Management of Common Bile Duct Stones - A Single Center Experience

 Dr.Katheresan.V¹, MCh Resident
 Dr.Somasekar.R.D.R MCh², Assistant Professor
 Dr.Sathasivam.S MCh³, Assistant Professor
 Dr.Ponchidambaram.M MCh⁴, Associate Professor
 Dr.Kesavan.B MCh , Associate Professor
 Dr.Sivasankar.A MCh⁶ , DNB , HOD and Professor
 Drepartment of Surgical Gastroenterology, GMKMCH, Salem, TamilNadu Corresponding Author: Dr.Sivasankar A MCh,DNB, Department of Surgical Gastroenterology, GMKMCH, Salem, TamilNadu

Abstract

Introduction: Endoscopic retrograde cholangiopancreatography (ERCP) with consequent laparoscopic cholecystectomy (LC) has been the favoured approach for the treatment of choledocholithiasis for a long time; however recently, laparoscopic common bile duct exploration (LCBDE) has been offered to patients with choledocholithiasis. Objective and aim of this work is to compare the efficacy, safety, and the outcomes of LCBDE, OCBDE(Open common bile duct exploration) and ERCP followed by LC and evaluate the most suitable method for patients with choledocholithiasis.

Methods: A prospective clinical study was carried out in 75 patients with cholecystocholedocholithiasis who were divided into three groups: 40 patients who underwent ERCP followed by LC in two stages, 10 patients who underwent LCBDE with LC in one stage, and 25 patients who underwent OCDBE.

Results: All three groups were similar in pre-operative findings except for MRCP findings where < 8 mm of CBD diameter was seen only in ERCP group. Stones more than 10 mm size was more in other two groups than that of in ERCP group (15/40). But there was higher success rate in laparoscopic (90%) and open procedure (100%) in comparison with ERCP group. Complication is very minimal in single stage laparoscopic approach group (2/10) when compared with other two groups (8/40 in ERCP and 7/25 in open group).

Conclusions: Although every approaches have its own advantage and disadvantages, LCBDE is better in terms of fewer procedures, better success rate and lesser complications compared with ERCP + LC and OCBDE in selected group of patients.

Keywords: Bile duct stones, Endoscopic retrograde cholangiopancreatography, Laparoscopic common bile duct exploration, Laparoscopic cholecystectomy

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I. Introduction:

Gall stone disease affects people all over the world irrespective of their gender, ethnicity or age. More than 95% of biliary tract disorders are related to gallstone¹. Most bile duct stones are stones that have originated from the gallbladder. Stones are non-crumbling compactions more than 2mm in diameter and biliary microlithiasis are particles 2mm or less in diameter even though there is no globally accepted definition². Sludge is holdup of cholesterol monohydrate crystals, calcium bilurubinate granules, and or other calcium salts with or without microlithiasis of gall bladder mucus. Sludge is a form of gall stone disease and may influence to macroscopic stones or directly cause pancreatitis and other illness. In spite of presence of good surgical procedures, about 8% to 16% of patients have retained stones in common bile duct following conventional choledocholithotomy ^{3, 4}. Common bile duct stone is defined as retained if they are discovered within two years of surgery or recurrence if they are detected more than two years after surgery.⁵

Cholelithiasis is a common surgical condition which makes cholecystectomy one of the most often executed surgical method. CBD stones thwart the working and management of cholelithiasis requiring supplementary diagnostic and therapeutic methods and add to outcome of gall stone disease. Common bile duct stones are present in approximately 5% of the patients undergoing elective cholecystectomy and 10% of patients with acute cholecystitis. Intraoperative cholangiography / choledochoscopy are gold standards for diagnosis, but

CBD stones can be diagnosed preoperatively with ultrasound or MRCP. If CBD stones are detected preoperatively, numerous diverse treatment modes can be employed. The aspects that govern the optimal method include the patient's age and general condition. It is also significant to contemplate the local proficiency of the Surgeon and the gastroenterologist in managing CBD stones. Hence the procedure for dealing these patients will differ from one setting to another. There are specific indications that mandate CBD exploration and therefore, the practicing surgeon must be well versed in these techniques. Although the stones in the CBD may be quiet and asymptomatic sometimes, the development of symptoms is potentially serious; obstructive jaundice, ascending cholangitis, acute pancreatitis are all linked with grave morbidity and at times, mortality which need instantaneous care.

Management of symptomatic or suddenly found choledocholithiasis is still uncertain. There is no evident on the best restorative approach (endoscopic versus surgical)⁶.

Laparoscopic common bile duct exploration (LCBDE) was existing more than 15 years back and different surgical conferences have established that it has a high success rate and is similarly as prolific and protected as preoperative or postoperative ERCP related with laparoscopic cholecystectomy (LC), in this way avoiding the need to conduct extra methods^{7, 8}. After LCBDE, primary closure or T-tube drainage will be connected by the state of CBD and experience of surgeon. In 1991, Phillip initially announced the procedure of LCBDE and T-tube drainage in treatment of CBD calculi .⁹ In recent years, there have been many articles published about the efficacy and safety of LCBDE compared with ERCP.^{10,11}

Hence this study is intended to evaluate the safety and efficacy of techniques used to manage the gallstone disease with biliary duct calculi and comparing the procedure related complications. This study was planned with primary outcome as success rate in terms of complete CBD clearance and secondary outcome as procedure related complication and post operative outcomes.

II. Methods

This prospective clinical study was carried out in Department of surgical gastroenterology, Government Mohan Kumaramangalam Medical College from January 2018 to December 2020. It included 75 patients with the study population consists of patients admitted in the SGE/MGE ward diagnosed with radiologically proven gallstone disease with biliary duct calculi who were divided into three groups:

• Group A: preoperative endoscopic retrograde cholangio pancreatography (PreERCP) f/b laparoscopic cholecystectomy (LC) - two stage procedure.

- Group B: LC with laparoscopic common bile duct exploration (LCDBE) single stage procedure.
 - Group C: Open cholecystectomy with common bile duct exploration- single stage procedure.

The study was approved by the local ethics committee. A written consent form was obtained from all patients after detailed explanation of the procedures and its possible complications. The main inclusion criteria were patients of > 18 years of age group irrespective of LFT values, radiologically documented proven gallstones and biliary duct calculi and hemodynamically stable patients. The main exclusion criteria were hemodynamically unstable patients with features of cholangitis & severe acute biliary pancreatitis and patients of age < 18 years.

All patients of our study were evaluated clinically before the operation and underwent standard laboratory investigations, as well as radiological study, including abdominal ultrasonography. MRCP was done in all patients.

Statistical analysis:

Collected data from our study were tabulated. Quantitative data were expressed by the mean± standard deviation and qualitative data were expressed as number and percent (%). T-student test or ANOVA was used to compare numerical data and Chi- square test or Kruskal wallis test was used to compare qualitative data, and P value was considered to be significant if it was <0.05.

III. Results

During the study period, from January 2018 through December 2020, a total of 75 patients were randomized for the treatment of CBD stones. Patients were randomized in to PRE- ERCP+LC (Group A) 40 patients, LCBDE (group B) 10 Patients and OCBDE (group C) 25 patients.

Characteristic	PRE- ERCP/LC(40)	LCDBE(10)	OCBDE(25)	P value
Age in years.	52.63±16.86	50.53±14.64	51.52±14.79	0.944
Males Females	18(45%) 22(55%)	5(50%) 5 (50%)	15(60%) 10(40%)	0.499

This study was carried out on 75 patients, 38 males (50.6%) and 37 females (49.4%). Their ages ranged between 28 and 84 years with a mean age of 52.63 years in group (A), 50.53 years in group (B) and 51.52 in group (C). The most common clinical presentations in patients of this study are shown in Table (2). In all patients, the main presenting complaint was biliary colic followed by jaundice.

PRESENTING COMPLAINTS	PRE-ERCP/LC(40)	LCDBE(10)	OCBDE(25)	P value
Biliary colic	25	6	17	0.86
Jaundice	13	5	10	0.06
Pruritus	10	3	7	0.651
Fever	16	2	5	0.172
Vomiting	0	0	0	NA
Cholangitis	5	0	3	0.501
Pancreatitis	0	1	1	0.188

Table 2: Shows the clinical	presentations of studied	patients.
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There was disturbance in liver functions in most of cases, elevated serum bilirubin level was detected in most of the patients (60.0%). Laboratory investigations showed no significant difference among the three groups regarding total serum ALT, AST, ALP whereas total bilirubin was bit higher in Laparoscopy group(11.23 ± 11.05), though it was elevated in the 3 groups with no significant difference among them, the same was noted regarding levels of ALT and AST. ALP levels were also similar in all three groups. But it was obvious that liver parameters are deranged in all three groups. The results were shown in Table (3).

Table 5. Eaboratory and Wilker data among groups prior to procedure				
Characteristic	PRE-ERCP/LC(40)	LCDBE(10)	OCDBE(25)	P value
ALT (Mean, IU/l)	103.95±102.81	85.9±69.73	96.04 ± 75.32	0.256
AST (Mean, IU/l)	96.52±89.86	80.30±45.54	70.72±56.82	0.162
Total bilirubin (Mean, mg/dl)	5.02±4.39	11.23±11.05	5.15±4.62	0.008
ALP	296.7±156.70	325.3±170.76	327.6±168.96	0.617
MRCP Findings				
CBD diameter:≤8mm CBD diameter:>8mm	8 (20%) 32 (80%)	0 10(100%)	0 25 (100%)	0.01
Largest stone diameter: (Mean) >10mm ≤10mm	15(37.5%) 25(62.5%)	9(90%) 1(10%)	18(72%) 7(28%)	0.016
Stone number: SINGLE MULTIPLE	35 (87.5%) 5(12.5%)	4(40%) 6(60%)	12(48%) 13 (52%)	0.001

Table 3: Laboratory and MRCP data among groups prior to procedure

MRCP revealed dilated CBD in most of the included patients while 8 (20%) of patients in ERCP group had CBD diameter less than 8 mm. In both the other single stage groups (open and laproscopic), all the patients had CBD diameter more than 8 mm.

The largest stone diameter was exceeding 10mm in (33/75; 44%) with no significant difference among the three groups. Multiple stones were detected in totally 24 out of 75 patients (32%) but with no significant difference among the three groups.

In Group (A), the procedures were completed in 32cases (80%). Eight cases of 40 (20%) were converted to open CBD exploration and stone extraction followed by T-tube and drain insertion. The T-tube was removed after 14 days following T-tube cholangiography, and the drain was removed. The reasons for conversion were deformed duodenum (two patients), impacted stone (two patient), periampullary diverticulum with failed cannulation (two patients) and benign CBD stricture (two patients). In group B one patient converted from Lap to open CBD exploration due to adhesions.

Table 4: Success rate				
PROCEDURE	PRE-ERCP/LC(40)	LCDBE(10)	OCDBE(25)	P value
SUCCESS	32(80%)	9(90%)	25(100%)	0.001
FAILURE	8 (20%)	1	0	0.001

Post procedure complications were recorded. Regarding wound infection 6 patients had wound infection in OCBDE group and three patients had fever in same group, while vomiting and bile leak was seen only in LCDBE group in single patient. Bleeding was recorded in one patient in the ERCP group and no patients

P value PRE-ERCP/LC(40) LCDBE(10) OCBDE(25) Variable No(%) No(%) No(%) Pancreatitis 5(12.5%) 0 0 0.006 0.454 1(2.5%) Perforation 0 0 1(2.5%) 0.454 Bleeding 0 0 0.454 1(2.5%) Cholangitis 0 0 0.013 Wound infection 0 0 6(24%) 0.153 Fever 0 0 3(12%) Bile leak 0 1(10%)0 0.454 Vomiting 0 1(10%) 1(4%) 0.108

 Table 5: Complications in various procedures

in the other 2 groups had bleeding. Pancreatitis was seen in 5 patients in ERCP group. No significant difference

was noted among the three groups regarding other complications

During the first 24h after surgery, the pain score was lower in group B (4.9 ± 1.9) than in group A and C (5.6 \pm 2.4and 6.7 \pm 2.5) with a p value of 0.023. The hospital stay for patients of group B (4.3 \pm 2.4 days) was significantly shorter compared with group A and C $(5.2\pm3.1 \text{ and } 6.4\pm4.3 \text{ days})$ with p value of 0.04. Patient satisfaction score was measured on a verbal rating scale of 0-3 at 1 month after surgery. Patients in group B had higher satisfaction scores (2.42 ± 0.3) compared with patients in group A and C (2.01 ± 0.4) and 1.70 ± 0.9 ; P=0.006).

IV. Discussion

Bile duct stones are found in 7–20% of patients with symptomatic gallstones. The nearness of common bile duct stones essentially increases the morbidity, mortality, and expenses of patients with gallstones.¹²The management of CBD stones has experienced different phases of advancement and development, and LCBDE is currently viewed as a better procedure compared with endoscopic extraction of stones, with comparable morbidity and a shorter hospital stay in fit patients.¹³ The major objective of treatment in choledocholithiasis is to accomplish ductal clearance with the least number of interventions, most minimal expense and least morbidity.¹⁴ Conventional surgical treatment involves intraoperative cholangiography to identify the presence of bile duct calculi pursued by choledocholithotomy and T-tube placement. For a long time this strategy offered successful treatment.

Although ERCP is effective and safe, this management option has several disadvantages, including a large number of normal ERCP's performed, up to 86% when ERCP is performed routinely for all patients and division of the choledochal sphincter in young adults, leading to loss of the normal physiologic barrier, with long term complications such as ampullary stenosis, duodenobiliary reflux, and recurrent stone formation.¹

It was reported that one stage operations have some benefits, as compared to two stage operations. Morbidity after one-stage operations was only 7.5% (2 times lower). The reported results of LCBDE when compared to data obtained after the two-stage procedure, show at least identical, rather improved safety for the patient and partial reduction of costs.¹⁶ Postponing laparoscopic cholecystectomy post ERCP makes it difficult to be performed due to the possibility of adhesions at the area of Calot triangle, this is in additional risk of second time anaesthesia.

The success rate for LCBDE in our study was 90%, which was comparable to that reported in the existing literatures (80–98.5%). Similar study carried out by Hong DF et al. denoted success rate of 80% ¹⁷.In other studies success rate of 80% to 95% were reported.¹⁸

Our study showed similar success rates for the single- stage and two-stage procedures (100% vs. 80%), but the single-stage procedure was better in terms of a less number of procedures and higher patient satisfaction compared with two-stage management. This is consistent with previous research reports.

One meta-analysis of eight RCTs showed that LCBDE+LC was associated with a higher rate of CBD stone clearance than pre-ERCP+LC (90.17% vs. 85.71%, respectively.²⁰ However, a study conducted by Elgeidie et al showed that pre-ERCP+LC was associated with a higher success rate of CBD stone clearance.²¹ Our study has shown results similar to the meta analysis.

There were eight patients with retained common bile duct stones in group A- (Pre ERCP) (20%). This was in contrary to 12% of studied patients in the study carried out by Stanley et al.²⁷ Failure of procedure was due to multiple reason like failed cannulation or failed extraction or other reasons. In the study by Ding et al, the authors reported that LCBDE+LC had a lower recurrencerate.^{22.}

In our study T-tube drainage was done for all cases who underwent single stage LCDBE and OCBDE. In our study ERCP was successful for 32 of 40 patients (80%). Failed attempt for complete clearance of the CBD was seen in 8 patients who were converted into OCBDE (20%). LCBDE was completed for 9 of 10 patients (90%), and converted to OCBDE in one case (10%) due to adhesions. However other studies denoted

that the overall success rate of ERCP+LC in experienced hands is well established at about 95%.

Our study showed no significant difference between three groups regarding postoperative complications. Except for pancreatitis (N=5) in ERCP group and wound infection (n=6) in open cholecystectomy group. The complication rates in the literature have not differed significantly between the two strategies. A meta-analysis found the morbidity rates to be 19% in the single-stage group and 15.2% in the two-stage group, and the difference was not statisticallysignificant.²³There was minor or no complication in LCDBE group.

The study also showed similar success rates for the single-stage and two-stage procedures, but the single-stage laparoscopic procedure was better in terms of a shorter hospital stay and higher patient satisfaction.

V. Conclusion

Although all treatment methods have equivalent or nearby success rates, the one-stage management is better in terms of fewer procedures, and better overall satisfaction compared with the two-stage approach. In addition, the one-stage laparoscopic approach also avoided the complication associated with ERCP and sphincterotomy and kept the sphincter of Oddi intact. Hence, the outcomes of this study suggest that the one-stage laparoscopic management is the treatment of choice for patients with concomitant GB and CBD stones, especially in younger patients who have longer period of risk for recurrence of CBDstones.

To conclude patient present with < 8mm CBD diameter, smaller stones with few in numbers and distal CBD stones ERCP followed by LC is the preferred choice. Minimally invasive single stage LCBDE is preferred in > 8mm in CBD diameter, larger stones and proximal CBD stones. Even though OCBE has higher success rate, salvageable procedure in ERCP followed by LC and LCBDE failure patients.

LIMITATION OF THE STUDY

Although in this study LCBDE Is better than other therapeutic intervention, but the sample size (n=10) is not adequate to establish a strong acceptance. Further studies with large sample size or multi-center studies are required.

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