as provide vaccinations.

HEALTH COMMUNICATION METHOD

To get this health message across, posters were developed which covered important facts, signs and symptoms, importance of the vaccine as well as ideal age requirements to get HPV vaccines done. This message was provided to motivate members of the college to engage in HPV education. A college campus was selected as the setting of this study because it is convenient to portray this information to students where they are most available. Even if one is making their way across campus they still have access to this information. To provide accurate information to the public, we will rely on organizations such as the CDC, the WHO, the U.S department of health and human services, and other local stakeholders. These posters are accessible to large group of individuals within the age range for the vaccination.

Others modes of communication include the radio, newspaper, videos, PSAs, and more. Once the effectiveness of the posters are determined other modes of communication can be used in the future to help aid this process or reach those who are not on campus as often. Important factors when developing the poster included using colors that will attract the audience, keeping facts informative and concise, reducing the use of jargon, providing answers to most common questions as well as presenting other resources where these students will be able to get more information. We determined that focusing on a community level will incorporate more of the population as stakeholders for possible programs or better outreach in the future.

DISCUSSION

HPV vaccines are important measures of prevention; however, there are many factors that can influence one's decision on whether or not to get the vaccine. These factors may not be related to teen education which is our main approach in this intervention. For instance, parents may not have access to the same education which would influence them to get their children vaccinated younger. There may also be fear or stigma of promoting sexual activity by allowing their children to get this vaccine. In addition, the fear of

getting the vaccine done itself and whether there will be any negative effects associated with it may influence one's decision as well. Socioeconomic status may also influence whether one has access to these materials and transportation costs may also hinder their ability to complete the vaccination series.

We are hoping to encourage better decision-making among adolescence when it comes to their health. We are providing all necessary information or requested information relating to HPV as well as promoting the services already accessible to students. With access to all of these materials, the vaccination rates should increase. If this program is deemed as successful among this university, it can be applied to other schools to increase awareness and vaccination rates overall. We hope to continue this process, therefore, making HPV education and vaccination routine in each population. The more the community works together, the easier it will be to disperse this health message. Involving group leaders or other key stakeholders such as teachers, caregivers, media, and religious associations will help expand on the importance of the topic.[20, 21]

CONCLUSION

HPV is one of the most common preventable sexually transmitted diseases among adolescents; however, it is preventable with the use of the vaccine. According to the WHO, HPV vaccination report, "cervical cancer, caused by sexually transmitted HPV, is the second most common cancer in women worldwide and results in about 266,000 deaths each year." We hope to target the population that missed their opportunity to get vaccinated at a younger age due to lack of health education on HPV. The importance of this proposed plan is to determine if providing this information to adolescents who still have a chance to get vaccinated will indeed increase vaccination rates.

Posters are a common way of sharing details about important health issues. Our goal was to raise vaccination levels among students. To promote vaccinations, we aimed to reinforce these decisions made by students to prevent HPV related illnesses. The proposed study findings may be useful if applying posters to other universities in addition understanding what needs to be improved for better results.

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Case Report

Endodontic Management of Single-rooted Mandibular Canine with Two Canals: A Case Series

Dipali Dinkerrao Deshpande[1], Sharad Basavraj Kamat[2], Girish Shankar Nanjannawar[3], Rutuja Vijay Chopade[4]

[1]Post Graduate Student, Department of Conservative Dentistry and Endodontics, Bharati Vidyapeeth Deemed to be University, Dental College and Hospital, Sangli, Maharashtra, India, [2]Professor and HOD, Department of Conservative Dentistry and Endodontics, Bharati Vidyapeeth Deemed to be University, Dental College and Hospital, Sangli, Maharashtra, India, [3]Associate Professor, Department of Conservative Dentistry and Endodontics, Bharati Vidyapeeth Deemed to be University, Dental College and Hospital, Sangli, Maharashtra, India, [4]Assisstant Professor, Department of Conservative Dentistry and Endodontics, Bharati Vidyapeeth Deemed to be University, Dental College and Hospital, Sangli, Maharashtra, India

Abstract

The mandibular canine usually presents one root with a single large canal located centrally. The possible anatomical variation is the existence of a single root with two canals. The incidence of mandibular single-rooted canines with two canals is usually low. The clinicians should keep in mind, possible variations in the root canal anatomy to achieve predictable results.

Key words: Anatomic variations, Radiography, Root canal treatment

INTRODUCTION

A thorough knowledge of the root canal morphology and its variations are an indispensable prerequisite for the success of root canal treatment. Many roots have additional canals and a variety of canal configurations.[1]

Canine is called the "cornerstone" of the mouth because of its location, which reflects its dual function to complement the incisors and premolars during mastication. These teeth are able to withstand increased lateral pressure during the act of mastication, thus being an important abutment for any prosthetic reconstruction.[2] Mandibular canines present a complex internal anatomy. In general, mandibular canines contain a single root and root canal. There are reported cases of canines with a single root and two canals, three canals, two roots, or fused roots.[3]

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This paper describes successful management of two cases of single-rooted mandibular canine with two root canals joining short of the apex.

CASE REPORT

Case I

A 19-year-old female patient reported to the department of conservative dentistry and endodontics with the chief complaint of moderate, dull aching, and intermittent pain in the lower right front region of the teeth for 2 months. The patient medical history was non-contributory. On examination, the lower right canine revealed proximal caries on mesiobuccal and distobuccal side. The tooth was not mobile and periodontal probing around the tooth was within physiological limits. Thermal tests were positive and electric pulp testing elicited delayed response with the right mandibular canine. A diagnostic radiograph revealed a coronal mesioocclusal caries involving enamel and dentin, a coronal distoocclusal radiolucency involving the pulp space and widening of the periodontal ligament space. The radiograph also revealed an unusual anatomy of involved tooth. It showed the presence of two separate canals at the coronal and middle one-third of root and merging at the apical third of the root. Based on the clinical and

Corresponding Author: Dr. Dipali Dinkerrao Deshpande, Department of Conservative Dentistry and Endodontics, Bharati Vidyapeeth Deemed to be University, Dental College and Hospital, Sangli, Maharashtra, India. Phone: +91-9588455676.
E-mail: dipalideshpande60@gmail.com

radiographic findings, diagnosis of symptomatic apical periodontitis was rendered [Figure 1].

Case II

A 24-year-old female patient reported to the department of conservative dentistry and endodontics with the chief complaint of dull aching pain in the lower left front region of the teeth for 2–3 months. Aggravating factor was mastication. Intraoral examination revealed extensive tooth decay and fracture of distal part of the crown. The tooth had mild tenderness to percussion. On thermal testing, the tooth was responsive. Electric pulp testing revealed delayed response. Pre-operative radiographic examination revealed proximal radiolucency on distal aspect of canine involving pulp space, discontinued lamina dura, and widening of periodontal ligament space. The radiograph also revealed an unusual anatomy of involved tooth with two separate canals at the coronal and middle one-third of root and uniting at the apical third of the root. From the clinical and radiographic findings, a diagnosis of symptomatic apical periodontitis was made.

Local anesthesia was administrated and caries was removed in both the cases. Conventional access cavity preparation was done with Endo Access Round Diamond Bur (Dentsply/Maillefer, Ballaigues, Switzerland) and an Endo-Z tapered safe end bur. Lingual modification of conventional access cavity was done to locate extra canal lingual to main canal. Exploration and negotiation of two root canals were done with a size 15 K-file. Radiographic working length measurement was done with Kodak RVG 5100 Digital Dental Unit (Kodak) and confirmed using apex locator (Root ZX J Morita). Cleaning and shaping of root canals were done using K-files (Dentsply, Maillefer) by conventional method till 30 K-file. During root canal preparation, the root canals were irrigated with sodium hypochlorite (5.2%) and normal saline solution. The root canals were dried using absorbent paper points and obturated with 2% gutta-percha cones (DIADENT Group International, Korea) and AH Plus sealer (DeTrey Dentsply, Konstanz, Germany) by lateral condensation technique. Post-endodontic restoration was done with composite resin (3 M ESPE, A G Seefeld, Germany) [Figure 2].

DISCUSSION

Mandibular canines present a complex internal anatomy. There are reported cases of canines with a single root and two canals, three canals, two roots, or fused roots. Hence, the complex nature of root canal morphology of mandibular canines should be thoroughly understood because additional root canals if not detected, can be a major reason for failure of root canal treatment.[4]

In the majority of cases, the mandibular canines are recognized as usually having one root and one root canal. Green and Vertucci reported that 15% of mandibular canines possess two canals with one or two foramina.[5] In the Iranian population, Aminsobhani *et al.* reported single canal in 71.8% and two canals in 28.2% in mandibular canines. Green reported the presence of accessory canals in mandibular canine to be 10%.[1] Cone beam computed tomography study revealed incidence of single-rooted mandibular canines with two canals and one foramen (Type II) is 3.2% in Indian population.[1]

It is essential that clinicians know the clinical and radiographic signs that suggest the presence of extra

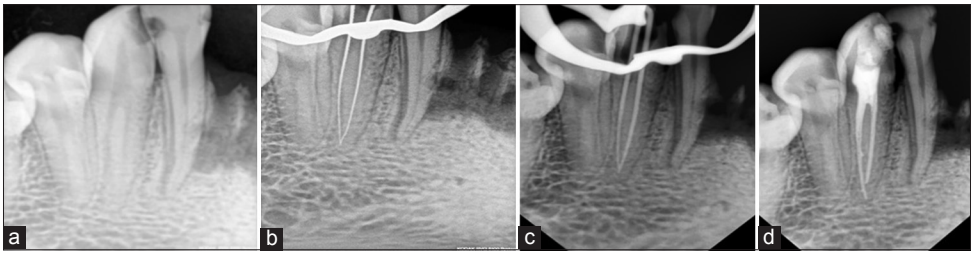

Figure 1: Case I - (a) Pre-operative image, (b) working length determination, (c) master cone selection, (d) post-obturation image

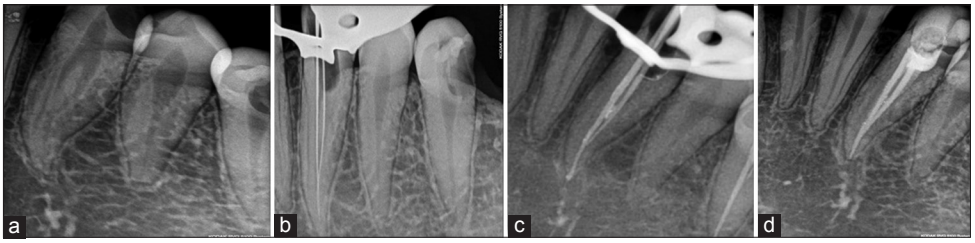

Figure 2: Case II - (a) Pre-operative image, (b) working length determination, (c) master cone selection, (d) post-obturation image

canals. The presence of continuous bleeding in teeth with pulpitis or normal pulp in spite of complete instrumentation, presence of an apical rarefaction on the lateral side of the root, extensive location of endodontic file, feeling of catch on wide and unobstructed canal during instrumentation, radiolucent line running parallel to the canal, champagne bubble test, and use of magnification are other aids of determining the presence of additional canals.[6]

CONCLUSION

Clinicians should be aware of anatomical variations in the teeth they are managing and should never assume that canal systems are simple. Although mandibular canines have single root and single root canal, search for the second canal should be carried out. Careful clinical, as well as radiographical examination accompanying with advance diagnostic images, should be carried out for locating extra canal.

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