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ORIGINAL ARTICLE

Appropriate Patient Selection Is Essential for the Success of Primary Closure After Laparoscopic Common Bile Duct Exploration

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Abstract
Background Laparoscopic common bile duct exploration (LCBDE) is being increasingly used for management of common bile duct (CBD) stones. Primary CBD closure has been reported to have better short-term outcomes compared to T-tube placement. However, primary CBD closure cannot be performed in all patients.
Aim This study aims to evaluate the short- and long-term outcomes of LCBDE with primary CBD closure in appropriately selected patients and compare them with T-tube drainage.
Methods Retrospective analysis of patients undergoing LCBDE in our department from June 2011 to October 2014 was performed. Primary closure was performed in 52 patients (group A), and a T-tube was placed in 33 patients (group B). Patient demographics, intraoperative findings, postoperative stay, complications, and long-term follow-up data were recorded and compared.
Results The mean operating time was much longer in group A compared to group B (113.92 vs. 95.92 min, $p = 0.032$). The overall complication rate (9.6 vs. 6.3%, $p = 0.701$) and hospital stay (4 vs. 5.11 days, $p = 0.088$) were similar in both groups. No patient required conversion to the open procedure. Bile leakage was more frequent in group A (5.78 vs. 0%, $p = 0.279$), but this was not statistically significant. All three patients with bile leakage were treated successfully by conservative measures and gradual drain withdrawal. On long-term follow-up, recurrent stones were detected in two patients in group A. No patient was found to develop CBD stricture.
Conclusion LCBDE and primary CBD closure has excellent short- and long-term outcomes when performed in appropriately selected patients.

Keywords Common bile duct · Laparoscopic surgery · Common bile duct stone · Primary closure · T tube · Common bile duct exploration

Introduction

Common bile duct (CBD) stones are present in 10–15% of patients with gallstone disease [1]. Endoscopic retrograde cholangio-pancreatography (ERCP) with stone extraction is a common and preferred method for the treatment of CBD stones [2]. However, since the introduction of laparoscopic common bile duct exploration (LCBDE), more patients are being considered for surgical treatment as gallstones and CBD stones are removed in a single-stage procedure with reduced hospital stay and a similar success rate to the usual ERCP and stone extraction procedure [3–5].

Traditionally, CBD is closed over a T-tube in both the open and laparoscopic techniques to avoid bile leakage; this prevents stenosis of the bile duct [6]. However, the T-tube has its own postoperative complications such as slippage, blockage, and patient discomfort [7].

Several studies have reported on the safety and feasibility of primary closure without a T-tube after LCBDE

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[1, 2, 8–16]. However most of these studies reported only short-term outcomes [8–16]. Also, primary CBD closure cannot be performed in all of the patients. Indeed, appropriate patient selection is important to avoid bile leakage or stricture after primary CBD closure. Second, very few studies report long-term outcomes of primary closure after LCBDE [1, 2, 11].

Considering the potential for long-term complications of primary closure after LCBDE such as bile duct strictures, recurrent cholangitis, or stones, it is important to undertake long-term studies to obtain supporting data before strongly recommending its use. In this study, we present our short- and long-term outcomes of primary closure of the CBD after LCBDE in selected patients and compare it with patients requiring T-tube drainage.

Methods

Patients

A retrospective review of patients undergoing LCBDE from June 2011 to October 2014 at the Department of Hepatobiliary Surgery, Foshan Hospital Affiliated to Southern Medical University (Foshan, Guangdong Province, China), was conducted. The study was approved by the hospital's ethics committee, and informed consent was obtained from all patients. All the procedures were performed by the same surgical team. The patients were diagnosed with choledocholithiasis based on their clinical history, physical examination, biochemical data, preoperative abdominal ultrasonography, and magnetic resonance cholangiopancreatography. After LCBDE, patients satisfying all the following criteria were selected for primary CBD closure (group A):

- CBD diameter >10 mm.
- Absence of risk factors for bile duct obstruction such as liver fluke disease, intrahepatic bile duct stones, or preoperative acute pancreatitis.
- Free bile flow across the bile duct without any distal obstruction.
- Absence of tissue loss or extensive damage to the blood supply of the bile duct.

Patients who underwent LCBDE with T-tube drainage were included in group B.

Surgical Procedure

Laparoscopic cholecystectomy (LC) was performed using the standard four-port technique. We used a 30-degree video-laparoscope (Stryker; Kalamazoo, MI) placed through a 10-mm umbilical port with a 10-mm port placed in the epigastrium and two 5-mm ports placed in the right upper quadrant. After dividing the cystic duct close to the gallbladder, transcystic intraoperative cholangiography was performed through an additional stab incision in the right hypochondrium to confirm the biliary anatomy as well as the number, size, and location of bile duct stones. The anterior surface of the CBD was dissected carefully, and choledochotomy was performed with a longitudinal incision of 8–20 mm depending on the size of the stones using cold knife. Next, a choledochoscope (Olympus; Tokyo, Japan) was inserted into the CBD.

The bile duct stones were extracted under direct vision of the choledochoscope with the help of a basket, suction, and/or electrohydraulic lithotripsy. After clearing the bile duct, a ureteric catheter (5 Fr) was passed through the choledochoscope into the CBD to ensure patency of the distal passage of the bile duct. Subsequently, T-tube drainage or primary closure of the CBD was performed with a continuous 5-0 polydioxanone (PDS) suture depending upon the previously mentioned criteria. A latex drain was placed in all the cases, which was removed on the second postoperative day after starting an oral diet if the drainage was non-bilious with output <10 ml/day. A cholangiogram was performed at the end of surgery in both groups only when the intraoperative findings were different from those of the preoperative diagnosis or the stone could not be found using choledochoscopy during the operation [17]. In group B, the patients were discharged with a T-tube in situ, and the T-tube was removed 4 weeks later after cholangiography had been performed to rule out a residual stone, bile leakage, or stenosis of bile duct.

For follow-up, the patients in group A were routinely assessed in the outpatient clinic for at least 2 years after discharge using ultrasound (CT scan if necessary) and liver function tests. Magnetic resonance cholangiopancreatography or ERCP was performed when indicated.

Statistical Analysis

The variables were expressed as mean and standard ± deviation when their distributions were normal. Analysis of the statistical significance of differences between two groups of data was performed with X^2 analysis or Fisher's exact test when appropriate for qualitative data and Student's t test for quantitative data. A level of $p < 0.05$ was considered statistically significant. Calculations were performed using SPSS v20 statistical software (IBM SPSS, Armonk, NY).

Results

Out of 96 patients undergoing surgery for choledocholithiasis during the study period, LCBDE with primary closure was performed in 52 patients (group A) and

LCBDE with T-tube placement in 33 (group B). Patients who underwent laparoscopic cholecystectomy with endoscopic CBD stone extraction ($n = 10$) and open CBD exploration ($n = 1$) were excluded. Patient characteristics and the perioperative data are shown in Table 1. The sex ratio, BMI, and diameter of the common bile duct were similar between the two groups ($p > 0.05$). One patient was converted to open surgery because of dense adhesions, and one patient was referred for ERCP after laparoscopy because of dense adhesions. The mean operating time was much longer in group A than in group B (113.92 ± 15.14 min vs. 95.92 ± 13.14 min, $p = 0.032$). The length of postoperative hospital stay was similar in both groups (4 ± 1.12 vs. 5.11 ± 1.80 days, $p = 0.088$). There was no mortality in either group. The incidence of overall postoperative complications was similar in both groups (9.6 vs. 6.0%, $p = 0.701$).

In group A, the overall complication rate was 9.6% (5/52). Bile leakage was observed in three patients of group A (5.78%). As per the classification proposed by the International Study Group of Liver Surgery [18], grade A bile leakage was detected in one patient, but it spontaneously resolved in 4 days with conservative treatment. Two patients developed grade B bile leakage. As they had low output fistulas with no evidence of peritonitis or cholangitis, these patients were discharged on postoperative day 9 and 13 and followed up at the outpatient clinic. Initially, no endoscopic biliary drainage (ENBD) or tube cholangiography was performed in these patients; later, 3 weeks after surgery, cholangiography was performed, but it failed to delineate the exact site of bile leakage. However, the latex drain was found to be abutting the bile duct at the suture site. Hence, the drain was gradually withdrawn. After withdrawal of the drain, the bile leak stopped, and no further action was required. Table 2 shows the postoperative complications and their management in group A. In the T-tube drainage group, two patients (6.0%) experienced postoperative complications, and both the complications were related to accidental slippage/removal of the T tube. In one patient, T-tube slippage occurred at 2 weeks after surgery and was successfully managed by observation. In another patient, bile peritonitis was seen after T tube removal, which was treated by placement of a new tube over the guidewire under fluoroscopy. The new tube was successfully removed after 3 months. On follow-up, two patients were detected to have residual stones in group B at 4 weeks during T-tube cholangiography, which were treated by extraction via the T-tube tract using choledochoscope in one patient and by ERCP in another patient. No patient in group A was detected to have residual stones. However, two (3.8%) patients in group A presented with recurrence of stones at 8 and 13 months after surgery, respectively, and both were successfully treated by ERCP. No CBD stricture was detected in any of the groups during the study period (Figs. 1, 2).

Discussion

This study found that LCBDE with primary CBD closure, when performed in appropriately selected patients, can have excellent short- and long-term outcomes. Recurrent stones were detected in only 3.8% of cases with no incidence of biliary stricture during the long-term follow-up period. A study by Lee et al. [1] reported the long-term outcomes of both primary closure and T-tube placement

Table 1 Perioperative characteristics

Characteristics	Group A ($n = 52$)	Group B ($n = 33$)	*P*
Age (years)	56.6 ± 14.5	54.1 ± 15.1	0.323
Sex ratio (male/female)	22/30	10/13	0.925
BMI (kg/m^2)	22.31 ± 1.86	23.41 ± 1.76	0.533
Diameter of common bile duct (mm)	12.32 ± 1.71	13.11 ± 1.68	0.659
Conversion to open surgery (%)	0	0	
Operating time (min)	113.92 ± 15.14	95.92 ± 13.14	0.032
Postoperative hospital stay (days); median (range)	4.00 ± 1.12	5.11 ± 1.80	0.088
Residual stones	0	2 (6.0%)	
Recurrent stones	2 (3.8%)	0	
Complications	5 (9.6%)	2 (6.3%)	0.701
Bile leakage	3 (5.8%)	0	0.279
Abdominal infection	1 (1.9%)	0	1.00
Complications related to T-tube	NA	2 (6.3%)	
Pneumonia	1 (1.9%)	0	1.00

BMI body mass index

Table 2 Postoperative complications in group A and their management

Dindo-Clavien classification	Complication	No. of patients	Management
I	Bile leakage Grade A	1	Observation
	Bile leakage Grade B	2	Observation
II	Abdominal infection	1	Antibiotics
	Pneumonia	1	Antibiotics
III	0		
IV	0		

Postoperative complications were grouped according to the Dindo-Clavien classification [21]:

Grade I: any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions

Grade II: requiring pharmacological treatment with drugs other than those allowed for grade I complications

Grade III: requiring surgical, endoscopic, or radiological intervention

Grade IV: life-threatening complications requiring intensive care unit management. The definition and classification of bile leakage as provided by the International Study Group of Liver Surgery [18]

Grade A: bile leakage requiring little or no change in clinical patient management

Grade B: bile leakage requiring additional diagnostic or interventional procedures or grade A bile leakage prolonged for more than 1 week

Grade C: bile leakage requiring relaparotomy

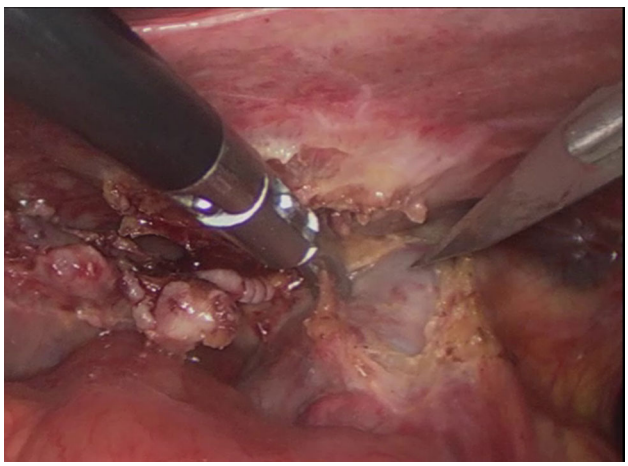

Fig. 1 Intraoperative photo showing choledochotomy being performed by cold knife below the insertion of the cystic duct

after LCBDE by choledochotomy. The authors found the incidence of recurrent stones to be 5.4 and 6.6% after primary closure and T-tube placement, respectively; no patients had signs of bile duct stricture. Another similar study by Yi et al. [2] reporting outcomes in 142 patients with a mean follow-up period of 48.8 months found the incidence of recurrent stones to be 4.4 and 5.9% after primary closure and T tube placement, respectively, with no biliary stricture.

Regarding potential long-term complications, results from these studies (including our own study) underscore the safety of primary closure after LCBDE. Appropriate patient selection was likely the main reason behind the better outcomes seen in our study as the criteria for selecting patients for primary closure were relatively unclear in the two aforementioned studies by Lee et al. and Yi et al. The incidence of immediate postoperative bile leakage in this study (5.8%) was comparable to the previous reports (2.9–8.1%) [16, 19–21]. We believe that the use of patient selection criteria followed in this study is critical for the successful outcomes. Any factor that is likely to cause distal bile duct obstruction will lead to elevated intraductal pressure and ischemia at the suture site, therefore increasing the chances of bile leakage and subsequent stricture formation.

In this study, we employed both preoperative imaging and intraoperative methods to rule out distal obstruction. Intraoperatively, we used a choledochoscope and ureteric catheter to ensure that the distal passage was clear before performing CBD closure. In patients with suspected distal obstruction we preferred T-tube placement. Another important patient selection criterion was the diameter of the CBD. A minimum diameter of 10 mm is essential to perform safe choledochotomy and stone extraction. In patients with smaller duct diameter, we employed endoscopic CBD clearance.

In this study, the operative time for group A was longer because of the time required for CBD closure. But with increasing experience, it is likely to decrease. Contrastingly, in the study by Leida et al. [8], the operative time in the T-tube group was longer, probably because of the use of a T-tube in difficult cases. In the present study, the hospital stay was comparable between the two groups. However, there are studies reporting decreased hospital stay for patients undergoing primary CBD closure [13]. In

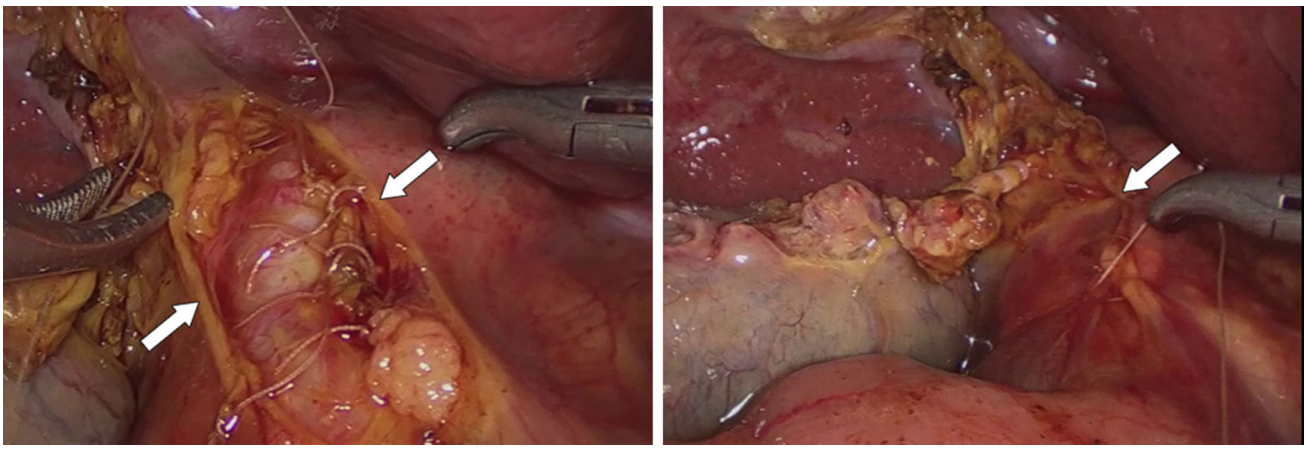

Fig. 2 Intraoperative photographs showing the tunica serosa of the common bile duct (*white arrows*), which is being sutured after primary closure of the choledochotomy

our study, the biliary complications were similar in the two groups though less severe in the primary CBD closure group. An important finding in this study was that all three bile leakages had controlled biliary fistulas and could be successfully managed by conservative measures and drain withdrawal. We believe that the use of a latex drain with appropriate placement close to the suture site helped in avoiding peritoneal spillage as latex accelerates sinus tract formation and acts as a T-tube. A meta-analysis of 1762 patients who underwent LCBDE also found no significant difference in biliary complications between the primary CBD closure and T-tube groups [22].

There are some limitations of this study. First, this was a single-center, retrospective study with only a small sample size. Second, the long-term follow-up of group B was not performed meticulously. Hence, the reported incidence of recurrent stones in group B may not be accurate, leading to statistical bias.

In conclusion, primary CBD closure after LCBDE in appropriately selected patients has excellent short- and long-term outcomes. Compared to T tube drainage, primary closure can improve the quality of life and avoid the complications associated with the usage of a T-tube.

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Author's Contribution G-QL and TS conceived and designed the study; S-QW, SY, G-QL, and Q-HH retrieved and analyzed the data; X-YX and QW drafted the manuscript; GQ-L and MW assisted in the data analysis and reviewed the manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standard For this type of study formal consent is not required.

Animal rights This article does not involve any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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