Totally laparoscopic versus laparoendoscopic management of concomitant common bile duct and gallbladder stones: randomized controlled study

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Background
The current preferred technique in most institutes is endoscopic management of common bile-duct (CBD) stones followed by laparoscopic cholecystectomy (LC). This study addressed the success of totally laparoscopic versus laparoendoscopic management in patients with concomitant CBD and gallbladder stones.

Patients and methods
Between January 2019 and May 2020, consecutive patients diagnosed with concomitant CBD and gallbladder stones were randomized into two groups. Group-A patients underwent single-stage management of their stones via laparoscopic common bile-duct exploration (LCBDE) and LC, while group-B patients underwent endoscopic retrograde cholangiopancreatography (ERCP) followed by LC within 72 h. The primary endpoint was technique success, which was defined as successful biliary clearance and LC. Secondary outcomes included total operative duration, hospital stay, number of procedures per patient, and postoperative complications.

Results
A total of 122 patients were randomized into two groups: 54 patients in group A and 53 patients in group B were finally subjected to analysis after exclusion of protocol violators. Technique success was similar in both groups: 90.7% (49/54 patients) in the LCBDE+LC group versus 86.8% (46/53 patients) in the ERCP+LC group. The total operative duration was longer in the LCBDE+LC group than in the ERCP+LC group (140.5 ± 49.44 vs. 99.89 ± 49.16 min) and total hospital stay was longer in the LCBDE+LC group (2.33 ± 1.26 days) than in the ERCP+LC (1.87 ± 1.68 days). The number of procedures per patient was significantly shorter in the LCBDE+LC than in ERCP+LC (1.04 ± 0.19 vs. 1.89 ± 0.51 days). Both groups were matched for postoperative complications (22.2 and 20.75% in the LCBDE+LC and ERCP+LC groups, respectively).

Conclusion
Both groups were equally effective in managing concomitant CBD and gallstones with the same risk of complications. ERCP+LC had a shorter operative duration and hospital stay than LCBDE+LC, despite LCBDE+LC having fewer procedures per patient.

Keywords:
choledocholithiasis, common bile-duct stones, laparoscopic common bile-duct exploration

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Introduction

Choledocholithiasis is a common problem, with an incidence of ~15–20% among patients with gallbladder stones [1,2]. The management of choledocholithiasis has gone through different phases, mainly through open surgery, and endoscopic management started to gain attention in the 1980s, followed by laparoscopic common bile-duct exploration (LCBDE) [3,4].

Two main philosophies address this topic: the first is the endoscopic management of CBD stones together with laparoscopic cholecystectomy (LC). The second philosophy is the total laparoscopic management of CBD stones and gallstones. The goal of therapy is to attain CBD clearance with the least morbidity and fewest interventions [5,6].

The Society of American Gastrointestinal and Endoscopic Surgeons and the British Society of Gastroenterology have encouraged in their recent guidelines the training of surgeons in LCBDE; however, only ~20% of American surgeons regularly perform LCBDE, while 75% of them prefer preoperative endoscopic retrograde cholangiopancreatography (ERCP) [6–10].

Patients and methods

This study was conducted in consecutive patients diagnosed with CBD stones and gallstones who were referred to our institute between January 2019 and May 2020. All patients provided their informed consent according to the ethical guidelines of the Medical Research Institute of Alexandria University (reference number: IORG 0008812).

Exclusion criteria:

(1) Suspected malignancies.
(2) American Society of Anesthesiology class-4 and class-5 diseases.
(3) Uncontrolled medical conditions.
(4) Evidence of suppurative or necrotizing cholecystitis, gallbladder empyema, gallbladder perforation, severe cholangitis, or pancreatitis.
(5) Pancreatic cholelithiasis or pancreatic divisum.
(6) Previous cholecystectomy.
(7) CBD diameter less than 6 mm.
(8) Age less than 18 years.
(9) Pregnancy.

Patients were prospectively evaluated before enrollment in the study. The radiological assessment by preoperative magnetic resonance cholangiopancreatography (MRCP) to avoid invasive interventions in patients with absent choledocholithiasis and to rule out other associated lesions.

The minimum sample size was calculated to be 50 patients for each group, to achieve 80% power to detect a 20% difference in biliary stone clearance together with a successful LC, with a significance level of 0.05, using the χ^2 test.

Patients were randomized using computer-generated numbers in closed envelopes, which were numbered serially to achieve concealed allocation and block randomization.

Technique for group-A patients (laparoscopic common bile-duct exploration+laparoscopic cholecystectomy)

Under general anesthesia, four ports were inserted, as in classical LC with the surgeon and the assistant standing on the patient's left side. Dissection of the junction of the cystic duct with CBD was established, followed by clipping of the cystic duct toward the gallbladder to prevent further stone passage into the CBD.

In patients with the trans-cystic approach, a trans-cystic cholangiogram was performed using a 4- or 6-Fr catheter to confirm the presence of CBD stones and identify their size and number. CBD clearance was later attempted using a Dormia basket guided by the C-arm and confirmed by a trans-cystic cholangiogram.

Trans-CBD clearance was performed after a failed trans-cystic approach or primarily in situations such as a narrow cystic duct, medial insertion of the cystic duct, CBD stones more than 10 mm in diameter, multiple CBD stones, stones proximal to the insertion of the cystic duct, or inflamed scarred cystic duct gallbladder amalgam.

Detected stones were removed using a choledochoscopic-guided Dormia basket or balloon extraction until CBD clearance was achieved.

According to the surgeon's preference, the choledochotomy was closed directly with interrupted absorbable sutures or over a T-tube. The operation was completed by laparoscopic removal of the gallbladder and placement of a tube drain in the Morrison's pouch.

Technique for group-B patients (endoscopic retrograde cholangiopancreatography+laparoscopic cholecystectomy)

ERCP was performed in the surgical endoscopy unit as a day-care procedure. Stones were extracted using balloon sweeping or a Dormia basket.

Patients with successful endoscopic clearance of CBD were scheduled for LC within 3 days after ERCP.

Meanwhile, in patients with failed stone extraction, a plastic stent was inserted to ensure biliary drainage and referred for surgical intervention, while in the case of failed cannulation, ERCP was performed within 7 days of the first trial before documenting technique failure.

All patients were followed up for 6 months.

Primary outcome measured

The technique was declared successful when the CBD stones and gallbladder were successfully removed using the intended approach. The failure to remove the gallbladder laparoscopically in group-B patients was identified as a technique failure.

Secondary outcomes measured

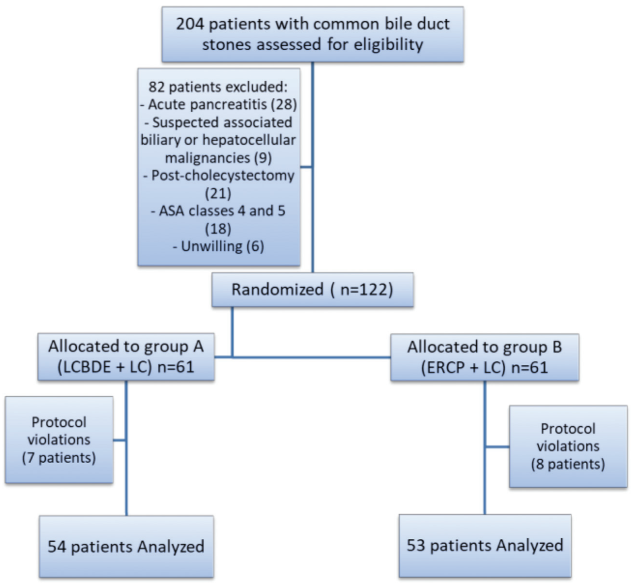
These included total operative duration, hospital stay, number of procedures per patient, and postoperative complications. Postoperative complications were classified according to the Clavien–Dindo classification to avoid subjective or ambiguous terms [11].

Results

During the study period, 204 patients with CBD stones were referred to our department. Eighty-two patients were excluded for various causes, as delineated in the CONSORT diagram (Fig. 1).

Both groups were well matched in terms of demographic data, patient comorbidities, preoperative laboratory results, and radiological investigations (Tables 1-3).

Figure 1



CONSORT pathway for our study.

Primary outcome

Biliary clearance alone was attained in 90.7 and 88.7% of the patients in group A and group B, respectively.

In group-A patients, only two patients had successful trans-cystic biliary exploration, while the remaining 47 patients had a trans-choledochal approach. CBD closure after successful biliary clearance was direct closure in 37 patients or over a T-tube in 10 patients.

Biliary clearance in group A could not be attained in five (9.3%) patients due to dense pericholecystic adhesions in one patient and distally impacted CBD stone in four patients. These patients were managed by laparoscopic choledochoduodenostomy in one patient and conversion to open surgery in the remaining four.

Failed endoscopic clearance occurred in six (11.3%) patients, where failed cannulation occurred in one patient, and the other five patients had large CBD stones with a distal normal CBD segment, which did not allow safe extraction of the stones.

Secondary outcomes

Both total operative time and total hospital stay were significantly longer in the LCBDE+LC group than in the ERCP+LC group (140.52 ± 49.44 vs. 99.89 ± 49.16 min and 2.33 ± 1.26 vs. 1.87 ± 1.68 days in both groups, respectively).

In contrast, the total number of procedures per patient was significantly lower in the ERCP+LC group than in the LCBDE+LC group.

Table 1 Demographic and preoperative data in the studied groups

	Group A (*N*=54) [*n* (%)]	Group B (*N*=53) [*n* (%)]	Test of significance	*P*
Sex				
Male	24 (44.4)	22 (41.5)	χ^2=0.094	0.759
Female	30 (55.6)	31 (58.5)		
Age (years)	56.44 ± 15.69	51.51 ± 16.20	*t*=1.600	0.113
Symptoms				
Pain	48 (88.9)	49 (92.5)	χ^2=0.401	^{FE}P=0.742
Jaundice	40 (74.1)	42 (79.2)	χ^2=0.399	0.527
Fever	9 (16.7)	12 (22.6)	χ^2=0.605	0.437
Comorbidities				
No	33 (61.1)	34 (64.2)	χ^2=0.106	0.745
Yes	21 (38.9)	19 (35.8)		
Hypertension	13 (61.9)	10 (52.6)	χ^2=0.351	0.554
Diabetes mellitus	9 (45.0)	11 (57.9)	χ^2=0.648	0.421
Ischemic heart disease	3 (14.3)	2 (10.5)	χ^2=0.129	^{FE}P=1.000
Stroke	2 (9.5)	1 (5.3)	χ^2=0.261	^{FE}P=1.000
Atrial fibrillation	2 (9.5)	0	χ^2=1.905	^{FE}P=0.488
Glaucoma	1 (4.8)	0	χ^2=0.928	^{FE}P=1.000
Bronchial asthma	1 (4.8)	0	χ^2=0.928	^{FE}P=1.000
Rheumatoid arthritis	2 (9.5)	0	χ^2=1.905	^{FE}P=0.488

χ^2, χ^2 test; FE, Fisher exact test; *t*, Student *t* test. *P*: *P* value for comparing between the studied groups

Table 2 Preoperative laboratory investigations of the studied patients

Investigations	Group A (*N*=54)	Group B (*N*=53)	Test of significance	*P*
WBCs (×10³/mm³)	8.2 (4.30–27.68)	8.10 (3.30–19.89)	*U*=1259.0	0.284
Prothrombin activity %	90.99±9.21	90.47±10.64	*t*=0.272	0.786
INR	1.07±0.09	1.08±0.10	*t*=0.173	0.863
ALT	47 (10–426)	81 (15.9–482)	*U*=1194.5	0.141
AST	44 (14–411)	62 (14.3–423)	*U*=1257.0	0.278
Bilirubin total	2.26 (0.18–18.73)	1.98 (0.5–12.4)	*U*=1368.0	0.695
Bilirubin direct	1.25 (0.01–16.02)	1.32 (0.11–10)	*U*=1426.0	0.975
ALP	192.5 (56–740)	220 (71–999)	*U*=1208.50	0.166

ALP, alkaline phosphate; ALT, alanine aminotransferase; AST, aspartate aminotransferase; INR, international normalized ratio; *t*, Student *t* test; *U*, Mann–Whitney test; WBC, white blood cell. *P*: *P* value for comparing between the studied groups.

Table 3 Preoperative magnetic resonance cholangiopancreatography findings

	Group A (*N*=54)	Group B (*N*=53)	Test of significance	*P*
Stone number	*n* (%)	*n* (%)		
1	24 (44.4)	24 (45.3)		
2	11 (20.4)	12 (22.6)		
3–4	8 (14.8)	8 (15.1)	χ^2=0.234	0.972
>5	11 (20.4)	9 (17.0)		
Stone size (mm)				
Mean±SD	13.65±4.88	12.30±3.17	*U*=1136.50	0.066
Median (range)	14 (4–31)	12.5 (3.5–24)		
CBD diameter (mm)				
Mean±SD	14.84±4.74	13.86±3.12	*U*=1265.0	0.300
Median (range)	15 (6–30)	14 (8–21)		

χ^2, χ^2 test; CBD, common bile-duct; *U*, Mann–Whitney test. *P*: *P* value for comparing between the studied groups.

Table 4 Secondary outcomes

	Group A (*N*=54)	Group B (*N*=53)	Test of significance	*P*
Total operative time (min)				
Mean±SD	140.52±49.44	99.89±49.16	*U*=635.0*	<0.001*
Median (range)	130.5 (35–298)	91 (38–295)		
Total hospital stay (days)				
Mean±SD	2.33±1.26	1.87±1.68	*U*=898.5*	<0.001*
Median (range)	2 (1–8)	1 (1–10)		
Number of procedures	1.04±0.19	1.89±0.51	*t*=11.452*	<0.001*
Postoperative complications	12 (22.2)	11 (20.75)	χ^2=0.0341	0.853
Bile leak into the drain	6 (11.1)	0		^{FE}P=0.027*
Pancreatitis	0	6 (11.3)		^{FE}P=0.013*
Cholangitis	1 (1.85)	1 (1.88)		^{FE}P=1.000
Port-site infection	2 (3.7)	2 (3.77)		^{FE}P=1.000
Surgical emphysema	1 (1.85)	0		^{FE}P=1.000
Obstructed T-tube	1 (1.85)	0		^{FE}P=1.000
Intraperitoneal bile collection	1 (1.85)	0		^{FE}P=1.000
Post-ERCP duodenal perforation	0	1 (1.88)		^{FE}P=0.495
Postprocedure bleeding	0	1 (1.88)		^{FE}P=0.495
Grading of complications according to Clavien–Dindo classification				
Class I	9 (16.67)	6 (11.3)	χ^2=0.634	0.426
Class II	1 (1.85)	4 (7.5)	χ^2=1.948	^{FE}P=0.205
Class III				
III a	1 (1.85)	0	χ^2=0.991	^{FE}P=1.000
III b	1 (1.85)	1 (1.88)	χ^2= 0.000	^{FE}P=1.000
Class IV				
Iva	0	0	χ^2= 0.000	^{FE}P=1.000
IVb	0	0	χ^2= 0.000	^{FE}P=1.000
Class V	0	0	χ^2= 0.000	^{FE}P=1.000

χ^2, χ^2 test; ERCP, endoscopic retrograde cholangiopancreatography; FE, Fisher exact test; MC, Monte Carlo test; *t*, Student *t* test; *U*, Mann–Whitney test. *P*: *P* value for comparing between the studied groups.

Postoperative complications occurred almost equally in both groups (22.2% in group A vs. 20.75% in group B) (Table 4).

In group A, class-I complications included six patients with self-limited bile leak, two patients with surgical-site infection at the epigastric port, and one patient with postoperative surgical emphysema. The patient with postoperative surgical emphysema had a smooth postoperative course and was discharged on the second postoperative day.

In group B, class-I complications were attributed to mild post-ERCP pancreatitis in four patients and postcholecystectomy port-site infection in the other two patients. Those patients with pancreatitis were only diagnosed with elevated serum amylase and lipase levels at routine post-ERCP follow-up. They were scheduled to undergo cholecystectomy without delay, which went smoothly.

Class-II complications, a single case in group A developed postoperative fever, abdominal pain, low T-tube output, and leukocytosis. A diagnosis of cholangitis was suggested after obtaining normal abdominal sonography and an early T-tube cholangiogram showing no filling defects with adequate passage of the dye proximally and distally. Discharged on the sixth day after antibiotic changed. In group B, class-II complications were caused by post-ERCP pancreatitis in two patients (required hospitalization due to vomiting and abdominal pain), cholangitis in one patient, and tiny post-ERCP retroduodenal perforations that were managed conservatively.

More serious class-III complications requiring further intervention occurred in two patients in group A and one in group B. In group A, one patient showed jaundice after successful LCBDE with a noted associated low output of the T-tube. Urgent T-tube cholangiogram showed a displaced T-tube with its proximal end obstructing the CBD. Urgent ERCP was performed with endobiliary plastic stent insertion. The second one in group A had a class-IIIa complication (nondrained abdominal collection), which was aspirated percutaneously under ultrasound guidance. In group B, one patient expressed class-IIIb complications in the form of post-ERCP melena and hematemesis managed endoscopically.

Discussion

Only two studies routinely conducted MRCP in their study groups as our protocol with notable associated negligible negative interventions [12,13]. Other studies only depended on intraoperative cholangiogram findings rather than preoperative MRCP [14–16].

Recent studies have encouraged early LC after ERCP, with an increased risk of recurrent CBD stones, conversion rates, and morbidity with a prolonged time between ERCP and cholecystectomy [17–19]. This justifies our choice to perform LC within 72 h of successful, uncomplicated ERCP in group B. We encountered one patient who required conversion to open surgery during LC in group B, owing to the presence of dense fibrosis and adhesions. The failure in both groups was directly caused by failed attainment of biliary clearance.

Our success rates were 90.7 and 86.8% for LCBDE+LC and ERCP+LC, respectively, with no statistical differences between the groups. Ding *et al.* [13] reported total success rates of 93.64 and 94.54% for LCBDE+LC and ERCP+LC, respectively.

Other studies reported only the biliary clearance rate, with no significant differences in their results. Mohamed *et al.* [20] reported successful biliary clearance of 92 and 96% in the LCBDE+LC and ERCP+LC groups, respectively [21]. The same as Koc *et al.* [14].

We were interested in the detailed analysis of the causes of this higher biliary-clearance rate proposed by Singh and Kilambi [22] in their meta-analysis. They attributed this difference to the varying definitions of success in most studies and the varying primary outcomes being measured. They also noted that some studies excluded patients who did not complete the second-stage cholecystectomy from the final analysis, considering them protocol violators instead of being defined as technique failure [14,23]. They mentioned that some publications were biased by performing ERCP as a diagnostic tool, ending with half of their studied patients not having choledocholithiasis, an incidence stated by Rogers *et al.* [16] themselves as a possibility of type-II error in their study.

The total operative time in our study was significantly longer in the LCBDE+LC group (140.5 ± 49.44 min) than in the ERCP+LC group (99.89 ± 49.16 min). This finding was coherent with two similar studies in which Bansal *et al.* [12] reported a mean operative duration of 135 ± 36.6 min in the LCBDE+LC group and 72.4 ± 27.6 min in the ERCP+LC group ($P \leq 0.001$) and Gonzalez *et al.* [24] reported a mean operative duration of 117 min in the LCBDE+LC group and 98 min in the preoperative ERCP+LC group ($P \leq 0.001$).

In contrast, many studies have reported a shorter operative duration in the LCBDE group [14,16,20,25]. We attribute these differences to operator experience, average stone size, stone impaction, and the prevalence of the trans-choledochal approach among patients undergoing LCBDE.

The total hospital stay was significantly shorter in the ERCP+LC group than in the LCBDE group, with a mean of 1.87 ± 1.68 versus 2.33 ± 1.26 days. This finding was not consistent with the literature, where most of the studies reported the inverse [22,26,27]. Mohamed *et al*. [20] reported almost equal hospital stay between both groups (2 ± 0.53 and 2 ± 0.57 days). Despite the longer hospital stay in the LCBDE group, we noticed that our means among both groups were consistent with other publications or even shorter. For example, Lu *et al*. [25] had a hospital-stay mean of 5.1 ± 2.5 days in the LCBDE group and 7.9 ± 3.9 days in the ERCP+LC group, while Bansal *et al*. [12] reported a mean of 4.6 ± 2.4 days in the LCBDE group and 5.3 ± 6.2 days in the ERCP+LC group. Pan *et al*. [28] reported a mean of 4.94 and 6.62 days in the two groups, respectively.

Our justification for this distinctive shorter hospital stay in the ERCP+LC group was mainly related to two main reasons. The first is the outpatient management of ERCP patients, which is our institute's policy where only complicated cases were admitted to the surgical ward. The second reason was scheduling patients with successful endoscopic biliary clearance for LC in 3 days without admitting patients.Despite having longer operative time and hospital stay, LCBDE had a fewer number of procedures per patient than the ERCP+LC (1.04 ± 0.19 days in LCBDE+LC vs. 1.89 ± 0.51 days). This difference is significant and constant in almost all publications comparing both techniques [22,26,28]. We find this point of clinical significance as some patients lack compliance and may neglect or postpone cholecystectomy after ERCP.

Postoperative complications were matched in both groups, with an incidence of 22.2 and 20.75% in groups A and B, respectively. Bile leak was the most common complication after LCBDE, while pancreatitis was the most common complication after ERCP. Several similar studies supported this finding, where no significant differences in morbidity were reported in two recent meta-analyses [22,27]. Lyu *et al*. [27] also reported a significantly higher incidence of pancreatitis after ERCP and bile leak after LCBDE.

The bottom line shows that both techniques are equally effective and safe, with some advantages for each technique at certain points. The choice of the appropriate approach will be tailored to the patient's circumstances and the operator's experience.

Conclusion

LCBDE+LC was as effective as ERCP+LC in the management of concomitant CBD and gallstones with an almost equivalent risk of complications. ERCP+LC superseded LCBDE+LC in having a shorter operative duration and total hospital stay, despite having a higher number of procedures per patient. Therefore, both techniques are almost head-to-head, and continuous training in both fields is advised.

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Conflicts of interest

There are no conflicts of interest.

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