Management of concomitant gallbladder and common bile duct stones: one stage versus two stages

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Background
The ideal management plan for patients diagnosed with concomitant cholelithiasis and choledocholithiasis has been a great matter of debate among hepatobiliary surgeons. Some surgeons prefer a single-stage approach (laparoscopic cholecystectomy LC with laparoscopic common bile duct exploration, LCBDE), while others prefer two-stage approaches (preoperative endoscopic stone extraction followed by interval LC). Herein, we compare the outcomes of the previous two approaches in our Egyptian tertiary care setting.
Methods
Sixty-four patients were eligible for our randomized trial and were randomly assigned into two groups: Group A was scheduled for the single-stage approach and Group B was scheduled for the two-stage approach. Periprocedural outcomes, including success rates, were assessed in the two groups.
Results
Failed stone extraction was encountered in three patients in Group B (success rate 90.62%). However, we were able to completely free the CBD in all patients in Group A (100% success). Operative time was significantly prolonged in Group A (173.13 vs. 75.97 min in Group B). However, Group A patients had a shorter hospitalization period compared with Group B (5 vs. 7 days). Bile leakage was more encountered in Group A, while the incidence of pancreatitis was higher in Group B. All patients were conservatively managed with no further intervention.
Conclusion
A higher, but not statistically significant, success rate was reported with the single-stage approach. Despite this, this technique was preferred due to a shorter hospital stay and higher clearance rates reported in our study.

Keywords:
choledocholithiasis, cholelithiasis, single stage, two stages

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Introduction

Cholelithiasis is a common pathological biliary problem that affects about 6% and 9% of the male and female populations, respectively [1]. However, it does elicit relevant symptoms in only 10–25% of affected individuals [2]. Major complications secondary to cholelithiasis occur mainly through secondary gallstone migration to the common bile duct (CBD), causing calcular obstructive jaundice, cholangitis, and even pancreatitis [3]. These dreadful complications could occur in 1–2% of patients with symptomatic gallstone disease [2].

Annually, it is estimated that 3–15% of patients scheduled for cholecystectomy for cholelithiasis harbor CBD stones [4]. These CBD stones should be properly managed to decrease the risk of perioperative complications, especially bile leakage [5]. Choledocholithiasis has multiple therapeutic options considering laparoscopic cholecystectomy (LC) as the gold standard modality. That has led to the presence of numerous therapeutic policies for managing concomitant cholelithiasis and choledocholithiasis [6,7]. The primary objective of any approach is to excise the gallbladder with its contacting stones and completely free the CBD from the stones [2,8].

The two-stage approach, which entails endoscopic CBD clearance (by endoscopic retrograde cholangiopancreatography, ERCP) followed by LC, is a common option for many surgeons [9]. Other surgeons prefer the single-stage approach, in which LC

is done with laparoscopic CBD exploration (LCBDE) in the same setting [10,11]. Nonetheless, it is still unclear which approach is superior [2].

In the current trial, we compare the single approach (LC with LCBDE) and the two-stage approach (ERCP then interval LC) in managing patients presented with concomitant gallstones and CBD stones regarding success and complication rates to decide which is best for such cases.

Patients and methods

This randomized, prospective trial was conducted at the Assiut University General Surgery Department over a 2-year period, from January 2021 to December 2022. Our trial gained ethical approval from the local ethics scientific committee of our medical school. The study was designed for adult individuals diagnosed with combined cholelithiasis and choledocholithiasis who presented to our outpatient clinic during the previous period.

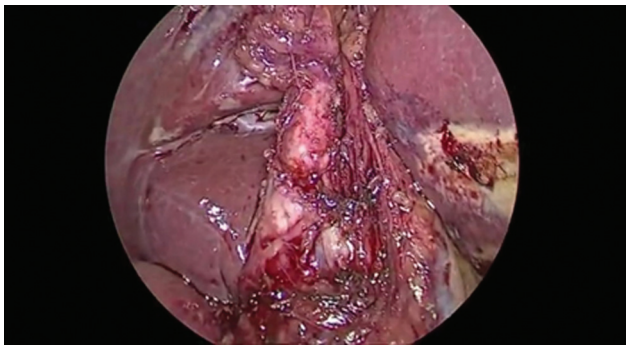
Patient evaluation included routine history taking (focusing on the main complaint and its duration), clinical assessment (focusing on complexion and local abdominal examination), laboratory investigations (focusing on serum bilirubin and cholestatic markers), in addition to preoperative radiological assessment. These included both pelviabdominal ultrasonography and magnetic resonance cholangiopancreatography (MRCP). The former was done by an experienced hepatobiliary radiologist to give a preliminary idea about the liver parenchymal status, biliary system, and other intraabdominal organs, whereas the latter was ordered for objective delineation of the biliary tree and confirmation of the diagnosis.

After the previous assessment, we excluded patients with biliary or pancreatic neoplasms, previous endoscopic CBD clearance, pregnancy, intrahepatic stones, acute pancreatitis, liver cirrhosis, previous upper abdominal surgery, or contraindications for MRCP examination, general anesthesia, or laparoscopy.

Sixty-four were found eligible for our trial. They signed written consent before participating in the study. Using the 'sealed envelope' technique, our patients were randomly assigned into two groups; Group A (n=32) was scheduled for the single-stage approach (LC with LCBDE) and Group B (n=32) was scheduled for the two-stage approach (preoperative ERCP then interval LC).

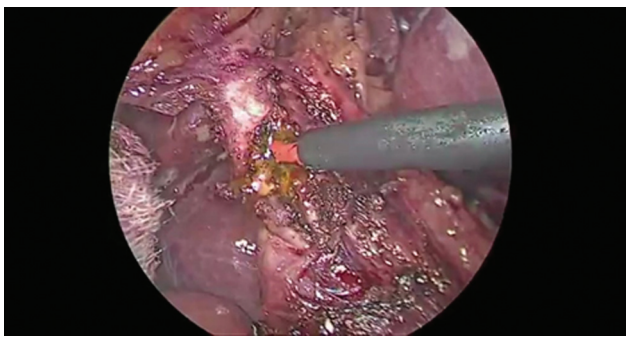
In Group A, general anesthesia was used during the surgery while the patient was in the French position, with the operating surgeon between the patient's legs. Five ports were used; one for the camera, two working, and two assistant ports. Cholecystectomy was initially done after dissection at the Calot triangle and identification of the critical view of safety. After clipping and division of the cystic duct and artery, the gallbladder was separated from the underlying liver bed by a diathermy hook. After the cholecystectomy procedure, we started dissection over the free border of the lesser omentum till identification of the supraduodenal portion of the CBD (Fig. 1) A 1-cm choledochotomy was done just above the duodenum (Fig. 2), and any visible stones were extracted. CBD exploration was then done proximally and distally through the balloon or dormie basket till complete CBD clearance (Figs. 3 and 4). An intraoperative cholangiogram was done to confirm duct clearance and the free passage of the dye to the duodenum. The choledochotomy was closed by interrupted Vicryl sutures (2/0) over a T-tube, followed by insertion of a surgical drain at the Morrison pouch and closure of the abdominal ports.

Figure 1



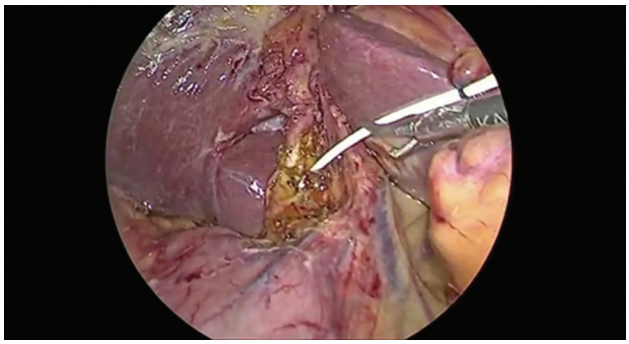
CBD exposure.

Figure 2



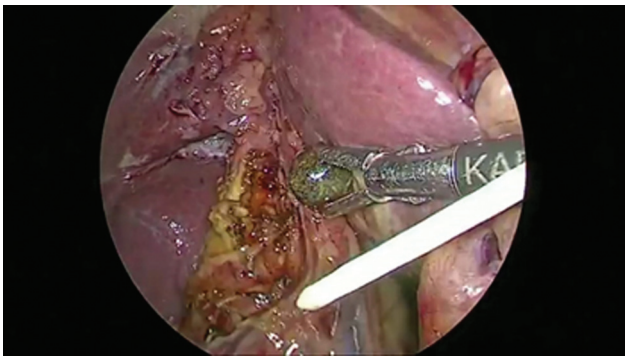
Choledechotomy.

Figure 3



Stone extraction from the CBD by Dormia basket.

Figure 4



Stone extraction from the CBD.

In Group B, the first stage included ERCP that was done under propofol-induced sedation when the patient was in the left lateral position. After identification of the duodenal papilla, cannulation and cholangiography were done. Existing stones were extracted through the balloon or the Dormia basket after making a wide papillotomy. An occlusion cholangiogram was done to ensure duct clearance, followed by good hemostasis for the papillotomy. Patients were transferred to the internal ward for monitoring of their general condition. Hemoglobin, serum amylase, and bilirubin were ordered the following day as indicators for bleeding papillotomy, duct clearance, and pancreatitis, respectively. Patients were kept in the ward till the second stage. That ranged between 1 and 5 days based on the clinical condition, incidence of complications, and availability of operative rooms. In the second stage, the procedure was done when the patient was in a reverse Trendelenburg position with a slight tilt to the left. The cholecystectomy procedure was performed like in Group A, but only four ports were used (one for the camera, two working, and one assistant port).

In both groups, the patients were transferred to the internal ward after proper recovery, where early ambulation and strict monitoring were recommended. Oral fluid intake was allowed 6–8 h after the procedure, unless complications were encountered. Any early postoperative complications, including hemorrhage, pancreatitis, bile leakage, surgical site infection, or cholangitis, were recorded and managed.

Patients were discharged from the hospital after adequate oral intake, good analgesic management with oral medications, and without complications. The duration of hospitalization was recorded in both groups. Stitches were removed within 2–3 weeks after surgery. A T-tube cholangiogram was done after 2 weeks for all patients in Group A to confirm duct clearance. Transtubal cholangiogram was done in the presence of C-arm, and an injection of 10 ml of the dye (Scanlux) diluted with 10 ml saline in a very low rate of injection was given at low pressure until a complete picture of intrahepatic and extrahepatic biliary channels and confirmed free spillage of the dye into the duodenum. Routinely in our center, before transtubal cholangiogram, prophylactic antibiotic (ceftriaxone 1 gm) is given, which can decrease the risk of cholangitis. If it was, the tube was removed. All patients were then followed up for 6 months, and any delayed complications were recorded.

Our main outcome (primary) was clinical success, which was defined as successful gallbladder removal with complete clearance of CBD stones by the selected treatment modality [12]. Secondary outcomes included operative time, procedure-related complications, and the duration of hospitalization.

Sample size calculation

We relied on the previous findings reported by Li and his colleagues, who reported success rates of 91.59% and 85.74% for the single- and two-stage approaches, respectively [13]. To achieve a 5% significance level and 95% power, we needed 32 patients to be enrolled in each study group.

Statistical analysis

Numerical data were reported as means and standard deviations (if not skewed) or medians with ranges (if skewed), and categorical variables were presented as numbers and percentages. Two-independent groups with categorical variables were compared using the χ^2 test. Either the Student-t or Mann–Whitney tests were used to compare numerical variables. The SPSS software (version 26 for MacOS) was used for data

tabulation and the previous tests, and any *P* value less than 0.05 was regarded as significant.

Results

Basic patient criteria, including age distribution, Sex status, and body mass index (BMI), showed comparable findings between the two groups (Table 1). In addition, the prevalence of hypertension, diabetes mellitus, and smoking was also comparable ($P>0.05$).

The duration of patients' symptoms had median values of 5 and 6 weeks in Groups A and B, respectively. All patients reported right hypochondriac pain, while jaundice was present in 62.5% and 68.76% of cases in the same groups, respectively. Other presentations included fever, vomiting, and pruritus.

Table 1 Basic demographic data in the two groups

	Group A (*n*=32)	Group B (*n*=32)	*P* value
Age (years)	41.56±8.64	41.59±9.66	0.989
Sex			
Female	23 (71.88%)	25 (78.13%)	0.564
Male	9 (28.12%)	7 (21.87%)	
BMI (kg/m^2)	32.80±3.06	33.60±3.56	0.336
'Systemic comorbidities			
Diabetes	4 (12.5%)	5 (15.63%)	0.719
Hypertension	4 (12.5%)	4 (12.5%)	1
Smoking	3 (9.38%)	3 (9.38%)	1

Regarding cholestatic markers, total bilirubin had median values of 3.8 and 4.6 mg, while direct bilirubin had median values of 1.8 and 1.95 mg/dl in the same groups, respectively. Serum alkaline phosphatase had median values of 273 and 330 IU/l in the same groups, respectively (Table 2).

The majority of the included cases had multiple gallstones (93.75% and 96.87% of cases in Groups A and B, respectively), while the remaining cases had a single gallstone. By MRCP, CBD had mean diameters of 15.33 and 15.53 mm in the same groups, respectively. As regards the number of CBD stones, most patients had a single CBD stone (78.13% and 90.63% of cases in the two groups, respectively), whereas the remaining cases had multiple CBD stones. The previous radiological criteria showed no significant difference between the two groups (Table 3).

For the ERCP stage in Group B, procedure time had a median value of 47 min. Successful stone extraction was achieved in 90.62% of cases using either the balloon (24 cases) or the Dormia basket (5 cases). We encountered failure in three cases, either due to failed cannulation of the papilla, a large stone, or a benign CBD stricture distal to the stone. The time interval to cholecystectomy ranged between 1 and 5 days (median = 4 days).

The three failed cases were managed as follows: two patients were managed by open cholecystectomy and

Table 2 Clinical presentation and basic laboratory markers of the patients in the two study groups

	Group A (*n*=32)	Group B (*n*=32)	*P* value
Duration of manifestations (week)	5 (1-8)	6 (3-8)	0.109
Presentation			
Abdominal pain	32 (100%)	32 (100%)	____
Jaundice	20 (62.5%)	22 (68.76%)	0.599
Fever	1 (3.12%)	1 (3.12%)	1
Vomiting	16 (50%)	13 (40.63%)	0.451
Pruritis	9 (28.13%)	11 (34.38%)	0.590
Total bilirubin (mg/dl)	3.8 (1-8)	4.6 (1-8)	0.581
Direct bilirubin (mg/dl)	1.8 (0.30-6.8)	1.95 (0.3-6.2)	0.936
Alkaline phosphatase (IU/l)	273 (100-453)	330 (111-475)	0.110

Table 3 Preoperative radiological assessment of patients in the two groups

	Group A (*n*=32)	Group B (*n*=32)	*P* value
Number of gallstones			
Single	2 (6.25%)	1 (3.13%)	0.554
Multiple	30 (93.75%)	31 (96.87%)	
CBD diameter (mm)	15.33±2.67	15.53±3.21	0.784
Number of CBD stones			
Single	25 (78.13%)	29 (90.63%)	0.168
Multiple	7 (21.87%)	3 (9.37%)	

open CBDE, while the other one with a stricture had cholecystectomy, CBDE, and Roux-en-Y hepaticojejunostomy proximal to the stricture (Table 4).

There was a significant prolongation in the operative time in Group A compared with the other group (173.13 vs. 75.97 min, respectively – $P<0.001$) (Table 5).

In Groups A and B, respectively, 100% and 90.62% of cases experienced procedure success, with no statistically significant differences ($P=0.07$). No conversion to the open approach was noted in either group. Also, no retained stones were noticed in all of our participants on subsequent assessments (Table 6).

The hospitalization period showed a significant increase in group B (7–5 days in Group B, $P<0.001$). Bile leakage showed a significant increase in Group A (12.5% vs. 0% in the other group, $P=0.03$). However, all cases were conservatively managed, with spontaneous resolution of leakage. A surgical site infection occurred in one case in each group (3.13%). No cases developed hemorrhage or cholangitis in the two groups. There was a significant increase in the incidence of pancreatitis in Group B (12.5% vs. 0% in Group A, $P=0.03$). All of these cases were mild and regressed spontaneously with medical treatment (Table 7).

Discussion

Currently, it is unclear which approach is better for managing patients with combined cholelithiasis and choledocholithiasis: the single-stage or the two-stage approach. That is why we conducted our trial to compare the previous two approaches. Our study has some strengths. It discussed a challenging surgical matter. Also, our results should have a decreased risk of bias as our preoperative parameters were comparable between the two groups due to our proper randomization.

In our study, ERCP failed to extract the stone in three cases (9.38%). As the literature reported a range of failure between 5% and 15%, the failure rate of our study is within that reported range [14]. Cannulation failure and impacted stones are among the most common causes of ERCP failure [15,16].

In the current study, the time interval between ERCP and LC in Group B ranged between 1 and 5 days. We preferred to perform the second stage in Group B during the same admission to decrease the risk of recurrent stone passage to the CBD. We also believe that early LC following ERCP is easier than late LC, as the fibrinous adhesions would become fibrous, making the operation more difficult with time. This was confirmed by Vries *et al.*, who showed higher conversion to the open approach in patients with late LC after ERCP compared with early LC [17].

In our study, we noted a significant prolongation in the operative time in Group A. It is reasonable that two

Table 4 Data related to the initial ERCP in group B

Variable	Data (n=32)
Procedure time (minutes)	47 (32–59)
Successful stone extraction	29 (90.62%)
Method of stone extraction (n=29)	
Balloon	24 (82.76%)
Dormia basket	5 (17.24%)
Causes of failed stone extraction (n=3)	
Failed papilla identification	1 (33.33%)
Large stone	1 (33.33%)
CBD narrowing distal to the stone	1 (33.33%)
Time interval to cholecystectomy (days)	4 (1–5)

Table 5 Operative time in the two study groups

	Group A (n=32)	Group B (n=32)	P value
Operative time (minutes)	173.13±13.87	75.97±10.59	<0.001

Table 6 Outcome of the two study groups

	Group A (n=32)	Group B (n=32)	P value
Success	32 (100%)	29 (90.62%)	0.076
Failure			
Conversion to open CBDE	0 (0%)	NA	_____
Conversion to open cholecystectomy	NA	0 (0%)	_____
ERCP failure	NA	3 (9.38%)	
Retained stones	0 (0%)	0 (0%)	
Lost follow-up	0 (0%)	0 (0%)	

Table 7 Postoperative data, hospital stay, and incidence of complications in the two study groups

	Group A (n=32)	Group B (n=32)	P value
Hospital stay (days)	5 (5–6)	7 (4 –9)	<0.001
Bile leakage	4 (12.5%)	0 (0%)	0.039
SSI	1 (3.13%)	1 (3.13%)	1
Hemorrhage	0 (0%)	0 (0%)	____
Cholangitis	0 (0%)	0 (0%)	____
Pancreatitis	0 (0%)	4 (12.5%)	0.039

procedures (LC and LCBDE) would take longer than one (LC). Bansal *et al.* agreed with our findings as the one-stage approach had a mean operative time of 135.7 min compared with 72.4 min in the two-stage approach ($P<0.001$) [18]. One could also notice the increased operative time in Group B compared with any traditional LC (which is nearly one hour). LC is known to be challenging and to have a higher complication rate following endoscopic CBD clearance as the latter induces swelling and fibrosis in and around Calot's triangle [19,20].

As stone clearance was successfully achieved in all cases within the single-stage approach compared with 90.62% of cases in Group B, our study showed the superiority of the former over the latter. Nonetheless, that difference was statistically insignificant ($P=0.076$). Bansal *et al.* also confirmed the upper hand of the single approach over the two-stage one. Success was achieved in 93.3% of cases in the single-stage approach, compared with only 73.3% in the two-stage group. However, that 20% difference was not sufficient to make a significant statistical difference ($P=0.32$) [12]. Another study reported success rates of 88.1% and 79.8% for the single- and two-stage approaches, respectively ($P=0.2$) [18]. 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, $P=0.76$) [21].

In our study, there was a significant prolongation in the duration of hospitalization in group B. That could be explained by the time interval between the first and second stages in Group B, as the patient had to stay in the hospital during that period. In the same context, Lv *et al.* reported a shorter duration of hospital stay in the single-stage group in comparison to the two-stage group (6.72 days and 10.91 days, respectively) ($P<0.01$) [22].

In the current study, no patients in the two groups required conversion from the laparoscopic approach to the open one during the surgical procedure. Lv *et al.* reported a 0% conversion rate in a previous similar study [22].

Our findings 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. Another previous study reported a significant increase in the same complication in the single-stage group (16.7% vs. 2.4% in the other group, $P=0.002$) [18]. Bansal *et al.* also reported a higher incidence of bile leakage in association with the single-stage approach (13.3% vs. 0% in the two-stage approach). Nonetheless, that difference turned out to be insignificant in statistical analysis ($P=0.48$) [12].

In the current study, we noted a significant increase in the incidence of pancreatitis in Group B (12.5%), a complication that was not reported in Group A ($P=0.039$). This is in accordance with the current literature, which reports that post-ERCP pancreatitis can occur in 2–10% of randomly selected cases. This incidence was also reported to increase up to 40% in high-risk patients [23]. Another study reported an increased incidence of pancreatitis with the two-stage approach (3.6% compared with 0% in the single-stage one) ($P=0.2$) [18]. In addition, Ding *et al.* reported an incidence of 2.7% or the same complication in the two-stage group versus no cases in the single-stage group ($P=0.53$) [21].

In this study, surgical site infection was reported only in one case in each of the two groups (3.13% per group). Ding and colleagues reported an incidence of 1.82% and 1.8% for the same complication in the single- and two-stage groups, respectively ($P>0.05$) [21]. Nonetheless, surgical site infection was reported at a higher incidence of 13.3% and 15.3% of cases in the single- and two-stage groups, respectively ($P=1$), as shown by Bansal and colleagues [12].

Our trial has some limitations. The relatively small sample size collected from a single institution and the lack of long-term follow-up are the main limitations. However, this should not be disappointing and future studies could overcome these limitations for more powerful results.

Conclusion

The two approaches did not differ statistically significantly from one another, despite the fact that the single-stage group (LC + LCBDE) had a greater success rate than the two-stage method (ERCP followed by LC). Despite this, we still favor the first strategy because it results in a shorter hospital stay and a higher clearance rate.

Acknowledgments

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Nil.

Conflicts of interest

Nil.

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