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Original Research Article

Single-stage laparoscopic management for concomitant gallstones and common bile duct stones versus two stages using endoscopic retrograde cholangiopancreatography procedures

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ABSTRACT

Background: The optimal treatment for common bile duct (CBD) stones remains debated, with options including open or laparoscopic exploration, and endoscopic retrograde cholangiopancreatography (ERCP) before, during, or after laparoscopic cholecystectomy (LC). This study compared outcomes of one-stage (LECBD+LC) and two-stage (ERCP+LC) procedures for patients with gallstones and CBD stones, focusing on complications and patient satisfaction.
Methods: A randomized retrospective and prospective study included 200 patients with gallstones and CBD stones. Patients were divided into group I (n=100), undergoing one-stage laparoscopic CBD exploration (transcystic or transcholedochal) plus LC, and group II (n=100), undergoing two-stage preoperative ERCP then LC. Outcomes included operative time, complications, hospital stay, residual stones, and patient satisfaction.
Results: Mean age was 43.16±12.66 in group I and 41.52±9.44 in Group II, with no significant gender differences. Preoperative jaundice was present in 88 group I and 86 group II patients. Operative times, conversion rates, and complication rates were similar. The visual analogue scale (VAS) score at 24 hours was lower in group I but comparable at 3 days. Hospital stays were similar, with 3% residual stones in group I and 0% in group II. Patient satisfaction and mortality rates showed no significant differences.
Conclusions: One-stage LCBDE with LC is equivalent to two-stage ERCP plus LC in terms of operative time, complications, hospital stay, residual stones, and patient satisfaction. Both approaches are effective, with no significant differences in outcomes.

Keywords: Common bile duct stones, Laparoscopic common bile duct exploration, Endoscopic retrograde cholangiopancreatography, Laparoscopic cholecystectomy

INTRODUCTION

Common bile duct (CBD) stones are the second most common complication of cholecystolithiasis, which are detected in 10-20% of individuals with symptomatic gallstones and in around 5% of patients with normal bile ducts who do not exhibit symptoms as determined by trans-abdominal USG at time of cholecystectomy.[1]

Although the best course of action for CBD stones is still unknown, open CBD exploration (OCBDE), LCBDE, and ERCP carried out prior to, during, or following LC are all viable choices.[1] As surgeons become more skilled in laparoscopic techniques, a growing number of them are now providing a single-stage to their patients LCBDE. Other therapy approaches such as intraoperative and postoperative ERCP for clearing ducts are still not

accepted. Currently, the two most prevalent techniques for treating gallstones with CBD stones are single-stage laparoscopic exploration of the CBD and ERCP coupled with LC (two-stage).[2]

Studies show that individuals receiving LCBDE (75%-100%) and ERCP (62%-96%) had similar CBD stone removal rates. The benefits of LCBDE + LC comprise fewer procedures and a shorter hospital stay. The most widely adopted approach for managing CBD stones involves a two-stage treatment process. There is a dearth of information in the literature currently in publication on the costs of treating CBD stones in one step as opposed to two stages. Two randomized investigations indicated that the one-stage procedure was more cost-effective, according to their in-hospital cost assessments. Studies that aren't randomized, using either propensity scores or cost analysis, have also found that one-stage procedures are associated with lower total in-hospital costs compared to two-stage methods.[3]

The objective of this study was to evaluate the outcomes of managing concomitant gallstones and CBD through a two-stage process (ERCP followed by LC) versus a one-stage process (LCBDE plus LC) in terms of: operative time, conversion rates, intraoperative and postoperative complications, hospital stay and patient satisfaction ratings.

METHODS

This retrospective and prospective randomized study included 200 patients with concomitant gallstones and CBD stones in general surgery department, Sohag university hospital, in the period between January 2016 and December 2023 after approval of Sohag ethics committee.

Patients eligible for treatment were randomly assigned into two groups via sealed envelopes to receive either single-stage or two-stage therapy. The 100 patients in group I had a single-stage LC with either a trans-choledochal (n=70) or trans-cystic (n=30) bile duct clearing procedure (Figure 2-4). In group Π, 100 patients underwent a two-part treatment process: pre-operative ERCP was performed to endoscopically remove CBD stones, and then, within the same hospital stay, LC was carried out (ERCP + LC) (Figure 5 and 6).

The study included patients aged from 16 to 70 years, encompassing both male and female participants, those with jaundice as well as those without, and individuals with gallstones, along with concomitant stones in the CBD.

Acute cholecystitis, acute pancreatitis, liver cirrhosis, an intrahepatic gallbladder, a liver mass or abscess, malignancy, recurring gallstones in the bile duct, malignant pancreatic or biliary tumours, and an uncurable bleeding disease were among the exclusion criteria.

Morbidity associated with treatment:[4] CBD injury, haemorrhage, bile leakage, wound infection, post-ERCP bleeding, pancreatitis, and perforation. At a six-week follow-up evaluation, overall satisfaction was evaluated using a verbal rating scale with scores from 0, indicating not satisfied, to 3, denoting very satisfied, with intermediate scores of 1 and 2 representing partially satisfied and moderate satisfied, respectively.

Statistical analysis

The analysis was conducted using the v26 version of SPSS software, which is provided by IBM Inc. and is located in Chicago, Illinois, U.S.A. The data were presented as the mean with standard deviation (SD), and an unpaired Student's t-test was used to compare the two groups statistically. Whenever required, the Chi-square or Fisher's exact tests were used for analysis, and frequencies and percentages (%) were used to qualitatively depict the variables. A two-tailed p value was deemed statistically significant if it was less than 0.05.

RESULTS

A total of 219 patients were initially considered for participation in the study, but 11 of them failed to meet the necessary requirements, while 8 further declined to participate. The remaining patients were divided into two equal-sized groups using random assignment, each consisting of 100 patients. All patients assigned to the allocated groups were tracked and statistically evaluated as shown in (Figure 1).

The difference in age and sex between the two groups was negligible (Table 1).

There was no discernible difference between the two groups as regard preoperative presentation of jaundice in the two groups, also pre-operative levels of the total bilirubin and direct bilirubin were essentially the same (Table 1).

The two groups' operating times differed just little. Conversion to alternative therapies was necessary for 3 patients in group I which converted to open exploration of CBD and 3 patients in group II converted to open cholecystectomy. The two groups' adoption of alternative approaches did not vary in any appreciable way (Table 1).

Intraoperative complications (biliary injury, bleeding and duodenal perforation) were insignificantly different between both groups (Table 1).

In the two groups, post operative jaundice was insignificantly different, also total bilirubin after the surgery was nearly the same in both groups, while postop levels of direct bilirubin were significantly higher in

group I compared to group II, with the p value of 0.03 (Table 2).

After 24 hours, group I's VAS score was significantly lower than group II's (p<0.001), but after three days, there was no difference between the two groups that could be seen. The duration of hospitalization did not differ significantly between the two groups (Table 2).

Postoperative complications (wound infection, pancreatitis, bile leak) were insignificantly different between both groups (Table 2).

There was no appreciable difference between the two groups having retained CBD stone, with three (3%) of the patients in group I and no (0%) patients in group II. Concerning patient satisfaction scores, 7 (7%) patients reported partial satisfaction in group I and 9 (9%) in group II, while 15 (15%) patients were moderately satisfied in group I and 16 (16%) in group II. Additionally, 78 (78%) patients expressed a high level of satisfaction in group I and 75 (75%) in group II. The patient satisfaction scores were not significantly different between the two groups. No patients in either group experienced mortality (Table 3).

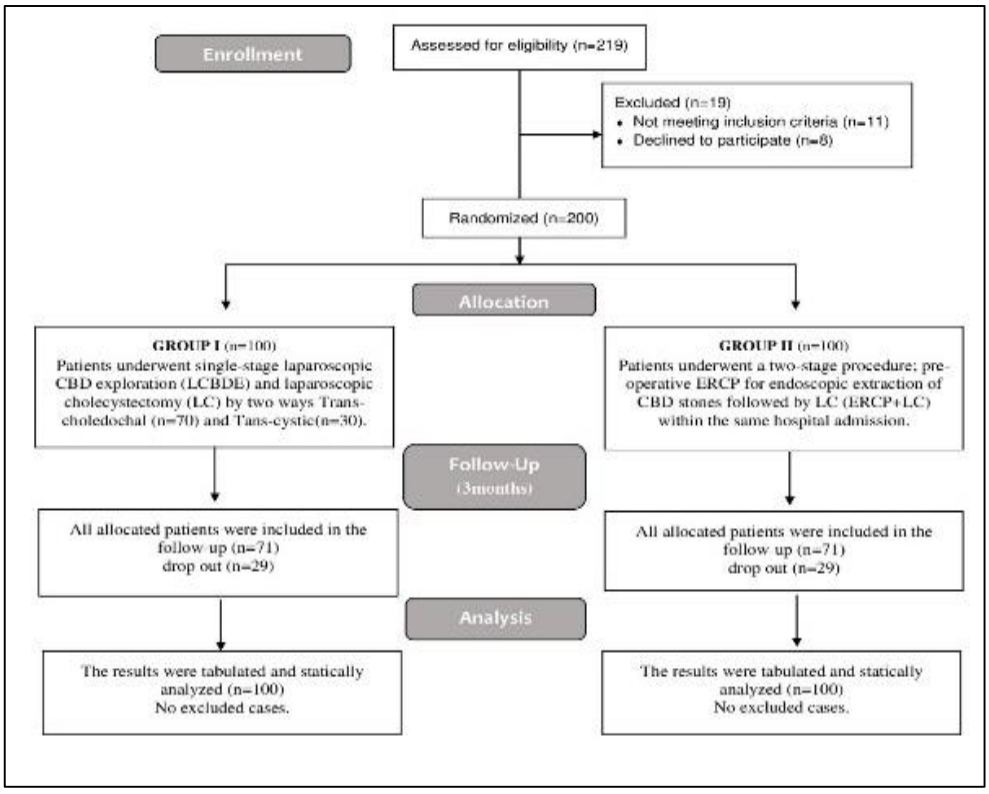

Figure 1: CONSORT flowchart of the enrolled patients.

Table 1: Demographic data, preoperative jaundice, total bilirubin, direct bilirubin, operative time, conversion rate and intraoperative complications of the studied groups.

Variables		Group I, (n=100) (%)	Group II, (n=100) (%)	P value
Age (in years)	Mean±SD	43.16±12.66	41.52±9.44	0.106
	Range	19-68	18-68	
Sex	Male	42 (42)	32 (32)	0.143
	Female	58 (58)	68 (68)	
Preoperative jaundice		88 (88)	86 (86)	0.674
Total bilirubin		2.8±1.36	2.75±1.56	0.820
Direct bilirubin		2.33±1.28	2.24±1.49	0.641
Operative time (min)	Mean±SD	138.3±20.4	140.85±43.98	0.600
Conversion to other procedures	Yes	3 (3)	3 (3)	1.00
Intraoperative complications				
Biliary injury		0 (0)	0 (0)	-------
Bleeding		4 (4)	3 (3)	0.542
duodenal perforation		0 (0)	0 (0)	--------
None		96 (96)	97 (97)	0.700

Table 2: postoperative jaundice, postoperative total bilirubin, postoperative direct bilirubin, VAS after 24 hours, VAS after 3 days, hospital stay and postoperative complications of the studied groups.

Variables	Group I, (n=100) (%)	Group II, (n=100) (%)	P value
Postoperative jaundice	4 (4)	10 (10)	0.096
Total bilirubin	2.8±1.36	2.75±1.56	0.820
Direct bilirubin	1.01±0.59	0.83±0.62	0.030*
VAS (After 24 h)	5.34±1.02	6.3±1.02	<0.001*
VAS (After 3 days)	1.42±0.88	1.52±1.06	0.468
Hospital stay (days)	6.8±2.08	7.18±2.28	0.219
Postoperative complications			
Wound infection	3 (3)	3 (3)	1.00
Pancreatitis	2 (2)	2 (2)	1.00
Bile leak	1 (1)	0 (0)	0.535
None	94 (94)	95 (92)	0.940

*Significant as p≤0.05, VAS: visual analog scale, CBD: Common bile duct, n: number, SD: standard deviation.

Table 3: Comparison of the studied groups for retained CBD stone, mortality and patient satisfaction.

Variables		Group I, (n=100)	Group II, (n=100)	P value
Retained CBD stone	Yes	3 (3)	0 (0)	0.621
	No	97 (97)	100 (100)	
Patient satisfaction score	Partially satisfied	7 (7)	9 (9)	0.843
	Moderate satisfied	15 (15)	16 (16)	
	Very satisfied	78 (78)	75 (75)	
Mortality	None	0 (0)	0 (0)	----

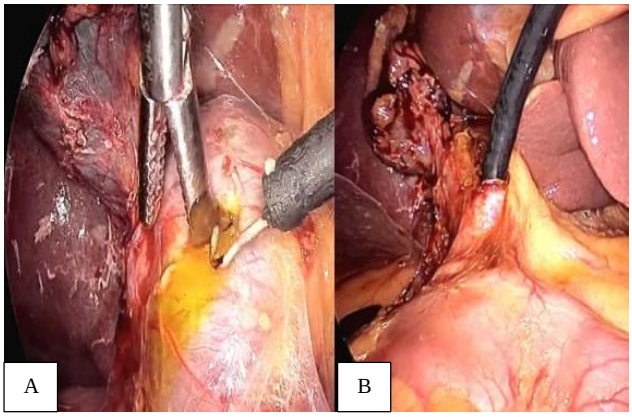

Figure 2 (A and B): Choledochotomy by diathermy and insertion of choledochoscope.

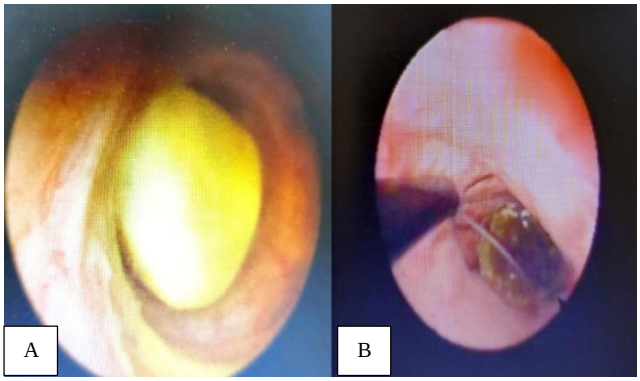

Figure 3 (A and B): Stone through choledochoscope and extraction by dormie basket.

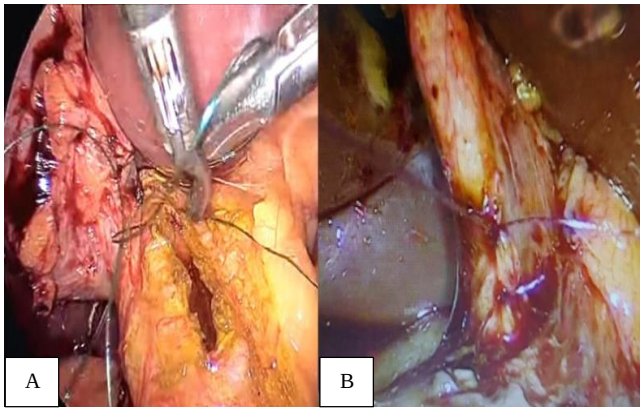

Figure 4 (A and B): Closing of CBD opening.

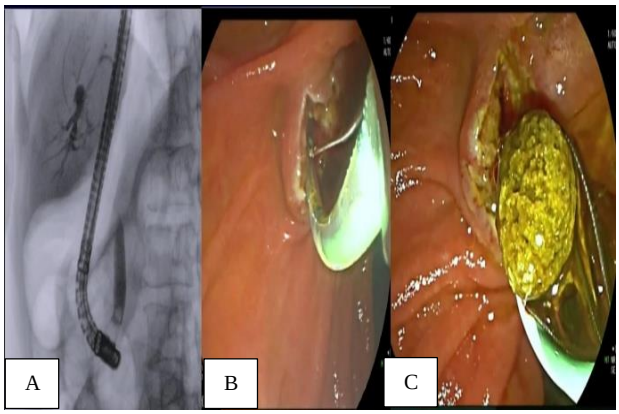

Figure 5 (A-C): ERCP showing single stone in CBD and sphincterotomy and stone extraction by basket.

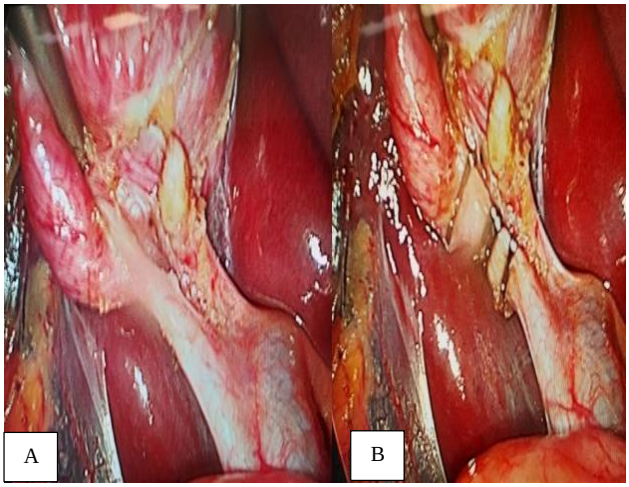

Figure 6 (A and B): Clipping of cystic duct during LC.

DISCUSSION

In the present study, the difference in age and sex between the two groups was negligible. Mean for group I 43.16±12.66 and for group II 41.52±9.44. In a similar way, Gaied et al sought to compare a one-session technique with a sequential sessions approach for the treatment of choledocholithiasis, and their findings are somewhat in agreement with ours. The results indicated that group (A) had an average age of 50.25±13.45 years, whereas group (B) had an average age of 42.17±8.95 years. In both groups, the percentage of male patients was 33.3% and the percentage of female patients was 66.7%. Neither group differed significantly from the other in terms of gender or age.[7]

There was no obvious difference between the two groups with regard to the development of preoperative jaundice with 88 (88%) patients of group I and 86 (86%) patients of group II, and the preoperative total and direct bilirubin levels were basically the same. This comes in line with Bansal et al with no significance differs between the two groups.[16]

There was no discernible difference in the operative time took to complete the procedures for the two groups in this study. The results were in line with those of Li et al who showed that the two groups' total operating time was not significantly different (p=0.30).[6] However, Gantois et al found that the surgical group's operating time was greater.[13] Because the one-stage technique had a mean operating duration of 135.7 minutes, whereas the two-stage approach had a mean operative time of 72.4 minutes (p<0.001), Bansal et al disagreed with our findings.[16] Mohamed et al noted a significant prolongation in the operative time in group A.

It is reasonable that two procedures (LC and LCBDE) would take longer than one (LC). One could also notice the increased operative time in group B compared with any traditional LC (which is nearly one hour).[11]

According to the comparison of conversion rate between the studied groups, in group I only 3% is converted to open exploration and in group II also patient underwent ERCP are successful (0% failure rate) but 3% of patient underwent LC was converted to open cholecystectomy, also Gaied et al showed that in group (A), all cases who underwent ERCP succeeded to complete operation (0% failure rate) while when they underwent lap. cholecystectomy in the same session there was 13.3% conversion rate due to distended stomach and duodenum post ERCP procedure resulting from insufflation. In group (B), three cases who underwent ERCP failed to complete operation due to large CBD stone and they underwent CBD exploration after multiple ERCP sessions while when they underwent lap. cholecystectomy in the same session there was 20% conversion rate due to multiple adhesions. A p=0.024 indicated that there was a statistically significant difference between the two groups.[7] Allen et al and Donkervoort et al found that LC was more difficult and had a greater rate of complications in patients following ERCP. This was mainly due to inflammation and fibrosis in and around Calot's triangle. Acute cholangitis, severe biliary pancreatitis, and possibly prolonged obstructive jaundice all benefit from ERCP because of how fast it may eliminate biliary obstruction.[9,10]

A study by El-Geidie et al involving 98 patients, who were split into two groups consisting of 45 LC/LECBD patients and 53 ERCP/LC patients, yielded comparable findings to our research, with the study noting a lack of significant disparity in the success and failure rates between the two groups.[12]

Gantois et al compared a one-stage surgical procedure with a two-stage strategy that included endoscopy and surgery. Surgical intervention was found to be substantially more effective than ERCP in removing stones from the CBD. Following surgery, the success rate was 92.5%, compared to 73.8% after ERCP treatment. The endoscopy group had a significantly higher rate of casting the CBD with multiple stones, at 45.2% as compared to 25%, with a p=0.24.[13] A literature review by Dasari et al have shown that the conversion rate is 14% for the endoscopic group and 8% for the surgical group. It was determined that was not statistically significant.[15]

In our research, case with intraoperative complications, such as bleeding (4 patient in group I and 3 patients in group II) controlled by diathermy and packing, no need for further intervention needed. Bile injury and duodenal perforation didn't happen. This also reported by Elbegawy et al who said that intraoperative complications that have been registered in all patients were hemorrhage and collection, which were significantly less in group A, with p value less than 0.001.[21]

Postoperative jaundice appeared nearly the same in both group (4 patients in group I and 10 patients in group II),

On the other hand, postoperative direct bilirubin levels were significantly higher in group I than in group II with a p=0.03. Dasari et al mentioned same results with no significant difference in postoperative levels of bilirubin in the studied patients, however Liu et al found slight increase in postoperative jaundice in patients with LECBD.[14,15]

Although group I's VAS score was significantly lower than group II's after 24 hours (p<0.001), there was no difference between the two groups after three days. Bansal et al also has similar results with no significant difference between postoperative pain after 24 hour or after 6 weeks.[16]

There was no significant difference in the length of hospital stay for both groups in our study, in accordance, Li et al discovered no statistically significant difference between the two groups with regard to the duration of hospital stays (p=0.30).[14] This disagrees with Gaied et al who demonstrated that group (A) had an average hospital stay of 2.0±1.78 days and group (B) of 7.0±3.53 days. The length of time that group (A) spent in the hospital was significantly shorter than that of group (B) (p<0.001).[13]

In the present study, in both groups patients with intraoperative complications had significantly higher pain scores after 24 hours, longer hospital stays, and lower patient satisfaction compared to those without complications. These findings are consistent with other studies that have reported increased morbidity, longer hospital stays, and lower patient satisfaction associated with intraoperative complications during gallstone surgery.[17,18]

Our study cases complicated with post operative pancreatitis only 2% (2 patients in group I and 2 patients in group II) underwent conservative management. While, Gaied et al showed that two patients in group (A) had postoperative complications as they reported pancreatitis while 13 patients in group (B) showed postoperative complications. Group (B) showed statistically significant increase in postoperative complications compared to group (A) (p=0.003).[7] The study of Lin et al disagrees with our results as it reported that the overall morbidity like post operative pancreatitis, cholangitis bleeding and biliary leakage in the in the laparoendoscopic rendezvous group was lower than the two-stages management.[8]

postoperative bile leak was not encountered in group II while only one case (1%) in group I showed bile leak postoperative, whereas Mohamed et al showed an increased incidence of postoperative bile leakage in group A. One could attribute that increase to the choledochotomy performed in group A compared with the intact duct in group B. also noted a significant increase in the incidence of pancreatitis in group B (12.5%), a complication that was not reported in group A (p=0.039).[11]

Surgical site infection was reported in 3% in group I and 3% in group II, but in Mohamed et al wound infection only in one case in each of the two groups (3.13% per group).[11] As reported by Lu et al postoperative morbidity was found to impact 15.2% (54 of 355) of patients in the two-stage (ERCP/EST + LC) group, whereas it impacted 19.0% (65 of 343) of patients in the single-stage (LC + LCBDE) group. There was no statistical significance, according to the research Li et al findings, which showed no discernible difference in post-operative morbidity between the two groups, are in line with this one.[5,6]

In the current study, patients with postoperative complications in both groups had significantly higher bilirubin levels, longer hospital stays, higher pain scores after 3 days, and lower patient satisfaction compared to those without complications. These results align with previous studies that have demonstrated the negative impact of postoperative complications on patient outcomes, including prolonged hospital stays, increased pain, and reduced satisfaction.[19,20]

In treating contemporaneous gallstones and CBD stones, rate of retained CBD stones was 0% in group II while group I showed 3 cases (3%) of retained CBD stones, this is consistent with a meta-analysis conducted by Li et al that sought to evaluate the safety and efficacy of two-stage LC+ERCP/endoscopic sphincterotomy (EST) vs single-stage LC + LCBDE, regarding residual stone (p=0.71), conversion to alternative techniques (p=0.23), and CBD stone clearance (p=0.12), there was no discernible difference between the two groups.[6]

Results for patient satisfaction were not significantly different between the two groups in our research, in contrast, in study by Bansal et al the patient satisfaction score was measured on a verbal rating scale of 0-3 at 6 weeks after surgery. The patients in group 1 had higher satisfaction scores than the patients in group 2 (2.26±0.3 vs. 1.92±0.7; p=0.006).[16]

We have no mortality in our research (0% in both groups), This is in line with Gantois et al although a greater prevalence of laparotomy in group S, there was no difference in mortality between group S and group ES, according to his report. There was no statistically significant difference in the overall postoperative death rates between the two groups.[13]

The current study has certain limitations. This study incorporates both retrospective and prospective study designs, potentially leading to the presence of selection bias and confounding factors. Due to the small sample size, it is unclear whether the results apply to a wider population. The generalizability of the results may be compromised due to the study's specific setting. There is no way to assess long-term efficacy or rates of stone recurrence because the length of the follow-up period is not specified. By combining a one-stage LCBDE with LC

or a two-stage ERCP with LC, surgeons can effectively treat gallstones and CBD stones.

Decision on the procedure should be made with consideration of individual patient characteristics including age, co-existing health conditions and anatomical factors. Additional research with bigger study groups and extended observation periods is necessary to verify these results and evaluate long-term consequences, encompassing rates of stone recurrences.

CONCLUSION

The one-stage strategy combining LCBDE with LC and the two-stage strategy comprising ERCP + LC produce results that are equivalent for intraoperative complication rates, conversion rates, total operative time, postoperative complication frequencies, lengths of hospital stay, postoperative mortality rates, remaining CBD stone rates, and patient satisfaction. The outcomes for patients in both groups are less favourable in cases where complications arise both during and after surgery.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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