Is T-tube drainage no longer needed for laparoscopic common bile duct exploration? A retrospective analysis and literature review

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Abstract

Introduction: *Primary closure (PC) following laparoscopic common bile duct exploration (LCBDE) is increasingly becoming a safe and effective option for choledocholithiasis. However, whether T-tube drainage (TTD) is no longer needed for LCBDE remains under debate.*
Aim: *To evaluate the safety and efficacy of PC and TTD following LCBDE, and discuss their indications for selection of the procedure, combined with a literature review.*
Material and methods: *826 consecutive patients who underwent LCBDE with PC or TTD at Shanghai Tenth People's Hospital were reviewed. The clinical data of postoperative outcomes were compared and analyzed. Propensity score matching (PSM) was used to adjust for potential baseline confounding.*
Results: *Of these patients, 796 underwent PC and 30 underwent TTD. Twenty-eight (3.52%) cases occurred in bile leakage in PC, and all of them were treated successfully with conservative therapy. Additionally, there was no evidence of bile duct stricture and death in all PC cases. TTD was mainly performed in patients with a higher rate of cholangitis (50.00%), large stones (26.67%), impacted stones (23.33%) and laser lithotripsy (26.67%). After PSM, 23 cases with PC and TTD were included. In the PC group, the operative time, postoperative stay, hospital expenses and recurrence rate were significantly shorter or less than in the TTD group. However, there were no significant differences between the two groups in postoperative drainage time, complications, reoperations and bile duct stricture rate.*
Conclusions: *PC following LCBDE is safe and effective for choledocholithiasis. TTD is a safe alternative method for bile duct closure in certain special cases, such as acute cholangitis, large stones, impacted stones, and laser lithotripsy.*

Key words: *choledocholithiasis, laparoscopic common bile duct exploration, primary closure, T-tube drainage.*

Introduction

Choledocholithiasis is the second most prevalent complication of cholecystolithiasis, which accounts for approximately 3–16% of patients with gallstones [1]. Additionally, prompt medical attention is recommended for patients with symptomatic choledocholithiasis to avoid life-threating acute cholangitis, biliary pancreatitis and severe inflammation [2].

The standard care for choledocholithiasis remains debatable. At present, endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy is considered as a mainstream

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method for choledocholithiasis [3]. However, laparoscopic common bile duct exploration (LCBDE) has increasingly been proven to be a safer and more effective method in recent years, with fewer short-term and long-term complications [4]. In particular, as a one-stage procedure, LCBDE with bile duct primary closure (PC) also has the advantages of faster postoperative recovery, shorter hospital stay and lower costs [5–7].

Traditionally, T-tube drainage (TTD) has been widely applied in laparoscopic or open choledochotomy, which not only can decompress the biliary tree and reduce the risk of bile leak and biliary stricture, but also can provide the access for cholangiography to detect and remove the residual stones [8, 9]. However, the rate of complications related to TTD is also as high as approximately 15%, which can prolong the hospital stay and increase the expenses [10]. Thus, the indications to determine in which situation we should choose the way of bile duct closure, TTD or PC, following LCBDE, is worth discussion.

Aim

In this study, we aimed to evaluate the safety and efficacy of PC and TTD following LCBDE, and discuss the indications of methods of selection for bile duct closure combined with a literature review.

Material and methods

Patients and data collection

From January 2014 to February 2019, a collected database of 826 patients who underwent LCBDE at Shanghai Tenth People's Hospital was reviewed. LCBDE was performed for patients with a diagnosis of choledocholithiasis confirmed by preoperative computed tomography (CT), magnetic resonance cholangiopancreatography (MRCP), and/or abdominal ultrasonography. The clinical data, such as demographic information, clinical symptoms, characteristics of stone, dimeters of common bile duct (CBD), medical history, operative process, methods of bile duct closure, and postoperative outcomes, were recorded and analyzed.

The stones were classified into two categories according to their location: one for common bile duct stones and the second for 'other', the latter being defined as stones located in the intrahepatic duct, common hepatic duct or cystic duct stones. 30-day readmission indicated that the patient was readmitted to the hospital within 30 days of discharge, except for the reason of removing the T-tube. Mortality was defined as the patients who died during hospitalization or within 30 days of discharge. The expenses of the T-tube drainage group included two parts: LCBDE and T-tube removal. Operative complications were classified with the Clavien-Dindo classification system [11, 12]. Recurrence was defined as the stone rediscovered more than 6 months after LCBDE, and the diagnosis depends on imaging examination [13].

This study was approved by the Institutional Review Board of Shanghai Tenth People's Hospital (SHSY-IEC-4.1/21-143/01).

Operative technique

The operative technique for LCBDE was as described previously, using the "four-port and six-step" approach under general anesthesia [14, 15]. Briefly, after successfully dissecting Calot's triangle, the cystic duct was isolated and clamped with an absorbable clip (Lapro-Clip; Tyco Healthcare, Covidien, Norwalk, Conn., USA), which prevented the gallbladder stones sliding into the CBD during the operation. Then, the CBD was fully exposed and the choledochoscope was used to detect and remove stones following longitudinal choledochotomy. A Dormia basket (FG-24X-1; Olympus), high-pressured saline irrigation, and/or laser lithotripsy (World of Medicine, Berlin, Germany) were selectively used to extract stones. After confirmation of clearance of the bile duct stones, the bile duct was closed with absorbable 4-0 PDS II sutures (Ethicon Inc., Somerville, NJ, USA) in continuous over-and-over locking fashion or dwelling T-tube drainage. After ensuring no bile leakage from the CBD incision, the gallbladder was removed routinely. A silicone drainage tube was routinely placed in the foramen of Winslow.

Statistical analysis

Statistical analyses were performed with SPSS version 26.0 (IBM Corporation, Armonk, NY, USA) and R software version 4.0.4 (R Project for Statistical Computing, Vienna, Austria). Student's *t*-test or the Mann-Whitney *U* test was applied for the analysis of quantitative variables, which were presented as mean ± SD or median (quartiles); the χ^2 test or Fisher's exact test was used for comparing qualitative

Table I. Baseline characteristics of all LCBDE patients

Parameter	Total (*n* = 826)	PC (*n* = 796)	TTD (*n* = 30)	*P*-value
Follow-up time [months]	38.02 (27.70, 53.51)	38.21 (27.83, 53.53)	30.68 (24.28, 52.03)	0.152
Sex, female, *n* (%)	449 (54.36)	436 (54.77)	13 (43.33)	0.217
Age [years]	63.00 (55.00, 72.00)	63.00 (55.00, 72.00)	65.50 (59.00, 74.25)	0.236
BMI [kg/m^2]	23.42 ±3.17	23.44 ±3.15	22.88 ±3.80	0.343
Symptoms, *n* (%):				
Abdominal pain	743 (89.95)	721 (90.58)	22 (73.33)	0.006
Jaundice	222 (26.88)	205 (25.75)	17 (56.67)	< 0.001
Cholecystitis	617 (74.70)	596 (74.87)	21 (70.00)	0.547
Cholangitis	272 (32.93)	257 (32.29)	15 (50.00)	0.043
Pancreatitis	32 (3.87)	30 (3.77)	2 (6.67)	0.745
CBD diameter [mm]	11.00 (10.00, 12.00)	11.00 (10.00, 12.00)	12.00 (11.00, 14.25)	0.006
CBD stone, *n* (%):				
Size ≥ 15 mm	77 (9.32)	69 (8.72)	8 (26.67)	0.003
Number ≥ 3	279 (33.78)	262 (33.08)	17 (56.67)	0.007
Location, other	34 (4.12)	27 (3.39)	7 (23.33)	< 0.001
Impaction	67 (8.11)	60 (7.54)	7 (23.33)	0.006
Mirizzi syndrome	7 (0.85)	6 (0.75)	1 (3.33)	0.229
Serum liver biochemical indicators:				
ALT [U/l]	92.35 (22.53, 254.83)	94.05 (22.00, 256.63)	53.00 (34.30, 164.95)	0.627
AST [U/l]	53.40 (22.80, 149.70)	53.20 (22.50, 150.20)	53.80 (25.75, 122.80)	0.929
GGT [U/l]	266.10 (70.80, 506.55)	262.70 (64.35, 503.65)	336.30 (139.85, 607.90)	0.169
ALP [U/l]	142.75 (88.23, 233.65)	141.70 (88.08, 227.45)	211.05 (118.83, 330.25)	0.017
TBIL [μmol/l]	21.70 (12.80, 57.25)	21.50 (12.60, 55.50)	33.25 (14.68, 99.18)	0.036
DBIL [μmol/l]	9.10 (4.30, 36.70)	9.00 (4.25, 35.70)	22.30 (6.48, 74.50)	0.009
Operative treatment process, *n* (%):				
Abdominal adhesion	694 (84.02)	670 (84.17)	24 (80.00)	0.720
Post-cholecystectomy	50 (6.05)	46 (5.78)	4 (13.33)	0.189
Post-ERCP	35 (4.24)	33 (4.15)	2 (6.67)	0.833
Laser lithotripsy	31 (3.75)	23 (2.89)	8 (26.67)	< 0.001
Comorbidities and past history, *n* (%):				
Hypotension	415 (50.24)	397 (49.87)	18 (60.00)	0.276
Diabetes	138 (16.71)	131 (16.46)	7 (23.33)	0.322
Coronary heart disease	58 (7.02)	57 (7.16)	1 (3.33)	0.659
Fatty liver	154 (18.64)	148 (18.59)	6 (20.00)	0.846
Viral hepatitis	477 (57.75)	458 (57.54)	19 (63.33)	0.528
Urinary calculus	96 (11.62)	94 (11.81)	2 (6.67)	0.567

ALP – antileukoproteinase, ALT – alanine aminotransferase, AST – aspartate aminotransferase, BMI – body mass index, CBD – common bile duct, DBIL – direct bilirubin, ERCP – endoscopic retrograde cholangiopancreatography, GGT – γ-glutamyltranspeptidase, LCBDE – laparoscopic common bile duct exploration, PC – primary closure, TBIL – total bilirubin, TTD – T-tube drainage.

variables, which were reported as frequencies with percentages. Propensity score matching (PSM) at a 1 : 1 ratio was utilized to reduce significant imbalances in baseline characteristics. Matching was performed for baseline characteristics including demographic and preoperative data, using a caliper width of 0.05. Kaplan-Meier curves depicting the cumulative recurrence probability were constructed to compare long-term outcomes between different groups. In addition, linear regression and Cox proportional-hazards regression were conducted to further reduce bias. A *p*-value of < 0.05 was considered statistically significant.

Results

During the research period, a total of 826 participants who underwent LCBDE were included and reviewed. Demographic and preoperative characteristics are shown in Table I.

Table II. Outcomes of patients undergoing primary closure

Variable	PC (*n* = 796)
Conversion to open surgery, *n* (%)	7 (0.88)
Operative time [min]	111.00 (87.00, 144.00)
Blood loss [ml]	20.00 (20.00, 50.00)
Bile leakage, *n* (%)	28 (3.52)
SSSI, *n* (%)	1 (0.13)
Perforation, *n* (%)	1 (0.13)
Postoperative stay [days]	6.00 (5.00,8.00)
Postoperative drainage time [days]	5.00 (4.00,6.00)
30-day readmission, *n* (%)	2 (0.25)
Second operation, *n* (%)	2 (0.25)
Mortality, n (%)	0 (0.00)
Clavien-Dindo classification, *n* (%):	
1	763 (95.85)
2	21 (2.64)
3a	5 (0.63)
3b	1 (0.13)
4a	6 (0.75)
4b	0 (0.00)
5	0 (0.00)
Bile duct stricture, *n* (%)	0 (0.00)
Recurrence, *n* (%)	37 (4.65)

PC – primary closure, SSSI – skin and skin structure infection.

Of these patients, 796 were treated with PC, and the most frequent clinical symptoms were abdominal pain (90.58%), cholecystitis (74.87%), cholangitis (32.39%), jaundice (25.75%), and pancreatitis (3.77%). For characteristics of stones, the size ≥ 15 mm was noted in 8.72%, the number ≥ 3 in 33.08%, another location in 3.39%, impaction in 7.54%, and Mirizzi syndrome in 0.75%. The median CBD diameter was 11.00 mm, ranging from 5 to 35 mm. In addition, about 5.78% of the patients had undergone cholecystectomy, and 4.15% had experienced a failed ERCP before LCBDE.

The operative outcomes of patients with PC are summarized in Table II. Only 7 (0.88%) patients were temporarily converted to open surgery intraoperatively for dense adhesion, unclear anatomy and Mirizzi syndrome. The median operative time was 111.00 min, and median blood loss was 20.00 ml. Bile leakage occurred in 28 (3.52%) patients, and all patients were treated by conservative management, including drainage and intravenous antibiotics. The median postoperative stay and drainage time were 6.00 days and 5.00 days. In summary, there were few serious postoperative complications after LCBDE with PC, and surgery-related death was not observed. After a long-term follow-up with the median at 38.21 months, recurrent stones were detected in 37 (4.65%) patients without any bile duct stricture events.

T-tube drainage was indwelled in 30 patients. The clinical characteristics are summarized in Table I, which shows that TTD was performed in patients with a higher rate of jaundice (56.67%), cholangitis (50.00%), large stones (26.67%), multiple stones (56.67%), impacted stones (23.33%) and laser lithotripsy (26.67%). After PSM, 23 patients with PC and TTD were included and analyzed (Table III). The results showed that there were no significant differences between the two groups in blood loss, postoperative drainage time, bile leakage rate, 30-day readmission rate, complication rate, second operation rate and bile duct stricture rate. However, the operative time, postoperative stay and hospital expenses in the PC group were significantly shorter than in the TTD group (Table IV, Figure 1). The same results were obtained by univariate and multivariate linear regression analysis of the complete cohorts (Figure 2).

Kaplan-Meier curves and Cox proportional hazards regression were conducted to analyze the recurrence of bile duct stones. The Kaplan-Meier curves

Table III. Baseline characteristics of patients after propensity score matching (PSM)

Parameter	PC (*n* = 23)	TTD (*n* = 23)	*P*-value
Sex, female, *n* (%)	12 (52.17)	11 (47.83)	0.768
Age [years]	70.00 (65.00, 77.00)	64.00 (59.00, 74.00)	0.057
BMI [kg/m^2]	23.24 ±2.31	23.35 ±3.50	0.898
Symptoms, *n* (%):			
Abdominal pain	19 (82.61)	18 (78.26)	1.000
Jaundice	6 (26.09)	11 (47.83)	0.127
Cholecystitis	19 (82.61)	17 (73.91)	0.475
Cholangitis	12 (52.17)	10 (43.48)	0.555
Pancreatitis	0 (0.00)	1 (4.35)	1.000
CBD diameter [mm]	12.00 (10.00, 15.00)	12.00 (11.00, 14.00)	0.902
CBD stone, *n* (%):			
Size ≥ 15 mm	9 (39.19)	6 (26.09)	0.345
Number ≥ 3	10 (43.48)	13 (56.52)	0.376
Location, other	5 (21.74)	5 (21.74)	1.000
Impaction	4 (17.39)	6 (26.09)	0.475
Mirizzi syndrome	1 (4.35)	1 (4.35)	1.000
Serum liver biochemical indicators:			
ALT [U/l]	49.40 (19.30, 185.10)	42.80 (23.60, 168.40)	0.701
AST [U/l]	41.00 (27.00, 132.40)	53.40 (26.00, 108.00)	0.921
GGT [U/l]	363.70 (56.80, 584.30)	302.10 (105.00, 563.80)	0.974
ALP [U/l]	196.00 (81.70, 374.80)	170.60 (91.00, 270.50)	0.835
TBIL [µmol/l]	17.20 (11.60, 41.70)	24.20 (14.60, 99.00)	0.184
DBIL [µmol/l]	8.30 (4.40, 31.90)	13.50 (5.10, 69.00)	0.160
Operative treatment process, *n* (%):			
Abdominal adhesion	22 (95.65)	19 (82.61)	0.343
Post-cholecystectomy	3 (13.04)	3 (13.04)	1.000
Post-ERCP	2 (8.70)	2 (8.70)	1.000
Laser lithotripsy	5 (21.74)	7 (30.43)	0.502
Comorbidities and past history, *n* (%):			
Hypotension	17 (73.91)	13 (56.52)	0.216
Diabetes	5 (21.74)	5 (21.74)	1.000
Coronary heart disease	0 (0.00)	1 (4.34)	1.000
Fatty liver	0 (0.00)	4 (17.39)	0.116
Viral hepatitis	15 (65.22)	15 (65.22)	1.000
Urinary calculus	1 (4.35)	2 (8.70)	1.000

ALP – antileukoproteinase, ALT – alanine aminotransferase, AST – aspartate aminotransferase, BMI – body mass index, CBD – common bile duct, DBIL – direct bilirubin, ERCP – endoscopic retrograde cholangiopancreatography, GGT – γ-glutamyltranspeptidase, PC – primary closure, TBIL – total bilirubin, TTD – T-tube drainage.

Table IV. Outcomes between the primary closure and T-tube drainage group patients

Variable	PC (*n* = 23)	TTD (*n* = 23)	*P*-value
Conversion to open surgery, *n* (%)	0 (0.00)	5 (21.74)	0.058
Operative time [min]	123.00 (86.75, 155.00)	173.50 (125.00, 258.75)	0.005
Blood loss [ml]	20.00 (10.00, 50.00)	50.00 (25.00, 100.00)	0.111
Bile leakage, *n* (%)	1 (4.34)	0 (0.00)	1.000
SSSI, *n* (%)	0 (0.00)	0 (0.00)	1.000
Perforation, *n* (%)	0 (0.00)	0 (0.00)	1.000
Postoperative stay [days]	7.00 (6.00, 9.00)	9.00 (8.00, 12.00)	0.007
Postoperative drainage time [days]	5.00 (4.00, 7.00)	6.00 (5.00, 7.00)	0.213
30-day readmission, *n* (%)	0 (0.00)	2 (8.70)	0.470
Second operation, *n* (%)	0 (0.00)	2 (8.70)	0.470
Mortality, *n* (%)	0 (0.00)	0 (0.00)	1.000
Clavien-Dindo classification, *n* (%):			0.103
1	20 (86.95)	18 (78.26)	
2	1 (4.35)	4 (17.39)	
3a	0 (0.00)	1 (4.35)	
3b	0 (0.00)	0 (0.00)	
4a	2 (8.70)	0 (0.00)	
4b	0 (0.00)	0 (0.00)	
5	0 (0.00)	0 (0.00)	
Hospital expenses, $	5235.07 (4730.26, 5539.07)	5424.77 (5053.81, 6987.28)	0.042
Bile duct stricture, n (%)	0 (0.00)	1 (4.34)	1.000

PC – primary closure, SSSI – skin and skin structure infection, TTD – T-tube drainage.

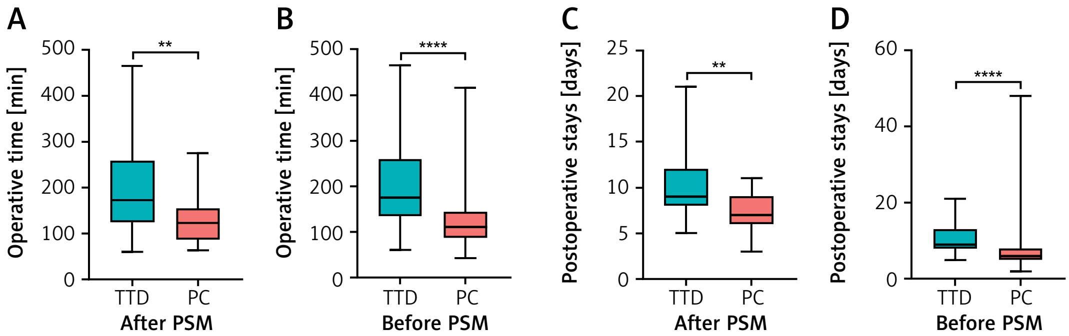

Figure 1. Operative time and postoperative stay between PC and TTD group. **A** – Operative time after PSM, **B** – operative time before PSM, **C** – postoperative stay after PSM, **D** – postoperative stay before PSM

*PC – Primary closure, PSM – Propensity score matching, TTD – T-tube drainage. **P < 0.01, ****p < 0.0001.*

showed that the cumulative recurrence probabilities in the TTD group were higher than in the PC group, with the *p*-value being 0.002 (Figure 3). The crude and adjusted HR of Cox proportional hazards regression were 4.03 (95% CI: 1.58–10.25) and 3.56 (95% CI: 1.35–9.39) respectively (Figure 4).

Discussion

In the past two decades years, ERCP was considered as a mainstream treatment for patients with common bile duct stones. However, with recent advances in laparoscopic technique, accumulating

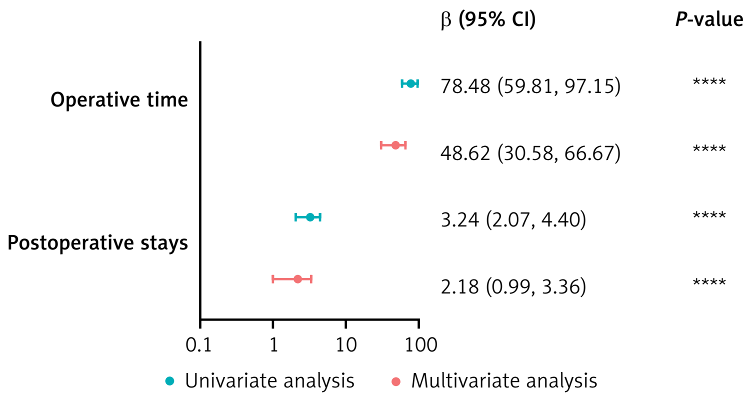

Figure 2. Linear regression of operative time and postoperative stay regarding TTD, taking PC as reference

*CI – confidence interval, PC – primary closure, TTD – T-tube drainage. ****P < 0.0001.*

studies have demonstrated that LCBDE had a higher stone clearance rate, lower retained stone rate, lower lithiasis recurrence rate, shorter hospital stay and lower total charges than the ERCP procedure in these patients [4]. In addition, the LCBDE preserves the function of the sphincter of Oddi, which reduces the risk of refluxing cholangitis, pancreatitis and stone recurrence [16, 17]. Thus, the LCBDE procedure is increasingly becoming an optimal treatment choice for the patient with cholecysto-choledocholithiasis.

Our study also confirmed that LCBDE is effective and safe for the management of choledocholithiasis. In these patients, 96.37% of cases underwent primary closure, and T-tube drainage was inserted in only 3.63% of cases. The total successful stone clearance rate is 99.88% (data not shown). There was nearly no bile duct injury, hemorrhage, perforation or postoperative surgery related death. Postoperative bile leakage was 3.39% and all of the cases were managed successfully with conservation therapy (data not shown). The median follow-up period was 38.02 months, with evidence of bile duct stricture in only 1 patient.

Although LCBDE has proven safety and efficacy for the treatment of choledocholithiasis, and it was also included in the guidelines of the British Society of Gastroenterology, how to choose the method of common bile duct closure, primary closure or T-tube drainage remains debatable [2, 5]. Traditionally, open choledocholithotomy with T-tube drainage was the standard care for the treatment of choledocholithiasis. In the last twenty years, with the rapid development of minimally invasive laparoscopic surgical techniques, laparoscopic choledochotomy with

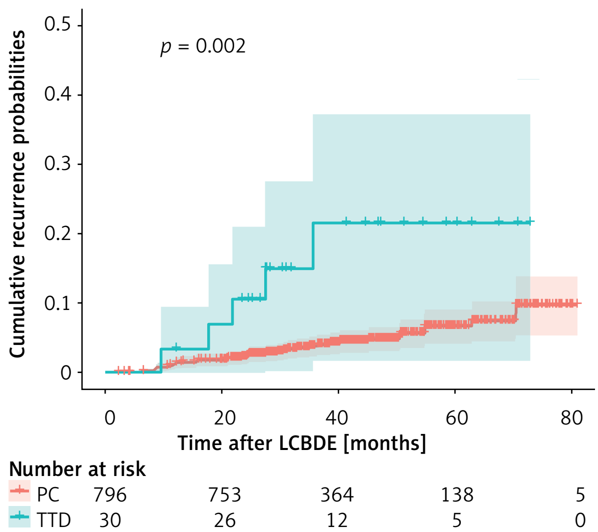

Figure 3. Kaplan-Meier curves for the cumulative recurrence probabilities of bile duct stones in patients undergoing successful LCBDE

LCBDE – laparoscopic common bile duct exploration, PC – primary closure, TTD – T-tube drainage.

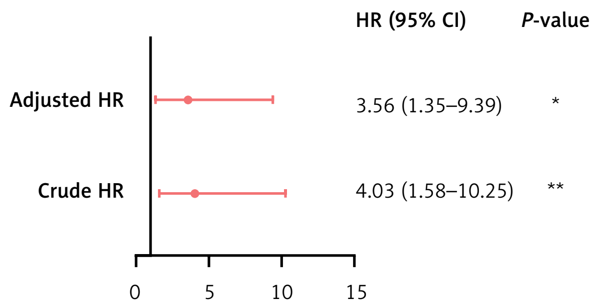

Figure 4. Cox proportional hazards regression of recurrence risk regarding TTD, taking PC as reference

*CI – confidence interval, HR – hazard ratio, PC – primary closure, TTD – T-tube drainage. *P < 0.05, **p < 0.01.*

T-tube drainage has been widely adopted in these patients [9]. The traditional viewpoint was that T-tube placement not only could decompress the biliary tree and reduce the risk of postoperative complications, such as bile leak and biliary stricture, but also could provide access to postoperatively detect and remove the residual stones by using cholangiography [8, 9].

However, we also noted that T-tube drainage not only caused tube-related complications, such as bile leakage, biliary peritonitis, T-tube displacement, bile duct obstruction, wound infection and skin excoriation around the T-tube, but also led to the patients experiencing loss of appetite, malnutrition and inconvenience in daily life, which also prolonged the hospital stay and recovery and increased hospital expenses [5, 6, 18].

Recently, with the advances in surgical instruments, technique, and knowledge, primary closure (PC) for common bile duct after LCBDE was preferentially recommended [19]. The results from several studies demonstrated that LCBDE with PC is a safe and effective method with shorter operating time, lower medical expenses, shorter postoperative hospital stay, and fewer postoperative complications than TTD [20–22]. Additionally, PC can achieve the same rate of postoperative bile leakage and stone clearance compared with TTD and avoid the disadvantages associated with TTD [18, 19]. Exceptionally, our study demonstrated for the first time that primary closure would reduce the recurrence rate of bile duct stones and the T-tube is a potential factor that promotes stone formation [14, 23].

Based on previous studies, although T-tube drainage has numerous disadvantages and complications, it still has value for specific cases, such as acute suppurative cholangitis, multiple or large stones, suspicious residual stones, distal bile duct obstruction, when the biliary tract is thin, which would be beneficial in preventing bile leakage or bile duct strictures, or in providing access for removal of retained stones, or in providing effective biliary decompression in patients with incomplete stone removal after choledochotomy [8, 21, 24, 25]. Also, as shown in this study, a higher rate of T-tube drainage occurred in the patients with cholangitis, large stones, impacted stones and laser lithotripsy, which has a high rate of suspicious residual stones. Therefore, in our experience, TTD is also a valuable option if the patient presents with the above-mentioned conditions. Thus, although PC is preferred, many surgeons still believe in specific cases that the appropriate method of bile duct closure should be chosen based on the preoperative imaging manifestations, specific status of the bile duct, location and size of stones in the operation and the operator's personal experience.

This study also had some limitations. First, it was a retrospective study with an inherent bias in data collection. Second, this was a single-center study, and the patient sample was relatively small. In particular, there were only 30 patients in the TTD group, which made the PSM matching less efficient. Third, we did not consider the patients' peribiliary anatomical conditions, such as diverticula and common bile duct angulation. Therefore, further multi-center prospective studies with larger populations are necessary for further confirmation.

Conclusions

Primary closure following LCBDE is safe and effective in patients with choledocholithiasis. Although there are a variety of disadvantages for T-tube drainage, such as longer operative time, longer postoperative stay, higher hospital expenses and a higher recurrence rate, it still has value and is a safe alternative bile duct closure method in certain special cases, such as acute cholangitis, large stones, impacted stones and laser lithotripsy.

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Wangcheng Xie, Weidi Yu, and Zhou Zhang contributed equally to this study.

Conflict of interest

The authors declare no conflict of interest.

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