Primary closure with knotless barbed suture versus traditional T-tube drainage after laparoscopic common bile duct exploration: a single-center medium-term experience

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Abstract

Objective: Primary closure of the common bile duct (CBD) after laparoscopic CBD exploration (LCBDE) is a technical challenge. The present study was performed to evaluate the safety and effectiveness of this surgical method.

Methods: This retrospective study of surgical efficacy and safety involved 79 patients who underwent primary CBD closure with a knotless unidirectional barbed suture or traditional T-tube drainage after LCBDE for CBD stones.

Results: The average suturing time, operation time, and postoperative hospital stay were significantly shorter in the primary closure group than T-tube group. There were no significant differences in the mean diameter of the CBD, number of stones, or incidence of postoperative complications between the two groups. No patients developed recurrence of CBD stones during the median follow-up of 21.5 months.

Conclusions: After LCBDE and intraoperative choledochoscopy, primary closure with knotless unidirectional barbed sutures is a safe and effective therapeutic option for patients with cholelithiasis and concurrent CBD stones. This is especially true when the CBD is dilated more than 8 mm.
Keywords
Choledocholithiasis, laparoscopic common bile duct exploration, unidirectional barbed suture, primary closure, choledochoscopy, common bile duct dilation, T-tube drainage

Background
Stones in the common bile duct (CBD) are found in about 3% to 10% of patients with cholelithiasis. Timely extraction of CBD stones is helpful to avoid potential complications such as hepatic dysfunction, acute cholangitis, and biliary pancreatitis. Although therapies for CBD stones have undergone various developmental stages and improvements, laparoscopic CBD exploration (LCBDE) is still the most common treatment. This is because it is a single and minimally invasive option that avoids the sequelae of endoscopic sphincterotomy, such as bleeding, perforation, and papillary stenosis. Moreover, LCBDE is more cost-effective and requires a shorter postoperative hospital stay than endoscopic clearance of stones; however, its morbidity and mortality are comparable with those of endoscopic clearance.

In most cases, a T-tube is inserted during the LCBDE procedure to prevent postoperative stricture of the CBD and biliary leakage. Nevertheless, LCBDE with T-tube drainage is often associated with complications such as peritoneal or biliary infections that ascend through the drain, removal of the T-tube before the scheduled time, and inconvenience because of the prolonged T-tube placement. Many systematic reviews have recently shown that primary closure of the CBD after LCBDE provides better short- and long-term outcomes than does T-tube drainage after LCBDE.

Laparoscopic closure of the CBD with intracorporeal suturing and knots is an incredibly difficult procedure to perform for most surgeons, especially for inexperienced surgeons. A barbed suture is a type of knotless unidirectional surgical suture that has numerous small barbs on its surface. Previous studies have demonstrated that barbed sutures can facilitate laparoscopic suturing because the barbs can penetrate the tissue and lock them into place. The efficacy and suitability of performing suturing with barbed sutures for various surgical procedures, including intestinal anastomoses, pancreatic procedures, and esophageal surgery, have recently been confirmed.

In this retrospective cohort study, we evaluated the efficacy and safety of performing primary closure with knotless barbed sutures following LCBDE and compared the perioperative and medium-term outcomes of this technique with those in patients who underwent LCBDE with traditional T-tube drainage.

Methods

Patient selection
The inclusion criteria were a CBD diameter of ≥8 mm as shown by magnetic resonance cholangiopancreatography (MRCP), preoperative confirmation of CBD stones using ultrasonography and MRCP, performance of all operations by the same attending surgeon, and complete medical records. Patients with a history of concomitant acute suppurative cholangitis, hepatolithiasis, Mirizzi syndrome, or bile duct or
gallbladder carcinoma were excluded from the study.

Patients who underwent primary closure with knotless barbed sutures after LCBDE from November 2013 to June 2018 were retrospectively enrolled in the study. The study also included a control group of patients who underwent LCBDE with traditional T-tube drainage during the same period. This study was approved by the ethics committee of our university, and written informed consent was obtained from all patients. The medical data analyzed in this study included the patients’ demographics, clinical features, CBD stone characteristics, and surgical outcomes.

**Operative techniques**

All surgical procedures were performed by an attending surgeon using a standard procedure. Briefly, the patient was placed in the supine position and underwent general endotracheal anesthesia. The surgeon stood on the patient’s left side, and the assistant stood on the opposite side. A 10-mm trocar was inserted into the umbilical region, a 5-mm trocar was inserted into the right midclavicular region, and a 5-mm trocar was inserted in the right anterior axillary line. Additionally, a 10-mm trocar was inserted into the medial epigastric area for the flexible choledoscope. After dissection of Calot’s triangle, the cystic duct was clipped with a 10-mm plastic clip (Weck® Hem-o-lock®; Teleflex Inc., Wayne, PA, USA) to prevent the passage of any gallbladder stones into the CBD during the procedure. The dissection was continued to expose the anterior surface of the CBD. An approximately 10- to 15-mm longitudinal incision was then made in the CBD using an endoscopic scissors, and the CBD stones were directly removed through this incision using atraumatic forceps, saline irrigation with suction (Figure 1(a)), or a wire basket under the flexible choledoscope (CHF-V; Olympus, Tokyo, Japan). CBD clearance was confirmed by exploring the CBD downward to the entrance of the ampulla of Vater and upward to the bifurcation at the left and right hepatic ducts (Figure 1(b)). After removing the stones, the CBD was closed with a continuous suture using 4-0 knotless Stratafix™ (Ethicon Inc., Somerville, NJ, USA) (primary closure group), or a T-tube was placed in the CBD and closed with the same suture material and technique (T-tube drainage group). Stratafix™ is a unidirectional barbed suture and a monofilament synthetic absorbable wound closure device that can prevent loosening of the knots (Figure 1(c, d)). A closed suction drain was then inserted through the lateral trocar (5 mm) and placed in Morison’s pouch at the end of the procedure in both groups.

**Perioperative management and follow-up**

Oral intake was routinely resumed 6 hours postoperatively. If the drainage fluid was <50 mL and contained no bile on postoperative day 2, the drain was removed. The T-tube was removed about 1 month postoperatively after confirming the absence of remnant stones or severe stricture of the CBD on a T-tube cholangiogram.

The first outpatient visit was scheduled at 2 weeks after the operation. Physical examinations, liver function tests, and abdominal ultrasonography were regularly carried out at the 3- or 6-month follow-up and whenever any abdominal symptoms developed during follow-up. Imaging studies such as MRCP or computed tomography were performed if there were any unusual findings.

**Statistical analyses**

Results are expressed as mean ± standard deviation and were analyzed using SPSS 21.0 statistical software (IBM Corp.,
Armonk, NY, USA). Patients who underwent primary closure of the CBD were compared with those who underwent T-tube drainage after LCBDE. Categorical variables were compared between the two groups using the $\chi^2$ test or Fisher’s exact test, while measurement variables were compared using the t test or Mann–Whitney U test. A P value of $<0.05$ was considered statistically significant.

Results
This study included 79 patients with choledocholithiasis who underwent LCBDE with primary closure of the CBD (primary closure group, n = 38) or T-tube drainage (T-tube group, n = 41). The patients’ clinical characteristics are listed in Table 1. There were no significant differences in age (52.7 ± 11.6 vs. 50.9 ± 10.8 years) or weight (body mass index, 25.0 ± 2.8 vs. 25.2 ± 3.0 kg/m$^2$) between the two groups. No significant differences in the average number or size of stones were observed between the two groups (1.5 ± 0.9 vs. 1.6 ± 0.8 and 7.8 ± 1.5 vs. 7.0 ± 1.4 mm, respectively). The mean diameter of the CBD was almost identical between the two groups (11.5 ± 2.1 vs. 11.4 ± 1.8 mm).

All surgical procedures were successfully performed without conversion to other procedures (Table 2). The average suturing time was significantly shorter in the primary

Figure 1. Surgical techniques of laparoscopic common bile duct (CBD) exploration using primary closure with knotless unidirectional barbed sutures and intraoperative choledochoscopy. (a) CBD stones were removed using forceful saline irrigation and suction through the choledochotomy. (b) CBD clearance was confirmed by intraoperative choledochoscopy. (c) The choledochotomy was closed by a single layer of continuous running 4-0 knotless unidirectional barbed suture. (d) The gallbladder was routinely resected after closure of the CBD.
The average operating time and length of postoperative stay were significantly shorter in the primary closure group than in the T-tube group (95.6 ± 10.3 vs. 129.2 ± 14.9 minutes and 4.8 ± 1.3 vs. 7.8 ± 2.5 days, respectively; P < 0.001 for both). There was no significant difference in the estimated blood loss volume between the two groups (28.0 ± 10.1 vs. 34.4 ± 18.5 mL), and no perioperative transfusions were required in either group. The CBD stones were successfully removed in all patients. The drainage volume was <50 mL/day and free of bile. Postoperative complications were observed in two patients in the primary closure group. One patient had biliary leakage and the other had abdominal blood oozing, but both patients recovered with conservative treatments. However, four patients in the T-tube group developed postoperative complications: two had abdominal blood oozing, one had an abdominal infection, and one had biliary leakage. All patients recovered without requiring reoperation.

**Table 1.** Patients’ demographic data.

|                          | Primary closure group | T-tube group | P  |
|--------------------------|-----------------------|--------------|----|
| Patients                 | 38                    | 41           |    |
| Age, years               | 52.7 ± 11.6           | 50.9 ± 10.8  | 0.457 |
| Sex ratio, F:M           | 20:18                 | 24:17        | 0.646 |
| BMI, kg/m²               | 25.0 ± 2.8            | 25.2 ± 3.0   | 0.724 |
| Number of CBD stones     | 1.5 ± 0.9             | 1.6 ± 0.8    | 0.573 |
| Size of CBD stones, mm   | 7.8 ± 1.5             | 7.0 ± 1.4    | 0.065 |
| CBD diameter, mm         | 11.5 ± 2.1            | 11.4 ± 1.8   | 0.930 |

Data are presented as n or mean ± standard deviation.

BMI, body mass index; CBD, common bile duct; F, female; M, male

**Table 2.** Surgical outcomes.

|                          | Primary closure group (n = 38) | T-tube group (n = 41) | P       |
|--------------------------|-------------------------------|-----------------------|---------|
| CBD suturing time, minutes| 9.8 ± 1.3                     | 16.5 ± 2.4            | <0.001  |
| Operation time, minutes  | 95.6 ± 10.3                   | 129.2 ± 14.9          | <0.001  |
| Estimated blood loss, mL | 28.0 ± 10.1                   | 34.4 ± 18.5           | 0.065   |
| Perioperative transfusion, units | 0                          | 0                     |         |
| Postoperative stay, days | 4.8 ± 1.3                     | 7.8 ± 2.5             | <0.001  |

**Complications**

- Blood oozing: 1 (2.6) vs. 2 (4.9); 0.602
- Bile leakage: 1 (2.6) vs. 1 (2.4); 0.957
- Biliary stricture: 1 (2.6) vs. 0 (0.0); 0.296
- Abdominal infection: 0 (0.0) vs. 1 (2.4); 0.333
- Death: 0 (0.0) vs. 0 (0.0); 0.000
- Recurrence of stones during follow-up: 0 (0.0) vs. 0 (0.0); 0.000

Data are presented as n, n (%), or mean ± standard deviation.

CBD, common bile duct

Bold P values are statistically significant.
The median follow-up period was 21.5 months (range, 6–47 months). During the follow-up period, MRCP imaging showed a mild bile duct stricture in one patient in the primary closure group (the diameter of the CBD was 6 mm after the operation) without any discomfort. In contrast, no bile duct strictures were found in the T-tube group.

**Discussion**

Cholelithiasis with concurrent CBD stones is a surgically managed disease that is generally treated with preoperative endoscopic retrograde cholangiopancreatography and sphincterotomy; it is then followed by laparoscopic cholecystectomy in most countries. With improvements in operative techniques and increased numbers of skilled professionals in laparoscopic surgery, many surgeons have performed single-session management of choledocholithiasis by laparoscopic cholecystectomy with LCBDE during the last two decades. In 2008, United Kingdom guidelines recommended LCBDE for treatment of CBD stones in patients undergoing laparoscopic cholecystectomy. The main advantage of LCBDE is that it treats the patient in one session for both problems instead of requiring a two-stage endoscopic–laparoscopic approach. Previous studies have shown a success rate of 88% to 100% for laparoscopic clearance of stones from the CBD, which is as effective as preoperative and postoperative endoscopic retrograde cholangiopancreatography with similar morbidity and mortality. Choledochoscopy enables the complete clearance of stones and ensures that no residual stones are left before application of the primary suture. In the present study, the intraoperative flexible choledochoscope revealed a stone clearance rate of 100%. Moreover, previous studies have indicated the superiority of LCBDE in terms of its lower rate of postoperative complications, quicker recovery, shorter postoperative hospital stay, and lower medical costs compared with the two-stage procedure. In the present study, the average postoperative time before discharge in the primary closure group was 4.8 days, which is slightly shorter than that in previous reports. In addition, LCBDE has been more frequently recommended for younger patients; this procedure maintains both the structural and functional integrity of the sphincter of Oddi, which may be helpful to avoid bile juice regurgitation and reduce stone recurrence or the occurrence of cholangitis.

Exploration of the CBD is customarily followed by placement of a T-tube. However, use of the T-tube is associated with a high complication rate (10.5%–20.0%). Such complications generally include disturbances of water and electrolyte metabolism, premature dislodgement, sepsis, localized pain, biliary leakage, biliary peritonitis, wound infection, and biliary stricture. The unidirectional barbed suture is a specialized suture that contains many diminutive and directional protrusions that can prevent slippage of the suture after passing through tissue. Additionally, the preset loop on one side of the suture makes placement of the first knot more convenient than when using the traditional method. The efficacy and safety of barbed sutures have been confirmed in various abdominal surgical operations, including intestinal anastomosis, transabdominal preperitoneal laparoscopic hernia repair, gastrojejunostomy, and laparoscopic or open choledocholithotomy. In the present study, the average suturing time was 9.8 minutes and the average total procedure time for primary closure was 95.6 minutes. These times were obviously shorter than those in the T-tube group, indicating that intracorporeal suturing with barbed sutures is relatively easier to perform. However, the LCBDE procedure requires excellent...
laparoscopic skills, including suturing and knotting with laparoscopic instruments, which are indispensable in reducing biliary leakage and CBD stricture after the operation. Bile duct stricture is a main concern for patients who have undergone LCBDE. Yi et al. reported no bile duct strictures in patients who underwent T-tube or primary closure after LCBDE at a median follow-up of 48.8 months. In the present study, only a mild bile duct stricture occurred in one patient in the primary closure group. No abnormal liver function or discomfort occurred in this patient.

Many surgeons are concerned about postoperative biliary leakage after the primary closure following LCBDE. Several studies have compared postoperative biliary leakage after primary closure of the CBD with T-tube drainage and revealed no significant differences between these two surgical techniques. Lee and Yoon performed primary closure of the CBD in 15 patients during choledochotomy and observed no biliary leakage in any patients; however, these patients required another endoscopic procedure to remove the endobiliary stent 1 month after surgery. In Mexico, Fernandaz et al. also proved that the use of unidirectional knotless barbed suture was safe and feasible in LCBDE for primary CBD closure. In our study, mild biliary leakage was observed in only one patient in each group, and they recovered with no further complications after conservative treatments.

Conclusions
After LCBDE and intraoperative choledochoscopy, primary closure with knotless unidirectional barbed sutures is a safe and effective therapeutic option for patients with cholelithiasis and concurrent CBD stones; this is especially true when the CBD is dilated >8 mm. Because the sample size of this study was small, further trials with larger sample sizes may be necessary to verify the long-term effectiveness of this technique, such as calculi recurrence and biliary stricture.

Declaration of conflicting interest
The authors declare that there is no conflict of interest.

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