The Scientific Journal of Medical Scholar

SJMS

Volume 1, Issue 4, July 2022

https://realpub.org/index.php/sjms

Online ISSN: 2833-3772

The Scientific Journal of Medical Scholar

Available online at Journal Website
https://realpub.org/index.php/sjms/index
Subject (General Surgery)

Original Article

Comparative Study of Endoscopic Retrograde Cholangio-Pancreatography versus Surgical Open and Laparoscopic Exploration of CBD in Management of CBD Stones

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Article information

Submitted: April, 10th, 2022

Accepted: June, 28th, 2022

Published: July, 1st, 2022

DOI: 10.55675/sjms.v2021i4.30

Citation: Farag MZZ, Elramah AF, Sarhan AA. Comparative Study of Endoscopic Retrograde Cholangio-Pancreatography versus Surgical Open and Laparoscopic Exploration of CBD in Management of CBD Stones. SJMS 2022; 1 (4) July: 115-121. DOI: 10.55675/sjms.v2021i4.30

ABSTRACT

Introduction and Aim: Choledocholithiasis are common presentations in daily surgical practice. Endoscopic retrograde cholangiopancreatography (ERCP) remains the gold standard management approach. However, researching new approaches is continuing due to their associated complications. The current study aimed to address the efficacy, safety, and outcomes of different treatment modalities to recognize the most appropriate technique for patients with choledocholithiasis.

Patients and methods: The current work included 60 patients with choledocholithiasis. They were divided randomly into three equal groups. Group I for intraoperative ERCP plus LC, group II for LCBDE plus LC, and group-III for open common bile duct exploration plus cholecystectomy. Each patient was subjected to full history taking, physical examination, and different investigations (laboratory and radiological). The postoperative follow-up had been performed in the clinical and radiological follow-up.

Results: The three groups were comparable regarding patient age, sex, body mass index, operative time, size of the common bile duct, stone number per patient, postoperative pain score, duration of hospital stay, satisfaction score. The success rate was 75%, 70% & 85% of the group I, II & III, respectively; while the mortality rate was 5%,10% & 0% in groups I, II, and III. However, there was a statistically significant higher frequency of morbidity among Group-I than the other two groups (30% in group I compared to 5% for each of the second and third groups). Also, there was a higher rate of retained stones (25%, 30%) for groups I & II with no retained stones among the third group (open surgery). There was no significant difference between groups regarding complications.

Conclusion: The three approaches have comparable outcomes in success, mortality, morbidity, failure, and complications. The clearance and retained stone rates after primary intervention showed significant improvement in the open surgery group compared to the other groups.

Keywords: Choledocholithiasis; Common Bile Duct; ERCP; Laparoscopic Cholecystectomy; LCBDE.

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INTRODUCTION

In the field of surgery, gall bladder and/or bile duct stones are very common presentations. The common bile stones (CBS) could be predicted by preoperative clinical and laboratory workup, and there are many scoring systems used to predict CBD stones' existence. However, these scores are not specific regardless of their higher sensitivity. Among biochemical predictors, bilirubin levels and alkaline phosphatase (ALP) are the most sensitive independent predictors. The diameter of the bile duct is the third independent predictor. Different imaging modalities are used to detect CBD stones with variable sensitivities and specificities. These include, but not limited to, abdominal ultrasound (US), endoscopic ultrasound, computed tomography (CT), and magnetic resonance cholangiopancreatography (MRCP) [1-2].

Endoscopic retrograde cholangiopancreatography (ERCP) is the standard treatment modality for CBD stones. It is the commonest performed intervention to manage CBD stones in intact gallbladder settings. However, ERCP is associated with long and short-term comorbidities. These complications increased when the procedure is associated with the sphincterotomy. Besides, the recurrence rate is up to 15%. Sphincter dilatation by the balloon carries similar risks and is associated with a 13.5% recurrence rate [3-4].

Laparoscopic management of CBD stones is increasingly performed with supporting evidence, especially if cholangitis is absent. The reported clearance rate is up to 90.0% in the study of Martin *et al*. [5].

The first bile duct exploration was described in the 1990s. It seems to succeed with a lower rate of complications. The incidence of complications (intra- or post-operative) after CBDE is up 7%. The reported intraoperative complications included jammed baskets, in addition to and all other complications of laparoscopic cholecystectomy. However, bile leak, bleeding, and intra-abdominal collections represented the most commonly reported postoperative complications [2,6].

With technological advances in digital imaging, small-sized cameras are now available and contributed to significantly improved visualization and extraction of stones. The removal of bile duct stones under direct vision has the advantage of direct vision of clearance rather than radiological imaging, which depends on a column of contrast to specifying no filling defect [7].

The current study aimed to address the efficacy, safety, and outcomes of different treatment modalities: (the intraoperative ERCP plus LC; laparoscopic common bile duct exploration (LCBDE) plus LC; and open common bile duct exploration plus cholecystectomy) to recognize the most appropriate technique for patients with choledocholithiasis.

PATIENTS AND METHODS

It is a double-blind, randomized clinical trial; completed at the Department of General Surgery, Al-Azhar University Hospital-(New Damietta). It included patients with calcular obstructive jaundice or proven common bile duct (CBD) stones.

Inclusion criteria:

1) Patients with suspected or proven CBD stones before open or LC, and 2) Patients have CBD stones at open or LC. On the other hand, **exclusion criteria** included 1) Malignant obstructive jaundice, 2) Patients with intrahepatic stones and biliary stricture, 3) Chronic liver disease and/or chronic kidney disease, 4) Patients on radio or chemotherapy, 5) Contraindication of surgery in general

Sampling:

A convenient sample of 60 patients fulfilling the inclusion have participated. Patients were allocated into three equal intervention arms (group allocated to intraoperative ERCP plus LC), group allocated to LCBDE plus LC, and group allocated to open common bile duct exploration plus cholecystectomy) by simple random sampling technique using sealed envelope technique. All patients were followed up for one postoperative month.

Methods:

Each patient was subjected to full history taking, physical examination, and different investigations (laboratory and radiological). Laboratory investigations included liver function tests (aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin (direct, indirect), alkaline phosphatase, Gama glutamyl transferase (GGT), and serum albumin. The radiological investigations were in the form of abdominopelvic US, MRCP & CT abdomen with contrast.

The surgical procedure was complete as described previously [8]. All LCs were performed under general anesthesia in the lithotomy position of LCBDE and supine position for the ERCP plus LC group. All participants received routine prophylactic antibiotics according to our department protocol. The procedure was completed as described in Cok *et al*. [8]

The postoperative follow up had been performed in the form of clinical follow up for one month. In addition, abdominal ultrasonography had been performed after one week, one month, and three months from the date of surgery. Furthermore, MRCP had been performed when indicated. All data were documented and submitted for statistical analysis.

Statistical analysis and data interpretation:

Data were fed to the computer and analyzed using IBM SPSS Corp. Released 2013. IBM SPSS Statistics for Windows,

Version 22.0. Armonk, NY: IBM Corp. Qualitative data were described using number and percent. Quantitative data were described using the mean, the standard deviation for parametric data after testing normality using the Kolmogorov-Smirnov test. The significance of the obtained results was judged at the (0.05) level. For qualitative data, Chi-Square test for comparison of two or more groups. However, the Monte Carlo test was used as a correction for the Chi-Square test when more than 25% of cells have to count less than 5 in tables (>2*2). Otherwise, Fischer Exact test was used as a correction for the Chi-Square test when more than 25% of cells must count less than 5 in 2*2 tables. On the other line, the One-Way analysis of variance (ANOVA) test was used to compare more than two independent groups with the Post Hoc Tukey test to detect pair-wise comparison.

Ethical consideration:

The study protocol was submitted to the IRB committee in The Damietta Faculty of Medicine (AL-Azhar University) and approved after extensive review (IRP number: IRB 00012367-18-12-002). Informed consent was obtained from every patient share in the study after confirmation of confidentiality and personal privacy. The data collected from patients was not used for other purposes than the present research.

RESULTS

In the current work, 80 patients with calcular obstructive jaundice or proven CBD stones were assessed for eligibility. Twenty were excluded (15 did not meet the inclusion criteria, and five refused to participate). Thus, 60 were allocated into three equal intervention groups (first group; intraoperative ERCP plus LC, second group; LCBDE plus LC and third group; open surgery (open CBDE plus open cholecystectomy). Table (1) illustrated that no statistically significant difference was found between studied groups regarding their age, sex, and body mass index.

Table (2) demonstrated that there is no statistically significant difference between studied groups regarding mean operative time (162.7, 161.75 &171.45), mean maximum size of the common bile duct (0.937, 0.996 and 0.918), the mean number of procedures per patient (1.45, 1.35 and 1.45) for groups I, II & III, respectively. Similarly, stone numbers illustrate no statistically significant difference between groups.

Table (3) illustrates no significant difference between studied groups regarding mean 24 hours' pain score, mean hospital stay duration /days, mean patient satisfaction score for groups I, II, and III, respectively.

Figure (3) shows no statistically significant difference between studied groups regarding success rate with 75%, 70% & 85% of the group I, II & III, respectively have successful techniques.

Table (4) showed no significant difference between studied groups regarding mortality rate (5%,10% & 0% in groups I, II, and III, respectively). However, there was a statistically significant higher frequency of morbidity among Group-I than the other two groups (30% in group I compared to 5% for each of the second and third groups). Also, there was a significantly higher rate of retained stones after the primary intervention (25%, 30%) for groups I & II with no retained stones among the third group (open surgery). Thus, the clearance rate was 75.0%, 70.0%, and 100.0% for groups I, II, and III, respectively. In group I, two patients need conversion to open technique compared to one patient from group II. There was no significant difference between groups regarding complications (Complications were in the form of pancreatitis (1), hemorrhage (1), cholangitis (3), and duodenal perforation (1)).

Figure (1) showed no statistically significant difference between studied groups regarding patients' clinical presentation with calcular obstructive jaundice. The most common clinical presentation was right upper quadrant pain, and the least common was pancreatitis. Figure (2) showed no statistically significant difference between studied groups regarding elevated enzymes (serum bilirubin, alkaline phosphatase, gamma-glutamyl transferase, SGOT, and SGPT).

Table (1): Demographic characteristics of the studied groups.

		Group I	Group II	Group III	Test of	Within-group significance
Age/years		45.75±8.98	47.05±8.49	48.45±6.29	F=0.569; p=0.57	P1=0.61; P2=0.29; P3=0.07
Sex	Male Female	6(30.0) 14(70.0)	3(15.0) 17(85.0)	4(20.0) 16(80.0)	MC; p=0.50	P1=0.26; P2=0.47; P3=0.68
BMI (kg/m²)		37.40±2.74	37.50±2.46	35.65±3.63	F=2.43; p=0.097	P1=0.92; P2=0.07; P3=0.06

F: One Way ANOVA test, MC: Monte Carlo test, P1: difference between I and II groups, P2: difference between I and III groups, P3: the difference between II and III groups. p: probability; *Statistically significant (if p<0.05); BMI: Body mass index

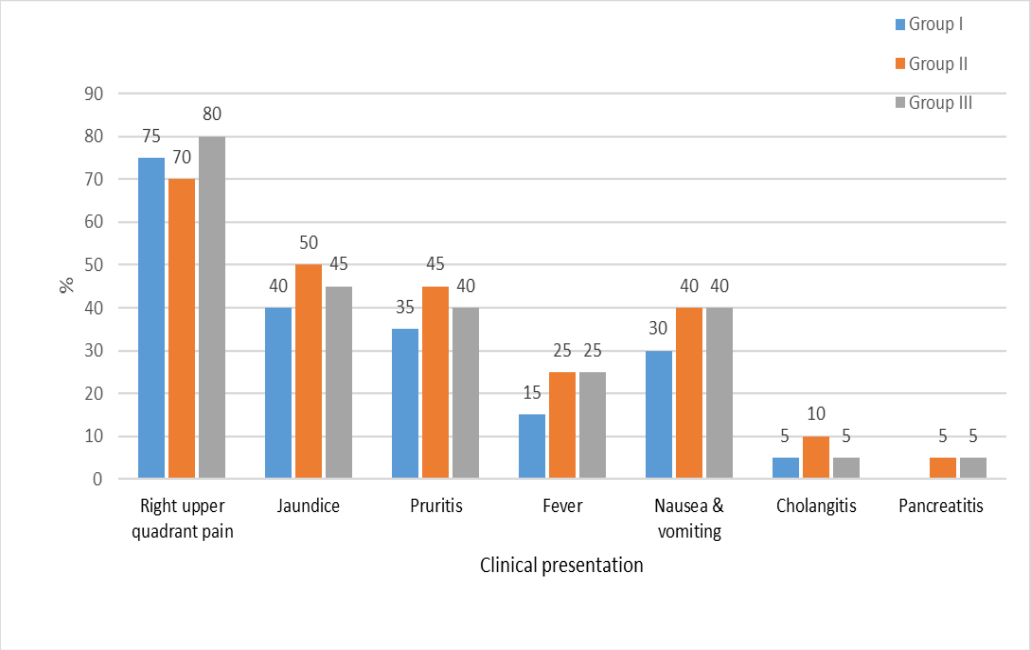

Figure (1): Clinical presentation among studied groups.

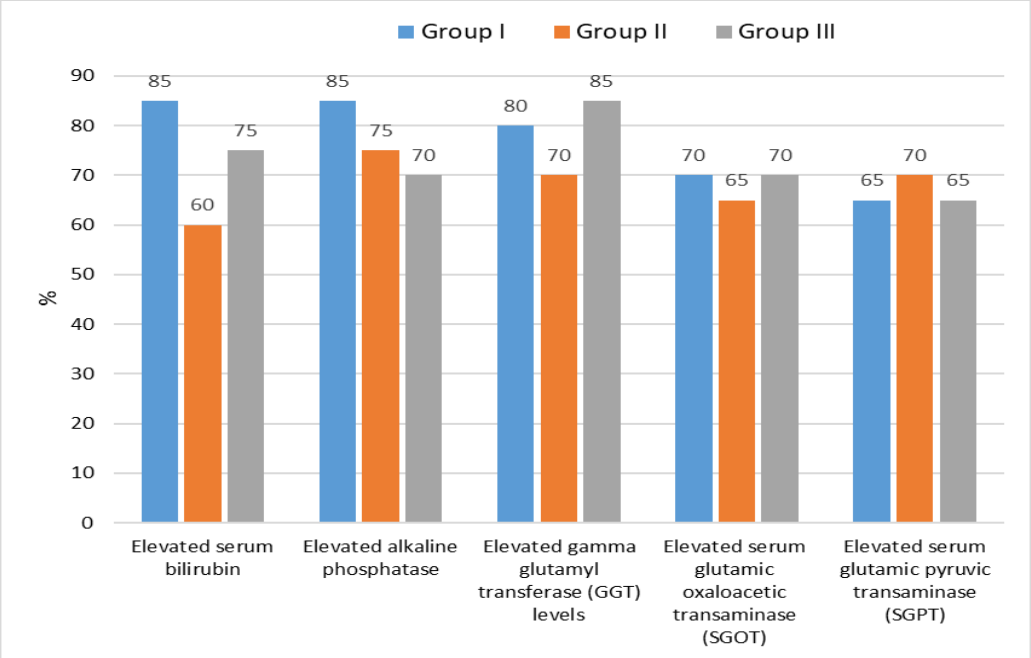

Figure (2): Laboratory results among studied groups.

Table (2): operation time and stone characters' distribution among the studied groups.

	Group I	Group II	Group III	Test	Within-group significance
Operative time/minutes	162.7±19.1	161.8±11.9	171.5±17.5	F=2.10 P=0.132	P1=0.86; P2=0.10; P3=0.068
Max. size of CBD stones (cm)	0.94±0.13	0.99±0.19	0.92±0.14	F=1.37 P=0.262	P1=0.23; P2=0.70; P3=0.12
Number of stones **Single CBD** **Multiple CBD stones**	 9(45.0) 11(55.0)	 7(35.0) 13(65.0)	 10(50.0) 10(50.0)	 χ2=0.950 p=0.622	 P1=0.52; P2=0.75; P3=0.34
Number of procedures per patient	1.45±0.69	1.35±0.49	1.45±0.69	F=0.169 P=0.845	P1=0.62; P2=1.0; P3=0.62

F: One Way ANOVA test, χ2=Chi-Square test, P1:difference between group I and II, P2:difference between group I & III, P3: difference between group II& III. p: probability; *Statistically significant (if p<0.05).

Table (3): Pain score, hospital stay, and patient satisfaction among studied groups.

	Group I	Group II	Group III	Test	Within-group significance
24 h pain score	5.55±0.60	5.55±0.83	5.85±0.81	F=0.88; P=0.418	P1=0.66; P2=0.20; P3=0.39
Hospital stay/days	3.80±0.59	3.75±0.72	4.10±0.55	F=1.65; P=0.201	P1=0.81; P2=0.16; P3=0.10
Patient satisfaction	5.95±0.89	5.25±1.33	5.70±0.98	F=1.39; P=0.256	P1=0.10; P2=0.45; P3=0.36

F: One Way ANOVA test, χ2=Chi-Square test, P1: difference between-group I and II, P2: difference between group I & III, P3: difference between group II& III. p: probability
*Statistically significant (if p<0.05).

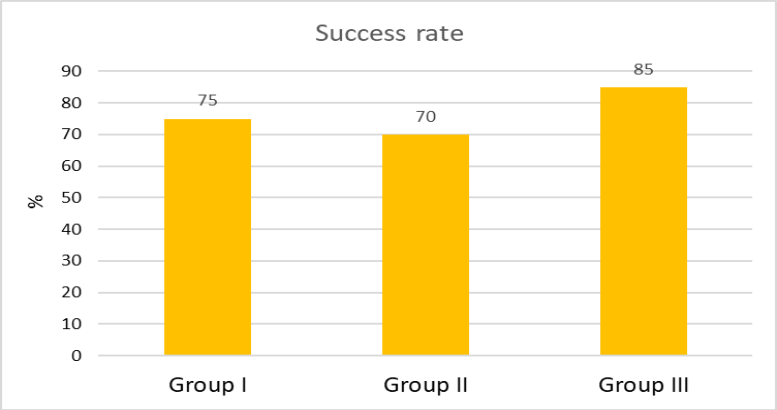

Figure (3): Success rate distribution among studied groups

Table (4): Mortality, morbidity, and complications among studied groups

	Group I	Group II	Group III	Test	Within-group significance
30 days mortality	1(5.0)	2(10.0)	0(0.0)	MC; P=0.349	P1=1.0; P2=1.0; P3=1.0
Morbidity	6(30.0)	1(5.0)	1(5.0)	MC; P=0.027*	P1=0.09; P2=0.09; P3=1.0
Failure of procedure	5(25.0)	6(30.0)	3(15.0)	χ2=1.304; P=0.521	P1=0.72; P2=0.42; P3=0.26
Retained stones	5(25.0)	6(30.0)	0(0.0)	χ2=6.90; P=0.032*	P1=0.07; P2=0.016*;P3=0.007*
Clearance rate	15(75.0)	14(70.0)	20(100.0)	χ2=6.90; P=0.032*	P1=0.07; P2=0.016*; P3=0.007*
Conversion to open	2(10.0)	1(5.0)	….	FET; P=1.0	
Complications	3(15.0)	2(10.0)	1(5.0)	MC; P=0.574	P1=1.0; P2=0.60; P3=1.0

MC: Monte Carlo test, FET: Fischer exact test χ2=Chi-Square test, P1: difference between-group I and II, P2: difference between group I and III, P3: the difference between group II& III. p: probability; *Statistically significant (if p<0.05)

DISCUSSION

The current work was designed to determine the most appropriate approach for patients with choledocholithiasis. Three interventional groups (each group had 20 patients) were assigned. The first group (intraoperative ERCP plus LC; the second group (LCBDE plus LC), and the third group (open surgery). Our patient's mean age was 45.75, 47.05, and 48.45 years among groups I, II, and III, respectively, with female sex predominance. The most common clinical presentation was right upper quadrant pain, and the least common was pancreatitis and no significant difference between groups. Redwan and Omar [9] conducted their study on 250 patients with choledocholithiasis and demonstrated that their ages ranged from 20 to 60 years (mean=40 years), with a slight female predominance. The main presentation was calcular obstructive jaundice (54.3%), biliary colic (14.3%), cholangitis (10%), or accidental discovery (21.5%).

The present study demonstrated that the mean operative time was (162.7, 161.75, and 171.45) in groups I, II, and III, respectively. There was no significant difference between groups, and also, studied groups were comparable regarding the mean maximum size of the common bile duct, the mean number of procedures per patient (1.45, 1.35 &1.45 respectively), and stone numbers. In harmony with the current study, Zhu *et al.* [10] and Lu J, *et al.* [11] demonstrated that the total operation durations were similar between two-stage (LC+ERCP) and single-stage (LC+LCBDE) management, with no statistically significant difference.

On the other hand, Redwan and Omar [9] demonstrated that the operative time was considerably reduced in the endoscopic group (20–45 min) and the open surgery group (60–180 min) versus the laparoscopic group (70–292 min); this was highly statistically significant differences (P=0.000). Besides, Bansal *et al.* [12] revealed that the mean operative time was significantly longer in LCBDE+LC compared to ERCP plus LC (135.7±36.6

vs. 72.4±27.6 min; p ≤ 0.001), but the overall hospital stay was significantly shorter (4.6±2.4 vs. 5.3±6.2 days; p = 0.03).

Such alterations among the current study and other researchers may be due to various hand skills, devices, patients' characteristics, and associated comorbidities. The current study revealed no statistically significant differences between studied groups regarding mean 24 hours' pain score, mean hospital stay duration, and mean patient satisfaction score. These results agree with Rogers *et a*l. [13] who demonstrated that hospital service and total charges for index hospitalization were likewise lower for LC+LCBDE than ERCP/S+LC, but the differences were not statistically significant. Besides, they reported that patient acceptance and quality of life scores were equivalent for both groups.

Similarly, Lu J, *et al*. [11], in their meta-analysis, revealed that the length of hospital stays, total operative time. Two-stage (LC + ERCP/EST) management clearly required more procedures per patient than single-stage (LC + LCBDE) management. On the contrary, Redwan and Omar [9] demonstrated that there were statistically significant differences as regards mean hospital stay duration (8, 1, and 3.2 for surgery, endoscopy, and laparoscopy, respectively) and subsequently return to work (16, 3.5, and 7.5 for surgery, endoscopy and laparoscopy respectively) (p<0.05).

It was suggested that single-stage management is advantageous, as it had a shorter hospital stay duration [11]. One probable explanation was the variations in hospital stay's definition, which had its impact on the validity of data. Some studies defined it as the duration between the last finished procedure and discharge, whereas others defined it as the entire duration from admission to discharge [11,13].

Regarding success rate, group III (85%) demonstrated a high success rate followed by group I (75%) then group II (70%) with no statistically significant differences. Similarly, Redwan and Omar [9] revealed that the success rate was (100%, 98% and 70% for surgery, endoscopy and laparoscopy, respectively) with no statistically significant differences (P=0.245).

Studied groups were comparable regarding mortality. However, there was a significantly higher frequency of morbidity among the group I than the other 2 groups (30% versus 5% for each group). The retained stones were higher in groups I and II (25%, 30%, respectively) with no retained stones among open surgery groups; two patients of group I and one patient of group II need conversion to open technique. There was no statistically significant difference between studied groups regarding complications frequency.

Redwan and Omar [9] revealed that there was no significant difference among the studied procedures as regards failure rate (zero, 2, 1 case in surgery, endoscopy, and laparoscopy respectively), mortality (zero in all groups), morbidity (15%, 9% and 10% for surgery, endoscopy, and laparoscopy respectively), while they were in disagreement with the current study in terms of retained stone and clearance rate as they there reported no significant differences among all the studied groups.

Besides, Gad *et al*. [14] found a significant correlation between open choledochoscopy and both higher stone clearance rate and lower missed stone rates; similarly, Ford *et al*. [15], Desai and Shokouhi [16], and Korontzi *et al*. [17] detected better stone clearance rate when open choledochoscopy was used where these rates ranged between 97% and 98% in their studies.

In the same line, Dasari *et al*. [18] demonstrated that there was no significant difference in the mortality between LC + LCBDE and ERCP +LC (0.7% vs. 1%). Besides, there was no significant difference in the morbidity between the two groups (15% vs. 13%). Moreover, they reported no significant difference between the two groups in the number of participants with retained stones (8% vs. 11%). Besides, there was no significant difference in the conversion rates of LCBDE to open surgery compared with pre-operative, intra-operative, and postoperative ERCP groups.

Similarly, Bansal *et al*. [12] demonstrated that laparoscopic CBD exploration and ERCP's success rates for clearance of CBD were similar (91.7 vs. 88.1 %). The overall success rate also was comparable: 88.1 % in group 1 and 79.8 % in group 2. The two groups did not differ significantly in postoperative wound infection rates or major complications.

Furthermore, a meta-analysis conducted by Lu J *et al*. [11] detected no statistically significant difference between the two groups in, postoperative morbidity (RR = 0.79, P = 0.16), mortality (RR = 2.19, 95% P = 0.42) and conversion to other procedures (RR = 1.21, P = 0.39), while they were in disagreement with the current study as regards stone clearance from the common bile duct (risk ratios (RR) = -0.10, 95%, P = 0.17).

Some studies showed that LCBDE is equal in efficacy and safety to preoperative ERCP+LC for subjects with CBD stones. However, stones were more frequent during ERCP+LC than LCBDE; this is probably because ERCP permits fluoroscopic and endoscopic recognition of small stones and sludge immediately cleared by the pushing action of the contrast during the antegrade cholangiography phase of LCBDE [13].

The difference in the current results between laparoscopic and endoscopic clearance rate, which was comparable in many studies, may be explained by using choledochoscope techniques alone for detection, extraction of CBD stones, and assessment of CBD clearance during laparoscopy versus cholangiogram that is used during ERCP. Therefore, an intraoperative cholangiogram is crucial in LCBDE and must be available to detect CBD stones and assure CBD clearance

during the procedure to guard against these pitfalls.

In conclusion, the current study demonstrated that the three studied groups (LCBDE+LC, ERCP plus LC, and open surgery) seemed to have comparable outcomes in terms of success rate, mortality rate, morbidity rate, failure rate, and complications, while clearance rate and retained stones after primary intervention showed significant improvement in open surgery group in comparison with the other groups.

Financial and Non-Financial Relationships and Activities of Interest: none

Authors contribution: All authors contributed equally in this work.

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The Scientific Journal of Medical Scholar

SJMS

Volume 1, Issue 4, July 2022

https://realpub.org/index.php/sjms

Online ISSN: 2833-3772