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Laparoscopic common bile duct exploration with primary suture: A preliminary exploration of safety, efficacy, and quality of life—A retrospective analysis ☆,☆☆

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Introduction

Common bile duct (CBD) stones are the second most common complication of gallbladder stones. At the time of cholecystectomy, approximately 5% of asymptomatic patients with normal bile duct diameters will be found to have common bile duct stones, while 10%-20% of patients with signs or symptoms of possible common bile duct stones will be confirmed to have CBD stones.[1,2] The primary treatment for gallbladder stones is surgical cholecystectomy, while the main treatment strategies for CBD stones include surgical intervention or endoscopic stone extraction. Surgical options are represented by CBD exploration and stone extraction, whereas endoscopic treatment is represented by endoscopic retrograde cholangiopancreatography (ERCP). Each treatment approach has its own advantages and disadvantages. Traditional surgical treatment for CBD stones involves open surgery, performing CBD exploration and stone extraction, along with T-tube placement to support decompression and bile drainage, thereby avoiding or alleviating potential bile leaks and strictures. The T-tube is typically removed after 2 months, and if residual stones remain, an endoscopic examination can be performed via the T-tube or via the fistula tract to retrieve retained common duct stones Endoscopic treatment of CBD stones is another minimally invasive option that involves preoperative and intraoperative ERCP with the placement of a nasobiliary drain or biliary stent, followed by primary closure of the CBD

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(PCCBD).[3] With the advancement of laparoscopic techniques, minimally invasive methods for treating CBD stones have become the trend. Increasing evidence shows that laparoscopic CBD exploration reduces patient trauma and facilitates recovery.[4,5] However, this approach still necessitates T-tube placement, which can lead to negative outcomes such as decreased quality of life, increased risk of bile leaks, nursing-related difficulties, T-tube dislodgment, bile loss, and repeat postoperative examinations.[6-8] Endoscopic treatment of CBD stones is another minimally invasive option that involves preoperative or intraoperative ERCP. However, ERCP carries associated risks, such as cannulation failure, stone retrieval failure, pancreatitis, and bleeding, along with the potential need for endoscopic sphincterotomy (EST) if ERCP is unsuccessful, increasing the risk of complications like duodenal perforation.[9-11]

To improve patient quality of life while ensuring safety, surgeons have explored various strategies. Initially, primary biliary duct suturing was performed, but this still required ERCP for the placement of a nasobiliary drain or biliary stent to facilitate CBD healing after PCCBD.[12] Following stent placement, a second ERCP is required postoperatively to remove the implanted biliary stent. This additional ERCP not only carries risks of stent blockage and displacement but also increases the incidence of ERCP-related complications.[11] To mitigate ERCP-related risks, surgeons have attempted LCBDE combined with PCCBD without any biliary drainage (including T-tubes, nasobiliary drains, or biliary stents). This technique is more challenging as it demands advanced laparoscopic skills and anatomical precision. Recent studies have elucidated the advantages of LCBDE combined with PCCBD over traditional T-tube drainage.[13-17] However, the clinical outcomes, postoperative complications, and quality of life for patients undergoing this technique remain unclear,[18] Therefore, we designed a retrospective study to evaluate the safety, efficacy, and postoperative quality of life of LCBDE combined with PCCBD without biliary drainage.

Materials and methods

Study design

This is a retrospective cohort study aimed at assessing the safety, efficacy, and postoperative quality of life of LCBDE-PCCBD without biliary drainage. Patients diagnosed with common bile duct stones accompanied by gallbladder stones who underwent LCBDE-PCCBD without biliary drainage at our institution from June 2022 to June 2024 were included. All LCBDE-PCCBD procedures were performed by surgeons with over 10 years of clinical experience who had independently completed at least 100 bile duct explorations. Informed consent was obtained from all patients and/or their guardians prior to the procedure, in accordance with medical ethics requirements.

Patients enrollment and data collection

Relevant data from enrolled patients were collected and analyzed. All clinical data were sourced from our hospital's medical record database, and quality of life scores were obtained through postoperative telephone or outpatient follow-up. Inclusion criteria were as follows: (1) a definitive diagnosis of bile duct stones; (2) consent for primary closure of the CBD; (3) preoperative MRCP indicating a CBD diameter of $\geq$7 mm; (4) no residual CBD stones intraoperatively; (5) no obstructive jaundice preoperatively; (6) no biliary duct injury intraoperatively; (7) no coexisting hepatobiliary malignancies; (8) patient consent for LCBDE-PCCBD; and (9) patients with detailed clinical data records for analysis and follow-up completion. Exclusion criteria included: (1) patients with hepatobiliary malignancies; (2) Patients who underwent T-tube or nasobiliary tube placement or ERCP for various reasons (such as intraoperative discovery of residual stones, suspected bile duct injury during surgery, etc.); (3) patients with acute pancreatitis; (4) those with preoperative obstructive jaundice; (5) patients whose clinical data could not be analyzed;

and (6) lost to follow-up patients. Primary observational indicators included demographic data, preoperative and postoperative liver function results, intraoperative conditions, postoperative recovery processes, and clinical outcomes during the follow-up period. Postoperative complications were assessed according to the Clavien-Dindo classification system and criteria for bile leakage. The Gastrointestinal Quality of Life Index (GIQLI) is a questionnaire tool used to assess the quality of life of patients with gastrointestinal diseases. Multiple studies have employed it to evaluate the postoperative quality of life in biliary surgery patients.[19-21] This study also utilized the GIQLI score to assess patients' postoperative quality of life.

Surgical procedures

Patients were placed in a head-down, feet-elevated position at a 30° angle. Following endotracheal intubation under general anesthesia, a carbon dioxide pneumoperitoneum was established at a pressure of 10-13 mmHg via a puncture in the subumbilical region. The standard 4-trocar technique was employed, with a 10 mm trocar placed in the subumbilical area as the laparoscopic observation port, a 10-12 mm trocar as the main operative port for choledochoscope access, and a 5 mm trocar in the midclavicular line serving as an auxiliary port. If necessary, abdominal and gallbladder adhesions were dissected first. Then, the Calot triangle was dissected to expose the cystic duct and cystic artery while identifying the CBD. The cystic artery was clamped and divided, followed by clamping the cystic duct to fully expose the CBD. Using a low-power electrocautery, the serosa and anterior wall of the CBD were carefully incised, creating a longitudinal incision approximately 7 mm long, just larger than the stone diameter, based on preoperative MRI-MRCP findings. Bile duct stones were removed using a retrieval basket through the choledochoscope. The duodenal papilla was clearly visualized, and the bile duct was fully examined 3 times for residual stones, ensuring no stones remained. After complete stone removal, a primary closure of the CBD was performed using 4-0 absorbable v-lock (V-LOCK, Covidien Inc., Tullamore, Ireland) sutures, with a margin of about 1.0 mm and a needle spacing of about 1.5 mm (Fig 1). If any bile leakage occurred, intermittent sutures were applied at the leakage site using 4-0 absorbable sutures (Polysorb, GL-45-MG, Covidien Inc., Tullamore, Ireland), with at least 4 knots tied for each intermittent suture. Finally, the cystic duct was transected and the gallbladder was completely removed, with a clip left on the cystic duct stump. If removal of the gallbladder or stones from the abdominal cavity was difficult, the incision could be appropriately enlarged, or the gallbladder could be placed in a retrieval bag and crushed prior to extraction. Before concluding the procedure, a drain was placed in both the gallbladder fossa and the splenic fossa.

Patient management and follow–up

All patients were discharged around the fourth postoperative day after the splenic fossa drain was removed, and a liver function test was completed before discharge. Patients returned for follow-up on the ninth postoperative day, and if no abnormalities were found with the gallbladder fossa drain, it was removed. Sutures were removed on the 14th postoperative day, and patients who returned for suture removal underwent outpatient quality of life scoring, while those who had sutures removed at other facilities were followed up via telephone. All patients underwent at least 1 postoperative liver function test and abdominal ultrasound (USS) to assess the need for further evaluation, such as MRI-MRCP, and subsequent treatment. For those with recurrent bile duct stones, ERCP was performed; if ERCP failed, surgical intervention was repeated. For patients with postoperative bile duct strictures, biliary stenting was performed. During follow-up, patients with normal liver function and imaging results, without subjective discomfort, did not require further examinations.

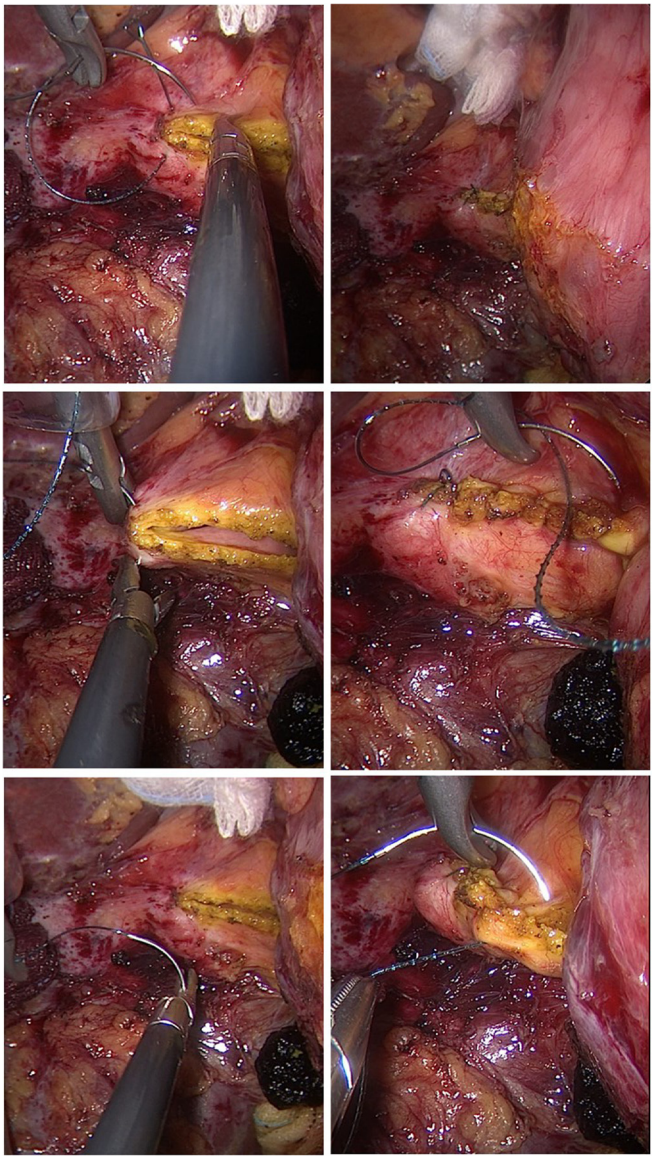

Fig. 1. The detailed steps for continuous suturing of the common bile duct using 4-0 absorbable V-LOCK: Begin suturing from the proximal end, with the first stitch placed 1-2 mm from the proximal edge of the incision. For each subsequent stitch, the needle entry points on both sides should be approximately 1.0 mm from the edge, with a vertical stitch spacing of about 1.5 mm. The final stitch should be placed 1-2 mm from the distal end of the incision.

Table 1
Preoperative and intraoperative clinical data of the patients.

Female/male	144/110
Age (years)	58.18 ± 14.77
BMI (kg/m²)	24.50 ± 3.07
Obstructive jaundicea yes/no	0/254
Preoperative total bilirubin (μmol/L)	17.35 ± 7.24
Alanine aminotransferase (U/L)	120.07 ± 109.74
Aspartate aminotransferase (U/L)	67.66 ± 109.74
Previous abdominal surgery history yes/no	25/229
CBD diameter (mm)	9.99 ± 2.73
Operative duration (min)	68.64 ± 16.51
Blood loss (ml)	33.51 ± 10.08

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; CBD, common bile duct.

Statistical analysis

Continuous variables are expressed as mean ± SD and mean (range).

Results

Preoperative date

A total of 254 eligible patients were enrolled, including 144 females and 110 males, with an average age of 58.18 ± 14.77 years. The average BMI was 24.50 ± 3.07, and no patients presented with obstructive jaundice preoperatively. The mean total bilirubin level before surgery was 17.35 ± 7.24 μmol/L, and preoperative MRI-MRCP confirmed the presence of CBD stones, with no intrahepatic stones detected. The average diameter of the CBD before surgery was 9.99 ± 2.73 mm, and during hospitalization, no patients underwent ERCP. Detailed preoperative clinical data are summarized in Table 1.

Intraoperative data

Intraoperative data are summarized in Table 1. Among the 254 patients undergoing LCBDE-PCCBD, all underwent continuous suturing. The average operation time was 68.64 ± 16.51 minutes, with an average intraoperative blood loss of 33.51 ± 10.08 ml. Postoperatively, all patients had 2 drainage tubes placed.

Postoperative and follow–up data

There were 5 cases of Grade A bile leakage (5/254, 1.97%), which resulted in prolonged drainage time; the drains were removed after the bile leaks healed. All bile leak patients received anti-inflammatory treatment and maintained fluid and electrolyte balance, with no need for reoperation. Two patients (2/254, 0.79%) experienced recurrence of common bile duct stones 21 and 27 months postoperatively, respectively, and underwent ERCP for stone removal. Postoperative pathological examination in all patients did not reveal any malignant lesions. The average length of hospital stay was 5.16 ± 1.88 days, and all patients underwent liver function tests before discharge, with an average total bilirubin level of 16.25 ± 7.30 μmol/L at discharge. The average follow-up period was 15.79 ± 6.92 months. At the end of follow-up, no patients experienced

Table 2
Postoperative and follow-up outcomes of the patients.

Abdominal drainage removal time (Days)	5.16(3, 13)
Postoperative total bilirubin (μmol/L)	16.25 ± 7.30
Postoperative infection	0
Postoperative hemorrhage	0
Postoperative biliary leakage	5
Follow-up time (Months)	21.79(9, 33)
Stone recurrence	2
Complications classified as Clavien-Dindo grade I or higher	0
Biliary stricture	0
Malignant lesions	0
Postoperative hospital time (Days)	5.16 ± 1.88
GIQLIQ	133.30 ± 7.79
Cost (CNY Yuan)	16,006.64 ± 1848.64

CNY, Chinese Yuan; GIQILQ, Gastrointestinal Quality of Life Index.

postoperative infections, bleeding, stone remnants, or bile duct strictures, and no other complications classified as Clavien-Dindo grade I or higher occurred. Detailed postoperative follow-up data are summarized in Table 2.

Discussion

Biliary tract stones are a common condition, and with the development of minimally invasive technology, traditional open cholecystectomy, CBD exploration, and T-tube drainage are no longer the first choice of treatment for most patients. Although ERCP combined with simultaneous or delayed laparoscopic cholecystectomy (LC), or LC with LCBDE and T-tube drainage, offers the advantages of minimally invasive treatment and is considered a better therapeutic option, ERCP itself has inherent limitations.[11,10] Additionally, ERCP for CBD stones accompanied by gallstones still requires simultaneous or delayed LC under general anesthesia, which necessitates specific equipment, personnel, and technical skills. For most patients, ERCP cannot be the preferred option, especially in regions with limited medical resources.

With the advancement of minimally invasive techniques, LC-LCBDE with T-tube drainage has become the preferred treatment option for most patients, as well as a salvage approach when ERCP fails. Compared to open surgery, laparoscopic surgery offers significant advantages in terms of being minimally invasive. However, the prolonged placement of T-tubes postoperatively can lead to a decline in patients' quality of life and various complications: 1. T-tube dislodgment increases nursing difficulty, and patients with dislodged T-tubes may require reoperation. 2. T-tube drainage can result in bile loss and electrolyte imbalances, delaying recovery and adversely affecting the return to normal work and social activities. 3. Some patients may experience bile leakage after T-tube removal, leading to biliary peritonitis, which can be fatal in severe cases. 4. Local scarring after T-tube removal may result in persistent long-term biliary strictures. 5. Current studies indicate that the overall complication rate associated with T-tubes ranges from 13.8% (open surgery) to 15.5% (laparoscopic surgery)[8].Importantly, the complication rates associated with T-tubes are not dependent on whether the surgery is open or laparoscopic, but rather on the process of T-tube placement and removal itself. The incidence of bile leakage post-T-tube removal is about 10%, with reports of biliary peritonitis occurring in 54% of those cases and a mortality rate of 14%. Studies by Wills et al. and Maghsoudi et al.[7] found complication rates of 15.3% (42/274) and 2.47% (34/1375) respectively, with associated mortality rates of 0.73% and 5.9%. Furthermore, the presence of a T-tube has been linked to a decline in patients' quality of life; Leida et al. reported that T-tube placement delayed patients' return to normal activities and work, and it may lead to persistent pain and discomfort.[22]

In recent years, surgeons have begun to explore the use of primary closure of the CBD (PCCBD) during laparoscopic CBD exploration (LCBDE). Initially, many patients still required ERCP to place a nasobiliary drain or biliary stent,[12,18,23,24] primarily to decompress the CBD and reduce postoperative bile leakage. However, these ERCP-involved approaches necessitate adequate facilities, equipment, and skilled personnel, and they carry the risk of ERCP-related complications. The nasobiliary drain also needs to remain in place for a period, contributing to bile loss. To address these shortcomings, some researchers have reported performing PCCBD during LCBDE without any biliary drainage (including T-tubes, nasobiliary drains, and biliary stents). This technique virtually eliminates the disadvantages of the traditional methods without increasing the complication rates. For instance, Zhan et al.[25] reported data from 408 LCBDE-PCCBD procedures, with an average CBD diameter of approximately 12 mm. They noted a postoperative bile leakage rate of 2.94%, 1 case of biliary stricture (0.25%), and 1 case of residual stones (0.25%). Tan et al. [26] reported clinical data from 27 patients undergoing LCBDE-PCCBD without biliary drainage, noting a median surgical time of 160 minutes (range 80-265 minutes), an average CBD diameter of 14.5 mm (range 7-30 mm), and intraoperative blood loss of 30 mL (range 10-50 mL). Yang et al.[27] studied 81 patients who also underwent LCBDE-PCCBD without biliary drainage; 32 patients (39.5%) received interrupted sutures while 49 patients (60.5%) had continuous sutures, with an average surgical time of 123 minutes and an average blood loss of approximately 40 mL, resulting in 2 cases of Grade A or B bile leakage (2.5%). Xu et al. [28] reported on 49 cases, with a median surgical time of 150 minutes (range 90-315 minutes), an average CBD diameter of 11 mm (range 8-12 mm), and intraoperative blood loss ranging from 5 to 200 mL. In terms of postoperative complications, Cai et al.[29] studied 137 patients with stage I choledochal suturing, finding a bile leakage rate of 4.5% (6 cases), with no other significant postoperative complications; Liang et al.[30] studied 94 patients, with a bile leakage rate of 4.3% (4 cases), and additional complications such as postoperative bleeding, cholangitis, pneumonia, and residual stones; Zhuang et al.[31] studied 102 patients with stage I choledochal suturing, observing a bile leakage rate of 3% (3 cases) along with complications such as postoperative bleeding and cholangitis.

Compared with the aforementioned studies, our research shows similar results. All 254 patients successfully underwent LCBDE-PCCBD without biliary drainage. Intraoperative data showed that both interrupted and continuous suturing were safe and effective, without increasing operative time or blood loss. Postoperatively, only 3 cases of Grade A bile leakage occurred, all of which were managed successfully with nonsurgical treatment. Previous literature indicates that the incidence of bile leakage after stage I suturing ranges from 3% to 4.5%. In this study, the bile leakage rate was 1.2%. This may be due to the fact that all surgeons in this study were experienced, and we conducted strict preoperative screening of patients. Before surgery, we conducted relevant examinations and adopted alternative treatments for patients with preoperative pancreatitis and obstructive jaundice. For patients with acute pancreatitis, we recommend delaying surgery because the edema of the pancreas in these patients severely affects the operation under laparoscopy, potentially increasing surgical risks. Therefore, we recommend anti-inflammatory treatment first, and proceed with surgical treatment after the inflammation is controlled. For patients with preoperative obstructive jaundice, considering that jaundice in some patients is not solely due to choledocholithiasis, rash primary suturing may lead to more severe surgical complications. Therefore, more conservative T-tube drainage was adopted for such patients. These relatively conservative measures may also help reduce the incidence of postoperative bile fistula. According to the Clavien-Dindo classification system, no other complications of Grade I or above occurred. Overall, liver function recovered well postoperatively. Notably, during the postoperative period or follow-up, there were no occurrences of biliary stricture or residual stones. In particular, no bile duct stricture or residual stones occurred during the postoperative period or follow-up. Additionally, Lamberts et al.'s[19] study showed that 12 weeks after cholecystectomy, patients' GIQLI scores increased from 103.5 ± 22.1 to 124.4 ± 13.7. We also performed GIQLIQ scoring for all patients, yielding an average score of 133.30 ± 7.79, indicating a satisfactory postoperative quality of life.

Based on the above findings, we propose the surgical indications for LC+BDE+PCCBD as follows: (1) preoperative liver function indicating no obstructive jaundice; (2) preoperative MRI

confirming CBD diameter of at least 7 mm; (3) preoperative imaging confirming no malignant tumors of the bile duct; (4) no acute pancreatitis preoperatively; (5) no residual stones intraoperatively; (6) no bile duct injury intraoperatively. The presence of residual stones can be assessed through intraoperative cholangioscopy and preoperative MRI+MRCP, and intraoperative cholangiography may be suggested if necessary. The above criteria may help in selecting the most suitable patients for LC+BDE+PCCBD.

Our current study is limited by the retrospective analysis of data from a single institution with an insufficient sample size. Compared to other studies, our surgical indications were relatively conservative, and we did not include some patients who might benefit (such as those with obstructive jaundice solely due to choledocholithiasis) in our study. Additionally, although we conducted careful intraoperative cholangioscopy, we did not perform intraoperative cholangiography due to limitations in conditions. These findings need to be further confirmed in prospective studies with larger sample sizes, timely intraoperative cholangiography, and longer follow-up periods.

Conclusion

In selected patients, LC+BDE+PCCBD without biliary drainage is a safe and effective procedure. It promotes postoperative recovery, improves quality of life, and is associated with a low rate of complications.

Author contributions

Shengyi Zhou: Conceptualization, Methodology, Investigation, Writing – original draft. **Yizhou Sun:** Data curation, Formal analysis, Visualization, Writing – review & editing. **Liqun Xu:** Resources, Software, Validation. **Xiaodong Xu:** Project administration, Investigation. **Zijian Zhou:** Data curation, Formal analysis. **Yangyang Qian** (Corresponding author): Supervision, Funding acquisition, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no conflict of interest.

Data availability

The data supporting the findings of this study were collected from anonymized medical records and questionnaires. Due to privacy concerns and the sensitive nature of the data, they are not publicly available.

Ethical approval

This retrospective study was conducted in accordance with the ethical standards of the institutional and national research committees, as well as the 1964 Helsinki Declaration and its subsequent amendments. The Institutional Review Board of Yancheng First Hospital waived ethical approval for this study due to its noninvasive design and the use of de-identified patient data.

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