International Journal of Health Research and Medico-Legal Practice

RESEARCH PAPER

Learning curve experience in laparoscopic common bile duct exploration for concomitant cholelithiasis and choledocholithiasis

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Received: October, 2021
Editorial approval on: October 16, 2021
Revised on: June 30, 2021
Checked for plagiarism: Yes
Peer Review: Double-blinded
Peer review comments: 4

Background and aims: *Laparoscopic common bile duct exploration offers several advantages over endoscopic stone clearance for common bile duct stones with gall stones. However, lack of expertise and a learning curve has often been deterrents to widespread application. This study presents our initial experience and learning curve in managing concomitant cholelithiasis and choledocholithiasis with laparoscopic cholecystectomy (LC) and laparoscopic common bile duct exploration (LCBDE).* ***Methods:*** *Between January 2016 and January 2020, a total of 51 selected patients with concomitant cholelithiasis and choledocholithiasis underwent LC and LCBDE, and we reviewed our data retrospectively. The primary outcome measure was the common bile duct (CBD) stone clearance rate. Secondary outcome measures were conversion rate, morbidity, mortality and length of hospital stay.* ***Results:*** *A total of 51 selected patients with cholelithiasis and choledocholithiasis underwent LC and LCBDE in a single tertiary care centre over four years. The success rate for laparoscopic stone clearance was 96.07%. The conversion rate was 3.92%. The overall mean duration of the operation was 140 minutes. There was no significant postoperative morbidity and mortality. Hospital stay ranged from 4 to 6 days.* ***Conclusion:*** *For concomitant cholelithiasis and choledocholithiasis, LCBDE is a highly successful single-session minimally invasive procedure and safe even for beginners with basic laparoscopic training and facilities in selected patients.*

Keywords*: Cholelithiasis, learning curve, laparoscopic cholecystectomy, choledocholithiasis*

Cite this article*: Bordoloi BP, Kilambi R, Ahmed M. Learning curve experience in laparoscopic common bile duct exploration for concomitant cholelithiasis and choledocholithiasis. Int J Health Res Medico Leg Prae 2021 July-Dec.;7(2):29-33. DOI: 10.31741/ijhrmlp.v7.i2.2021.5*

INTRODUCTION

Approximately 3% to 14.7% of patients with gallstones have concurrent common bile duct (CBD) stones.[1] Because of complications of CBD stones, including pain, biliary obstruction, cholangitis, hepatic abscesses and pancreatitis, the European Association for Endoscopic Surgery recommends that these patients should be treated even when asymptomatic. [2]Though laparoscopic cholecystectomy (LC)

has become the 'Gold Standard' method for cholelithiasis, there is no consensus for managing choledocholithiasis.

With the increase in expertise with endoscopic procedures, preoperative endoscopic retrograde cholangiopancreatography (ERCP) and stone clearance followed by LC has emerged as a widely available and routine procedure for patients with choledocholithiasis and cholelithiasis. But it is a two-stage procedure. Other disadvantages of ERCP are that it is associated with some immediate though rare, life-threatening complications like pancreatitis, bleeding and duodenal perforation, papillary stenosis, and increased risk of bile duct cancer in the future.[3]

With refinements in technical expertise and improvements in equipment in the field of laparoscopic surgery, LCBDE has become a potential option for managing choledocholithiasis simultaneously with LC in a single-stage.[4] A few studies have suggested that this single-stage procedure is not only safe but offers lower morbidity, shorter length of hospital stay and is more cost-effective than the two-stage procedure.[5,6] Further, a recent meta-analysis has shown it to be better than the two-stage procedure in stone clearance.[7]

Though the benefits of a single stage LCBDE seem apparent, the lack of expertise and an uncertain learning curve has often been held as deterrents to its widespread application. Hence, we planned this study to present our initial experience with LCBDE and our learning curve.

MATERIAL AND METHODS

Between January 2016 and January 2020, in 4 years, a total of 51 highly selected patients with concomitant cholelithiasis and choledocholithiasis underwent LC and LCBDE in a single tertiary care centre by a single surgeon. Consecutively collected data were reviewed retrospectively. As a beginner for LCBDE, we had planned LC and LCBDE in a selected group of patients in a tertiary care centre with an established Department of Gastroenterology where well-equipped and highly experienced Gastroenterologists are available. ERCP and Endoscopic Sphincterotomy (ES) are routinely done here. Patients' selection criteria were: Uncomplicated cholecystitis in Ultrasonography (USG) with well-delineated CBD stone/stones in Magnetic Resonance Cholangiopancreatography (MRCP), dilated CBD (10/>10 mm), preferably single stone (but up to 3) and stone size of 8/>8 mm. With gaining experience in the later part of the study, we had included some patients where ERCP was not feasible or had failed. One patient with Roux-en-Y gastrectomy 20 years back and four patients with periampullary duodenal diverticulum was included later in the study period. Clinical evidence of cholangitis and biliary pancreatitis was omitted for acute cholecystitis patients. Institutional board approval was obtained for the study. Informed consent was taken from all patients, and the possibility of conversion to open and postoperative ERCP if indicated. The primary outcome measure was the CBD stone clearance rate. Secondary outcome measures were conversion rate, morbidity, mortality and length of hospital stay.

Operative technique

After all necessary preoperative workups, all patients received prophylactic antibiotics at the time of induction after a negative skin test. The procedure was performed using a standard four-port technique for LC, with slight variation. The epigastric port was placed a little to the right to maintain maximum alignment with CBD during choledochoscopy. The correct subcostal port was slightly lower, and a fifth port was placed in the left upper quadrant, maintaining the ergonomics for suturing the choledochotomy. LCBDE was done via the transcholedochal route in all patients because of the large stone size. After adequately identifying CBD and removing the anterior peritoneal layer, a longitudinal supraduodenal choledochotomy was made, initially a small nick by the hook than extension by the scissor, which was determined by the largest stone size. Often, stone/stones are extracted with simple manipulation over the duodenum. Otherwise, we used forceful irrigation, first proximal CBD/common hepatic duct (CHD), then distal CBD is irrigated by inserting an 8 French infant feeding tube precisely as done in open surgery. In case of failure, we used a Fogarty balloon catheter. Complete ductal clearance was confirmed by choledochoscopy, and choledochotomy was closed over a T-tube with interrupted 3-0 polyglactin 910 (Vicryl) in all cases. A leak test was done routinely, and an external non-suction tube drain was left in the right subhepatic region, removed on a post-operative day 1 (POD1) if there was no abnormal drain content. We did not do completion cholangiography. The procedure was converted to open if stone clearance could not be achieved laparoscopically. Dindo-Clavien classification was used to stratify the severity of operative and postoperative complications.[8]

RESULTS

Between September 2016 and September 2020, in 4 years, a total of 51 selected patients with concomitant cholelithiasis and choledocholithiasis underwent LC and LCBDE at our institute. The two surgeons operated on all cases (BPB and MA). Both had less than two years of laparoscopic experience at the beginning of the study, mainly in the form of laparoscopic cholecystectomies.

The male to female ratio of the patients was 4.1:1, with a median age of 42 years (range 24 to 68 years). Most of the

patients present with biliary colic, jaundice and with or without subclinical cholangitis (**Table 1**).

Table 1 Patients' parameters

Variable	Patients (51)
Age	24 to 68 years
Gender (Male/Female)	41/10
BMI	22-30
ASA	
ASA I	30 (58.82%)
ASA II	12 (23.52%)
ASA III	9 (17.64%)
Hx of biliary pain	51 (100%)
Hx of jaundice	18 (35.29%)
Mean CBD diameter	8-22mm

BMI: body mass index, Hx: history, ASA: American Society of Anaesthesiology (ASA.)

All patients underwent elective LCBDE, and CBD was successfully cleared in 49 patients (96.07%) with a 3.92% conversion rate and one patient required hepaticojejunostomy. The first failure was a single large (22mm) impacted stone in the distal CBD. The second failure was stoned with sharp edges. We could not retrieve the stone even after conversion in the first case, so the patient was managed by Roux-e Y hepaticojejunostomy. In the second case, out of two, one stone could not be retrieved and during manipulation Fogarty balloon repeatedly ruptured. This was a failed ERCP patient due to a sizeable periampullary diverticulum. The patient was successfully managed by open surgery.

The overall mean duration of the operation was 140 minutes (range, 130–180 minutes). Intraoperative blood loss was minimal(**Table 2**).

Table 2 Operative parameters

Variable	Patients (51)
LCBDE	51(100%)
CBD clearance	49 (96.07%)
Conversion	2 (3.92%)
Transcholedochal	51 (100%)
T-tube	50 (98.03%)
Operative time	140min (130-180 min)
No of CBD stones	1-3
Stone size	8mm-22mm
Blood loss	20-100 ml
Blood transfusion	0

There were no mortalities and no intraoperative complications. Three patients developed postoperative fever, 3 had a transient elevation of liver enzymes and 2 had umbilical port site infection, and all were managed conservatively.

T-tube has clapped on a post-operative day (POD) three. During the hospital stay, patients were assessed clinically and by laboratory evaluation. The median length of hospital stay was four days. All patients were discharged home with clamped T-tube in situ, except one who underwent hepaticojejunostomy. T tube was removed on POD21 after a cholangiography showed no filling defect and free passage of contrast into the duodenum.

The mean follow-up was 9±3.4 months (6–54 months). No patients showed retained or recurrent stones, CBD stricture or cholangitis by clinical, laboratory and imaging studies.

DISCUSSION

Approximately 3% to 14.7% of patients with gallstones have concurrent common bile duct (CBD) stones and require treatment even when they are asymptomatic because of unpredictable complications. Options for management include open cholecystectomy with open CBD exploration, LC with pre-or post-operative ERCP, LC with LCBDE, and Laparoendoscopic rendezvous procedure. Among the methods, pre-operative ERCP and stone clearance followed by LC is the most popular procedure. However, this has its disadvantages; being a two-stage procedure, it is associated with higher costs and more extended hospital stay.

The introduction of LCBDE overcame the drawbacks of both two-staged ERCP with LC procedure and open CBD exploration.[9,10] However, the adoption of LCBDE has been relatively slow because of the anticipated requirement of the high level of technical expertise with laparoscopy and its instrumentation and fear of a long learning curve.[11,12]

The authors of this study did not have a long laparoscopic experience before this study (less than two years each). In the initial stage of the study, we included only selected patients. Gradually in the latter half of the study period, we were able to accept a broader range of patients, including those who had been intervened before. However, the senior surgeon (B.P.B.) had vast exposure to open surgery, which helps reduce the learning curve for laparoscopic surgery. Further, this study shows that very few cases are required to cross the learning curve if the surgeon has the essential laparoscopic experience, as in our case.

Interestingly, we didn't have any conversions in the first 28 cases. As discussed, the first conversion was on the 29th case, and the second was on the 43rd case. This also shows that, with selected patients and essential laparoscopic

experience, one can safely and successfully offer LCBDE to patients.

This study did LCBDE via the transcholedochal route because of the large stone size. The CBD clearance rate was 96.07%. The conversion rate was 3.92%, comparable to other studies.[13, 14] As a beginner in LCBDE, choledochotomy was closed over a T-tube to provide biliary decompression in all patients and prevent leaks. However, the literature suggests that primary closure with or without stenting is feasible and safe.[15] Complete ductal clearance was confirmed by intra-operative choledochoscopy, which is better and less time consuming than intra-operative cholangiogram.[16] Though this requires an initial investment in a choledochoscope, it is valid and saves on the cost of a C-arm and radiation risk. Other authors have used a nephroscope or cystoscope for the same purpose, reducing the costs of additional instruments. The median length of hospital stay was three days with low morbidity and without mortality, again commensurate with other studies.[6,13,14]

Though mean follow up was 9±3.4 months (6–54 months), usually, due to the extremely low incidence of delayed complications, LCBDE does not justify routine long-term follow-up.[6]

Limitations: This study's limitation is that it is a retrospective study in a selective group of patients and is therefore susceptible to selection bias. However, it is always advisable to select patients when starting a new procedure and include all-comers as experience grows, and this is what we have also done.

CONCLUSIONS

Very few studies have looked at the safety and efficacy of LCBDE during the learning curve. This is one of the few studies presenting data on the safety and effectiveness of LCBDE during the learning curve in India. LCBDE is a highly successful, single-session minimally invasive procedure for patients with concomitant cholelithiasis and choledocholithiasis, which is safe and cost-effective even in novice laparoscopic surgeons' hands with basic laparoscopic training and proper patient selection.

Acknowledgements: We acknowledge all the study participants for their help and support to carry out the research work.

Ethical Clearance: Taken.

Financial Support: None declared.

Conflict of interest: No conflict of interest associated with this work.

Contribution of Authors: We declared that this work was done by the authors named in this article, and the authors will bear all liabilities about claims relating to the content of this article.

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