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A COMPARATIVE STUDY BETWEEN LAPAROSCOPIC VS OPEN COMMON BILE DUCT EXPLORATION

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Abstract

Introduction: Although laparoscopic cholecystectomy has replaced the open surgery for management of gall bladder stones, however, bile duct stones or choledocholithiasis remains to be a challenging task. Bile duct stones are seen in almost every 7th to 10th patient having gall bladder stones[i]. There is controversy regarding the ideal approach for management of common bile duct (CBD) gallstones, more so, in view of availability of multiple options. Until the laparoscopic and endoscopic modalities came into picture, open cholecyststectomy was the only procedure for CBD exploration.

Materials and methods: Prospective Study was done in all patients with a diagnosis of choledocholithiasis in OPD in surgery department at Era's Lucknow Medical College and hospital posted for elective surgery. All the patients above 18 years of age presenting with uncomplicated choledocholithiasis undergoing elective CBD exploration were included. Patients with cholangitis, gall stone pancreatitis, abnormal liver enzymes (greater than thrice the upper limit of normal), immunocompromised patient were excluded. All patients with a diagnosis of choledocholithiasis in surgery OPD at ELMCH were chosen by SNOSE technique for open and laparoscopic CBD exploration. Demographic information was obtained. Blood specimen were obtained for hematological and biochemical assessment. Pre-operative sonographic assessment was also done and stone size was assessed. All patients received preoperative parental broad spectrum antibiotics. All procedures were operated by the same experienced surgical team, under general anesthesia.

Results: Out of a total of 88 patients enrolled in the study, a total of 44 (50%) underwent CBD exploration using laparoscopic procedure and comprised the Group 1 of study whereas remaining 44 (50%) patients underwent CBD exploration using open procedure and comprised the Group 2 of study. Majority of patients in both the groups were female. Proportion of males was 36.4% and 34.1% respectively in Groups 1 and 2. Overall, there were 31 (35.2%) males and 57 (64.8%) females. On comparing the data statistically, no significant difference was observed between the two groups with respect to sex of the patients (p=0.823). Mean neutrophil, lymphocyte,

eosinophil and monocyte count was 68.45±7.19, 26.45±7.51, 4.23±1.79 and 0.82±1.02% respectively in Group 1 as compared to 68.30±7.61, 27.32±7.69, 3.95±1.82 and 0.61±1.10% respectively in Group 2. For none of these variables, the difference between two groups was significant ($p>0.05$). Mean prothrombin time and INR were 12.12±1.62 seconds and 0.70±0.14 respectively in Group 1 as compared to 12.20±1.47 seconds and 0.68±0.11 respectively in Group 2. Statistically, there was no significant difference between two groups for both these parameters ($p>0.05$).

Conclusion: The findings of the study show that except for a slightly longer duration of procedure, laparoscopic procedure was associated with fewer complications (intraoperative blood loss, post-operative infection, wound dehiscence, residual stones and Incisional hernia), shorter duration of post-operative hospital stay and cheaper overall cost. Thus laparoscopic exploration of CBD offered a better clinical outcome with fewer outcomes and could be recommended as the preferred modality for exploration of CBD.

Key Words: laparoscopic cholecystectomy, prothrombin time, clinical outcome.

INTRODUCTION

Although laparoscopic cholecystectomy has replaced the open surgery for management of gall bladder stones, however, bile duct stones or choledocholithiasis remains to be a challenging task. Bile duct stones are seen in almost every 7th to 10th patient having gall bladder stones[ii]. There is controversy regarding the ideal approach for management of common bile duct (CBD) gallstones, more so, in view of availability of multiple options. Until the laparoscopic and endoscopic modalities came into picture, open cholecyststectomy was the only procedure for CBD exploration.[1] However, after the introduction of laparoscopic cholecystectomy and its reported benefits in terms of smaller incision, less intraoperative blood loss, reduced post-operative pain, early recovery, short hospital stay and better cosmetic results, has motivated the workers to exploit these benefits in CBD exploration too. Simultaneously, a number of workers proposed endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (EST) for extraction of bile duct stones, however, both these techniques are criticized for their failure to provide favourable outcomes in all the cases. Techniques like EST often end-up disturbing the integrity of oddi sphincter leading to duodenal biliary reflux that can be responsible for recurrence of CBD stones in the long-term.[2] It can also increase the risk of cholangiocarcinoma in view of transformation of duodenal biliary reflux into chronic cholangitis and long-standing inflammatory processes. Though, ERCP is an accepted modality for CBD exploration yet it is related with severe complications such as “pancreatitis, bleeding, and duodenal perforation. Hence, the focus has shifted mainly to laparoscopic or open procedures for their usefulness and efficacy for CBD exploration.[3]

Although open cholecystectomy has been used for CBD exploration for a long period, however, it exposes the patient to a greater level of invasiveness that leads to greater blood loss, deeper

wound pain, and complications associated (incisional hernia, wound infection, seroma, abscesses.[4]

On the other hand, although the minimal invasive procedures like laparoscopic exploration despite their promising role in reducing blood loss, pain operative pain and complications have their own complications. Laparoscopic exploration has been reported to be associated with complications like bile duct injury, bile leakage, hemorrhage, sub-hepatic access and retained bile duct stones.[5]

In view of these relative advantages as well as disadvantages, the appropriate option for CBD exploration still remains a controversial issue.

In our centre, both open as well as laparoscopic procedures are being regularly used to perform cholecystectomy and also for CBD exploration. Hence, the present study was planned to compare between laparoscopic and open CBD exploration for intraoperative and post-operative complications and ductal stone clearance.

AIM AND OBJECTIVES

AIM: To compare the efficacy of open and laparoscopic CBD exploration.

OBJECTIVE: To compare between the two techniques for operative time, intra operative bleeding, CBD injury, wound infections and dehiscence, post operative pain, hospital stay, residual stones, Incisional hernia, and total operative cost.

MATERIALS AND METHODS

Type of study: Prospective Study.

Study subjects: The study was done in all patients with a diagnosis of choledocholithiasis in OPD in surgery department at Era's Lucknow Medical College and hospital posted for elective surgery.

Study period: 2 years.

Sample Size Estimation: Sample size is calculated on the basis of odds ratio of risk of composite morbidity in open CBDE relative to laparoscopy using the formula.

Where OR = 2.19 the odds ratio of risk of composite morbidity in open CBDE relative to laparoscopy, (Ref. Halawani *et al*. 2017).

Risk ratio e = considered to be clinically significant

Type I error, a=5% (level of significance)

Type II error p=20% for setting power of study 80%

Data loss factor = 10%

The sample size was calculated to be n= 88 *i.e.* 44 in each group.

Inclusion Criteria: All the patients above 18 years of age presenting with uncomplicated choledocholithiasis undergoing elective CBD exploration.

Exclusion Criteria: Patients with cholangitis, gall stone pancreatitis, abnormal liver enzymes (greater than thrice the upper limit of normal), immunocompromised patient.

Approvals and Permissions: Approval for the study was obtained from the Institutional Ethics Committee, Era's Lucknow Medical College & Hospital, Lucknow. Informed consent was obtained from all the patients.

Method: All patients with a diagnosis of choledocholithiasis in surgery OPD at ELMCH were chosen by SNOSE technique for open and laparoscopic CBD exploration. Demographic information was obtained. Blood specimen were obtained for hematological and biochemical assessment. Pre-operative sonographic assessment was also done and stone size was assessed. All patients received preoperative parental broad spectrum antibiotics. All procedures were operated by the same experienced surgical team, under general anesthesia.

The treatment option was randomly assigned by one of the two procedures of either laparoscopic approaches or conventional surgery as a Group 1 (underwent laparoscopic CBD exploration in 60 patients), Group 2 (open CBD exploration in 60 patients).

The patients underwent LCBDE were placed supine. Some reversed Trendelenburg position with slight left rotation was sometimes required; the standard four-port configuration was used for LCBDE. A 10-12mm port was inserted in the subumblical area for cameras, another 10-12mm working trocar in the epigastric area. A 5 mm working trocar at the right midclavicular line-subcostal margin. The fourth one 5mm port was inserted in the anterior axillary line-subcostal margin.

Dissection and exposure of the Calot's triangle with skletonization of the cystic duct and artery. Careful dissection was used to identify the anterior surface of the supraduodenal part of the CBD, where a longitudinal choledochotomy was performed. A 5mm flexible fiberoptic choledochoscope was routinely used to visualize and to extract stones.

Different methods for stone extraction were used, saline irrigation, milking of the CBD, stone retrieval (Dormia) basket, or balloon extraction techniques through a choledochoscope. After the removal of stones, a choledochoscope was used to assess the clearance of the ductal system.

The choledochotomy incision was either primarily closed using 3-0 or 4-0 polygycolic acid suture in an interrupted or continuous manner or over a T-tube insertion according to the situation and intraoperative manipulations.

Transcystic approach was performed in the few cases where the CD was dilated; a longitudinal opening of the CD was done and choledochoscope was introduced to visualize the CBD and stones inside. The stone(s) was or were removed by the same previous methods. After CBD Clearance and closure laparoscopic cholecystectomy was done. A drain was routinely inserted in Morison's pouch.

The second group underwent conventional surgical approach includes open cholecystectomy and choledocholithotomy and also choledochotomy incision was either primarily closed or over a T-tube inserted with a sub hepatic drain in all cases.

Targeted outcomes in terms of duration of surgery, biliary leak/injury, other organelle injury and amount of blood loss was noted (in ml).

All the patients were followed up on day 3, 7 and 14 of surgery. Clinical signs of infection, wound dehiscence and VAS scores $\geq$3 (on a scale of 10) were noted as the follow-up outcomes. Duration of hospital stay was noted. At last follow-up a repeat USG scan was performed to assess any residual stone. Other post-operative complications, if any, were also noted.

Data Analysis: Data was analysed using Statistical Package for Social Sciences (SPSS) version 21.0. Chi-square and independent samples 't'-tests were used to compare the data. A 'p' value less than 0.05 indicated a statistically significant association.

RESULTS

The present study was carried out to compare laparoscopic and open common bile duct exploration for patients with choledocholithiasis. For this purpose, a total of 88 patients fulfilling the eligibility criteria were enrolled in the study and were randomized to one of the following two groups:

Table 1: Group wise distribution of patients

SN	Group	Description	No. of patients	Percentage
1.	1	Patients with uncomplicated choledocholithiasis in whom CBD exploration was done using laparoscopic procedure	44	50.0
2.	2	Patients with uncomplicated	44	50.0

		choledocholithiasis in whom CBD exploration was done using open procedure		

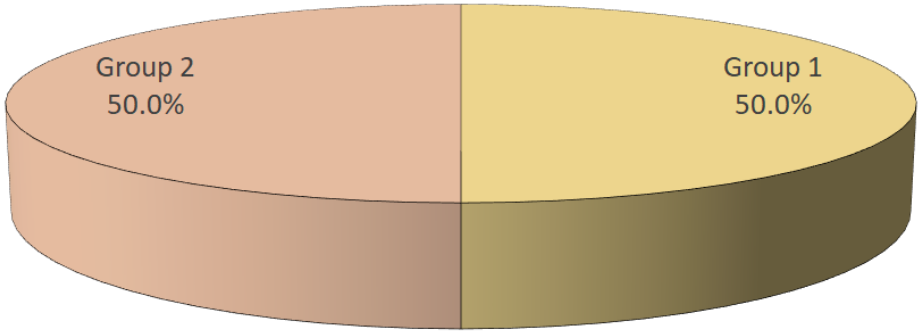

Fig. 1: Group wise distribution of study population

Out of a total of 88 patients enrolled in the study, a total of 44 (50%) underwent CBD exploration using laparoscopic procedure and comprised the Group 1 of study whereas remaining 44 (50%) patients underwent CBD exploration using open procedure and comprised the Group 2 of study.

Table 2: Comparison of age of patients in two study groups

SN	Age Group	Group 1		Group 2		Total	
		No.	%	No.	%	No.	%
1.	≤30 Years	10	22.7	10	22.7	20	22.7
2.	31-40 Years	17	38.6	19	43.2	36	40.9
3.	41-50 Years	13	29.5	14	31.8	27	30.7
4.	51-60 Years	3	6.8	0	0.0	3	3.4
5.	>60 Years	1	2.3	1	2.3	2	2.3
Mean age±SD (Range) in years		38.94±9.32 (25-68)		36.77±7.85 (23-62)		37.81±8.63 (23-68)	

't'=1.126; p=0.263

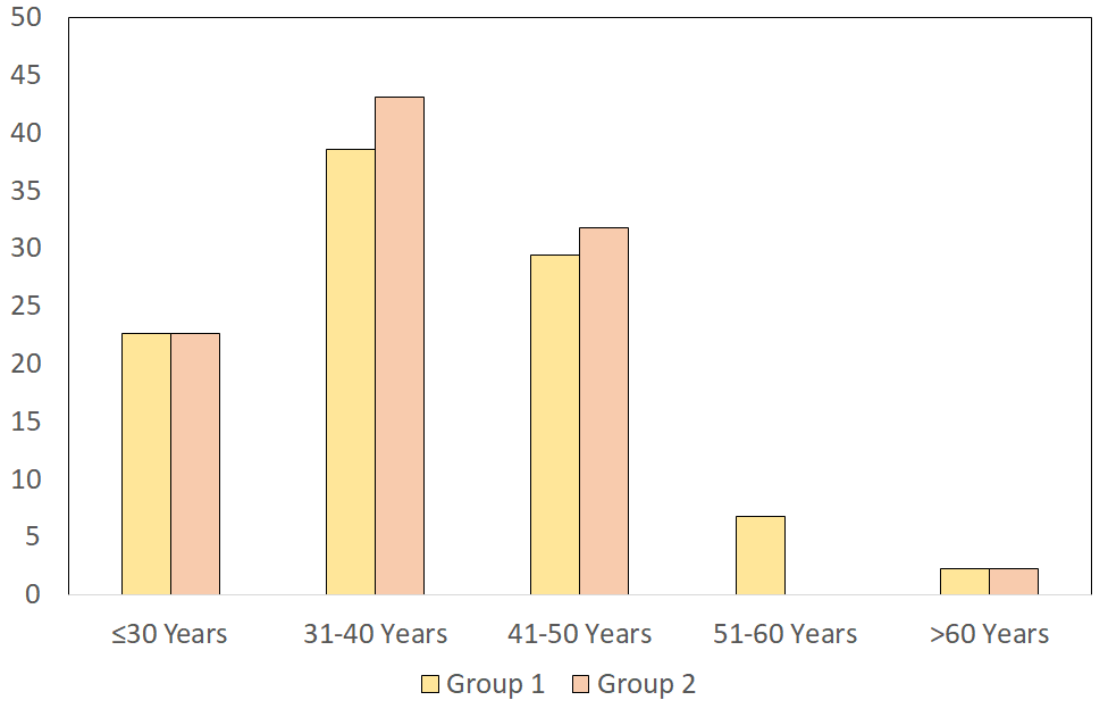

Fig. 1: Comparison of age profile of patients in two study groups

Age of patients ranged from 23 to 68 years. Majority of patients were aged ≤40 years (63.6%). There were only 5 (5.7%) patients aged >50 years. Mean age of patients was 37.81±8.63 years. In both the groups, majority of patients were aged ≤40 years. Mean age of patients in Groups 1 and 2 was 38.94±9.32 years and 36.77±7.85 years respectively. Statistically, there was no significant difference between two groups with respect to mean age of patients (p=0.263).

Table 3: Distribution of patients in two study groups according to sex

SN	Sex	Group 1		Group 2		Total	
		No.	%	No.	%	No.	%
1.	Male	16	36.4	15	34.1	31	35.2
2.	Female	28	63.6	29	65.9	57	64.8

χ^2=0.050; p=0.823

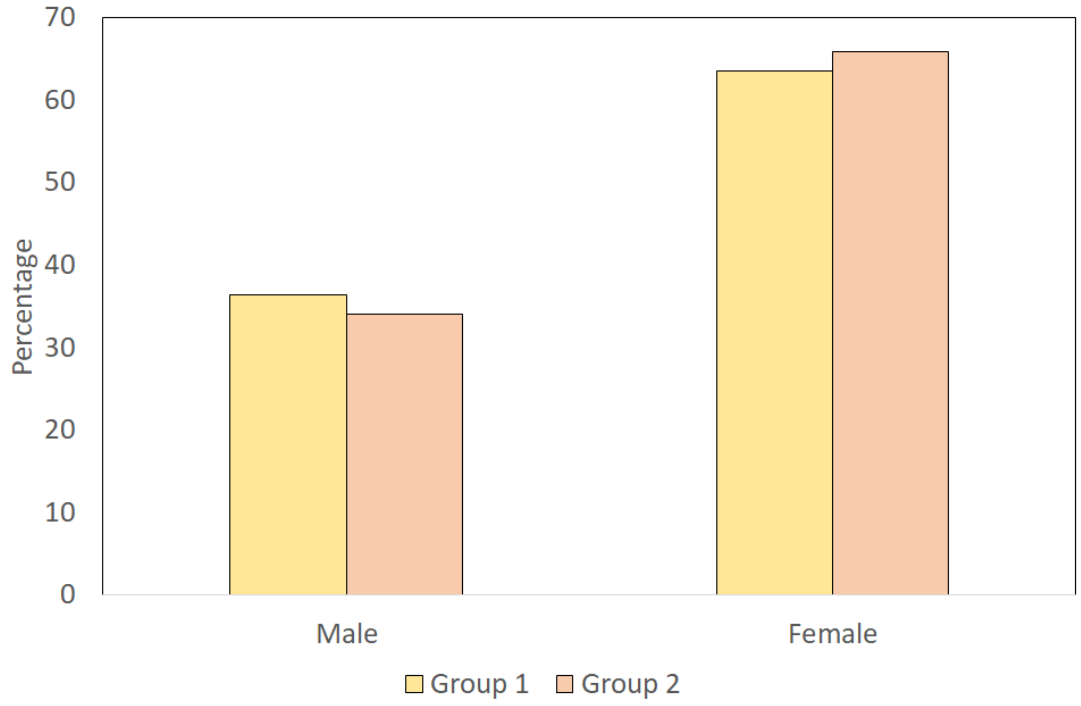

Fig. 3: Distribution of patients in two study groups according to sex

Majority of patients in both the groups were female. Proportion of males was 36.4% and 34.1% respectively in Groups 1 and 2. Overall, there were 31 (35.2%) males and 57 (64.8%) females. On comparing the data statistically, no significant difference was observed between the two groups with respect to sex of the patients (p=0.823).

Table 4: Comparison of Hematological Profile of patients in two study groups

SN	Characteristic	Group 1 (n=44)		Group 2 (n=44)		Statistical significance	
		Mean	SD	Mean	SD	t	p
1	Hb (g/dl)	12.54	1.08	12.23	1.26	1.229	0.222
2	TLC (‘000/cumm)	8.64	2.14	8.36	2.17	0.614	0.541
3	N (%)	68.45	7.19	68.30	7.61	0.101	0.920
4	L (%)	26.45	7.51	27.32	7.69	-0.533	0.595
5	E (%)	4.23	1.79	3.95	1.82	0.709	0.480
6	M (%)	0.82	1.02	0.61	1.10	0.903	0.369
7	PT (seconds)	12.12	1.62	12.20	1.47	-0.266	0.791

8	INR	0.70	0.14	0.68	0.11	0.517	0.606

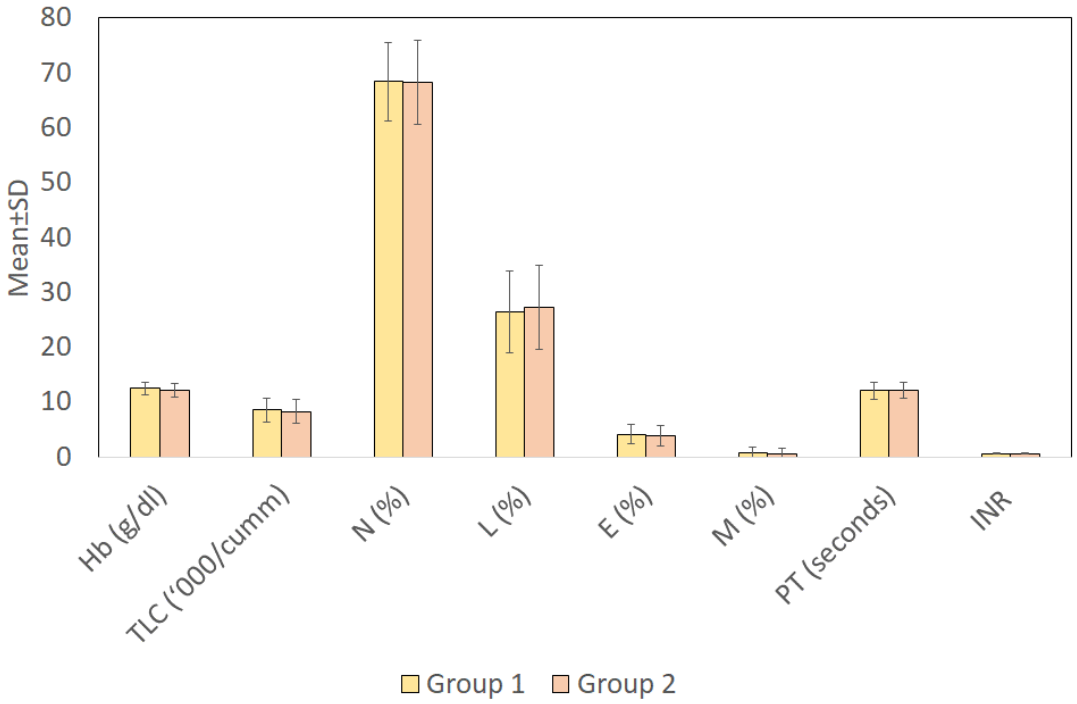

Fig. 4: Comparison of Hematological Profile of patients in two study groups

Mean haemoglobin and TLC levels were 12.54±1.08 g/dl and 8.64±2.11 thousands/cumm respectively in Group 1 and 12.23±1.26 g/dl and 8.36±2.17 g/dl respectively in Group 2. Statistically, there was no significant difference between two groups with respect to haemoglobin and total leukocyte count (p>0.05).

Mean neutrophil, lymphocyte, eosinophil and monocyte count was 68.45±7.19, 26.45±7.51, 4.23±1.79 and 0.82±1.02% respectively in Group 1 as compared to 68.30±7.61, 27.32±7.69, 3.95±1.82 and 0.61±1.10% respectively in Group 2. For none of these variables, the difference between two groups was significant (p>0.05).

Mean prothrombin time and INR were 12.12±1.62 seconds and 0.70±0.14 respectively in Group 1 as compared to 12.20±1.47 seconds and 0.68±0.11 respectively in Group 2. Statistically, there was no significant difference between two groups for both these parameters (p>0.05).

Table 5: Comparison of Liver functions, random blood sugar and Renal functions of patients in two study groups

SN	Characteristic	Group 1 (n=44)		Group 2 (n=44)		Statistical significance	
		Mean	SD	Mean	SD	t	p

1	S. Bilirubin (mg/dl)	0.70	0.17	0.66	0.17	1.071	0.287
2	SGPT (IU/L)	31.47	9.54	32.66	9.98	-0.570	0.570
3	SGOT (IU/L)	34.81	9.39	32.52	9.76	1.115	0.268
4	Random blood sugar (mg/dl)	155.54	12.06	155.86	10.58	-0.110	0.913
5	S. Urea (mg/dl)	52.93	16.96	46.75	12.63	1.940	0.056
6	S. creatinine (mg/dl)	1.00	0.32	0.97	0.33	0.363	0.717
7	S. Na^+ (mEq/L)	139.18	2.86	139.55	2.68	-0.615	0.540
8	S. K^+ (mEq/L)	4.03	0.31	3.95	0.34	1.113	0.269

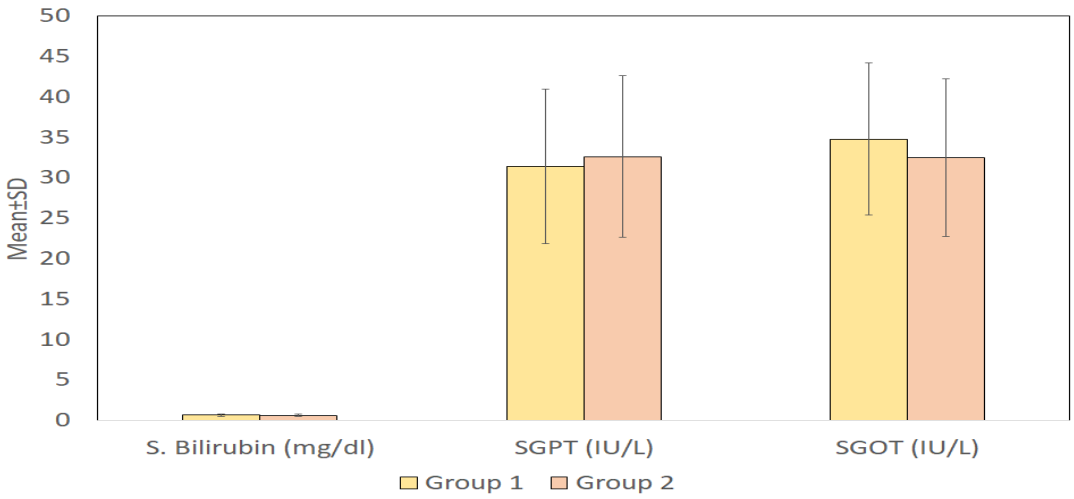

Fig. 5.1: Comparison of Liver function tests between two study groups

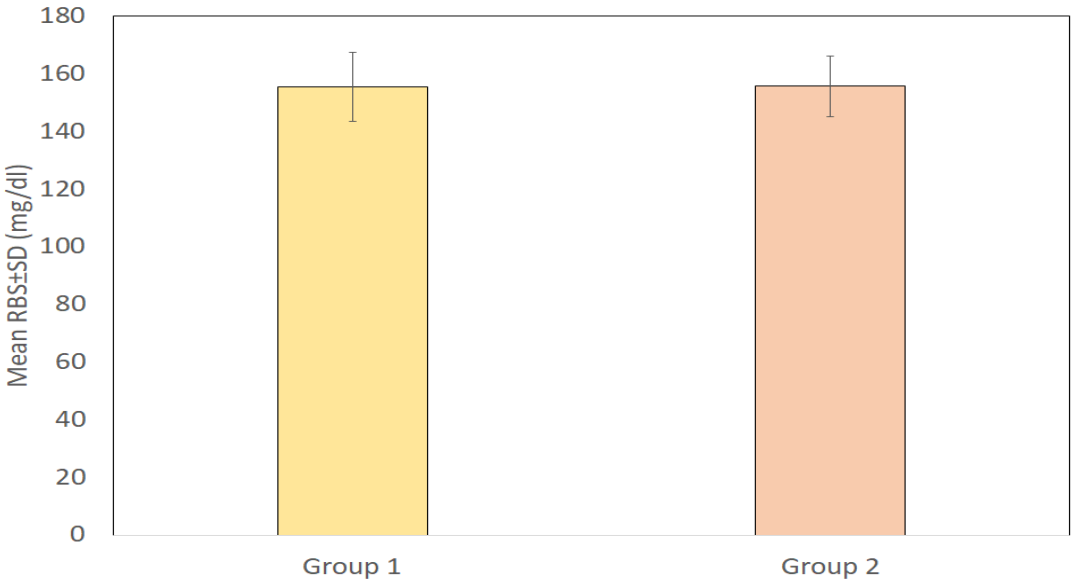

Fig. 5.2: Comparison of Random Blood Sugar levels between two study groups

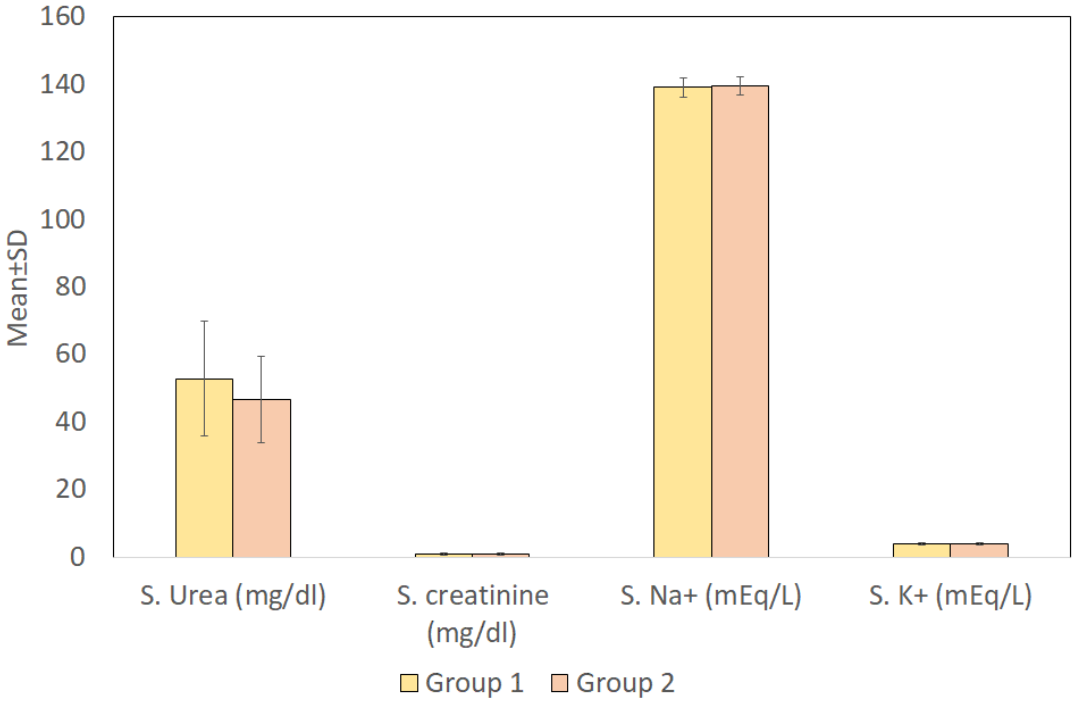

Fig. 5.3: Comparison of Renal functions and Serum electrolyte levels between two study groups

Mean serum bilirubin, SGPT and SGOT levels were 0.70±0.17 mg/dl, 31.47±9.54 IU/L and 34.81±9.39 IU/L respectively in Group 1 and 0.66±0.17 mg/dl, 32.66±9.98 IU/L and 32.52±9.76 IU/L respectively in Group 2. For all these parameters, the difference between two groups was not significant statistically (p>0.05).

Mean random blood sugar levels were 155.54±12.06 mg/dl and 155.86±10.59 mg/dl respectively in Groups 1 and 2 thus showing no statistically significant difference between two groups (p=0.913).

Mean serum urea and serum creatinine levels were 52.93±16.96 and 1.00±0.32 mg/dl respectively in Group 1 and 46.75±12.63 and 0.97±0.33 mg/dl respectively in Group 2. Statistically, the difference between two groups was not significant (p>0.05). Mean serum sodium and potassium levels were 139.18±2.86 and 4.03±0.31 mEq/L respectively in Group 1 and 139.55±2.68 and 3.95±0.34 mEq/L respectively in Group 2. For both the electrolytes the difference between two groups was not significant statistically (p>0.05).

Table 6: Comparison of Stone size and Intraoperative parameters of patients in two study groups

SN	Characteristic	Group 1 (n=44)		Group 2 (n=44)		Statistical significance	
		Mean	SD	Mean	SD	t	p
1	Stone size (mm)	7.66	2.37	7.75	2.08	-0.191	0.849
2	Duration of surgery (min)	127.73	26.40	115.68	19.70	2.426	0.017
3.	Blood loss (ml)	31.36	28.72	62.05	24.38	-5.402	<0.001

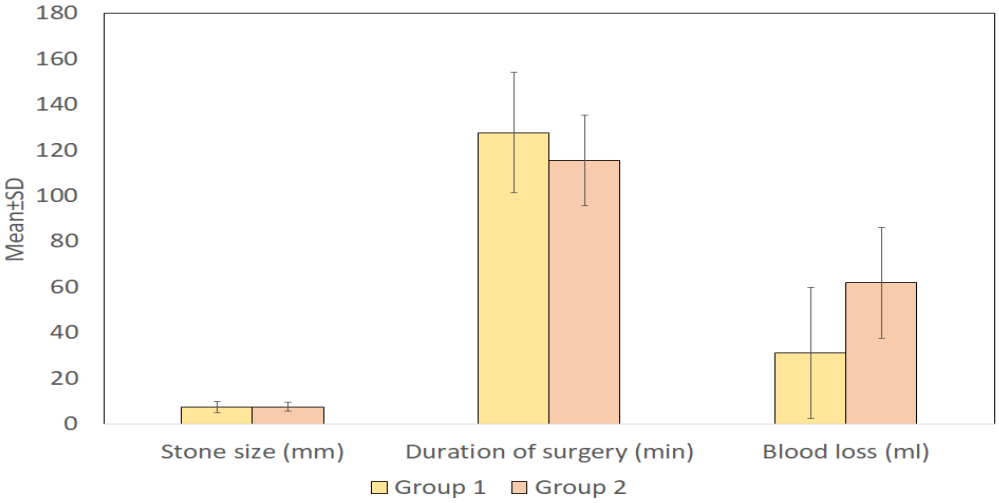

Fig. 6: Comparison of Intraoperative parameters of patients in two study groups

Mean stone size was 7.66±2.37 mm in Group 1 as compared to 7.75±2.08 mm in Group 2. Statistically, there was no significant difference between two groups with respect to stone size.

Mean duration of surgery was significantly longer in Group 1 (127.73±26.40 min) as compared to that in Group 2 (115.68±19.70 min) (p=0.017).

Mean amount of intraoperative blood loss was 31.36±28.72 ml in Group 1 as compared to 62.05±24.38 ml in Group 2, thus showing a statistically significant difference between two groups (p<0.001).

Table 7: Comparison of Post-operative outcomes of patients in two study groups

SN	Characteristic	Group 1 (n=44)		Group 2 (n=44)		Statistical significance	
		No.	%	No.	%	χ^2	p
Day 3							
1	Infection	7	15.9	10	22.7	0.656	0.418
2	Wound dehiscence	0	0	0	0	-	-
3	VAS >3	11	25.0	39	88.6	36.31	<0.001
Day 7							
1	Infection	7	15.9	10	22.7	0.656	0.418
2	Wound dehiscence	0	0	3	6.8	3.160	0.078
3	VAS ≥3	3	6.8	20	45.5	17.01	<0.001
Day 14							

1	Infection	7	15.9	10	22.7	0.656	0.418
2	Wound dehiscence	0	0	3	6.8	3.160	0.078
3	VAS ≥2	2	4.5	13	29.5	9.724	0.002

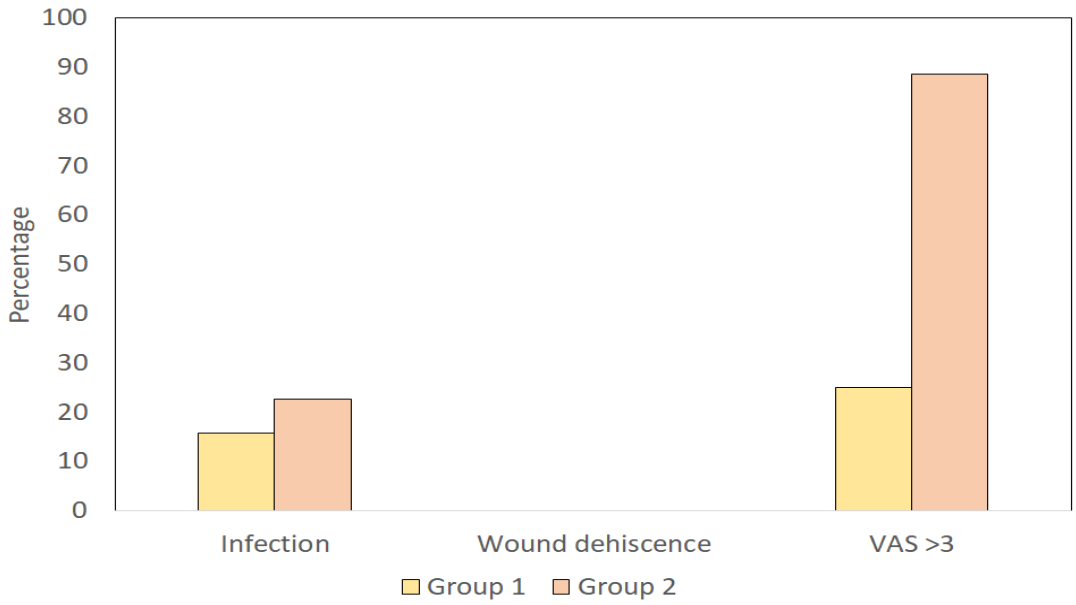

Fig. 7.1: Comparison of Post-operative Day 3 outcomes between two study groups

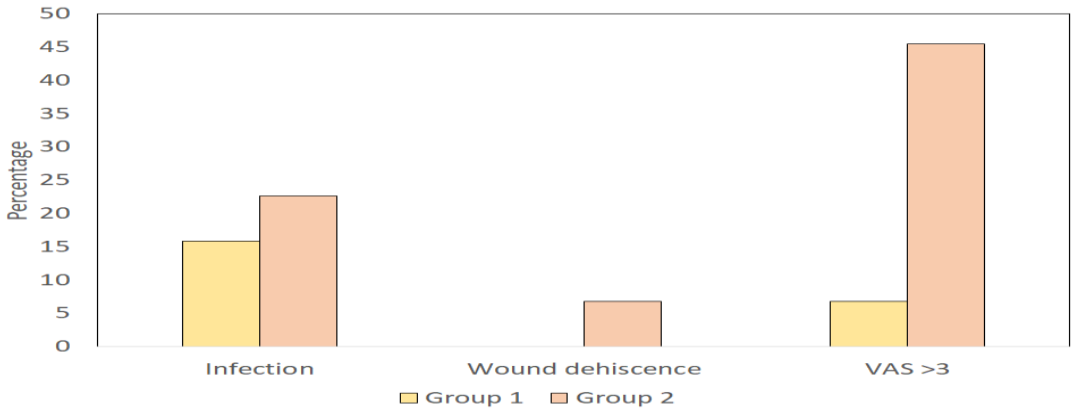

Fig. 7.2: Comparison of Post-operative Day 7 outcomes between two study groups

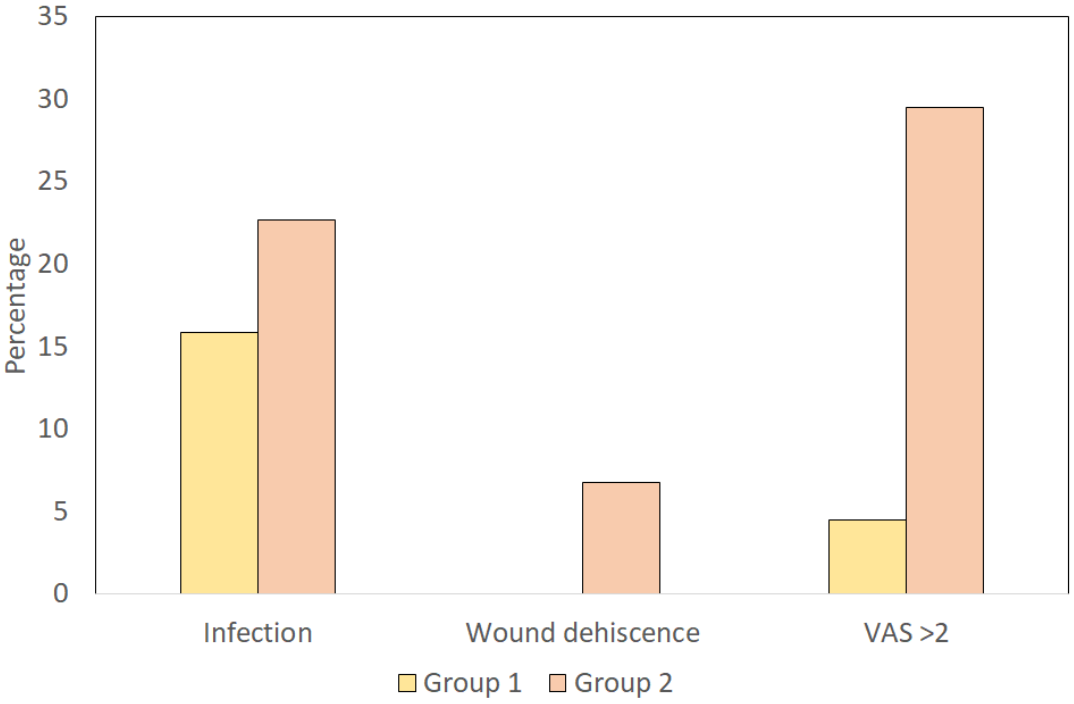

Fig. 7.3: Comparison of Post-operative Day 14 outcomes between two study groups

On day 3 post-operative interval, clinical signs of infection were seen in 7 (15.9%) of Group 1 and 10 (22.7%) of Group 2 patients, though the proportion of patients showing signs of infection was higher in Group 2 as compared to that in Group 1 yet this difference was not significant statistically. At this follow-up interval, none of the patients showed wound dehiscence. VAS scores >3 for pain were seen in only 25% of Group 1 as compared to 88.6% of Group 2 patients thus showing a significant difference between two groups ($p<0.001$).

By day 7 post-operative follow-up, clinical signs of infection were seen in 7 (15.9%) of Group 1 as compared to 10 (22.7%) of Group 2 patients. Wound dehiscence was not noticed in any patient in Group 1 as compared to 3 (6.8%) of Group 2 patients, statistically the difference between two groups was not significant for both infection and wound dehiscence ($p>0.05$). However, at day 7, proportion of patients reporting VAS scores for pain $\geq$3 was significantly higher in Group 2 (45.5%) as compared to that in Group 1 (6.8%) ($p<0.001$).

By day 14 post-operative follow-up, clinical signs of infection were seen in 7 (15.9%) of Group 1 as compared to 10 (22.7%) of Group 2 patients. Wound dehiscence was not noticed in any patient in Group 1 as compared to 3 (6.8%) of Group 2 patients, statistically the difference between two groups was not significant for both infection and wound dehiscence ($p>0.05$). However, at day 14, proportion of those showing VAS scores for pain $\geq$2 was significantly higher in Group 2 (29.5%) as compared to that in Group 1 (4.5%) ($p=0.002$).

Table 8: Comparison of Duration of hospital stay and other outcomes between patients in two study groups

SN	Characteristic	Group 1 (n=44)	Group 2 (n=44)	Statistical significance
1.	Mean duration of hospital stay ± SD (days)	5.61±1.88	8.73±1.39	t=8.832; p<0.001
2.	Residual stone	0	2 (4.5%)	χ^2=2.047; p=0.153
3.	Incisional hernia	0	1 (2.3%)	χ^2=1.011; p=0.315

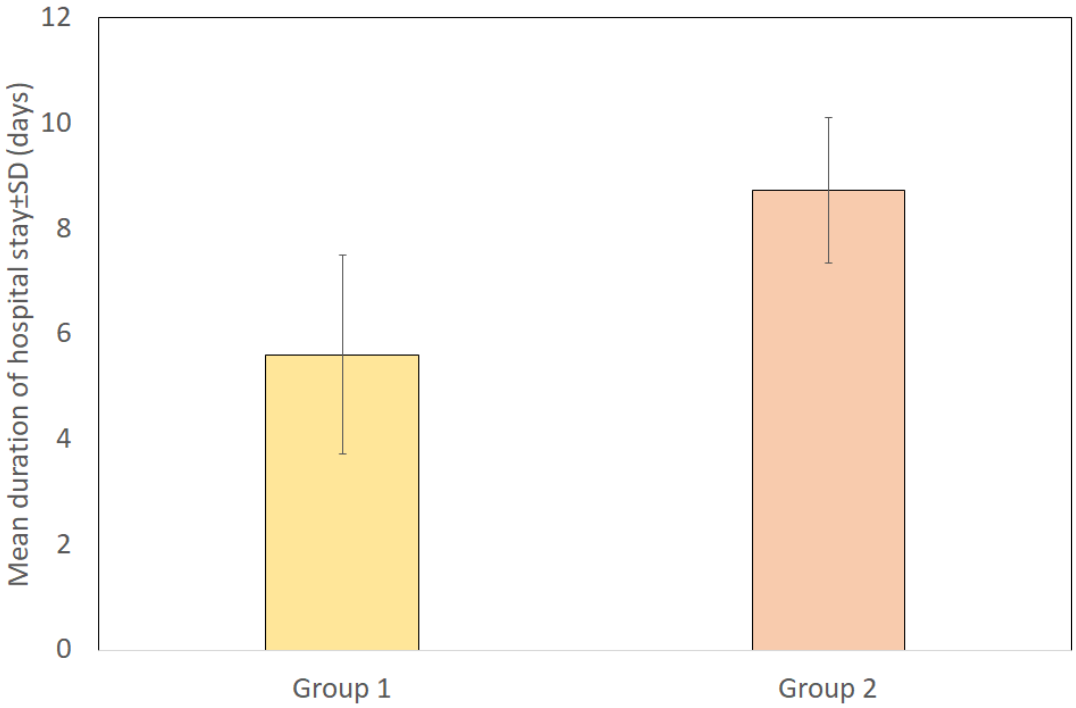

Fig. 8: Comparison of Duration of hospital stay between two study groups

Mean duration of hospital stay was significantly shorter in Group 1 (5.61±1.88 days) as compared to that in Group 2 (8.73±1.39 days) ($p<0.001$).

Residual stones and incisional hernia were seen in none of the Group 1 as compared to 4.5% and 2.3% of Group 2 patients. Statistically, the difference between the two groups was not significant for both these outcomes ($p>0.05$).

There was no case of bile duct injury in either of two groups.

None of the Group 1 patients required conversion to open surgery.

Cost of Procedure: In the present study, average cost of laparoscopic procedure (including cost of post-operative stay) was Rs 13927 (~Rs 14000/-) whereas in open procedure it was Rs 18251 (~Rs 18000/-). Thus on an average, the cost of surgery was nearly 22.2% higher in open as compared to laparoscopic procedure.

DISCUSSION

The present study compared laparoscopic and open options for common bile duct exploration for different outcomes. In the past laparoscopic and open CBDE exploration techniques have been compared with each other and with other competitive exploratory techniques and have shown variable comparative efficacies. The findings of the present study and their comparison with contemporary literature are as follows:

Age and Sex Profile

In the present study, majority of patients were aged ≤40 years (63.6%) and were females (64.8%). Mean age of patients was 37.81±8.63 years. There was no statistically significant difference between two groups with respect to age and sex of patients. Compared to the present study, Moon *et al.* reported a much higher mean age of patients in their study with mean age >65 years in both the study groups. Their study also had a dominance of males (51.9%).

Halawani*et al* found majority of cases to be above 55 years of age (56.6%) but similar to our study reported a dominance of females (59.8%).

The mean age and sex profile of the present study is comparable to the study by Bhar and Karmakar who reported the mean age of patients as 37.5 years and proportion of females as 62%. Redwan and Omar too in their study reported mean age of patients as 40 years which is comparable to the present study and a female dominance (77.7%) which is slightly higher than that in the present study.[6]

Gallstones/Choledocholithiasis is the most common indication for CBD exploration. The high prevalence of women and that of middle aged patients in different studies could primarily be attributed to the high prevalence of gall stone disease which is much higher in women as compared to men. Moreover, this disease has also been shown to be dependent on age with higher incidence in those aged 40 years or above**Error! Bookmark not defined.**. Thus age and sex profile of the patients in the present study was comparable to that of most of the cited literature and in terms of the epidemiological evidence available.

Preoperative Characteristics

In the present study, the two groups were matched for haematological and biochemical profile, stone size and as per inclusion criteria had uncomplicated choledocholithiasis with sound physical status of the patients.

While randomized studies are considered to be the gold standard of clinical research, it also has a disadvantage of a probable mismatch in patient characteristics owing to random allocation to the groups which could have an effect on the intervention outcome too[iii]. In clinical studies, unlike experimental studies a perfect matching between study groups is not possible and hence statistical matching determines that the patient characteristics do not pose a significant confounding effect due to random allocation. However, statistical matching for the patient characteristics in the two groups in the present study did not reveal a significant difference and hence the two groups were comparable for evaluation of role of the intervention.[7]

Intraoperative Outcomes

In the present study, there was no significant difference in stone size between two groups but duration of surgery was significantly longer in LCBDE group as compared to OCBDE group

whereas amount of blood loss was significantly more in LCBDE group as compared to that in OCBDE group.

Compared to the present study, a number of previous studies did not find a significant difference between two groups with respect to duration of procedure/ operative time. While some workers found LCBDE to be shorter in terms of duration of surgery as compared to the OCBDE. But most of the others similar to our study report the same to be shorter in OCBDE as compared to LCBDE. The differences in the trend of operative time in different studies could probably owing to difference in skill and exposure level for the two techniques in different studies. Surgeons who acquire experience in a particular technique become more skilful in that and tend to perform that particular procedure in a shorter time as compared to those who do not have adequate experience. However, in the present study, the procedure were performed by the same surgical techniques who have almost similar exposure to both the techniques as both these techniques are being performed routinely at our institution and hence we can claim that the pattern of differences in operative time as observed in the present study are more objective in terms of their suitability for a surgeon with equal exposure and sufficient exposure of both the techniques.

With respect to blood loss, greater blood loss in open procedure may be attributable to greater invasiveness of the procedure. Grubnik*et al.* too in their study highlighted the blood loss to be much higher in OCBDE as compared to LCBDE group. A similar observation was also made by Zhu *et al.* in their study. In fact, lesser amount of blood loss and minimal invasiveness of the procedure are the hallmarks of the LCBDE and make it a preferred option over CBDE. These features have an impact on post-operative outcomes too.

In the present study, there was no case of CBD injury or any other intraoperative complication. Compared to the present study, Salama*et al.* in their study reported instrument issues (balloon rupture and broken basket in one case each) in 2/36 (5.6%) of patients in their study. However, they might be an incidental finding as most of the other studies do not report any such complication and term both the procedures to be equally safe in terms of intraoperative complications.

Post-operative Complications

In the present study, no significant difference between the two study groups was observed with respect to post-operative day 3, 7 and 14 clinical infection and wound dehiscence rate despite the cumulative event rate for all these outcomes to be higher in OCBDE as compared to LCBDE group and mean pain scores at all the three follow-up periods were significantly lower in laparoscopic as compared to open procedure.

Thus, though for all the three outcomes, LCBDE had a slight edge over OCBDE yet for pain it was a definitive stronghold of LCBDE to be placed as a preferred modality. As such post-operative pain has not been considered as an issue of contention in different studies and has remained a relatively less addressed issue, however, it can directly be linked with the minimal

invasive nature of LCBDE that helps to reduce all the wound related complications. In various studies comparing outcomes for open and laparoscopic cholecystectomies too laparoscopic procedures have been shown to have an edge over Open procedure in terms of post-operative complications like infection, wound dehiscence and pain. The findings of the present study extend these benefits of laparoscopic procedure in patients undergoing CBD explorations too.

Hospital Stay/Other outcomes and Cost of Procedure

In the present study, patients in LCBDE group had a significantly shorter duration of hospital stay. Residual stones and Incisional hernia were seen in none of the laparoscopic as compared to 4.5% and 2.3% of open exploration group patients. Statistically, the difference between the two groups was not significant for both these outcomes. There was no case of bile duct injury and none of the laparoscopic group patients required conversion to open surgery. The average cost of procedure was Rs 14,000/- for Laparoscopic and Rs 18,000/- for Open procedure. Thus, cost of procedure was nearly 22% higher in open as compared to laparoscopic procedure.[8]

Most of the benefits of LCBDE over OCBDE in different studies have been depicted in terms of fewer postoperative morbidities, shorter duration of hospital stay and lower overall cost which might be primarily attributable to its minimal invasive nature. Grubnik*et al.* similar to our study highlighted low postoperative morbidity and shorter length of hospital stay as the key advantages of LCBDE over OCBDE in their study. Bayramov and Ibrahimova too in their study that compared two different laparoscopic approaches for CBD and gall bladder stones found both the laparoscopic approaches to be associated with shorter duration of hospital stay as compared to open approach group. They also found the complication rate to be lower in laparoscopic group as compared to open group.

Redwan and Omar found stone clearance rate to be 95% in open and 96% in open and laparoscopic groups but found the hospital stay to be significantly shorter and postoperative morbidity rate to be lower in laparoscopic procedure as compared to open procedure. Laparoscopy also permitted early return to work, thus showing an overall economic superiority too.

Contrary to the present study, where we observed retained stones in 4.5% of open as compared to none of the laparoscopic group patients, Halawani*et al.* in a retrospective record review of 2635 CBDEs found retained CBD stones to be 2.8 times more likely to occur in the LCBDE as compared to that in OCBDE. In the present study, though stone retention rate was higher in OCBDE as compared to LCBDE group yet this difference was not significant statistically, thus reflecting its chance nature. As far as the case of incisional hernia, it is a reported complication of OCBDE along with other postoperative complications like wound infection, seroma, abscess, *etc.* and it is where the minimal invasive procedure becomes the modality of choice.[9]

The findings of the present study are thus in agreement with most of the contemporary literature endorsing the usefulness of laparoscopic CBD exploration as a safe, cost-effective and less

complicated surgery as compared to open CBD exploration that ensure equal efficacy in terms of intraoperative outcomes and targeted surgical goals. Further studies on larger sample size with comparison of other alternative techniques are also recommended.[10]

CONCLUSION

The present study compared the efficacy of laparoscopic and open bile duct exploration in 88 patients requiring bile duct exploration for stone removal following cholelithiasis with choledocholithiasis who were randomized either to laparoscopic (n=44) or open (n=44) bile duct exploration groups. Following were the key characteristics and findings of the study:

Majority of patients were aged ≤40 years (63.6%) and were females (64.8%). Mean age of patients was 37.81±8.63 years. The two groups were matched statistically for age, sex, preoperative haematological and biochemical parameters. No significant difference between two groups was observed with respect to stone size as estimated by MRCP. Mean duration of surgery was significantly longer in laparoscopic group (127.73±26.40 min) as compared to that in open group (115.68±19.70 min). Mean amount of intraoperative blood loss was significantly lesser (31.36±28.72 ml) in laparoscopic exploration group as compared to that in open exploration group (62.05±24.38 ml). No significant difference between the two study groups was observed with respect to post-operative day 3, 7 and 14 clinical infection and wound dehiscence rate. However, mean pain scores at all the three follow-up periods were significantly lower in laparoscopic as compared to open procedure. Mean duration of hospital stay was significantly shorter in laparoscopic (5.61±1.88 days) as compared to that in open exploration group (8.73±1.39 days). Residual stones and incisional hernia were seen in none of the laparoscopic as compared to 4.5% and 2.3% of open exploration group patients. Statistically, the difference between the two groups was not significant for both these outcomes. There was no case of bile duct injury and none of the laparoscopic group patients required conversion to open surgery. The average cost of procedure was Rs 14,000/- for Laparoscopic and Rs 18,000/- for Open procedure. Thus, cost of procedure was nearly 22% higher in open as compared to laparoscopic procedure.

The findings of the study show that except for a slightly longer duration of procedure, laparoscopic procedure was associated with fewer complications (intraoperative blood loss, post-operative infection, wound dehiscence, residual stones and incisional hernia), shorter duration of post-operative hospital stay and cheaper overall cost. Thus laparoscopic exploration of CBD offered a better clinical outcome with fewer outcomes and could be recommended as the preferred modality for exploration of CBD.

REFERENCES

1. Verbesey JE, Birkett DH. Common bile duct exploration for choledocholithiasis. SurgClin North Am. 2008 Dec;88(6):1315-28, ix. doi: 10.1016/j.suc.2008.08.002
2. Squirrel DM, Majeed AW, Troy G, Peacock JE, Nicholl JP, Johnson AG. A randomized, prospective, blinded comparison of postoperative pain, metabolic response, and perceived health after laparoscopic and small incision cholecystectomy. Surgery, 1998; 123 (5): 485–495.
3. Shukla A, Seth S, Ranjan A. A comparative study between laparoscopic and open cholecystectomy in cases of cholecystitis with cholelithiasis: one year experience in tertiary care center. IntSurg J. 2017 Mar;4(3):903-907.
4. Kim SS, Kim SH, Mun SP. Should subcostal and lateral trocars be used in laparoscopic cholecystectomy? A randomized, prospective study. Journal of Laparoendoscopic& Advanced Surgical Techniques. 2009; 19(6): 749-753.
5. Gould J. Laparoscopic versus open inguinal hernia repair. SurgClin North Am. 2008;88:1073–1081.
6. Talpur KAH, Malik AM, Sangrasi AK, Memon AI, Leghari AZ, Qureshi JN. Comparative study of conventional open versus laparoscopic cholecystectomy for symptomatic cholelithiasis. Pak J Med Sci 2011;27(1):33-37.
7. Zhang R, Luo H, Pan Y, et al. Rate of duodenal-biliary reflux increases in patients with recurrent common bile duct stones: evidence from barium meal examination. GastrointestEndosc. 2015;82:660–665.
8. Natsui M, Saito Y, Abe S, et al. Long-term outcomes of endoscopic papillary balloon dilation and endoscopic sphincterotomy for bile duct stones. Dig Endosc. 2013;25:313–321.
9. Rodrigues J, Diehl DL. Cholangiocarcinoma: clinical manifestations and diagnosis. Tech GastrointestEndosc. 2016;18:75–82.
10. Lee HM, Min SK, Lee HK. Long-term results of laparoscopic common bile duct exploration by choledochotomy for choledocholithiasis: 15-year experience from a single center. Ann Surg Treat Res. 2014;86:1–6.