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Laparoscopic common bile duct exploration versus ERCP/ stenting and cholecystectomy: Is a single staged procedure better?

Raju Kadam, Dhananjay Saxena, Arun Singh Rana, Sanjeev Chhabra, Zeeshan Ahmed, Vikesh Vij, Jeevan Kankaria, Raj Kamal Jenaw

ABSTRACT

Aims: Choledocholithiasis is most common cause of obstructive jaundice. Laparoscopic choledocholithotomy has evolved as an alternative procedure to ERCP/ stenting in the management of choledocholithiasis. This study was aimed to compare the outcomes of laparoscopic CBD exploration with cholecystectomy (group 1) as compared to the conventional two staged procedure involving ERCP/ stenting (group 2). Methods: 60 patients admitted to our department (mean age = 45.52, SD = 17.71, 15 males, 45 females) for the management of choledocholithiasis from April 2014 to October 2015 were included in the study. We reviewed retrospectively the patients' data including age, sex, duration of the surgery, intra-operative and postoperative complications, duration of hospital stay, mortality and condition on follow-up. Results: Group 1 included 30 patients (mean age 50.76, 21 females, 9 males). The average operative time in this group was 110 minutes (96–145), stone clearance rate was 100%, and average hospital stay was 3.2 days (2–9). Group 2 also included 30 patients (mean age 44.36, 24 females, 6 males) with stone clearance rate of 70% (21 out of 30), average operative time 120.7 minutes (90–167), average hospital stay 9.1 (3–30) days and an average of 2.3 procedures per patient. Conclusion: In our study mean operative time, stone clearance rate, average hospital stay and average number of procedures per patient were found to be significantly lower in laparoscopic CBD exploration group. It can be concluded that laparoscopic CBD exploration with cholecystectomy is much safer and cost effective than the conventional two staged procedure involving ERCP/ stenting.

Keywords: Cholangiopancreatography, Choledocholithiasis, Common bile duct, Endoscopic Retrograde, Laparoscopic, Outcomes

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INTRODUCTION

Common bile duct (CBD) stones are the most common cause of obstructive jaundice and cholangitis. Primary CBD stones are rare, comprising about 15% of the cases, rest being secondary [1]. About 10–18% of patients with gallbladder stones will have CBD stones at the time of cholecystectomy [2, 3].

The diagnosis of choledocholithiasis can be preoperative, intraoperative or postoperative [2].

Transabdominal ultrasonography (sensitivity 20–80%), MRCP (sensitivity 81–100%, specificity 92–100%), ERCP/ EUS (sensitivity 88–97%, specificity 96–100%) are the primary imaging modalities that can detect CBD stones besides showing dilated biliary ductal system. Other imaging modalities available are intra-operative laparoscopic ultrasonography and helical CT cholangiography [4–6].

Management strategy of common duct stones involves either endoscopic common duct clearance followed by removal of the gallbladder surgically or surgical exploration and clearance of the CBD. Surgical exploration can be done by open choledocholithotomy or laparoscopically.

Laparoscopic choledocholithotomy has now evolved as an alternative procedure to circumvent the problems associated with ERCP/S in the management of choledocholithiasis [7].

Laparoscopic CBD exploration with laparoscopic cholecystectomy has been shown to be successful in 85% of patients and the results are comparable to those of endoscopic removal of CBD stones [8].

The aims and objectives of the study were to assess and compare the treatment outcomes of Laparoscopic CBD exploration with cholecystectomy as compared to ERCP/S + Laparoscopic Cholecystectomy for management of CBD stones.

MATERIALS AND METHODS

The present study was done on patients admitted for management of choledocholithiasis in surgery department SMS hospital in the year 2014–15. 60 patients of adult age group (>18 years) and either sex were divided into two groups of 30 patients each by single stage randomisation using pot chit method. Group 1 (mean age 50.76 years; 21 females and 9 males) underwent laparoscopic CBD exploration with cholecystectomy while group 2 (mean age 44.36 years; 26 females and 6 males) underwent endoscopic clearance of CBD followed by laparoscopic cholecystectomy.

Patients with radiological evidence of large stones [> 2cm], history of bleeding disorders, USG or CT evidence of intrahepatic gallbladder, liver mass or abscess or periampullary neoplasm, clinical or USG evidence of suppurative or necrotizing cholecystitis, gallbladder empyema, or perforation, multiple prior laparotomies, morbid obesity, pregnancy, severe systemic organ dysfunction (chronic liver, renal or heart diseases), HIV positive and those immunosuppressed were excluded from the study.

All the patients underwent transabdominal sonography or MRCP or CT scan for the confirmation of CBD stones. The patients presenting with cholelithiasis and confirmed choledocholithiasis underwent clinical and laboratory workup which comprised for complete hemogram, liver, pancreatic and renal function tests.

We reviewed retrospectively the patients' data including age, sex, duration of the surgery, conversion to open procedure and its reasons, intra-operative and postoperative complications, duration of hospital stay and condition on follow up visits. Duration of surgery was calculated from the time of insertion of first port to the time of cutting of last stitch after port site closure. Postoperative complications analyzed included bile leak / fistula, perforation, bleeding, wound infection, acute cholangitis and acute pancreatitis. Length of hospital stay was calculated in number of days patient had to spend in the hospital following the first intervention till the discharge. Follow-up was done at second week, 1st, 3rd and 6th.

Laparoscopic CBD exploration (Figure 1) was done using the standard four port method. After dissection around Calot's triangle and clipping of the cystic artery and duct, choledochotomy was made in the supraduodenal part using harmonic scalpel or unipolar cautery hook. Stones were expressed out by gentle milking of the common duct and using a dormia basket followed by flushing of the entire ductal system with copious amounts of normal saline. Ductal clearance was confirmed using a flexible choledochoscope inserted through the epigastric port. After ensuring CBD clearance, T-tube was then inserted via mid clavicular port into the CBD through the choledochotomy site. Choledochotomy was closed using absorbable suture (3-0 vicryl) sutures followed by completion of cholecystectomy and drain placement.

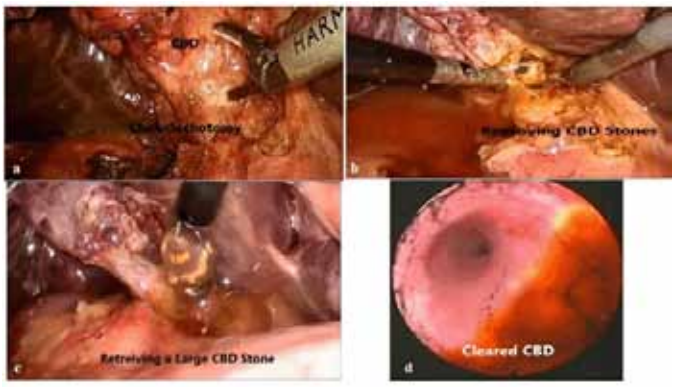

Figure 1: (a) Performance of choledochotomy using harmonic scalpel, (b, c) Retrieval of common bile duct stones using a dormia basket, and (d) Confirmation of common bile duct clearance by choledochoscopy.

For the control group, endoscopic management of CBD stones was performed under intravenous sedation using a side viewing endoscope (TGF 160). After visualizing the papilla, cannulation was done using a sphincterotome, followed by retrograde cholangiography, sphincterotomy and stone extraction using either a basket or by ballooning. In case of large stones, mechanical lithotripter was used to crush the stones before removal. After stone extraction, a check cholangiogram was performed to look for residual stones. Temporary stenting of the common bile duct was done if the stone clearance was incomplete. If there were no signs of complications, all patients underwent laparoscopic cholecystectomy after 48 hours but within four weeks of the endoscopic clearance.

All patients received similar parenteral antibiotics on postoperative day-0 with oral intake allowed on same evening and switched over to oral medications on post-operative day-1. Abdominal drains were removed when the output was <20 ml / 24 hours. All patients in group 1 were discharged with t-tube in situ. Follow up USG scans of abdomen were done in both groups to document stone clearance at 2 weeks and t-tube cholangiography in group 1 patients. The t-tube was removed if the cholangiogram was normal.

Success was defined by removal of CBD stones and gallbladder by the intended approach in both the groups.

RESULTS

Group I included 21 females and 9 males (mean age 50.76 years, range 22–109). The mean total bilirubin was 3.06 mg/dl, mean AST/ALT 83.4/70.1 IU/L respectively and the mean alkaline phosphatase was 590 IU/L. Among 30 patients 15 had single CBD stones (6 in the mid CBD and 9 in the distal CBD) and the remaining 15 patients had multiple CBD stones. Patients with stones of size >2 cm were excluded from the study. Laparoscopic CBD exploration was successful in all 30 patients with no conversion rate. The mean operative time was 110 minutes (range 96–145 minutes). The operative time decreased as the study progressed. None of the patients had residual stones on post-operative T-tube cholangiogram with a 100% stone clearance rate. Two patients (6.7%) developed minimal bile leak which subsided in 3–5 days with no requirement of any active intervention, one patient had epigastric port site infection and other minor symptoms like fever, vomiting complained by few patients. None of the patients developed pancreatitis, cholangitis or perforation. The average hospital stay was 3.2 (2–9) days. The average number of procedures per patient was 1.

Group II included 24 females and 6 males (mean age 44.36 years, range 22-87). The mean total bilirubin was 3.61 mg/dL, mean AST/ALT 88.5/73.3 IU/L respectively and mean alkaline phosphatase was 635 IU/L. Among 30 patients 13 had single CBD stones (3 in the proximal CBD, 3 in the mid CBD, 6 in the lower CBD and 1 impacted at cystic duct & CBD junction.) and the remaining 17 patients had multiple CBD stones. Endoscopic sphincterotomy with common bile duct clearance could be done in 21 out of 30 patients with a success rate of 70%. Fourteen patients required stenting of the CBD due to doubt in stone clearance and to relieve the jaundice. Following ERCP, laparoscopic cholecystectomy was successfully completed in 22 out of 30 patients. 9 out of 30 patients had failure in clearing the CBD stones by endoscopy. Two patients were subjected to repeat ERCP, out of which 1 succeeded to clear the stones and underwent laparoscopic cholecystectomy. Five patients were subjected to laparoscopic CBD exploration with stent removal and T-tube placement. Two patients were subjected to open CBD exploration with stent removal and T Tube placement. The mean operative time was 120.7 minutes (range 90–167 minutes). A total of 69 procedures were done on 30 patients with a mean of 2.3 procedures per patient. 5 patients developed pancreatitis (16.7%), two patients developed cholangitis (6.7%), 1 patient developed minimal bile leak after and 1 patient had epigastric port site infection. One patient had developed a life-threatening duodenal perforation and bleeding, while performing ERCP. Exploratory laparotomy with repair of duodenal perforation and cholecystectomy was performed soon after the confirmation of diagnosis but the patient could not survive due to irreversible shock. The average hospital stay was 9.1 (3–30) days. The average number of procedures per patient was 2.3.

There were no intraoperative complications in both study groups.

Chi square test (with Yates' correction) and *t*-test were used for statistical analysis of means for comparison of data between the two groups. The *p*-value of < 0.05 was taken as significant.

The results (Table 1) showed that there were significant differences between success rates of intended modality for CBD clearance. Group I (laparoscopic CBD exploration) was found to have 30% higher success rate (*p*-value 0.0038, highly significant; chi square test) than group II (ERCP/S).

The time taken for surgery was significantly less (*p*-value 0.019, t test) in group I (laparoscopic CBD exploration) as compared to the other group.

The t-test showed significant difference in number of procedures per patient (*p*-value <0.0001, very highly significant) with group II having 2.3 procedures per patient on an average as compared to group I (single procedure per patient).

When the development of complications were compared after the initial procedure for clearance of CBD, there were significant differences in the development of acute pancreatitis (*p*-value 0.0261, chi square test) with five patients in group II (ERCP/S) developing pancreatitis as compared to none in group I. Rest of the complication rates were similar in both groups.

The average hospital stay was significantly less in Laparoscopic CBD exploration group (*p*-value <0.001, *t*-test) as compared to group II (ERCP/S followed by laparoscopic cholecystectomy).

Table 1: Results

	Group I LCBDE	Group II ERCP/S followed by LC	p-value
CBD clearance rate	100% (all 30)	70% (21 out of 30)	0.0038*
Average time taken for surgery (min.)	110 (96–145)	120.7 (90–167)	0.019@
Average no. of procedures per patient	1	2.3	<0.0001@
Hospital stay (mean, no. of days)	3.2 (2-9)	9.1 (3–30)	<0.001@

* - chi square test
@ - *t*-test

No statistically significant differences were detected between the two groups in terms of age and sex distribution, preoperative biochemical profile and number of stones present in the CBD.

DISCUSSION

The current protocol at our institution for patients with gallstone disease and CBD consists of endoscopic CBD clearance followed by laparoscopic cholecystectomy (LC). Following the advent of techniques of laparoscopic ductal stone clearance, an alternative single-stage laparoscopic treatment was introduced for these patients [8]. The introduction of laparoscopic approach for choledocholithiasis worsened dilemma between choosing endoscopic approach and laparoscopy [9]. There are many randomized controlled trials, comparing preoperative endoscopic stone extraction followed by laparoscopic cholecystectomy with laparoscopic CBD exploration for choledocholithiasis.

Patients with confirmed common bile duct stones on either MRCP and/or endoscopic ultrasound were randomized to ERCP/S followed by laparoscopic cholecystectomy and single stage laparoscopic CBD exploration with cholecystectomy in both treatment arms. In our study, we did not perform intraoperative cholangiogram. Instead of intraoperative cholangiogram, we used choledochoscopy to check successful clearance and sometimes a basket extraction of adherent CBD stone.

The time interval between the ERCP and laparoscopic cholecystectomy is controversial. In EAES multicentric trial, the interval between ERCP and laparoscopic cholecystectomy was not specified [8]. In a trial by Sgourakis et al., laparoscopic cholecystectomy was performed within two days of endoscopic stone extraction [10]. Vries et al. have shown higher conversion rate, when the cholecystectomy was done after two weeks of ERCP [11]. Conversion rate was 4% when cholecystectomy was done within two weeks, 31% between two and six weeks and 16% after 6 weeks. In our study, we performed laparoscopic cholecystectomy as soon as possible in post-ERCP patients except in patients who developed ERCP induced complications like pancreatitis and cholangitis where the surgery done after 2–3 weeks. Although the number of patients was small in the present study but the trend did not show increased conversion rate in this study.

Both transcystic approach and direct choledochotomy methods were used in EAES [8] and Sgourakis trials [10]. In our study, CBD exploration was done by standard conventional choledochotomy incision with a cold knife due to large stone load. A vertical incision was made over CBD in the supra duodenal area for stone extraction. The CBD was closed over a T-tube and cholangiogram was done between post-operative day 14 and T-tube was removed after confirming the CBD clearance. Paganini et al., in a case series of 329 patients, performed transverse choledochotomy in 138 patients and proved its safety and efficacy with a long term follow up of 72 months [12].

In EAES trial T-tube was used in all patients [8]. There is an increasing trend towards primary closure of common bile duct. Decker et al. in a case series of 100 patients showed that primary closure of common bile duct is safe and precludes the need for T-tube in all cases [13]. Kim et al. used ante grade biliary stenting using modified biliary stents for biliary decompression as alternative to T-tube [14]. These modified biliary stents pass through gastrointestinal tract, but in few patients endoscopic removal may be required.

Martin et al. in 2006 reported a meta-analysis of 8 trials of 760 patients comparing open cholecystectomy + CBD exploration with preoperative ERCP/S +LC and found that ERCP/S was less successful than the open surgery in CBD stone clearance (odds ratio 2.89; 95% confidence interval) [2].

The overall success rate of ERCP in experienced hands is well established at about 95%. However, the minimum number of ERCP procedures necessary for competency has been suggested by Jowell et al. [15] and Vitale et al. [16] to be between 102 and 185 procedures to achieve a success rate of 85% to 90%. In our study, stone clearance by ERCP/S was 70%. There is, of course a possibility of type II error in our study due to small sample size.

Laparoscopic CBD exploration has developed over the last two decades as a means of dealing with CBD stones. In a retrospective review by Paganini and Lezoche of 284

patients undergoing LCBDE, an overall success rate of 94.6% was reported [17]. Stanley et al. in a prospective randomized study of 122 patients showed a stone clearance by LCBDE of 88% and ERCP/S clearance of 98% [18]. Sgourakis and Karaliotas [10] published in 2002 a randomized trial of ERCP/S+LC (n = 36) versys LCBDE+LC (n = 42). Stone clearance was equivalent between the groups 86% versus 84%. Bora Koc et al., in a prospective randomized study of 122 patients categorized into two groups: LCBDE+LC versus ERCP/S+LC found that the success rate of LCBDE+LC group (96.5%) was higher than for the ERCP/S+LC group (94.4%) [19]. In our study, the success rate of LCBDE for stone clearance (100%) was higher compared to ERCP/S+LC group (70%).

The mean operative time was 110 minutes (96–145) in our study for laparoscopic group. But none of the randomized trial calculated the operative time. The operative time was comparable with most of the case series reported (Shuchleib et al. 120-260 minutes, Petelin et al. 157.7 minutes and Rai et al. 128+/-32minutes) [20–22].

Heili et al. in a retrospective review, compared patients who underwent ERCP+LC with single staged LCBDE [23]. They reported a significant reduction in the length of hospital stay and overall morbidity in patients receiving single staged LCBDE group compared to ERCP+LC group. The most common complication for LCBDE was bile leak caused by retained stones. In a study by Riciardi et al., the overall morbidity for this approach was approximately 9.5%, with a 2.7% retained stone rate. In our study the bile leak rate was 6.7% with no retained stones [24]. Studies by Bora koc et al. reported complication rates of the LCBDE+LC and ERCP/S+LC groups as 7% and 11% respectively (In LCBDE bile leak rate 3.5% and in ERCP/S+LC pancreatitis 3.7%, duodenal perforation 1.8%). In our study, we observed less morbidity in LCBDE+LC group compared to ERCP/S+LC group (in LCBDE bile leak 6.7% and in ERCP/S+LC pancreatitis 16.7%, cholangitis 6.7% and duodenal perforation 3.3%).

Patients who had undergone single staged LCBDE+LC had a shorter hospital stay compared to patients who undergone two staged ERCP/S+LC (average 3.2 days vs. 9 days) and lesser number of procedures per patient (1 for LCBDE versus 2.3 for ERCP/S+LC).

CONCLUSION

Keeping in view the reduced morbidity, better stone clearance, lesser hospital stay, lesser number of procedures per patient, reduced time taken for surgery and reduced rates of complications, it can be concluded that a single staged laparoscopic common bile duct (CBD) exploration with cholecystectomy is much safer and cost effective than the conventional Endoscopic Retrograde Cholangiopancreatography followed by laparoscopic cholecystectomy for the management of choledocholithiasis. As surgical skills with laparoscopic CBD exploration improve, the need for routine ERCP will likely decrease, except in unique high risk situations like cholangitis and biliary pancreatitis.

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Author Contributions

Raju Kadam – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Revising it critically for important intellectual content, Final approval of the version to be published
Dhananjay Saxena – Substantial contributions to conception and design, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published
Rana Arun Singh – Acquisition of data, Analysis and interpretation of data, Drafting the article, Final approval of the version to be published
Sanjeev Chhabra – Acquisition of data, Drafting the article, Final approval of the version to be published
Zeeshan Ahmed – Acquisition of data, Analysis and interpretation of data, Critical revision of the article, Final approval of the version to be published
Vikesh Vij – Acquisition of data, Drafting the article, Final approval of the version to be published
Jeevan Kankaria – Substantial contributions to conception and design, Acquisition of data, Revising it critically for important intellectual content, Final approval of the version to be published
Raj Kamal Jenaw – Substantial contributions to conception and design, Acquisition of data, Revising it critically for important intellectual content, Final approval of the version to be published

Guarantor

The corresponding author is the guarantor of submission.

Conflict of Interest

Authors declare no conflict of interest.

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