Evaluation of laparoscopic common bile duct exploration versus intraoperative endoscopic retrograde cholangiopancreatography in the management of choledocholithiasis

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Objective

To evaluate laparoscopic cholecystectomy plus laparoscopic exploration of common bile duct (CBD) versus laparoscopic cholecystectomy plus intraoperative endoscopic retrograde cholangiopancreatography (ERCP) in patients with choledocholithiasis.

Background

With advancement in technique and increased experience in the field of minimal access surgery, single-stage approaches may shorten the length of hospital stay.

Patients and methods

This study included 120 patients with gallbladder and CBD stones. All patients were operated upon by laparoscopic cholecystectomy, and then CBD stones were treated in 60 patients with intraoperative ERCP (group A), whereas the other 60 patients were treated with laparoscopic CBD exploration (Group B). Follow-up period was 6 months.

Results

No mortality was seen. Operative time was significantly higher in group B (2.98 h) (P<0.001). However, no significant differences were found regarding conversion (P=0.2). Hemorrhage and collection was significantly less in group A (P<0.001). There was no pancreatic duct injury in group B (P=0.006). There was no significant difference between both groups regarding penetration (P=0.07) and recurrence of stone (P=0.2), but CBD stricture was high in group B (P=0.005).

Conclusion

Both procedures can be used efficiently for treating CBD stones. However, intraoperative ERCP is a more preferable option to a greater extent when facilities for this intervention are available, owing to being less invasive, less operative time, less blood loss, less hospital stay, no collection, and less postoperative CBD stricture.

Keywords:
choledocholithiasis, intraoperative endoscopic retrograde cholangiopancreatography, laparoscopic common bile duct exploration, outcomes

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Introduction

Gallstone formation occurs owing to certain nonsoluble substances like calcium bilirubinate and cholesterol exceed their solubility concentration in the bile; especially with concentrated bile, these substances precipitate as microscopic crystals with mucus, producing gallbladder sludge. Over time, the crystals increase and aggregate into stones [1,2].

Gallstones develop and may remain asymptomatic for decades. Migration of these stones may block cystic duct and produce biliary colic. Then, if it persists for more than a few hours, it may lead to acute cholecystitis [3].

The clinical manifestations of common bile duct (CBD) stone might vary from the absence of any symptoms at all to more serious consequences including cholangitis or pancreatitis. For many years, the reason why some people get pancreatitis whereas others do not did not have a satisfactory explanation. According to some research, an increased likelihood of pancreatitis is associated with the presence of relatively tiny stones that contain a disproportionately large number of cholesterol crystals. These very tiny stones have the potential to cause distal blockage, which may result in bile reflux into the pancreatic ducts [4,5].

In individuals suspected of having CBD stone, the first study to be performed is called a transabdominal ultrasound. It has a sensitivity ranging from 25 to 63% when it comes to identifying CBD stone, whereas its specificity is about 95%. However, magnetic resonance cholangiopancreatography is a diagnostic method that is more accurate and does not include any invasive procedures. It is possible that it will be beneficial, particularly for those who may need early intervention [6,7].

Regarding the treatment of gallstones, once they become symptomatic, definitive surgical therapy with cholecystectomy is indicated. Complications of gallstones may require special management to relieve obstruction and treat infection [8].

Cholecystectomy by laparoscopy is considered the 'gold standard' for the treatment of gallstones, but there is debate for the management of CBD stones. In open surgery, treatment was open cholecystectomy with open exploration of CBD despite its high complications [9].

Minimal invasive interventions like laparoscopic cholecystectomy with intraoperative endoscopic retrograde cholangiopancreatography (ERCP) gives a good option for treatment. However, these interventions carry the risk of life-threatening complications like duodenal perforation, pancreatitis, or bleeding in addition to sphincterotomy may be complicated with papillary stenosis [9].

With recent advances in the field of minimal access intervention, many centers have started one-stage management of CBD stones by combining LC with laparoscopic common bile duct exploration (LCBDE), owing to that fact that this procedure is safe and effective for clearing difficult CBD stones and is cost-effective [10–12].

Despite the successful stone clearance rates of LCBDE being more than 95% with shorter hospital stay and lower hospital costs, it has complications like laceration, bile leak, and late duct stricture [13].

Patients and methods

This was a prospective study on patients recruited from the General Surgery Department of Benha University Hospitals. This study included a total of 124 patients with gallbladder and CBD stones. All patients were operated upon by laparoscopic cholecystectomy and then CBD stones were treated in 62 patients with intraoperative ERCP (group A), whereas the other 62 patients were treated by LCBDE (group B). Patients were randomized into two groups by closed envelope technique.

This study included patients who were 18–80 years old, with concomitant gall balder and CBD stones less than 2 cm, and patients were fit for surgery, with American Society of Anesthesiologists (ASA) physical status I–III.

Patients were not allowed to participate in this trial if their CBD stone was larger than 2 cm. Patients who have a history of bleeding disorders, liver masses or abscesses, or periampullary tumors; patients who have evidence of suppurative or necrotizing cholecystitis; patients who have gallbladder empyema or perforation; patients who have a history of gallbladder perforation; patients who have a history of gallbladder perforation; patients who have a history of multiple prior laparotomies; patients with morbid obesity; patients who are pregnant; patients with severe systemic organ dysfunction (chronic liver, renal, or heart diseases); patients with ASA physical status IV; and patients who are immunosuppressed were not candidates for this procedure.

After obtaining approval from the local ethical committee of Benha University and obtaining written fully informed patients consent, patients were enrolled from May 2020 till December 2021. Follow-up period was 6 months. All procedures in this study were done according to the Declaration of Helsinki and its updates.

Clinical histories including presenting symptoms (pain and jaundice) and clinical examination were recorded for all patients. Investigations done were laboratory investigations, ultrasonography and magnetic resonance cholangiopancreatography.

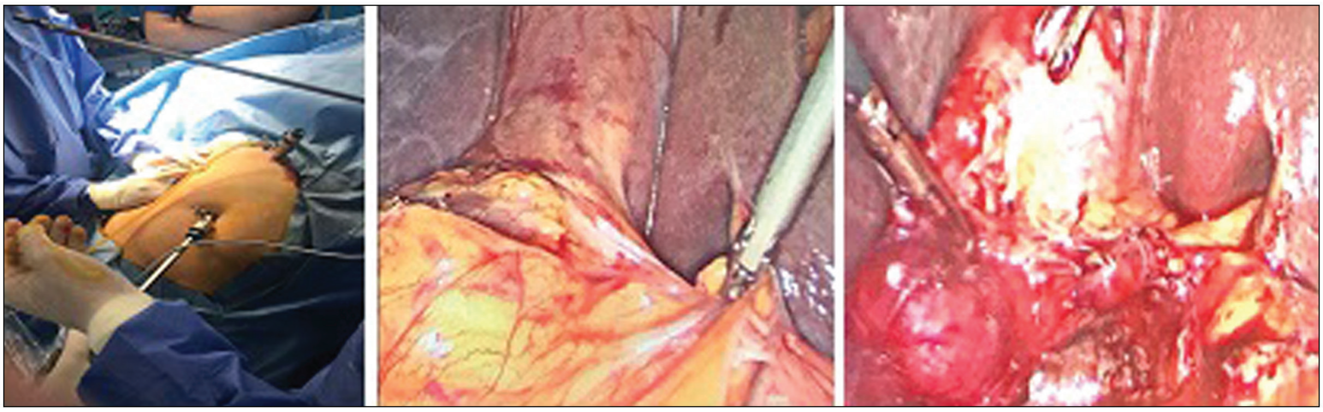
All patients were administered parenteral vitamin K; received antibiotics against gram-negative bacilli, which should achieve both therapeutic systemic levels and good penetration of the biliary system; and provided good hydration and mannitol as a prevention from renal failure.

Operative procedure

All operations were done under general anesthesia. The operations were performed by staff surgeons using the same techniques and rules. First of all, laparoscopic cholecystectomy was done (Fig. 1) and then the patients underwent the following procedures and were classified into two groups.

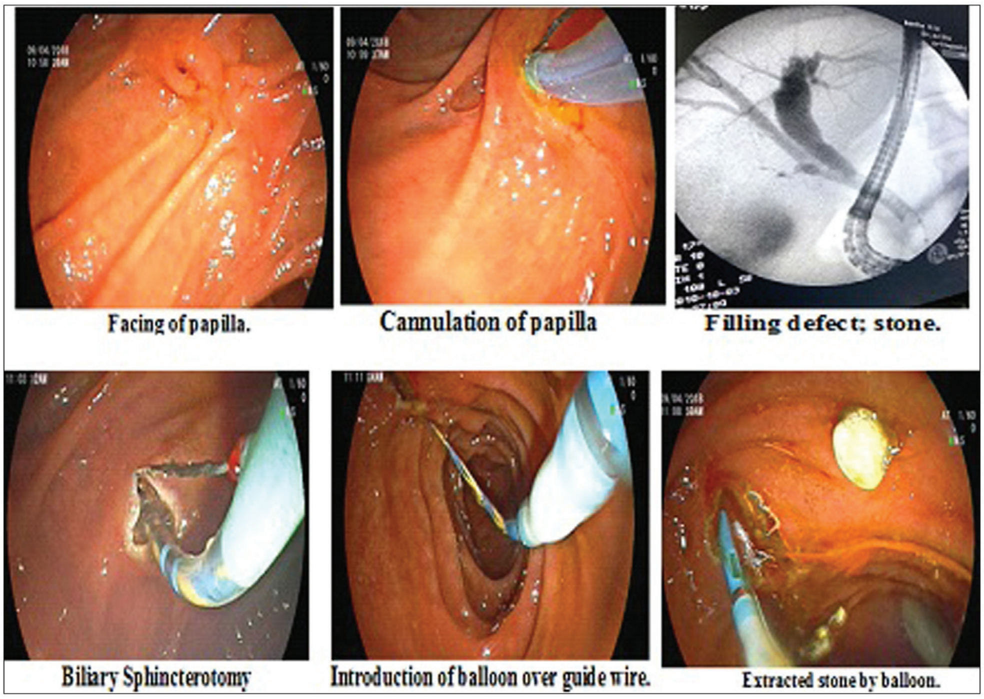
For the first group (group A): to perform an endoscopic procedure for the treatment of CBD stones, the patient is first positioned in a prone or semiprone position. The duodenoscope is then inserted through a mouth guard that has its own retention mechanism and advanced until it reaches the second part of the duodenum, with the lens facing the papilla and the tip in close proximity

Figure 1



Steps of laparoscopic cholecystectomy.

Figure 2



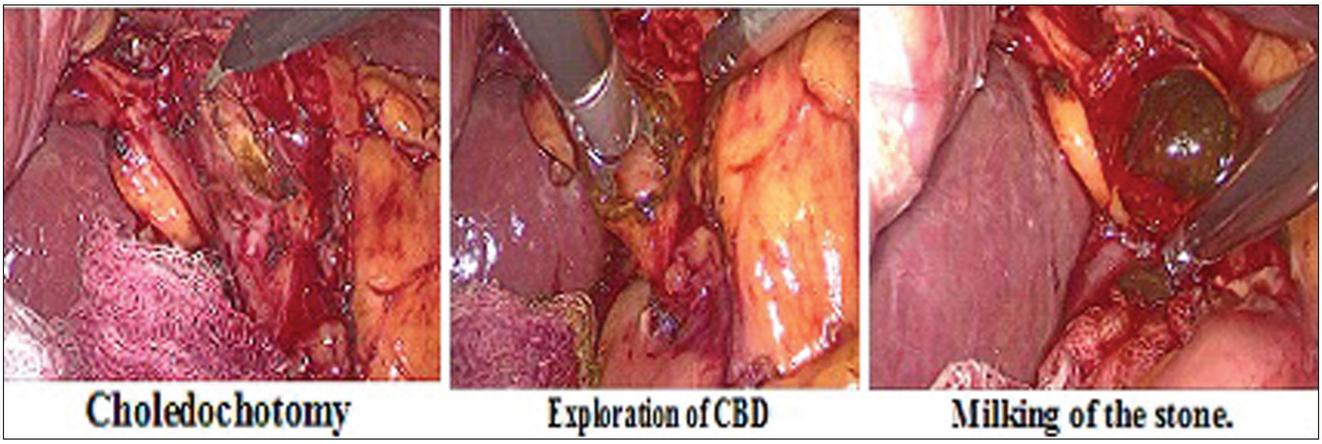
Steps of intraoperative ERCP in group A. ERCP, endoscopic retrograde cholangiopancreatography.

to the duodenal wall. This allowed for an upward approach to the papilla, which is more in line with the natural path of the CBD, which made it easier to cannulate the CBD. Positioning the scope so that the image of the papilla is in the upper portion of the video monitor also made it easier to cannulate the CBD. In most cases, the first step consisted of performing a biliary sphincterotomy to make it easier for the stone to move through the distal bile duct.

Cannulation was performed by inserting the tip of the cannulation device into the papillary orifice, which was then followed by the insertion of a guide wire into the CBD under fluoroscopy, which was followed by the injection of contrast to confirm the location. A cholangiogram was performed on the patient while they were in the prone or semiprone posture, either on a fluoroscopy table specifically designed for the procedure or under a portable C-arm device.

After that, either a stone extraction balloon or a stone basket (with or without the potential to crush the stone) was passed across the guide wire in the bile duct to assist in the delivery of the stone. In most cases, fluoroscopic imaging was carried out following the intervention to evaluate how well the therapy had been carried out (e.g. to look for residual filling defects in a bile duct after stone extraction). In cases where the stone removal was not complete, a temporary stenting of the CBD was performed (Fig. 2).

Figure 3



Steps of laparoscopic CBD exploration in group B. CBD, common bile duct.

For the second group (group B): laparoscopic examination of the CBD was performed. A surgical clip was put on the cystic artery, and another surgical clip was placed on the cystic duct at the level of the gallbladder. This was done after the neck of the gallbladder had been dissected, and the cystic duct had been identified. To perform an intraoperative cholangiogram, a tiny incision was made in the cystic duct right below the clip. The lumen of the cystic duct was then located during this process. A cholangiogram catheter with a 5-Fr diameter was placed percutaneously at a site that would, if required, make it easier to get additional access to the cystic duct and the CBD. The catheter would most often be positioned between the mid epigastric and the lateral ports, near to the costal edge. After being inserted into the abdomen, the catheter was cleared of air by being flushed with saline solution. After the catheter had been advanced into the ductotomy with the assistance of a dissector and fixed in place with a nonocclusive surgical clip, the procedure was complete. After that, contrast was administered via the catheter while fluoroscopy was being performed.

In the event that stones were discovered in either the CBD or the hepatic ducts, a decision was taken about the next course of action. Utilizing a Fogarty balloon catheter, an initial attempt was made to do a transcystic removal to remove these stones. To get around the stones in the CBD, graspers were used to implant a 4-Fr Fogarty catheter into the transcystic position. After that, the balloon was inflated, and using graspers, the catheter was carefully removed from the cystic duct in a gentle and careful manner.

A stone-retrieval basket was placed into the CBD after going through the cholangiogram catheter and into the duct itself. After that, the basket was opened using fluoroscopic guidance while going around the stone. The basket was then carefully removed, and the lid was placed on it. Choledochotomy was performed in the supraduodenal region of the patient using a harmonic scalpel or a unipolar cautery hook if transcystic removal was unsuccessful.

To expel the stones, a gentle milking motion was performed on the common duct while utilizing either a balloon or a dormia basket. This was then followed by a thorough flushing of the whole ductal system with a large quantity of normal saline. Cholangiograms that were performed more than once demonstrated that the ducts were clean. After confirming that the CBD had been cleared, the choledochotomy was either closed primarily with absorbable sutures (3–0) or closed over a T-tube that had been introduced into the CBD via the choledochotomy site. Both methods were performed after the CBD had been cleared. The cholecystectomy was then finished in the typical manner by dissecting between the gallbladder and its bed on the liver starting from the cystic duct and continuing all the way to the fundus until it became completely free. After this, the gallbladder was placed in a retrieval bag and then taken out through the epigastric port. After that, a drain was placed in the Morison pouch, the trocars were removed, and the sites of the trocars were closed (Fig. 3).

Postoperative management

The successful removal of CBD stones and the gallbladder was the benchmark for success. All of the patients were given a broad-spectrum antibiotic, analgesics, proton pump inhibitors, and intravenous fluids. In addition, the patients underwent daily examinations to look for the presence of primary symptoms and signs (such as pain and jaundice) as well as the clinical picture of complications (such as fever, tachycardia, hypotension, and abdominal tenderness, and rigidity). Finally, the drains were checked every day to ensure any bleeding or biliary leak. The primary result was the percentage of successful CBD clearing attempts. The duration of the operation, conversion to an open procedure and the reasons for it, intraoperative and postoperative problems, the length of time spent in the hospital, and the patient's status during follow-up visits were all considered secondary outcomes.

A bile leak or fistula, perforation, hemorrhage, wound infection, acute cholangitis, and acute pancreatitis are all examples of postoperative complications. The number of days that passed between the first intervention and the patient's release from the hospital was recorded. Six-month follow-up was carried out.

Statistical analysis

The version 25 of SPSS was used to conduct the statistical analysis (IBM, Armonk, New York, USA). Means and SDs were calculated using the numerical data that were collected. The registrar transcribed the categorical data into numbers and percentages. When comparing the two groups' numerical data, the independent *t* test was used, whereas comparisons of the groups' categorical data were conducted using either the χ^2 test or Fisher's exact test, depending on the circumstances. A multivariate linear regression analysis with control for all other characteristics was performed to determine the effect of utilizing reinforced staple line on the total amount of time needed for surgery. Calculations were made to determine the regression coefficient as well as the confidence intervals for 95%. Each and every *P* value was a two-sided statistic. *P* values lower than 0.05 were used to indicate statistical significance.

Results

This prospective interventional study was conducted on 124 cases in the Department of Surgery at Benha University. No mortality was reported, but four patients missed their follow-up. Therefore, the data were available for 120 cases only (60 cases in each group). There were no significant differences between both groups regarding demographic data, such as age, sex, ASA classification, and comorbidity (*P*=0.9, 0.7, 0.7, and 0.66, respectively) (Table 1 and Graphs 1 and 2).

Regarding clinical presentation, there were no significant differences between both groups regarding presentations, such as asymptomatic, pain, jaundice, and CBD ultrasound diameter (mm) (*P*=0.5, *P*=0.4, *P*=0.5, and *P*<0.001, respectively) (Table 2 and Graph 3).

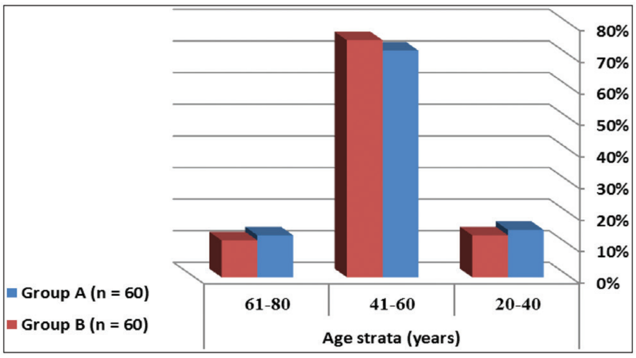
There were no significant differences between both groups regarding cystic duct dilatation (*P*=0.1). There was no significant difference between both groups regarding stone removal (*P*=0.2). Mean CBD diameter was significantly higher in group B (15 mm) compared with group A (10 mm), with *P* value less than 0.001. Operative time was significantly higher in group B (2.98 h) compared with group A (1.56 h), with *P* value less than 0.001. There was a significant difference in both groups regarding blood loss, with *P* value less than 0.001, but no significant differences regarding conversion, with *P* value of 0.2 (Table 3 and Graph 4).

Table 1 Demographic data in both groups

	Group A (*N*=60) [*n* (%)]	Group B (*N*=60) [*n* (%)]	*P* value
Age strata (years)			
20–40	9 (15)	8 (13.3)	0.9
41–60	43 (71.7)	45 (75)	
61–80	8 (13.3)	7 (11.7)	
Sex			
Males	28 (46.7)	26 (43.3)	0.7
Females	32 (53.3)	34 (56.7)	
ASA			
ASA I	42 (70)	46 (76.7)	0.7
ASA II	14 (23.3)	11 (18.3)	
ASA III	4 (6.7)	3 (5)	
Associated comorbidity	19 (31.7)	17 (28.3)	0.66

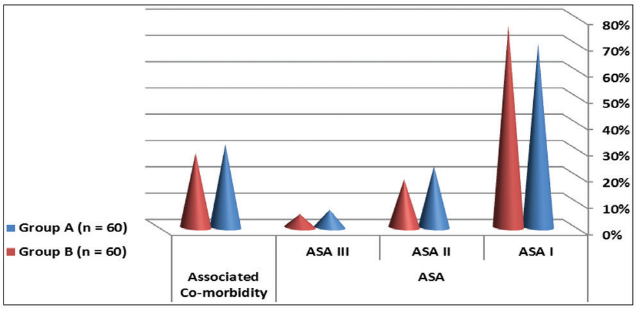
χ^2 test was used. ASA, American Society of Anesthesiologists.

Graph 1



Age distribution of the patients.

Graph 2



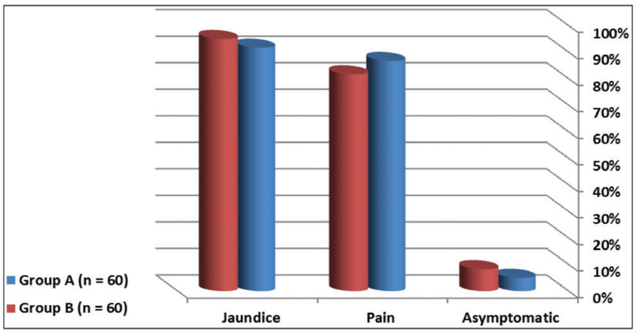
Preoperative characteristics.

Table 2 Clinical presentation

Presentation	Group A (*N*=60) [*n* (%)]	Group B (*N*=60) [*n* (%)]	*P* value
Asymptomatic	3 (5)	5 (8.3)	0.5
Pain	52 (86.7)	49 (81.7)	0.4
Jaundice	55 (91.7)	57 (95)	0.5
CBD ultrasound diameter (mm)	11 ± 2.9	14 ± 4.2	<0.001
CBD MRCP diameter (mm)	11.6 ± 2.2	15.2 ± 3.1	<0.001

Independent *t* test was used for numerical data. χ^2 test was used for categorical data. CBD, common bile duct; MRCP, magnetic resonance cholangiopancreatography.

Graph 3



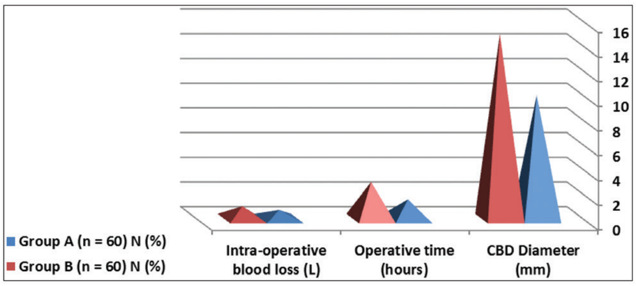
Clinical presentation.

Table 3 Operative data

Data	Group A (*N*=60) [*n* (%)]	Group B (*N*=60) [*n* (%)]	*P* value
Cystic duct dilatation	7 (11.7)	2 (3.3)	0.1
Stone removal	55 (91.7)	58 (96.7)	0.2
CBD diameter (mm) (mean±SD)	10 ± 4	15 ± 3	<0.001
Operative time (h) (mean±SD)	1.56 ± 0.69	2.98 ± 1.03	<0.001
Intraoperative blood loss (ml) (mean±SD)	700 ± 250	1000 ± 450	<0.001
Conversion	8 (13.3)	4 (6.7)	0.2

Independent *t* test was used for numerical data. χ^2 test was used for categorical data. CBD, common bile duct.

Graph 4



Operative data.

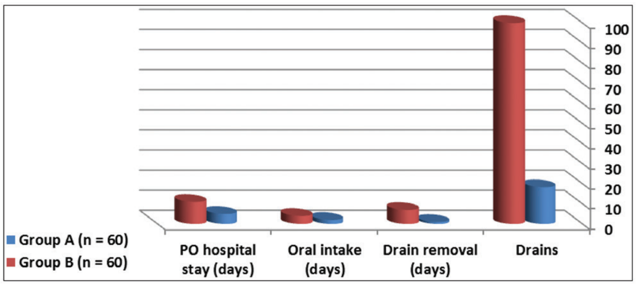
By reviewing postoperative events, need for drains was significantly less in group A, with *P* value less than 0.001. Time to remove drain was significantly less in group A, with *P* value less than 0.001. Oral intake started significantly early in group A, with *P* value less than 0.001. Hospital stay duration was significantly shorter in group A, with *P* value less than 0.001 (Table 4 and Graph 5).

Table 4 Postoperative events

Data	Group A (*N*=60) [*n* (%)]	Group B (*N*=60) [*n* (%)]	*P* value
Drains	11 (18.3)	60 (100.0)	<0.001
Drain removal (days)	2 (1–2)	9 (2–21)	<0.001
Oral intake (days)	2 ± 1	5 ± 1	<0.001
Duration of postoperative hospital stay (days) (mean±SD)	5 ± 1	11 ± 4	<0.001

Independent *t* test was used for numerical data. χ^2 test was used for categorical data.

Graph 5



Postoperative events.

Hemorrhage and collection were significantly less in group A, with *P* value less than 0.001. There was no pancreatic duct injury in group B, with *P* value of 0.006. There were no significant differences between both groups regarding penetration, with *P* value of 0.07, and recurrent stone, with *P* value of 0.2, but CBD stricture was high in group B, with *P* value of 0.005 (Table 5 and Graph 6).

Discussion

The availability of a skilled surgeon is taken into consideration before making a decision. In the treatment of CBD stones, there are two different kinds of treatments that are essential: (a) preoperative or postoperative ERCP with sphincterotomy as part of a two-stage surgery, and (b) surgical bile duct exposure and cholecystectomy as part of a single-stage operation. Both of these approaches of therapy have been shown to be beneficial in a number of randomized controlled studies [14,15].

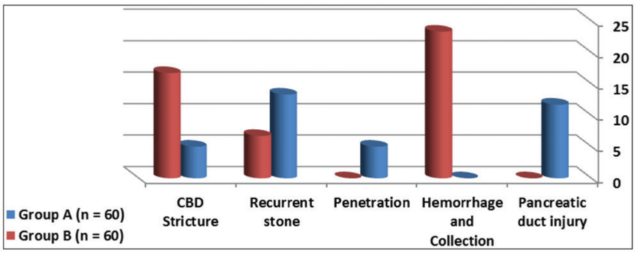
Kharbutli and Velanovich [16] observed that one-stage treatment of symptomatic CBD stones is accompanied with less mortality and morbidity (0.19 and 7%, respectively) than two-stage treatment (0.5 and 13.5%, respectively).

Table 5 Outcomes during follow up period

Data	Group A (*N*=60) [*n* (%)]	Group B (*N*=60) [*n* (%)]	*P* value
Pancreatic duct injury with elevated amylase	7 (11.7)	0	0.006
Hemorrhage and collection	0	14 (23.3)	<0.001
Penetration	3 (5)	0	0.07
Recurrent stone	8 (13.3)	4 (6.7)	0.2
CBD Stricture	3 (5)	10 (16.7)	0.005

χ^2 test was used. CBD, common bile duct.

Graph 6



Outcomes during follow up period.

In the current study, there were no significant differences between both groups regarding demographic data such as age, sex, ASA classification, and comorbidity, with *P* values of 0.9, 0.7, 0.7, and 0.66, respectively. Clinical presentation of cases were asymptomatic, pain, or jaundice, and there were no significant differences between both groups, with *P* values of 0.5, 0.4, and 0.5, respectively. These results are highly comparable to the results of Hong *et al.* [17] who worked on nearly double the number of patients (234 cases).

Operative time was significantly higher in group B (2.98 h) compared with group A (1.56 h), with *P* value less than 0.001. There were significant differences in both groups regarding blood loss, with *P* value less than 0.001, but there were no significant differences regarding conversion, with *P* value of 0.2. This difference is due to difficult and delicate procedure that needs high experience to do CBD exploration. ElGeidie *et al.* [18], who worked on IO-ERCP, showed nearly similar total duration of operation of 112 min compared with 110 min in our procedure. Ghazal *et al.* [19] obtained nearly the same mean operation time as ElGeidie and colleagues, as the mean surgical time in their study was 119 min. However, De Palma *et al.* [20] reported a mean surgical time of 97.7 min, which was less than ours. ElGeidie *et al.* [18] in another study compared two different techniques of ERCP showing the mean surgical duration using rendezvous technique of 125 min.

Complete stone removal of the CBD was nearly equal in both groups, as it was achieved in 55 (91.7%) and 58 (96.7%) in groups A and B, respectively. The five patients with failed ERCP in group A were converted to LCBDE in the same set, whereas the two patients in group B with failure of complete CBD clearance underwent intraoperative ERCP in the same set, which failed also to achieve complete stone removal, so both patients were converted to open CBD exploration. These results are similar to Tranter and Thompson [21] who observed a clearance of about 91% for IO-ERCP and 95% for CBD exploration and also similar to ElHanafy *et al.* [22] who worked on 50 patients and had a success rate of 94%. Our stone removal rate was more than that mentioned by Hong *et al.* [17] who reported 89% for LCBDE and 91% intraoperative ERCP.

After evaluating the postoperative events, we found that group A required considerably fewer drains (the *P* value for this finding was less than 0.001). In group A, the time needed to remove the drain was noticeably shorter; the corresponding *P* value was less than 0.001. In group A, oral consumption began much earlier than expected; the corresponding *P* value was less than 0.001. In group A, the length of time spent in the hospital was considerably lower; the corresponding *P* value was less than 0.001. These findings are similar to those that have been reported by other researchers [17,21,22].

Intra-abdominal drains were inserted in 60 (100%) of patients in group B, whereas only 11 (18.3%) patients in group A had drain insertion. The mean time of removal of drains in group A was only 2 days, whereas in group B was 9 days. This significant difference between the two groups in drain insertion and removal gave group A the advantage in the postoperative recovery, which by the way had a direct effect on the hospital stay, which was recorded as 5 and 11 days as a mean for the hospital stay for groups A and B, respectively. Our results in group A are similar to Williams and Vellacott [23], who reported that the hospital stay was 2.5 days, and Ghazal *et al.* [19], who reported the same mean hospital stay of 2.55 days. However, ElNakeeb *et al.* [24] reported a very short hospital stay duration of only 19 h. In contrast to the current study, Hong *et al.* [17] found that there was no difference between the two groups in the hospital stay (4.5 days for both groups).

Postoperative 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. There was no pancreatic duct injury in group B, with *P* value of 0.006. There were no significant differences between both groups regarding penetration, with *P* value of 0.07, and recurrent stone, with *P* value of 0.2, but CBD stricture was high in group B, with *P* value of 0.005. However, Enochsson *et al.* [25] reported postoperative morbidity in 9.8% of the study sample, with 2.7% having postoperative pancreatitis, and ElGeidie *et al.* [18] in their study showed only 4.5% morbidity rate. This is in contrast with Ghazal *et al.* [19], who worked on IO-ERCP and showed no morbidity rate in their study, and ElGeidie *et al.* [18], who in another study also reported no postoperative morbidities. There were no mortalities in our study, which is against Enochsson *et al.* [25], who reported 5.9% mortality rate. On the contrary, group B showed a significant increase in postoperative intra-abdominal collection, whereas collection was zero in group A. ElHanafy *et al.* [22] worked on 50 CBD explorations and reported leakage only in 2%. Lastly, only three (5%) cases in group A showed CBD penetration, and CBD stricture was reported more in group B, with 10 (16.7%) cases, which were managed by hepaticojejunostomy. These results were comparable to ElHanafy *et al.* [22]. Tranter and Thompson [21] compared between the same two groups and showed that the overall postoperative complications that occurred in patients who underwent IO-ERCP were 13%, with 1% mortality rate, whereas in patients who underwent CBD exploration, the overall postoperative complications were 8%, with a mortality rate of 1%. However, Hong *et al.* [17] showed that the two groups had the same postoperative complication rate (5–10%).

Conclusion

Both procedures can be used efficiently for treating CBD stones. However, intraoperative ERCP is a more preferable option to a greater extent when facilities for this intervention are available, being less invasive, less operative time, less blood loss, less hospital stay, no collection, and less postoperative CBD stricture.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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