

Original
Article

Comparing Two Stages Using Endoscopic Retrograde Cholangiopancreatography Procedures Versus One-Stage Laparoscopic Management for Concomitant Gallstones and Common Bile Duct Stones

Ahmed Abd El-Kahaar Aldardeer, Mohammed Tag El-din Mohammed Sayed, Magdy Khalil Abd El-Mageed, Alaa Ahmed Redwan

Department of General Surgery, Faculty of Medicine, Sohag University, Sohag, Egypt.

ABSTRACT

Background: Almost all repetitive cause of obstructive jaundice is common bile duct (CBD) stones. Although several alternatives exist the best plan is still unknown. These include endoscopic retrograde cholangiopancreatography (ERCP) before, during, or following laparoscopic cholecystectomy (LC), open or laparoscopic surgical investigation. The study compares the results of one- step laparoscopic technique common bile duct exploration (LCBDE+LC) versus two-step (ERCP then LC) for management of contemporaneous gallstones and CBD stones in terms of mortality rates, hospital stays, intra and postoperative complications, conversion to another procedure, and retained stones.

Patients and Methods: A total of 200 individuals with concurrent gallstones and CBD are included in this randomized trial. Eligible patients were randomly allocated to one group to undergo either one-stage or two-stage therapy using sealed envelopes: group I ($n=100$): Patients received LCBDE+LC in a single-stage either transcholedochal ($n=70$) or transcystic ($n=30$) procedures. Group II ($n=100$): During a single hospital stay, patients had ERCP+LC.

Results: With no discernible variation by sex, the mean age (years) for group I and group II was 43.16 ± 12.66 and 41.52 ± 9.44 years, respectively. 86 participants in group II and 88 individuals in group I had preoperative jaundice. The two groups' surgical times are nearly identical. Both groups' conversion rates were comparable. There was no relevant variation in intra- and postoperative consequences between the two groups. After 3 days, there was no discernible dissimilarity within the both groups, but group I's visual analog scale score was much lower than group II's at 24 h. Both groups' hospital stays were comparable. With 3% within group I and 0% within group II, CBD stone retention does not differ substantially between the two groups. The two groups' levels of patient satisfaction did not vary much, also there were no mortalities.

Conclusion: One-stage LCBDE+LC and two-stage ERCP+LC are comparable with reference to the need for change to other approaches, operative period, intra and postoperative problems, hospital stay, residual stones and mortality. Both have worse outcomes with intra- and postoperative complications.

Key Words: Common bile duct stones, Endoscopic retrograde cholangiopancreatography, Laparoscopic common bile duct exploration, Laparoscopic cholecystectomy.

Received: 15 February 2025, **Accepted:** 01 March 2025, **Published:** 1 July 2025

Corresponding Author: Mohammed Tag El-din Mohammed Sayed, MD, Department of General Surgery, Faculty of Medicine, Sohag University, Sohag, Egypt. **Tel.:** 01003625128, **E-mail:** mohamedtag987@yahoo.com

ISSN: 1110-1121, July 2025, Vol. 44, No. 3: 1112-1119, © The Egyptian Journal of Surgery

INTRODUCTION

Obstructive jaundice most commonly caused by common bile duct (CBD) stones. Approximately 15% of situations are primary CBD stones and remainder are secondary stones. After cholecystectomy, 10–18% of subjects along with gallstones may conceive CBD stones^[1]. It is possible to distinguish choledocholithiasis before, during, or after surgery. Abdominal ultrasound (sensitivity 20–80%), magnetic resonance cholangiopancreatography (MRCP) (sensitivity 81–100%, specificity 92–100%), and

endoscopic retrograde cholangiopancreatography (ERCP) (sensitivity 88–97%, specificity 96–100%) are principal illustration techniques for identifying CBD stones in addition to demonstrating a dilated biliary ductal system^[1].

Intraoperative cholangiography (IOC) was frequently used in the days of open cholecystectomy, and a T-tube had to be inserted, and the CBD had to be explored to identify CBD stones. The emphasis has switched from

surgical intervention for CBD stones to endoscopic treatments because of the development of laparoscopy and endoscopy, laparoscopic cholecystectomy (LC) as well been recognized as the conventional technique in favor of treatment of symptomatic cholelithiasis^[2].

Accessibility regarding alternative treatments led to a debate on the best way to treat CBD stones, namely whether one-stage or two-stage methods should be used. The gallbladder and CBD stones are removed in one-step during a single anesthesia session. One session of CBD stone therapy is followed by cholecystectomy under separate anesthesia induction, or the other way around^[2]. To compare the results of treating concurrent gallstones and CBD stones using a two-step technique (ERCP+LC) versus a one-step laparoscopic technique common bile duct exploration (LCBDE+LC), the current study focuses on the following factors: postoperative mortality, length of hospitalization, intraoperative and postoperative complications, conversion to alternative procedures, and retained CBD stones.

PATIENTS AND METHODS:

This retrospective and prospective randomized work was performed on 200 individuals with concomitant gallstones and CBD in the General Surgery Department at Sohag University Hospital in the period between January 2016 and December 2023 after approval of the Sohag Ethics Committee.

Eligible patients were randomly allocated to one of both groups to undergo either one-stage or two-stage therapy using sealed envelopes: group I ($n=100$): Patients received LC and LCBDE in a single step for transcholedochal ($n=70$) and transcystic ($n=30$) procedures Figures (1,2). Group II ($n=100$): During a single hospital stay, patients had ERCP then LC (ERCP+LC) Figures (3-5).

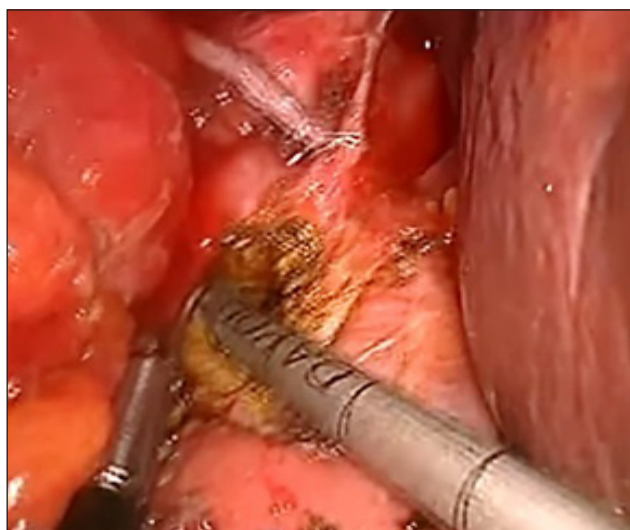


Figure 1: Cholecystectomy.



Figure 2: Stone extraction.

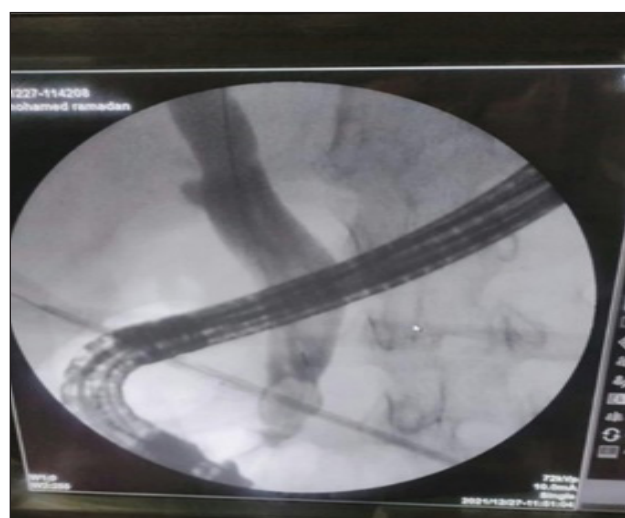


Figure 3: Endoscopic retrograde cholangiopancreatography showing single stone and extraction of stone by balloon.



Figure 4: Endoscopic retrograde cholangiopancreatography extraction of multiple stones.

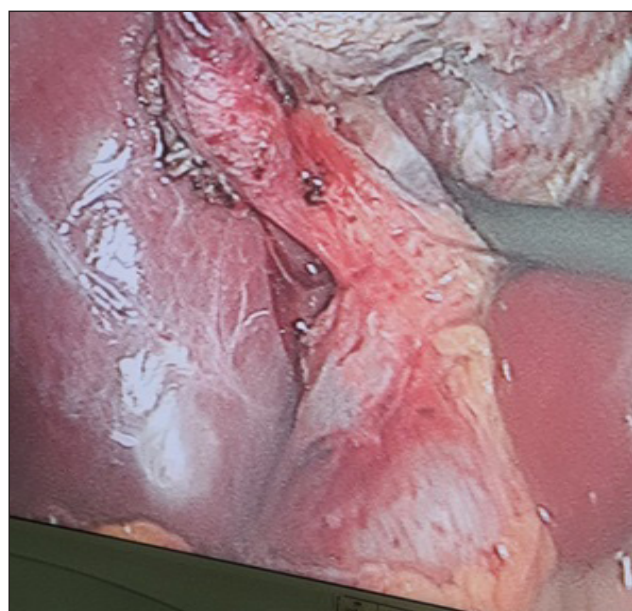


Figure 5: Laparoscopic cholecystectomy.

Patients of all sexes, ages 16 to 70, with or without jaundice, gallstones, and concurrent CBD stones were included in this research.

Patients with malignant pancreatic or biliary tumors, recurrent choledocholithiasis, cirrhosis, intrahepatic gallbladder, neoplasia, acute cholecystitis, acute pancreatitis, and uncorrectable coagulation disorders were excluded.

According to the targeted method, the primary goal was the elimination of gallbladder and CBD stones. The duration of hospitalization was estimated in group I as the whole days from operation until patient release, and in group II as the entire duration of stay for ERCP and LC. Secondary outcomes included the length of hospitalization and pain score, which was measured using a visual analog scale (VAS) ranging from 1 to 10.

Statistical analysis

Statistical analysis was performed through SPSS v26. The unpaired Student's *t*-test applicate to correlate statistical variables between the both groups. The variables were displayed as mean and standard deviation (SD). Qualitative variables were displayed as frequencies and percentages (%), and where needed, χ^2 or Fisher's exact test was used in the analysis. A two-tailed *P* value much less than 0.05 taken into consideration as statistically significant.

RESULTS:

Following an eligibility assessment of 219 participants, eight patients declined to participate in the trial, 11 patients did not match the study's requirements. There were two equal groups of 100 patients each, selected at random from

the remaining patients. Figure (6) shows the statistical analysis and follow-up of all assigned patients.

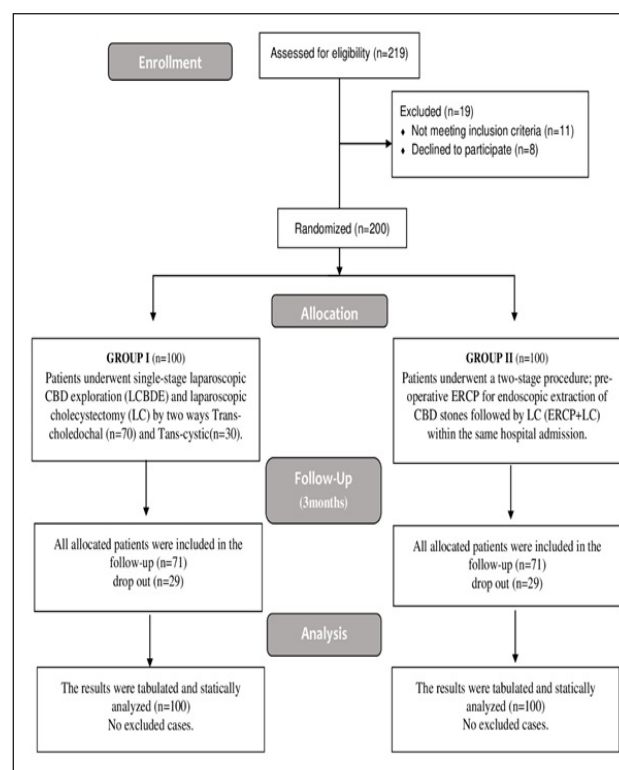


Figure 6: CONSORT flowchart of the enrolled patients.

Age and sex differences between the two groups were negligible (Table 1).

Regarding the development of preoperative jaundice, there was no discernible dissimilarity within the both groups. Furthermore, the preoperative levels of direct and total bilirubin were almost identical (Table 1).

There was no relevant disagreement in operative time between the two groups. Three (3%) individuals in group I and three (3%) individuals in group II underwent other procedures. There was no meaningful conflict in the switch to other approaches in the both groups (Table 2).

The VAS score at 24h was considerably diminished in group I than in group II ($P < 0.001$), but the VAS score at day 3 was not significantly different between the two groups. The duration of hospitalization was also not of great consequence, distinct between the two groups (Table 2).

There was no significant difference in intraoperative complications between the two groups (Biliary injury, bleeding and duodenal perforation) (Table 3).

Postoperative consequences (bile leakage, pancreatitis, and wound infection) do not significantly differ between the two groups (Table 3).

Both groups' postoperative total bilirubin levels were comparable, and there was no discernible difference in postoperative jaundice; however, group I's postoperative direct bilirubin levels were considerably greater than group II's ($P=0.03$) (Table 3).

There were three (3%) residual CBD stones in group I and 0(0%) residual CBD stones in group II and this was no relevant discrepancy in the ratio of residual CBD stones in the midst of both groups. Mortality was 0% in both groups (Table 4).

Table 1: Population data, preoperative jaundice, total and direct bilirubin of both groups:

	Group I (n= 100)	Group II (n= 100)	P value
Preoperative Jaundice, n(%)	88(88)	86(86)	0.674
Total bilirubin, mean±SD	2.8±1.36	2.75±1.56	0.820
Direct bilirubin, mean±SD	2.33±1.28	2.24±1.49	0.641
	Group I (n= 100)	Group II (n= 100)	P value
Age (years)			
Mean±SD	43.16±12.66	41.52±9.44	0.106
Range	19–68	18–68	
Sex, n(%)			
Male	42(42)	32(32)	0.143
Female	58(58)	68(68)	

Table 2: Comparison between both groups regarding operative time, conversion to other procedure, visual analog scale Score and hospital stay:

	Group I (n=100)	Group II (n=100)	P value
Operative time(min)			
Mean±SD	138.3±20.4	140.85±43.98	0.600
Conversion to other procedures, n(%)			
Yes	3(3)	3(3)	1.00
VAS (after 24h)			
Mean±SD	5.34±1.02	6.3±1.02	<0.001*
VAS (after 3 days)			
Mean±SD	1.42±0.88	1.52±1.06	0.468
Hospital stay (days)			
Mean±SD	6.8±2.08	7.18±2.28	0.219

Table 3: Intraoperative complications, postoperative complications, postoperative jaundice, total and direct bilirubin in both groups:

Intraoperative complications	Group I (N= 100) [n(%)]	Group II (N= 100) [n(%)]	P value
Biliary injury	0	0	–
Hemorrhage	4(4)	3(3)	0.542
Duodenal perforation	0	0	–
None	96(96)	97(97)	0.700
Postoperative complications	Group I (n= 100)	Group II (n= 100)	P value
Wound infection	3(3)	3(3)	1.00
Pancreatitis	2(2)	2(2)	1.00
Bile leakage	1(3)	0	0.535
	Group I (n= 100)	Group II (n= 100)	P value
Postoperative jaundice	4(4)	10(10)	0.096
Total bilirubin, mean±SD	2.8±1.36	2.75±1.56	0.820
Direct bilirubin, mean±SD	1.01±0.59	0.83±0.62	0.030*

Table 4: Residual CBD stone and mortality in investigated groups:

	Group I (n= 100)	Group II (n= 100)	P value
Residual CBD stone, n(%)			
Yes	3(5)	0(3)	0.470
No	97(97)	100(100)	
Mortality	0	0	–

DISCUSSION

Age and sex disparities between the two groups in this study were minimal; group I's mean was 43.16 ± 12.66 , while group II's was 41.52 ± 9.44 . Similar to our findings, Gaied et al. tried to evaluate single and sequential techniques for treating choledocholithiasis. They discovered that the mean in group (A) was 50.25 ± 13.45 years, whereas the mean in group (B) was 42.17 ± 8.95 years. Men made up 33.3% of the patient population in both groups, whilst women made up 66.7%. Age and gender had no meaningful discrepancy between the two groups^[3].

There was no relevant dissimilarity between the two groups concerning preoperative jaundice, which arise in 88(88%) patients in group I and 86(86%) patients in group II. Additionally, preoperative total and direct bilirubin levels were almost the same. This is comparable to Bansal et al.'s findings, which likewise showed no discernible difference between both groups^[4].

The disagreement in operative time between either groups in our investigation was negligible. This was in line with Li et al.'s findings with no discernible disagreement in the two groups' total operating time ($P= 0.30$)^[5]. However, Gantois *et al.*, found that the surgical group's operating time was greater^[6]. Our findings were contradicted by Bansal *et al.*, who found that the mean operation period for the one-stage technique was 135.7min, whereas the mean operation period for the two-step strategy was 72.4min ($P < 0.001$)^[7]. 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 1h)^[8].

Conversion to other procedures in this study occurred in three (3%) individuals in group I where laparoscopic exploration of CBD transformed to an open method and three (3%) individuals in group II with LC transformed to open cholecystectomy with a success rate of 100% for ERCP. Conversion to other procedures was insignificantly different between both groups. According to the Comparison of conversion rates between the studied groups, Gaied and colleagues

showed that in group A, all cases who underwent ERCP succeeded in completing the operation (0% failure rate) while when they underwent lap. cholecystectomy in the same session there was a conversion rate of 13.3% as four cases turned to open cholecystectomy due to a distended stomach and duodenum post-ERCP procedure resulting from insufflation. In group (B), three cases who underwent ERCP failed to complete the surgery due to enormous CBD stone and they underwent CBD exploration after multiple ERCP sessions, when they underwent LC in the same session there was a 20% failure rate as six cases turned to open cholecystectomy due to multiple adhesions. There was statistically significant variation among both groups ($P= 0.024$)^[3].

According to a study by El-Sweify et al., the sphincter of Oddi may be damaged during ERCP, allowing bacteria to settle in the bile duct. Furthermore, this damage may make dissection of the triangle of Calot more difficult and raise the threat of turning to open surgery^[9]. Gantois et al. aimed to evaluate the associated morbidity and fatality in the geriatric and the efficacy of single-phase surgical therapy against the two-phase method of endoscopy and surgery for CBD stone removal. In the study, surgery was found to be much more effective than ERCP for CBD stone removal. The success rate of surgery was 92.5%, while the success rate of ERCP was 73.8%. CBD casting with several stones was more common in the endoscopic group (45.2 vs. 25%, $P= 0.24$). A choledochoenteric bypass had to be performed since the ERCP failure rate in these individuals was estimated to be 50%^[6].

Dasari *et al.*, stated similar morbidity and fatality rates: 14% inside the endoscopic group and 8% inside the surgical group^[10]. Noble et al. indicated superior success rates for laparoscopic procedures compared to endoscopic ones, especially among high-risk patients^[11]. Vries et al. showed higher conversion to the open approach in patients with late LC after ERCP compared with early LC^[12]. Mohamed et al. showed that ERCP failed to extract the stone in three (9.38%) cases. As stone clearance was successfully achieved in all cases within the single-stage approach compared with 90.62% of cases in group B, they showed the superiority of the former over the latter. Nonetheless,

that variation was statistically insignificant ($P=0.076$). No participants in the two groups required a changeover out of the laparoscopic route to the open surgical process^[8]. Lv *et al.*, reported a 0% conversion rate in a previous similar study^[13]. Bansal *et al.* establish that the one-phase process was of higher quality than the two-phase process: the one-stage approach was successful in 93.3% of cases, compared with 73.3% for the two-stage approach. However, this 20% difference was not enough to make a statistically significant difference ($P=0.32$)^[4]. Bansal *et al.*, disclosed success percentage of 88.1% and 79.8% toward the single- and two-stage approaches, respectively ($P=0.2$)^[7]. Furthermore, Ding *et al.* reported comparable success rates between the same two approaches (93.64 vs. 94.59% for the single- and two-stage groups, respectively, $P=0.76$)^[14].

Four individuals in group I and three in group II had bleeding due to intraoperative complications, but these were managed with diathermy and packing and did not require additional treatment. There was no duodenal perforation or biliary damage. Elbegawy *et al.*, also reported this. Bleeding and healing were the intraoperative problems that were noted in every instance; group A experienced considerably fewer of these difficulties, with a P value of less than 0.001.

However, along with P value of 0.03, group I's postoperative direct bilirubin level was considerably greater than group II's. Both groups experienced equal levels of postoperative jaundice. Liu *et al.* noted a little rise in postoperative jaundice in patients with LECBD^[8], while Dasari *et al.* reported no discernible change in postoperative bilirubin levels^[13].

There was no difference between the two groups at day 3, but the VAS score at 24h was considerable diminished in group I than in group II ($P<0.001$), and Bansal *et al.*, observed no significant disparity within the boundaries of postoperative pain at 24h and 6 weeks^[4].

In the area of existing inquiry, the extent of hospital stay was not essentially dissimilar between the groups. The above-mentioned is consistent with the report of Gantois *et al.*, The period of hospitalization for older cases is often associated with their underlying conditions and is extended irrespective of their initial treatment due to the presence of various diseases^[6]. Li *et al.*, demonstrated that no significant variation existed in hospitalization duration between both groups ($P=0.30$) and mortality ($P=0.13$)^[5]. Also, Noble *et al.*, reported that both laparoscopic and endoscopic procedures exhibited no increase in complication rates or hospital stays^[11]. The mean hospital stay equal 2.0 ± 1.78 days in group A and 7.0 ± 3.53 days in group B, according to Gaied *et al.*,

the period of hospitalization was substantially shorter in group A than in group B ($P<0.001$)^[3]. Our findings are contradicted by research by Vttoretto *et al.* which found that the laparoendoscopic rendezvous group's length of hospital stay seemed to be reduced by around three days^[15]. Muhammedoglu's study, which found a correlation between shorter hospital stays and single-stage ERCP/LC, similarly contradicts our findings^[16]. The length of hospitalization in group B was significantly longer, according to Mohamed *et al.*, That could be explained by the span interval between the first and second phase in Group B, as the patient had to stay in the hospital during that period^[8]. In the same context, Lv *et al.* reported shorter hospital stays in the single-phase group in contrast to the two-phase group (6.72 and 10.91 days, respectively) ($P<0.01$)^[13].

In our study, only 2% (two individuals in group I and 2 individuals in group II) proceeding from whole cases had postoperative pancreatitis, whom conservatively treated. However, Gaied *et al.*, found that two individuals in group (A) had pancreatitis and 13 individuals in group (B) had postoperative complications. Postoperative complications were statistically considerably more in group (B) than in group (A) ($P=0.003$)^[3]. In an appraisal concerning our findings, Lin *et al.*, found a lower incidence of postoperative pancreatitis, cholangitis, hemorrhage, and bile leakage within the laparoscopic rendezvous group weighed against the two-level treatment group^[9].

Group II experienced no surgical bile leaks, but group I experienced one instance (1%) of postoperative bile leaks. However, Mohamed *et al.* found that group A had a higher rate of postoperative bile leakage.

Mohamed *et al.*, reported just one instance of wound infection in both groups (3.13% in each group), whereas 3% among group I and 3% in group II described surgical site infections in our study^[10]. After 3 days, patients in both groups who experienced surgical problems in the current trial had substantially higher bilirubin levels, longer hospital stays, and greater pain assessments than those who did not. These findings are consistent with other research showing the detrimental effects of surgical complications on patient outcomes, such as longer hospital stays and more pain^[15,16].

In our study, there were 0(0%) residual CBD stones in group II and three (3%) residual CBD stones in group I. The difference in residual CBD stones between both groups was negligible. Concerning the simultaneous therapy of gallstones and CBD stones, this is in accordance with the meta-analysis by Li *et al.*, which aimed to contrast the security and potency of one-phase LC with LCBDE and two-phase LC with ERCP and EST: dismissal of CBD stones ($P=0.12$), retained stones ($P=0.71$), conversion to

other treatment ($P=0.23$) didn't had major conflict between either groups^[5]. For single-stage and two-stage treatments, Sgourakis and Karaliotas showed similar residual stone rates^[17]. In their study, Rogers *et al.*, similarly found similar rates^[18].

In both groups, there were no patient deaths. This is in line with Gantois *et al.*'s findings showing, that, despite group S having a higher laparotomy rate, there was no discernible conflict in fatality between S and ES groups.

The present research has certain drawbacks. Due to its retrospective and prospective study design, confounding variables and selection bias may be introduced. Because of the small sample size, the results may not be as broadly applicable as they may be. Because the study was only carried out in one location, the results' external validity might be compromised. The evaluation of long-term results and rates of stone recurrence is precluded due to the lack of a specified follow-up period.

Surgeons can successfully treat gallstones and CBD stones using one-phase LCBDE+LC and two-phase ERCP+LC. The technique decision should be guided by the unique features of each patient, including age, comorbidities, and anatomical factors. To validate these findings and assess long-term consequences, such as rates of stone recurrence, longer follow-up, times and larger sample sizes are needed.

CONFLICT OF INTEREST

There are no conflicts of interest.

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