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Is Primary Closure Safe for Patients With Nonsevere Acute Cholangitis? A Single-Center Study on Laparoscopic Common Bile Duct Exploration

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ABSTRACT

Introduction: The safety and effectiveness of laparoscopic common bile duct exploration with primary closure in patients with nonsevere acute cholangitis remain debatable. The study aimed to evaluate the safety and effectiveness of laparoscopic common bile duct exploration with primary closure in patients with nonsevere acute cholangitis.
Methods: Patients with nonsevere cholangitis who underwent laparoscopic common bile duct exploration at our center between January 2014 and December 2024 were retrospectively reviewed. According to the manner of closure of the open common bile duct, patients were divided into Group A (primary closure) and Group B (T-tube insertion). Preoperative, intraoperative, and postoperative outcomes between the two groups were compared.
Results: Altogether, 373 patients were included, with 269 patients in Group A and 104 patients in Group B. The baseline characteristics of Group A were not significantly different from those of Group B. Compared with Group B, Group A was associated with less estimated blood loss ($P < 0.001$), shorter operative time ($P < 0.001$), and a lower rate of blood transfusion ($P < 0.001$). Group A was also associated with shorter total hospital stay ($P = 0.001$), shorter postoperative hospital stay ($P = 0.001$), and lower rates of common bile duct stricture ($P < 0.001$) and residual stones ($P < 0.001$). One patient in Group A died within 30 d after surgery.

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Conclusions: For patients with nonsevere acute cholangitis, primary closure is safe and effective, as it is associated with improved intraoperative outcomes and noninferior postoperative outcomes. However, these findings should be validated in prospective randomized controlled trials, given the biases related to patient selection and closure method.

Introduction

Common bile duct stones are among the most common biliary diseases, accounting for approximately 10%-15% of cholelithiasis cases.[1,2] The optimal treatment for choledocholithiasis varies according to the diameter of the common bile duct. Available treatment options include endoscopic retrograde cholangiopancreatography (ERCP), open surgery, laparoscopic surgery, and percutaneous interventions. Laparoscopic common bile duct exploration has been widely applied because of its minimal invasiveness, single-stage approach, lower risk of postoperative complications, shorter hospital stay, and lower costs.[3,4] Additionally, primary closure is superior to T-tube insertion as it is associated with less intraoperative injury, faster recovery, and significantly improved quality of life.[5-7]

Acute cholangitis is defined as a bacterial infection of the biliary tract caused by biliary obstruction, such as choledocholithiasis, malignant tumors, or obstructed biliary stents. The typical manifestations of acute cholangitis include abdominal pain, obstructive jaundice, and fever (the so-called Charcot triad). However, in older patients or those with compromised immune systems, these symptoms may be atypical, making diagnosis more challenging. The Charcot triad comprises abdominal pain, fever, and jaundice. Currently, there is no clear consensus on the definition of nonacute cholangitis. The so-called nonacute cholangitis usually includes IgG4-related cholangitis, primary sclerosing cholangitis, and chronic bacterial cholangitis (commonly observed in patients with abnormal biliary anatomy or after cholangiojejunostomy). For patients with nonacute cholangitis, abdominal pain and fever are uncommon, whereas cholestatic symptoms such as pruritus and jaundice are more common. Similarly, "emergent cholangitis" generally refers to severe acute cholangitis (Grade III). For these patients, emergent biliary drainage via ERCP, percutaneous transhepatic cholangiographic drainage, or common bile duct exploration is necessary to prevent septic shock and subsequent multiple organ failure.

As an acute onset of bacterial infection of the biliary tract owing to obstructed bile duct, acute cholangitis occurs in 0.3%-1.6% of patients with choledocholithiasis.[8,9] The Tokyo Guidelines 2018 (TG18) are widely adopted for the diagnosis, severity assessment, and management of acute cholangitis. For patients with acute cholangitis, ERCP and percutaneous transhepatic cholangiography are the preferred choices, especially for those with severe acute cholangitis. However, for patients with nonsevere acute cholangitis, the optimal treatment strategy remains controversial. For most patients with acute cholangitis undergoing ERCP, laparoscopic cholecystectomy (LC) is usually needed to deal with gallstones. However, factors such as periampullary duodenal diverticula or an altered gastrointestinal anatomy following surgery may hinder successful ERCP. Owing to the progress in laparoscopic instruments and surgical techniques, laparoscopic common bile duct exploration is increasingly performed even in emergent settings. Laparoscopic common bile duct with T-tube insertion has been proven safe in treating common bile duct stone in emergent cases.[10,11]

Primary closure is superior to T-tube insertion, and its safety has been proven in nonemergent cases. However, studies assessing the safety (e.g., major complications, intensive care unit [ICU] stay, and 30-d mortality) and effectiveness (e.g., conversion to open surgery, residual stones, postoperative hospital stay, bile duct stricture, and stone recurrence) in both severe and nonsevere acute cholangitis remain limited. For severe acute cholangitis, T-tube insertion is generally recommended over primary closure because of the higher risk of severe complications. However, the role of primary closure in nonsevere acute cholangitis remains controversial.

Thus, this study aimed to further evaluate the safety and effectiveness of primary closure following laparoscopic common bile duct exploration in patients with nonsevere acute cholangitis, providing valuable insights for future clinical practice.

Materials and Methods

Study design

The safety and effectiveness of primary closure among patients with nonsevere cholangitis were evaluated in a retrospective, single-center study. Acute cholangitis was diagnosed and graded according to the TG18.[12] Acute cholangitis was graded based on a combination of imaging findings, cholestasis, and systemic inflammatory response. Patients undergoing LC and common bile duct exploration at the Shenzhen People's Hospital between January 2014 and December 2024 were retrospectively reviewed. According to the method of common bile duct closure, patients were divided into Group A (primary closure) and Group B (T-tube insertion). All patients provided written informed consent. This study was approved by the Ethics Committee of Shenzhen People's Hospital, and the Declaration of Helsinki was adhered to during the whole process of this study.[13]

Common bile duct stones were diagnosed based on clinical manifestations, laboratory findings, and imaging examinations, including ultrasonography (USG), computed tomography (CT), and magnetic resonance cholangiopancreatography

(MRCP). The exclusion criteria were as follows: (1) concurrent intrahepatic bile duct stones, (2) severe acute cholangitis, (3) biliary tract malignancy, and (4) suspected Mirizzi syndrome. The following variables were retrieved from the medical system: age, sex, body mass index, comorbidities, American Society of Anesthesiologists classification, intraoperative outcomes (operative time and estimated blood loss), and postoperative outcomes (complications, ICU stay, 30-d mortality, common bile duct stricture, and recurrent stones).

Definitions

The following diseases were defined as pulmonary diseases: asthma, pleural effusion, pneumonia, and chronic obstructive pulmonary disease. The diameter of the common bile duct was measured on MRCP at the junction of the cystic duct and the common hepatic duct. Operative time was defined as the duration between skin incision and skin closure. Total hospital stay was defined as the duration between admission and discharge. Residual (remnant) stones were defined as those not completely removed during the surgery but identified within 6 mo after surgery. Stone formation occurring $\geq$6 mo after complete stone clearance during the initial operation was defined as recurrent stones. The Clavien–Dindo classification system was used to grade postoperative complications.[14] Grade III or higher complications were considered major complications.

Definition of nonsevere cholangitis

In this study, TG18 criteria were used to assess the severity of acute cholangitis.[12] According to TG18, three grades were defined. Grade III (severe) acute cholangitis was defined as acute cholangitis associated with dysfunction of at least one of the following organs/systems: cardiovascular (hypotension requiring dopamine $\geq$5 μg/kg/min or any dose of norepinephrine), neurological (disturbance of consciousness), respiratory ($PaO_2/FiO_2 < 300$), renal (oliguria or serum creatinine $>$ 2.0 mg/dL); hepatic (PT-INR $>$ 1.5); and hematological (platelet count $<$ 100,000/mm^3).

Grade II (moderate) acute cholangitis was defined as acute cholangitis associated with any two of the following: abnormal white blood cell count ($>$12,000/mm^3 or $<$4000/mm^3), high fever ($\geq$39°C); age $\geq$75 y, hyperbilirubinemia (total bilirubin $\geq$5 mg/dL), or hypoalbuminemia ($<$0.7 $\times$ standard value).

Grade I acute cholangitis did not meet the criteria of Grade III (severe) or Grade II (moderate) at initial diagnosis. Grade I and Grade II acute cholangitis were defined as nonsevere cholangitis.

Surgical techniques

Empirical antibiotic therapy was initiated upon admission. After blood culture results were obtained, targeted narrow-spectrum antibiotics were administered. All procedures were performed by experienced surgeons following standardized operative principles. After induction of general anesthesia with endotracheal intubation, patients were placed in the reverse Trendelenburg position, and a three-port technique was routinely used, with a fourth port added when necessary.

The first 10-mm trocar was inserted into the abdominal cavity through a subumbilical incision. Next, pneumoperitoneum was established, with pressure maintained between 12 and 14 mm Hg. A laparoscope with a 30° viewing angle was introduced to explore the abdominal cavity. Additional trocars were inserted under direct visualization.

Adhesions around the gallbladder were dissected to expose Calot's triangle. The cystic artery was then identified and clipped. The cystic duct was preserved for traction to expose the anterior wall of the common bile duct. After confirming the common bile duct, a longitudinal incision was made on its anterior wall using a biliary knife or electrocautery, with incision length determined by the size of the stones.

A choledochoscope was inserted into the common bile duct. Once stones were spotted, the stone extraction basket was inserted through the working channel. Additional techniques, including manual compression of the distal bile duct, saline irrigation, electrohydraulic lithotripsy, and laser lithotripsy, were used as needed to facilitate stone removal. After stone extraction, the choledochoscope was advanced to examine the extrahepatic and intrahepatic ducts to ensure complete clearance.

If the sphincter of Oddi was functional and a 5-mm choledochoscope could smoothly pass into the duodenum, the decision between opting for primary closure or T-tube insertion was made. Primary closure was preferred in the absence of significant bile duct wall edema or suppurative inflammation, whereas T-tube insertion was selected when marked edema or inflammation was present.

In this study, no patients underwent emergent operations, indicating that adequate preoperative management had been achieved and that bile duct inflammation was generally mild. However, given that primary closure in nonsevere cholangitis remains controversial, surgeons discussed the risks and benefits of both approaches with the patient or their authorized representative, and the final decision was made accordingly.

Polydioxanone (PDS-II) absorbable sutures were used for both primary closure and T-tube placement. The cystic duct was transected, and the gallbladder was removed and extracted through a subumbilical incision. The T-tube was exteriorized through a subxiphoid incision. A closed-suction drainage tube was placed near Winslow's foramen and exteriorized through a right upper abdominal incision.

Postoperative care and follow-up

Postoperatively, all patients received standard postoperative care. The drainage tube was removed when the drained fluid was $<$20 mL/d and no bile leakage was observed. The T-tube was removed 6-8 wk postoperatively, and a choledochoscopic evaluation was routinely performed before the removal.

All patients were scheduled for follow-up every 3 mo, which included physical examination, laboratory tests (complete blood count and liver function tests), and USG. CT or MRCP was performed when indicated.

The diagnosis of common bile duct stricture and recurrent common bile stones was based on clinical symptoms, laboratory findings, and imaging studies. During follow-up, patient-reported symptoms were assessed, and physical examinations were routinely performed. If biliary colic, jaundice, or fever occurred, liver function tests and MRI/MRCP were performed to evaluate for bile duct stricture or stone recurrence.

In cases of asymptomatic bile duct dilation detected on USG or CT, MRI/MRCP was also performed to assess for stricture or recurrence. When bile duct stricture or recurrent stones were confirmed and associated with symptoms, ERCP was performed for both therapeutic management and diagnostic confirmation.

Statistical analysis

Normally distributed quantitative variables were presented as mean $\pm$ standard deviation and compared using the Student's *t*-test. Nonnormally distributed variables were presented as median and interquartile range and compared using the Mann–Whitney *U* test. Categorical variables were expressed as frequencies and percentages, and comparisons were performed using the chi-squared test or Fisher's exact test, as appropriate.

Binary logistic regression analysis was performed to identify independent predictors of major complications. All statistical analyses were two sided, and *P* values <0.05 were considered statistically significant. All analyses were performed using Statistical Package for the Social Science (SPSS), version 22 (IBM, USA).

Results

Baseline characteristics

Altogether, 373 patients with nonsevere acute cholangitis caused by common bile duct stones were included. The mean age was 62.38 $\pm$ 16.236 y, and the male-to-female ratio was 211:162. Among these 373 patients, 269 (72.1%) underwent laparoscopic common bile duct exploration plus primary closure, and 104 (27.9%) underwent T-tube insertion. The comparisons between Group A (primary closure) and Group B (T-tube insertion) are presented in Table 1. Group A was not significantly different from Group B in terms of baseline characteristics.

Intraoperative outcomes

Compared with Group B, Group A was associated with a shorter operative time (194.64 $\pm$ 76.130 *versus* 194.64 $\pm$ 76.130 min, $P < 0.001$) and less estimated blood loss ($P < 0.001$). In all, 11 patients required intraoperative blood transfusion, including two in Group A and nine in Group B ($P < 0.001$). Comparisons between Group A and Group B regarding intraoperative outcomes are presented in Table 2.

Postoperative outcomes

The total hospital stay for Group A was significantly shorter than that for Group B (14.43 $\pm$ 7.47 *versus* 17.69 $\pm$ 8.89 d, $P = 0.001$). The postoperative hospital stay was also significantly shorter in Group A than in Group B (7.15 $\pm$ 5.10 *versus* 9.98 $\pm$ 5.81 d, $P = 0.001$).

Altogether, 12 patients developed biliary fistula, including 10 in Group A (3.7%) and two from Group B (1.9%). Group A was not significantly different from Group B in terms of biliary fistula ($P = 0.580$). Nine patients recovered uneventfully after conservative treatment, whereas three patients required USG-guided drainage.

Postoperative intraabdominal hemorrhage occurred in six patients, including four in Group A and two in Group B. Group A was not significantly different from Group B in terms of postoperative intraabdominal hemorrhage (1.5% *versus* 1.9%, $P = 1.000$). All six patients with postoperative intraabdominal hemorrhage recovered uneventfully with nonsurgical treatment.

Group A was not significantly different from Group B in terms of ICU stay (4.8% *versus* 6.7%, $P = 0.466$), recurrent stones (4.5% *versus* 8.7%, $P = 0.115$), acute pancreatitis (0.4% *versus* 0.0%, $P = 1.000$), pneumonia (1.9% *versus* 3.8%, $P = 0.456$), acute cardiovascular event (1.5% *versus* 0.0%, $P = 0.490$), abdominal infection (5.2% *versus* 3.8%, $P = 0.583$), hemobilia (0.0% *versus* 1.9%, $P = 0.136$), urinary retention (1.1% *versus* 0.0%, $P = 0.280$), urinary infection (0.4% *versus* 0.0%, $P = 1.000$), cardiac failure (0.4% *versus* 0.0%, $P = 1.000$) and respiratory failure (0.7% *versus* 0.0%, $P = 0.378$).

One patient in Group A died within 30 d after surgery. No patients in Group B died within 30 d. Patients in Group B were more likely to have residual stones (2.2% *versus* 25%, $P < 0.001$). Of the 32 patients with residual stones, 26 in Group B were managed with choledochoscopy via the T-tube sinus tract, whereas six in Group A were managed by ERCP. The median follow-up time was 8.6 mo (6.4-10.3 mo). During follow-up, 26 patients developed common bile duct stricture, of whom nine were from Group A and 17 from Group B (3.3% *versus* 16.3%, $P < 0.001$).

Independent predictive factors for major complications

As mentioned earlier, Clavien–Dindo Grade III or higher complications were defined as major complications. Initially, we identified factors significantly associated with major complications, and it was demonstrated that renal insufficiency was significantly associated with major complications ($P = 0.016$; Table 3). Renal insufficiency and other variables with *P* values <0.1 were then included in a multivariable logistic regression analysis to identify independent predictive factors for major complications. This analysis revealed that renal insufficiency was an independent predictive factor for major complications ($P = 0.023$, odds ratio = 7.635 and 95% confidence interval: 1.329∼43.844; Table 4).

Discussion

We assessed the outcomes of laparoscopic common bile duct exploration with primary closure among patients with nonsevere acute cholangitis due to choledocholithiasis. Our results showed that primary closure was associated with better outcomes than that via T-tube insertion in terms of operative

Table 1 – Comparisons between Group A (primary closure) and Group B (T-tube insertion) in terms of baseline characteristics.

Characteristics	Group A (N = 269)	Group B (N = 104)	Effect size	*P* value
Age	63.01 ± 16.646	60.79 ± 15.082	0.137	0.233
Gender			0.034	0.510
Male	155 (57.6%)	56 (53.8%)		
Female	114 (42.4%)	48 (46.2%)		
BMI	23.17 ± 3.41	22.42 ± 3.17	0.224	0.053
Obstructive jaundice			0.042	0.419
No	16 (5.9%)	4 (3.8%)		
Yes	253 (94.1%)	100 (96.2%)		
History of pancreatitis			0.079	0.127
No	233 (86.6%)	96 (92.3%)		
Yes	36 (13.4%)	8 (7.7%)		
History of abdominal surgery			0.093	0.071
No	201 (74.7%)	68 (65.4%)		
Yes	68 (25.3%)	36 (34.6%)		
History of cholecystectomy			0.098	0.416
No	229 (85.1%)	80 (76.9%)		
Yes	40 (14.9%)	24 (23.1%)		
Diameter of CBD (cm)	1.30 ± 0.406	1.35 ± 0.353	−0.128	0.262
Solitary/multiple stones			0.087	0.094
Solitary	132 (49.1%)	41 (39.4%)		
Multiple	137 (50.9%)	63 (60.6%)		
Maximum diameter of stones (cm)	0.86 ± 0.51	0.93 ± 0.65	0.127	0.328
Hypertension			0.010	0.846
No	173 (64.3%)	68 (65.4%)		
Yes	96 (35.7%)	36 (34.6%)		
Diabetes mellitus			0.028	0.583
No	235 (87.4%)	93 (89.4%)		
Yes	34 (12.6%)	11 (10.6%)		
Cardiovascular disease			0.006	0.901
No	229 (85.1%)	88 (84.6%)		
Yes	40 (14.9%)	16 (15.4%)		
Pulmonary diseases			0.089	0.085
No	234 (87.0%)	97 (93.3%)		
Yes	35 (13.0%)	7 (6.7%)		
Renal insufficiency			0.086	0.217
No	262 (97.4%)	104 (100.0%)		
Yes	7 (2.6%)	0 (0.0%)		
ASA score			0.110	0.209
1	139 (51.6%)	61 (58.6%)		
2	106 (39.4%)	40 (38.5%)		
3	23 (8.6%)	3 (2.9%)		
4	1 (0.4%)	0 (0.0%)		

ASA = American Society of Anesthesiologists; BMI = body mass index; CBD = common bile duct.

time, estimated blood loss, blood transfusion, residual stones, and common bile duct stricture. Thus, laparoscopic common bile duct with primary closure is a feasible and favorable choice for patients with nonsevere acute cholangitis due to choledocholithiasis.

Acute cholangitis is one of the most serious complications of choledocholithiasis, and in most cases, prompt treatment is required. It is estimated that approximately 80% of patients with acute cholangitis respond well to nonsurgical treatments, such as antibiotics and fluid resuscitation, while the

Table 2 – Comparisons between Group A (primary closure) and Group B (T-tube insertion) in terms of intraoperative outcomes and postoperative results.

Characteristics	Group A (N = 269)	Group B (N = 104)	Effect size	P value
Operative time (min)	152.48 ± 73.864	194.64 ± 76.130	−0.566	<0.001
Estimated blood loss (mL)			0.210	<0.001
<100 mL	248 (92.2%)	80 (76.9%)		
≥100 mL	21 (7.8%)	24 (23.1%)		
Blood transfusion	2 (0.7%)	9 (8.7%)	0.210	<0.001
ICU stay	13 (4.8%)	7 (6.7%)	0.038	0.466
Total hospital stay (d)	14.43 ± 7.47	17.69 ± 8.89	−0.413	0.001
Postoperative hospital stay	7.15 ± 5.10	9.98 ± 5.81	−0.533	0.001
Remnant stone	6 (2.2%)	26 (25.0%)	0.365	<0.001
Recurrent stone	12 (4.5%)	9 (8.7%)	0.082	0.115
Bile fistula	10 (3.7%)	2 (1.9%)	0.046	0.580
C-D I/II/IIIa/IIIb/IVa/IVb/V	5/0/0/5/0/0/0	1/0/0/1/0/0/0		
CBD stricture	9 (3.3%)	17 (16.3%)	0.229	<0.001
C-D I/II/IIIa/IIIb/IVa/IVb/V	3/0/0/6/0/0/0	7/0/0/10/0/0/0		
Acute pancreatitis	1 (0.4%)	0 (0.0%)	0.032	1.000
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/1/0/0/0/0/0	0/0/0/0/0/0/0		
Pneumonia	5 (1.9%)	4 (3.8%)	0.058	0.456
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/5/0/0/0/0/0	0/4/0/0/0/0/0		
Acute cardiovascular event	4 (1.5%)	0 (0.0%)	0.065	0.490
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/4/0/0/0/0/0	0/0/0/0/0/0/0		
Intraabdominal hemorrhage	4 (1.5%)	2 (1.9%)	0.016	1.000
C-D I/II/IIIa/IIIb/IVa/IVb/V	1/3/0/0/0/0/0	1/1/0/0/0/0/0		
Abdominal infection	14 (5.2%)	4 (3.8%)	0.028	0.583
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/12/2/0/0/0/0	0/4/0/0/0/0/0		
Hemobilia	0 (0.0%)	2 (1.9%)	0.118	0.136
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/0/0/0/0/0/0	0/2/0/0/0/0/0		
Urinary retention	3 (1.1%)	0 (0.0%)	0.056	0.280
C-D I/II/IIIa/IIIb/IVa/IVb/V	3/0/0/0/0/0/0	0/0/0/0/0/0/0		
Urinary infection	1 (0.4%)	0 (0.0%)	0.032	1.000
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/1/0/0/0/0/0	0/0/0/0/0/0/0		
Cardiac failure	1 (0.4%)	0 (0.0%)	0.032	1.000
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/1/0/0/0/0/0	0/0/0/0/0/0/0		
Respiratory failure	2 (0.7%)	0 (0.0%)	0.046	0.378
C-D I/II/IIIa/IIIb/IVa/IVb/V	0/0/0/0/0/1/1	0/0/0/0/0/0/0		
30-d mortality	1 (0.4%)	0 (0.0%)	0.032	1.000

C-D = Clavien–Dindo classification system; CBD = common bile duct.

remainder require surgical or endoscopic intervention as soon as possible.[11] According to most guidelines on acute cholangitis, endoscopic drainage is the first choice for patients with severe acute cholangitis.[15] However, for nonsevere acute cholangitis, the optimal treatment remains debatable. Usually, nonsurgical treatments are first used to control the infection, after which laparoscopic common bile duct exploration with cholecystectomy or ERCP, followed by LC, may be performed. For patients with choledocholithiasis and gallbladder stones, laparoscopic common bile duct exploration and cholecystectomy have been validated.[16,17] According to some recent studies, emergent laparoscopic common bile duct exploration was as safe and effective as elective surgery.[11,18] Either primary closure or T-tube insertion may then be performed to close the common bile duct. However, studies assessing the safety of primary closure among patients with nonsevere cholangitis are still scarce. We performed this study to further assess the safety and effectiveness of primary closure among patients with nonsevere cholangitis.

In this study, we demonstrated that laparoscopic common bile duct exploration plus primary closure is safe and effective

Table 3 – Univariate analysis for major complications by Clavien–Dindo classification system.

Characteristics	No major complications (N = 349)	Major complications (N = 24)	Effect size	*P* value
Age	62.29 ± 16.33	63.79 ± 15.01	−0.009	0.661
Gender			0.053	0.302
Male	195 (55.9%)	16 (66.7%)		
Female	154 (44.1%)	8 (33.3%)		
BMI	23.04 ± 3.32	21.82 ± 3.67	0.365	0.086
Obstructive jaundice			0.035	0.842
No	18 (5.2%)	2 (8.3%)		
Yes	331 (94.8%)	22 (91.7%)		
History of pancreatitis			0.040	0.662
No	309 (88.5%)	20 (83.3%)		
Yes	40 (11.5%)	4 (16.7%)		
History of abdominal surgery			0.081	0.119
No	255 (73.1%)	14 (58.3%)		
Yes	94 (26.9%)	10 (41.7%)		
History of cholecystectomy			0.026	0.831
No	290 (83.1%)	19 (79.2%)		
Yes	59 (16.9%)	5 (20.8%)		
Diameter of CBD(cm)	1.32 ± 0.40	1.24 ± 0.33	0.202	0.347
Solitary/multiple stones			0.047	0.367
Solitary	164 (47.0%)	9 (37.5%)		
Multiple	185 (53.0%)	15 (62.5%)		
Maximum diameter of stones (cm)	0.88 ± 0.56	0.88 ± 0.48	0.000	0.997
Hypertension			0.034	0.506
No	227 (65.0%)	14 (58.3%)		
Yes	122 (35.0%)	10 (41.7%)		
Diabetes mellitus			0.071	0.173
No	309 (88.5%)	19 (79.2%)		
Yes	40 (11.5%)	5 (20.8%)		
Cardiovascular disease			0.012	0.815
No	297 (85.1%)	20 (83.3%)		
Yes	52 (14.9%)	4 (16.7%)		
Pulmonary diseases			0.079	0.230
No	312 (89.4%)	19 (79.2%)		
Yes	37 (10.6%)	5 (20.8%)		
Renal insufficiency			0.125	0.016
No	344 (98.6%)	22 (91.7%)		
Yes	5 (1.4%)	2 (8.3%)		
ASA score			0.198	0.131
1	188 (53.9%)	12 (50.0%)		
2	137 (39.2%)	9 (37.5%)		
3	24 (6.9%)	2 (8.3%)		
4	0 (0.0%)	1 (4.2%)		
Operation method			0.081	0.119
Primary closure	255 (73.1%)	14 (58.3%)		
T-tube insertion	94 (26.9%)	10 (41.7%)		

ASA = American Society of Anesthesiologists; BMI = body mass index; CBD = common bile duct.

Table 4 – Multivariate logistic regression analysis identifying independent predictive factors for major complications by Clavien–Dindo classification system.

Characteristics	*B* value	Wald χ^2	OR value (95% CI)	*P* value
BMI	−0.103	2.234	0.902 (0.787 ∼ 1.033)	0.135
Renal insufficiency	2.033	5.195	7.635 (1.329 ∼ 43.844)	0.023
Operation method	0.730	2.662	2.076 (0.863 ∼ 4.992)	0.103

BMI = body mass index; CI = confidence interval; OR = odds ratio.

in carefully selected patients with nonsevere acute cholangitis due to choledocholithiasis. The operation time for the primary closure group was significantly shorter than that for the T-tube insertion group, which was consistent with some previous studies.[19,20] According to a meta-analysis published in 2020, primary closure was superior to T-tube insertion in terms of operation time.[21] This finding is intuitive, as primary closure is technically less time consuming than T-tube placement. Additionally, we demonstrated that the estimated blood loss during primary closure was significantly less than that observed during T-tube insertion, which has not been widely reported in previous studies.[19,22] It was also revealed in our study that primary closure was associated with a significantly lower rate of blood transfusion. The greater blood loss and higher transfusion rate in the T-tube group may reflect more severe inflammation around the common bile duct and gallbladder in these patients.

Both total hospital stay and hospital stay after surgery for the primary group were significantly shorter than those for the T-tube insertion group, consistent with previous studies.[23,24] Patients undergoing T-tube insertion require a longer recovery period and additional monitoring to confirm T-tube patency. Additionally, problems related to T-tube insertion, such as fluid and electrolyte imbalance, displacement of the T-tube, and persistent biliary fistula, are the main factors prolonging hospital stay after surgery and decreasing quality of life.[25]

In this study, 12 patients (3.2%) experienced biliary fistula, which was consistent with biliary fistula rates reported previously.[3,26,27] In our study, primary closure was not significantly different from T-tube insertion in terms of biliary fistula. In the study by Alhamdani *et al*., 33 patients undergoing primary closure after emergent laparoscopic common bile duct exploration were not significantly different from 48 patients undergoing primary closure after elective laparoscopic common bile duct exploration in terms of biliary fistula.[28] According to a study by Zhu *et al*., for patients with nonsevere acute cholangitis, T-tube insertion was recommended after common bile duct exploration to decompress the common bile duct and reduce incidence of biliary fistula.[29] In a study by Jiang *et al*., primary closure was not significantly different from T-tube insertion in terms of biliary fistula (4.3 *versus* 3.7%).[30] However, in our opinion, T-tube insertion is not the primary factor influencing the occurrence of biliary fistula. Several other factors likely play a more important role. First, suture technique is an independent predictive factor for biliary fistula, and suturing by experienced surgeons has been associated with a markedly lower incidence of biliary fistula.[31,32] At our center, primary closure was performed by experienced surgeons, and the incidence of biliary fistula was quite low. In addition, elevated intrabiliary pressure or papillary edema caused by residual stones in the distal common bile duct may increase the incidence of biliary fistula, as reported by Hua *et al*.[32] Systemic inflammation, hypoalbuminemia, and liver injury caused by acute cholangitis may also impair postoperative healing of the common bile duct.

Residual stone is another indicator used to assess the effectiveness of laparoscopic common bile duct exploration with primary closure. Incidence of remnant stones after laparoscopic common bile duct exploration plus primary closure varies from 0% to 3.5%.[33] There are few studies in which incidence of residual stones is zero. The incidence of residual stones in this study was 8.6% overall. The incidence of residual stones for the primary closure group and the T-tube insertion was 2.2% and 25%, respectively. For patients with nonsevere acute cholangitis, the primary goals of effective treatments are to relieve biliary obstruction and reverse the systemic inflammatory response. When multiple large or impacted stones are encountered during surgeries for patients with nonsevere acute cholangitis, all the stones may not be able to be removed, and T-tube insertion rather than primary closure should be preferred because prolonged operation time would be harmful. In such situations, removal of residual stones through the T-tube sinus tract is a reasonable management strategy.

Only one patient in the primary closure group experienced 30-d mortality. Altogether, 26 patients developed common bile duct stricture during follow-up. The primary closure group was not significantly different from the T-tube insertion group in terms of ICU stay, recurrent stone, acute pancreatitis, pneumonia, acute cardiovascular event, abdominal infection, hemobilia, urinary retention, urinary infection, cardiac failure, and respiratory failure. Common bile duct stricture was another important parameter for evaluating the effectiveness of primary closure. In this study, T-tube was inferior to primary closure in terms of common bile duct stricture. The diagnosis of common bile duct stricture was based on a combination of symptoms, laboratory findings, and imaging examinations. During follow-up, symptoms were assessed, and physical examinations were routinely performed. If biliary colic, jaundice, or fever occurred, liver function tests and MRI/MRCP were performed to assess whether stricture of the common bile duct existed. Sometimes, when asymptomatic dilation of the common bile duct was detected by USG or CT examination, MRI/MRCP would be performed to evaluate for common bile duct stricture. When common bile duct stricture with symptoms such as biliary colic, jaundice, or fever was confirmed by MRI and MRCP, ERCP was usually needed to alleviate these symptoms, and the common bile duct stricture was further confirmed through ERCP.

There are no definite explanations for the finding that T-tube insertion is more likely to result in common bile duct stricture. Several mechanisms may account for this association. First, long-term compression of the common bile duct wall by the T-tube may lead to ischemia and necrosis of local tissue, which in turn contributes to fibrosis and scar formation and then stricture occurs. Second, foreign bodies (i.e., T-tube and sutures) would trigger chronic inflammation, thickening of the common bile duct wall, and hyperplasia of fibrous tissue, which would eventually result in common bile duct stricture. Third, poor drainage by T-tube or misplacement of T-tube may result in cholestasis and serious inflammatory reactions on the common bile duct wall, all of which may further contribute to stenosis of the common bile duct. Fourth, cholangitis associated with cholestasis may further aggravate the inflammation of the common bile duct wall and accelerate the formation of common bile duct stricture. Fifth, patients with a scar-prone constitution are more likely to experience common bile duct because inflammation mentioned earlier and hyperplasia of fibrosis were more remarkable among these patients. However, studies assessing the effectiveness and safety of primary closure among patients with nonsevere cholangitis due to choledocholithiasis are scarce, and few, if any, have reported a higher incidence of common bile duct stricture with T-tube insertion than with primary closure. This difference between our study and previous studies may be explained by differences in patient selection and by the inclusion in our cohort of some asymptomatic strictures detected by MRI/MRCP and ERCP, which may not have been captured in other studies.

Considering all these results, we may conclude that for patients with nonsevere acute cholangitis due to choledocholithiasis, laparoscopic common bile duct plus primary closure is a safe choice, provided there is no severe bile duct inflammation, complete stone clearance is achieved, biliary obstruction is relieved, and the distal common bile duct is patent.

Despite the encouraging results, some limitations of this study should be acknowledged. First, this study is retrospective in design, and selection bias could not be completely avoided; therefore, prospective studies are needed to further validate our findings. In particular, the choice between primary closure and T-tube insertion was subject to potential selection bias. In this study, we have specified the criteria for selecting T-tube insertion and primary closure. The following aspects were considered when deciding between T-tube insertion or primary closure: risk of remnant stones, edema or suppurative inflammation, function of the sphincter of Oddi, and patency of distal common bile duct. However, edema or suppurative inflammation, function of the sphincter of Oddi, and patency of distal common bile duct could not be quantitatively assessed. Thus, we did not include these parameters in this study. In theory, when all these three conditions were met, primary closure would be performed. None of the patients in this study underwent emergent common bile duct exploration, suggesting that adequate treatment had been applied and inflammation of the common bile duct was mild, which was observed among most patients. Additionally, during common bile duct exploration, a choledochoscope was used to fully examine the bile duct tree. In this study, most patients had a patent distal common bile duct and stones observed under choledochoscope were extracted. However, after confirming the conditions mentioned earlier, the surgeons then explained the advantages and disadvantages of these two methods in detail, and the authorized trustee of each patient ultimately decided whether T-tube insertion or primary closure would be performed. This approach was adopted to avoid violating ethical principles, given that primary closure in nonsevere cholangitis remains controversial and is not yet supported by definitive guidelines or high-quality prospective randomized controlled trials. Thus, selection bias was reduced, although not eliminated, by this approach. Therefore, the primary closure group was comparable to the T-tube group in terms of these conditions. We then performed multivariable logistic regression analysis to identify independent predictive factors for major complications and 30-d mortality and found that primary closure was not an independent predictive factor for either outcome. Despite these efforts in minimizing biases related to patient inclusion and closure method selection, the findings of this study should be further validated by future prospective randomized controlled trials.

Second, this study was performed at one single center, and there was no external validation to support the findings of this study, warranting studies involving more institutions. Third, a relatively small number of patients were included, and the follow-up period was not sufficiently long, which could negatively affect the results of our study. Despite these shortcomings, our study may still provide useful clinical insights because there are relatively few studies investigating the application of primary closure among patients with nonsevere cholangitis, and we made every effort to minimize biases related to patient inclusion and closure method selection. However, as mentioned earlier, the findings of this study should be further validated by future prospective randomized controlled trials.

Conclusions

For patients with nonsevere acute cholangitis, primary closure is safe because it is associated with better intraoperative outcomes and noninferior postoperative outcomes. However, these findings should be validated in prospective randomized controlled trials because of the potential biases related to patient selection and closure method selection.

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Availability of Data

The data used to support the findings of this study are available from the corresponding authors upon reasonable request.

Consent for Publication

All authors have read the manuscript and approved the final version.

CRediT authorship contribution statement

Linsen Liu: Writing – original draft, Conceptualization. **Yan Wang:** Writing – review & editing, Data curation. **Lingna Deng:** Writing – review & editing, Software, Methodology. **Yawei Wang:** Data curation. **Shaolan Zhang:** Writing – review & editing, Conceptualization. **Tailai An:** Supervision, Conceptualization.

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