Evaluation of Laparoscopic Common Bile Duct (CBD) exploration versus Intraoperative Endoscopic Retrograde Cholangio-Pancreatography (ERCP) in the Management of Choledocholithiasis

Mohamed A. Elbegawy, MD; Ayman T. Mohamed, MD; Sherif A. Elgazzar, MD. Departments of General Surgery, Benha University, Egypt.

Abstract

It is our goal in this study to compare the outcomes of laparoscopic cholecystectomy with CBD exploration against laparoscopic exploration of CBD using intraoperative endoscopic retrograde cholangiopancreatography (ERCP). Single-stage procedures may reduce the time of hospital stay as a result of advances in technique and more expertise in the area of minimally invasive surgery. We have two groups of people to consider: A total of 120 individuals with gall bladder and CBD stones participated in this trial. All patients had laparoscopic cholecystectomy, and then intraoperative ERCP was used to cure CBD stones in 60 patients: the remaining 60 patients were treated with LCBDE (B). A six-month follow-up was required. In the end, there was no fatality. Group B's operating duration was substantially longer (2.98 hours); the P value for this difference was 0.001. As for conversion, there were no significant changes (P = 0.20). Group A had a considerably lower rate of haemorrhage and collection than group B (P 0.001). Group B had no pancreatic duct damage; the P value was 0.006. P values of 0.07 and 0.2 for penetration and recurrence of stones were found in both groups, however CBD Stricture was significantly higher in group B; P value, 0.005. The conclusion is that both techniques can be employed to treat CBD stones. The less intrusive intraoperative ERCP is, the less time it takes, the less blood it requires, the shorter the hospital stay, and the less likely it is to cause postoperative CBD stricture.

Keywords: Choledocholithiasis, Intraoperative ERCP, Laparoscopic CBD exploration, Outcomes.

Introduction:

In very concentrated bile, gallstone formation is caused by the presence of non-soluble compounds such as calcium bilirubinate and cholesterol. Sludge is formed when these compounds combine with mucus to form minute crystals. The crystals grow and become stones over time. (1) and (2)

Gallstones may form and go unnoticed for years before becoming a problem. These stones may cause biliary colic if they migrate and clog the cystic duct. Acute cholecystitis may develop if it continues for longer than a few hours. Asymptomatic CBDS might progress to more serious consequences including cholangitis or pancreatitis. As to why some people complain of pancreatitis while others do not, it remained a mystery for a long time. Gallbladder contractility and the presence of more cholesterol crystals in tiny stones may enhance the chance of developing pancreatitis. These tiny stones may cause bile reflux into the pancreatic ducts, resulting in distal blockage. In addition to these two,

In individuals with suspected CBDS, transabdominal ultrasound (TUS) is the primary line of inquiry. Between 25% and 63% of the time, CBDS may be detected with this method, with a 95% level of specificity. Magnetic Resonance Cholangiopancreatography (MRCP), on the other hand, is a more accurate and noninvasive diagnostic method. In patients who need early intervention, it may be beneficial. Biliary stone removal surgery (cholecystectomy) is the only treatment option after symptoms arise (6, 7). Gallstone complications might need specialised treatment in order to alleviate blockage and infection. For gallstones, laparoscopy-based cholecystectomy is the "Gold Standard," however there is dispute about how to handle CBD stones. However risky it may be, open cholecystectomy with open examination of the CBD remained the only option for patients who had open surgery. As a therapy option, less invasive procedures such laparoscopic cholecystectomy intraoperative with endoscopic retrograde cholangiopancreatography (ERCP) are a viable choice. In addition to sphincterotomy, these procedures pose the danger of lifethreatening consequences such duodenal perforation, pancreatitis, or haemorrhage. It is now possible to do minimally invasive laparoscopic CBD exploration in conjunction with LC, thanks to recent improvements in the area of minimally invasive intervention (LCBDE). Based on the fact that this treatment is now safe. effective, and cost-efficient for removing tough CBD stones. Despite the fact that Laparoscopic CBD exploration has a success rate of more than 95%, problems such as laceration, bile leak, and late duct stricture might occur. (13)



Patients and Methods:

A prospective research, patients for this investigation were recruited from the general surgery department of Benha university hospitals. A total of 124 individuals with gall bladder and CBD stones were involved in this research. Laparoscopic cholecystectomy was performed all patients, and on subsequently intraoperative ERCP was used to remove CBD stones in 62 patients: the remaining 62 patients were treated with LCBDE (B). Closed envelope randomization was used to divide patients into two aroups.

Patients in this research were between the ages of 18 and 80 and had gall balder and CBD stones less than 2cm in diameter; they were fit for surgery (I-III).

In this trial, patients were not allowed to participate if their CBD stone was larger than 2cm. the presence of liver mass or infection, gallbladder empyema. or perforation, or the history of bleeding should be taken problems into consideration while evaluating patients for this procedure, as should those who have a history of any of these conditions. Laparotomies have been performed on individuals with a history of several previous surgeries or morbid obesity; pregnancy; significant systemic organ failure; ASA IV; and immunosuppressed patients.

Patients were recruited from May 2020 to December 2021 after the Benha University's local ethics council approved the study and the signed agreement of the patients was obtained. There were no deviations from the Declaration of Helsinki and its subsequent amendments throughout the conduct of this research.

All patients had a detailed medical history, which included their current symptoms (pain and jaundice) as well as a physical examination. Laboratory tests, ultrasound, and MRCP were used in the studies.

All patients were given intravenous vitamin K, an antibiotic for Gram-negative bacilli, and excellent hydration and mannitol as a preventative measure against renal failure, as well as good nutrition.

The surgical procedure:

General anaesthesia was used for all procedures. Surgeons on staff used the same methods and guidelines to execute the procedures. After the laparoscopic cholecystectomy, Fig. (1) was taken as the final image.

This group (Group A): Endoscopic care of CBD stones, the patient is changed to an upright or semi-elevated prone posture, and the self-retaining mouth guard is used to insert and remove the duodenoscope, which is placed in the papilla and near to the duodenal wall. the video monitor's top section was rotated to provide a more natural approach to papilla, which is more in line with CBD's natural course, making it simpler to cannulate CBD more easily. Initially, a biliary sphincterotomy was used to ease the transit of the stone via the distal bile duct.

Before injecting contrast, the cannulation device tip was passed through the papillary orifice with the use of a guide wire and fluoroscopy to check its location in the CBD. A cholangiogram was taken while the patient was lying prone or semiprone on a specialised fluoroscopy table or under a portable C-arm device.

It was then passed across the guide wire to aid transport the stones, either by using a stone extraction balloon or a stone basket (either with or without stone crushing capabilities). Fluoroscopic imaging was also often used to evaluate the efficacy of therapy after intervention (e.g. to look for residual filling defects in a bile duct after stone extraction). The common bile duct was temporarily stented if the stone clearance was not complete. Figure (2)

First of all, let's talk about Group A. CBD testing was carried out using a laparoscopy. Cystic artery and gallbladder cystic duct were surgically clipped after gallbladder neck dissection and detection of cystic duct. During the procedure, a tiny cystic duct incision was made right below the clip, and its lumen was discovered by cholangiography. Using the 5 Fr Cholangiogram catheter, the cystic duct and the common bile duct might be reached if required. In most cases, the catheter would be positioned between the mid epigastric and lateral ports, close to the costal margin. The catheter was cleared of air after being treated with saline once it was in the abdomen. A nonocclusive surgical clip was used to secure the catheter after it was advanced into the ductotomy using a dissector. Under fluoroscopy, contrast was administered into the body through the catheter.

There was a choice to be taken on how to continue when stones were located in the common or hepatic channels. These



stones were originally removed using a Fogarty balloon catheter for transcystic removal. Transcystically implanted 4-Fr. Fogarty was used to remove stones from common bile duct. Finally, the catheter was drained using graspers once the balloon was inflated.

The cholangiogram catheter was introduced into the common bile duct, and a stone retrieval basket was inserted. Following that, the basket was opened using fluoroscopy to avoid damaging the stone within. After that, the basket was progressively pulled and the lid was shut. The supraduodenal region of the stomach was used to do a choledochotomy if transcystic removal failed.

A balloon or a dormia basket was used to gently milk the common duct,

followed by a thorough cleansing of the whole ductal system with normal saline. Repeated cholangiograms verified the absence of ductal obstruction. Closed either primary with absorbable suture (3-0) or over T-tube placed by mid-clavicular port into CBD, after clearing of CBD from the surgical site. Cholecystectomy surgery was accomplished by dissecting between the gall bladder and its liver bed, commencing at the cystic duct until it reached its fundus, and then putting it in a retrieval bag that could be retrieved by the epigastric port, according to standard procedure. Finally, a drain was inserted into the morison pouch, the trocars were removed, and the trocars' sites were sealed. Figure (3)

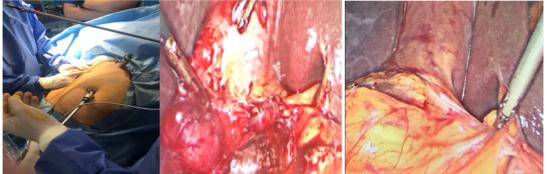
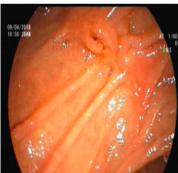
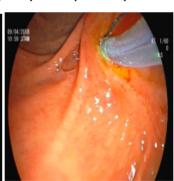


Figure (1): Steps of laparoscopic cholecystectomy.



Facing of papilla.



Cannulation of papilla



Filling defect; stone.



Biliary Sphincterotomy

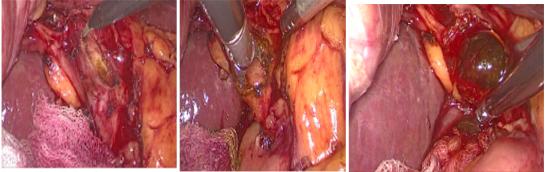


rotomy Introduction of balloon over guide wire. Extra Figure (2): Steps of intraoperative ERCP in Group (A).



Extracted stone by balloon.





Choledochotomy

Exploration of CBD

Milking of the stone.

Post operative management:

Success was defined by removal of CBD stones and gallbladder. All patients was received broad spectrum antibiotic, analgesics, proton pump inhibitors & IV fluids, daily examination of patients were done searching for presence of primary symptoms and signs (pain & jaundice) & clinical picture of complications (eg: fever, tachycardia, hypotension & abdominal tenderness & rigidity) and daily follow up of drains for early detection of bleeding or biliary leakage. Primary outcome which was the success rate of CBD clearance but Secondary outcomes which were duration of the surgery, conversion to open procedure and its reasons, Intraoperative and postoperative complications, duration of hospital stay or condition on follow up visits.

Postoperative complications includes bile leak / fistula, perforation, bleeding, wound infection, acute cholangitis and acute pancreatitis. Length of hospital stay in days following the first intervention till the discharge. Follow-up was done for 6 months.

Statistical analysis: Statistical analysis were done using SPSS vs.25. (IBM, Armonk, New York, United States). Table (1): Demographic data in both groups:

Figure (3): Steps of Japaroscopic CBD exploration in Group (B). Numerical data were registered as means and standard deviations. Categorical data were reaistered as numbers percentages. Comparisons between both groups were done using the independent ttest for numerical data but categorical data were compared using the Chi-square test or Fisher's exact test, if appropriate. Multivariate linear regression analysis was done for the effect of using reinforced staple line on the time of surgery, controlling for all other factors. The regression coefficient and 95% confidence intervals were calculated. All P-values were two-sided. P values less than 0.05 were considered significant.

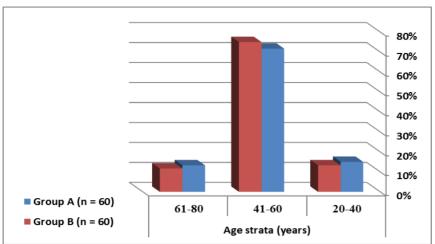
Results:

This prospective interventional study was conducted on 124 cases in the department of surgery at Benha University. No mortality but four patients escaped their follow up and there was no mortality; so the data was available for 120 cases only; 60 cases in each group. There were no significant differences between both groups as regard demographic data; age, gender, ASA classification and Comorbidity: P values were 0.9, 0.7, 0.7 and 0.66 respectively. Tab. (1), Graph. (1, 2).

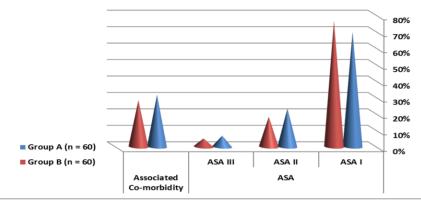
	~	Group A (n = 60) N (%)	Group B (n = 60) N (%)	P value
Age strata (years)	20-40	9 (15)	8 (13.3)	0.9
······································	41-60	43 (71.7)	45 (75)	
	61-80	8 (13.3)	7 (11.7)	
Gender	Males	28 (46.7)	26 (43.3)	0.7
	Females	32 (53.3)	34 (56.7)	
ASA	ASA I	42 (70)	46 (76.7)	0.7
	ASA II	14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

Chi-square test was used.









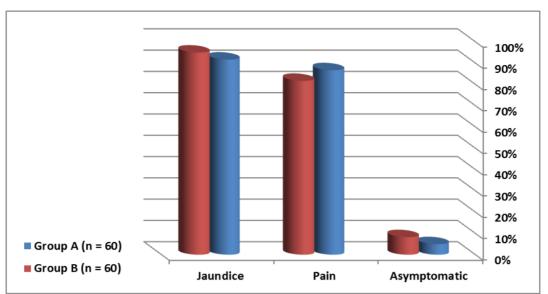
Graph. (2): Preoperative Characteristics.

As regard clinical presentation; there were no significant differences between both groups as regard presentation; Asymptomatic, pain, jaundice and CBD ultrasound diameter (mm). P values were 0.5, 0.4, 0.5 and < 0.001 respectively. Tab. (2), Graph (3). Table (2): Clinical presentation:

Presentation	Group A (n = 60)	Group B (n = 60)	P value
	N (%)	N (%)	
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. Chi-square test was used for categorical data.



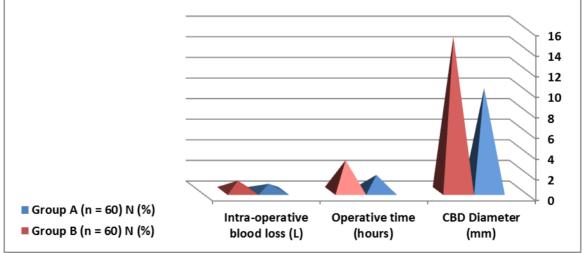


Graph. (3): Clinical presentation.

There were no significant differences between both groups as regard Cystic duct dilatation; P value, 0.1. There was no significant difference between both groups as regard stone removal; P value, 0.2. Mean CBD diameter was significantly higher in group B (15 mm) compared to group A (10 mm); P value, <0.001. Operative time was significantly higher in group B (2.98 hours) compared to group A (1.56 hours); P value, <0.001. There was significant difference in both groups as regard blood loss; P value, <0.001 but no significant differences regarding to conversion; P value, 0.2. Tab. (3), Graph (4).

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

Independent t test was used for numerical data. Chi-square test was used for categorical data.



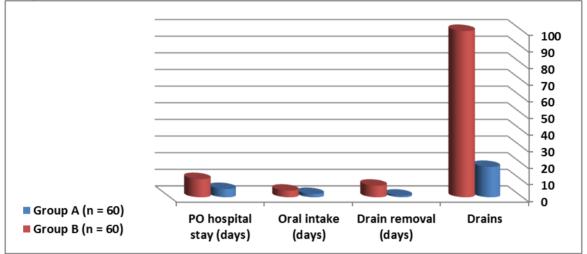
Graph. (4): Operative data.

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

Table (4): Post-Operative (PO) 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 PO hospital stay (days) (mean ±SD)	5±1	11 ±4	<0.001

Independent t test was used for numerical data. Chi-square test was used for categorical data.

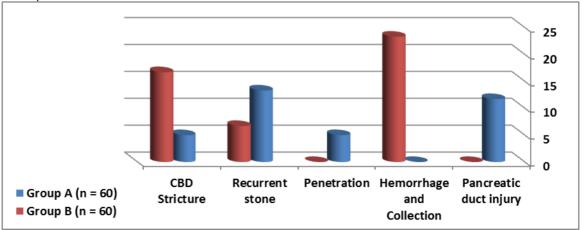


Graph. (5): Post-Operative (PO) events.

Hemorrhage and collection were significantly less in group A; P value, <0.001. There was no pancreatic duct injury in group B; P value, 0.006, there were no significant differences between both groups as regard penetration; P value, 0.07 and recurrent stone; P value, 0.2 but CBD Stricture was high in group B; P value, 0.005. **Tab. (5), Graph (6)**.

Table	(5):	Outcomes	during	follow up	period:
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Data	Group A (n = 60)	Group B (n = 60)	P value
	N (%)	N (%)	
Pancreatic duct injury with elevated amylase	7 (11.7)	0 (0.0)	0.006
Hemorrhage and Collection	0 (0.0)	14 (23.3)	<0.001
Penetration	3 (5)	0 (0.0)	0.07
Recurrent stone	8 (13.3)	4 (6.7)	0.2
CBD Stricture	3 (5)	10 (16.7)	0.005
Chi-square test was used.			



Graph. (6): Outcomes during follow up period. Discussion:

The availability of an expert surgeon

influences the decision-making process. A two-stage approach that includes pre- or postoperative ERCP and sphincterotomy and surgical bile duct exposure and cholecystectomy is critical in the treatment of CBD stones. There have been several randomised controlled studies showing that the efficacy of both treatment techniques is quite close to one another. (Page 14 and 15)

Therapy of symptomatic CBD stones in one step by Kharbutli et al. was associated with a lower mortality and morbidity rate (0.19 percent and 7.3 percent, respectively) than treatment in two stages (0.5 percent and 13.5 percent). (16)

A total of 0.9, 0.7, 0.7 and 0.66, respectively, were the statistical significance values for the demographic data of the two groups; age, gender, ASA classification, and co-morbidity. There were no significant differences between the two groups in terms of clinical presentation (P values of 0.5, 0.4, and 0.5) or pain or jaundice in any of the patients. When compared to the findings of (17) who dealt with 234 patients, these results are quite similar.

Group B's operating time (2.98 hours) was substantially greater than group A's (1.56 hours); P value, 0.001.

Р value 0.001 indicates substantial differences in blood loss across the two groups, however P value 0.2 indicates no significant changes in conversion. This discrepancy is the result of the time and skill required to do a routine bile duct investigation. When comparing their 112 minute IO-ERCP method to our 110 minute IO-ERCP treatment, the researchers (18) found a nearly identical operating time. While ElGeidie reported a mean surgery duration of 119 minutes, (19) reported a mean time of 97.7 minutes, which was shorter than ours. (18) Another research examined two ERCP procedures and found that the randezvous approach took on average 125 minutes to complete.

Group A and Group B obtained 91.7 and 96.7 percent, respectively, in the removal of common bile duct stones in both groups. When ERCP failed to remove all of the stones, the 5 patients in group A were transferred to Laparoscopic CBD exploration, whereas the 2 in group B who had failed to remove all of the stones were transferred to open CBD exploration in the same set. (21), who found that 91% of IOERCP patients were cleared and 95% of CBD patients were cleared; (22) found that 94% of the 50 patients they worked on were cleared, and (23), who worked on 50 patients, found that 94% of them were cleared. Laparoscopic CBD exploration and intraoperative ERCP stone removal rates reported by (17) were higher than ours.

Postoperative drain use was much lower in group A, according to an analysis of medical records; a 0.001-point difference between the two groups. Group A took substantially less time to eliminate the drain; the P value here is 0.001. Compared to group B, group A's oral intake began much earlier; the P value was 0.001. P 0.001 indicates that group A's hospital stay was considerably shorter. Those findings are in line with what we've seen in the past (17, 21, 22)

In group B, all 60 patients had intraabdominal drains implanted, but only 11 patients in group A had drains inserted (18.3%). Group A drains were removed in 2 days, whereas Group B drains were removed in 9 days. Drains insertion and removal differed significantly between groups A and B, which in turn had a direct influence on the length of the hospital stay, which was reported as 5 days for group A and 11 days for group B, respectively. Similarly, (23) who reported a 2.5-day hospital stay and (19) who reported a 2.55 -day stay are in our group A. While the hospital stay for patient number 24 was only reported to be 19 hours, this indicates a fairly brief hospital stay. In contrast to the present research, (17) showed that the hospital stay reported 4.5 days for both groups did not vary between the two groups at all.

Hemorrhage collection and were considerably lower in group A after surgery, with a P value of 0.001 in all patients. CBD Stricture in group B was higher (P=0.005), but there was no pancreatic duct damage (P=0.006), no significant differences in penetration (P=0.07), and no recurrence of stone (P=0.02) in group B. Only 4.5 percent of the patients in (25) and (18) developed postoperative pancreatitis, despite the fact that 9.8 percent of the research sample had postoperative morbidity. In contrast to (19), who studied IO-ERCP and found no postoperative morbidity, and (18), who did the same in a different research and likewise found no postoperative morbidity. Our research had a death rate of 0%, compared to the (25) who had a 5.9% mortality rate. Group B, on the other hand,



exhibited a considerable rise in intraabdominal collection after surgery, but group A had no post-operative collection. Only 2% of the 50 CBD experiments that (22) worked on reported leaking. The number of patients treated with hepaticojujenostomy in group B increased from 10 (16.7%) to three instances (5 percent) in group A, where there was evidence of CBD penetration and CBD stricture. When comparing patients who had IOERCP and CBD exploration, "Tranter and Thompson" found that the total postoperative problems that occurred in patients who had IOERCP were 13 per cent, while the death rate was 1 per cent. While (17) demonstrated that the postoperative complication rate was the same in both groups (5-10 percent).

The conclusion is that both techniques can be employed to treat CBD stones. The less intrusive intraoperative ERCP is, the less time it takes, the less blood it requires, the shorter the hospital stay, and the less likely it is to cause postoperative CBD stricture.

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