

## Original Article

# Improved outcomes and prognostic risk prediction for laparoscopic common bile duct exploration with primary closure versus T-tube drainage

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**Abstract:** Objective: To compare laparoscopic common bile duct exploration (LCBDE) with primary closure plus double-J stent versus T-tube drainage after LCBDE, and to identify risk factors for poor outcome. Methods: In this retrospective cohort study, a propensity score matching approach (1:1) was applied to eligible patients, dividing them into an observation group ( $n = 59$ , LC+LCBDE with primary closure and double-J biliary stent) and a control group ( $n = 59$ , LC+LCBDE with T-tube drainage), yielding a total sample size of 118 cases. Perioperative outcomes, liver function, inflammatory markers, postoperative complications, and stone recurrence were compared between the two groups. Univariate and multivariable logistic regression analyses were performed to identify prognostic risk factors. Results: The observation group showed a significantly higher overall clinical efficacy rate than the control group (94.92% vs. 81.36%,  $P = 0.030$ ) and a lower overall complication rate (10.17% vs. 25.42%,  $P = 0.030$ ). The observation group also showed shorter operative time, reduced intraoperative blood loss, shorter hospital stay, and lower total hospitalization costs (all  $P < 0.001$ ). Multivariate analysis identified age  $\geq 60$  years, BMI  $\geq 24$  kg/m $^2$ , common bile duct wall thickness  $\geq 6$  mm, and sphincter of Oddi dysfunction as independent predictors of adverse postoperative outcome (all  $P < 0.05$ ). Conclusion: LC+LCBDE with primary closure and double-J biliary stent placement is superior to T-tube drainage, offering greater efficacy, accelerated recovery, and fewer complications. Independent risk factors for adverse postoperative outcomes include advanced age, higher BMI, increased common bile duct wall thickness, and sphincter of Oddi dysfunction.

**Keywords:** Laparoscopic common bile duct exploration, primary closure, double-J biliary stent, T-tube drainage, choledocholithiasis

## Introduction

Choledocholithiasis, occurring in 5-20% of patients with gallstones (GS), poses a significant clinical challenge due to the risk of severe sequelae such as obstructive jaundice, cholangitis, and pancreatitis [1]. The management of concomitant GS and common bile duct stones (CBDS) has evolved into two principal minimally invasive pathways: sequential endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic cholecystectomy (LC), or single-stage laparoscopic cholecystectomy with common bile duct exploration (LCBDE) [2]. While ERCP followed by LC is widely practiced, its efficacy can be compromised by post-ERCP pancreatitis, bleeding, and technical failures in certain anatomic contexts [3]. In contrast, the

single-stage LC combined with LCBDE circumvents the need for a second procedure, reducing hospital stay and overall cost [4]. A major technical concern in LC with LCBDE is the management of choledochotomy.

For decades, T-tube drainage following LCBDE has been the conventional standard for biliary decompression [5]. Despite its established role, this practice is associated with considerable morbidity, including bile leakage, electrolyte disturbances, tube dislodgement, and patient discomfort during the extended period of external drainage, all of which can impede recovery [5, 6]. The pursuit of a more patient-friendly and physiologically sound alternative has thus spurred interest in primary duct closure. Initial experiences with primary closure alone,

however, raised justifiable concerns regarding the risk of bile peritonitis secondary to elevated biliary pressure or suture line failure [7].

The above concern has led to the paradigm of combining primary closure with internal biliary drainage, a strategy designed to offload pressure and ensure biliary continuity. Techniques such as antegrade stenting or nasobiliary drainage have been explored, with studies reporting promising reductions in T-tube-related morbidity [8, 9]. Among these, the use of a double-J biliary stent for internal drainage represents an evolution, theoretically providing secure internal decompression without the inference from a trans-nasal tube or external device [10]. Preliminary reports suggest its feasibility; however, the body of evidence remains fragmented and insufficient to instigate a change in clinical practice [11, 12].

Crucially, the existing literature is characterized by two principal limitations. First, there is a scarcity of robust comparative studies that systematically evaluate the double-J biliary stent technique against the T-tube benchmark across a comprehensive set of perioperative and recovery metrics [11, 12]. Second, and perhaps more significantly, the focus has predominantly been on short-term technical success. There is a pronounced lack of investigation into the determinants of long-term outcome. Identifying which patients are most likely to benefit - or conversely, those at heightened risk for complications or recurrence - is a critical yet unanswered question. Current evidence provides little guidance on pre- or intra-operative risk stratification, constraining personalized patient selection and postoperative management [13, 14].

Therefore, this study was designed to address these evidence gaps through a comparative analysis of LC+LCBDE with primary closure with double-J biliary stent placement versus traditional T-tube drainage. Beyond a simple comparison of efficacy and safety, we further employed multivariate regression modeling to identify independent risk factors for adverse postoperative outcome. Our aim was not only to decide a validated surgical alternative but also to provide a prognostic framework that can inform clinical decision-making, optimize patient selection, and ultimately improve long-term outcome for patients with choledocholithiasis.

## Materials and methods

### Study design and patient selection

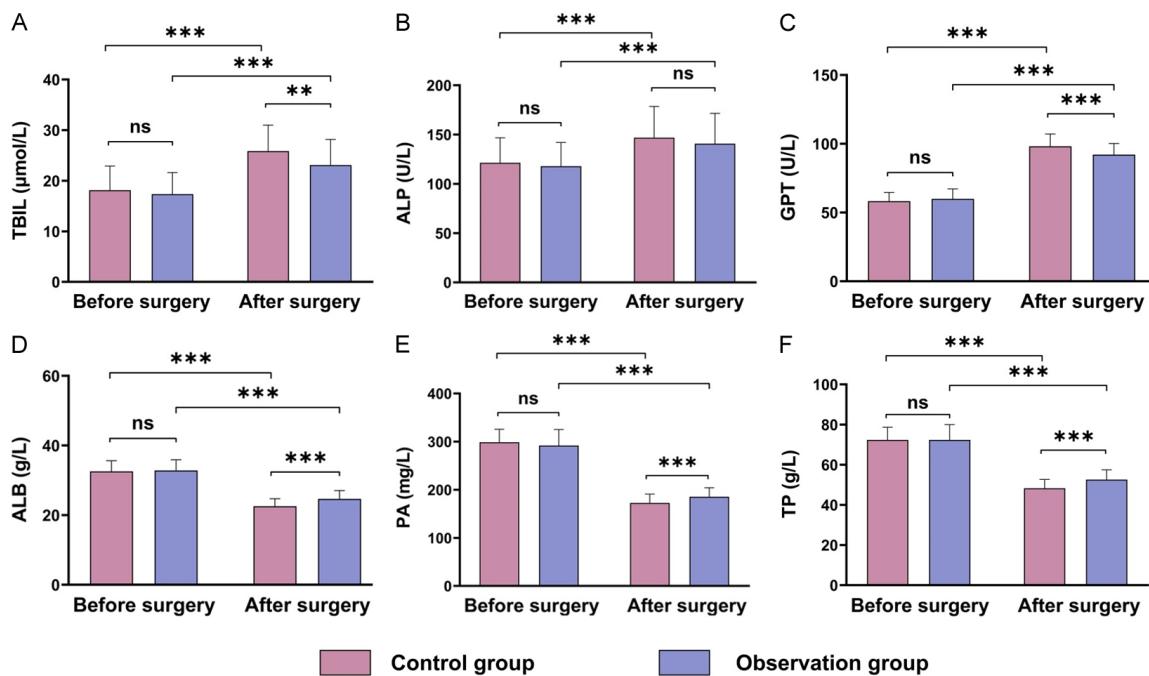
This single-center, retrospective cohort study was conducted after obtaining approval from the Institutional Ethics Committee of Hejiang People's Hospital (Approval Number: 202524), which waived the requirement for informed consent due to the retrospective nature of the research. We initially screened the medical records of all consecutive patients diagnosed with gallstones (GS) and common bile duct stones (CBDS) who underwent laparoscopic cholecystectomy combined with laparoscopic common bile duct exploration (LC+LCBDE) at our institution between January 2022 and June 2024.

**Inclusion criteria:** (1) Age  $\geq$  18 years; (2) Confirmed diagnosis of GS and CBDS by preoperative imaging (abdominal ultrasound, CT, or MRI for gallbladder stones and MRCP for CBDS) [10]; (3) CBD diameter  $\geq$  10 mm on preoperative imaging to facilitate closure; (4) Completion of the assigned single-stage LC+LCBDE procedure. **Exclusion criteria:** (1) History of previous upper abdominal surgery; (2) Presence of acute severe pancreatitis on admission; (3) Diagnosis of congenital biliary dilation (e.g., choledochal cyst) or stones at the ampulla of Vater; (4) Pre-existing severe liver dysfunction (Child-Pugh B or C), renal insufficiency, or concomitant hematological disorders.

To mitigate selection bias and enhance the comparability between the two surgical groups, we employed a 1:1 propensity score matching (PSM) strategy. Propensity scores were calculated using a logistic regression model that included key baseline variables such as age and sex. Matching was performed using the nearest neighbor algorithm with a caliper width of 0.02 standard deviations of the logit of the propensity score. This process yielded 59 well-matched pairs ( $n = 118$  total patients), forming the observation group (LC+LCBDE with primary closure and double-J biliary stent) and the control group (LC+LCBDE with T-tube drainage). The patient selection process is detailed in **Figure 1**.

### Data extraction

Data were retrospectively extracted from our hospital's electronic medical record (EMR) sys-



**Figure 1.** Comparison of liver function and synthetic markers between the two groups before and after surgery. A. TBIL. B. ALP. C. GPT. D. ALB. E. PA. F. TP. TBIL, Total bilirubin; ALP, Alkaline phosphatase; ALB, Albumin; PA, Prealbumin; TP, Total protein; GPT, Glutamic-pyruvic transaminase; ns, Not significant; \*\* $P < 0.01$ ; \*\*\* $P < 0.001$ .

tem by two independent investigators using a standardized data collection form. Any discrepancies were resolved through discussion or by consulting a third senior investigator.

The extracted data included: (1) Baseline demographic and clinical characteristics: age, sex, body mass index (BMI), smoking history, alcohol consumption history, family history of cholelithiasis, and comorbidities (hypertension, diabetes mellitus, coronary heart disease); (2) Disease-specific findings: Presence of concomitant intrahepatic bile duct stones, biliary strictures, CBD diameter, maximum stone diameter, CBD wall thickness, number of CBDS, and presence of sphincter of Oddi dysfunction (SOD); (3) perioperative and postoperative outcome data: Operative time, intraoperative blood loss, postoperative laboratory values (liver function, inflammatory markers), time to first flatus, time to first feeding, length of hospital stay, total hospital costs, postoperative complications, and stone recurrence during follow-up.

#### Outcome measures

The primary outcomes included the total clinical efficacy rate and the overall complication rate within 12 months postoperatively.

Clinical efficacy was assessed before discharge based on symptom resolution and stone clearance and was categorized as significant effective (complete resolution of signs/symptoms, 100% stone clearance), effective (significant improvement in signs/symptoms,  $\geq 50\%$  stone clearance), or ineffective (no improvement,  $< 50\%$  stone clearance) [11]. The total effective rate = (Significant effective cases + Effective cases)/total number of cases \* 100%.

Overall complication rate was assessed throughout the 12-month follow-up period through outpatient visits or WeChat video consultations, including incidents of acute pancreatitis, acute cholangitis, bleeding, or perforation, as well as the CBDS. (1) Acute pancreatitis: Characterized by a postoperative increase in serum lipase and amylase levels to three times the upper limit of normal, accompanied by upper abdominal pain. CT imaging may reveal peri-pancreatic edema and fluid accumulation; (2) Acute cholangitis: Presenting with right upper quadrant pain, elevated alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels, and associated fever; (3) Bleeding: Identified through postoperative hematemesis, melena, or serous drainage from the nasal biliary catheter, along with a decrease in hemo-

globin levels, necessitating medical management, endoscopic intervention, or transfusion; (4) Perforation: Confirmed by abdominal X-ray or CT imaging, with patients typically presenting severe abdominal pain and signs of peritonitis.

Secondary outcomes included: (1) Liver function: Serum total bilirubin (TBIL), alkaline phosphatase (ALP), glutamic-pyruvic transaminase (GPT), albumin (ALB), total protein (TP), and pre-albumin (PA), measured preoperatively and on postoperative day 1. (2) Inflammatory and stress indicators: C-reactive protein (CRP), procalcitonin (PCT), white blood cell count (WBC), and interleukin-6 (IL-6), assessed preoperatively and on postoperative day 1. (3) Postoperative VTE risk: Evaluated using the Caprini risk assessment model post-surgery, with risk stratified as low (0-1 points), moderate (2 points), high (3-4 points), or very high ( $\geq 5$  points). (4) Surgical and recovery data: Operative time, intraoperative blood loss, time to first flatus, time to first feeding, length of hospital stay, and total hospital costs. (5) Stone recurrence: Defined as radiologically confirmed recurrence of CBDS within the 12-month follow-up period.

#### *Patient prognosis analysis*

Based on these composite endpoints, subjects were stratified into two prognostic groups: the Poor Prognosis Group, consisting of patients who experienced one or more complications or had radiologically confirmed CBDS recurrence, and the Good Prognosis Group, comprising patients who did not experience any endpoint events during the follow-up period.

Preoperative and intraoperative variables that could potentially influence prognosis were analyzed, including age, BMI, presence of intrahepatic bile duct stones, duration of initial illness, presence of duodenal diverticula, biliary infections, history of biliary surgery, CBD wall thickness, number of CBDS, CBD diameter, maximum diameter of CBDS, and sphincter of Oddi dysfunction (SOD).

#### *Statistical analysis*

All statistical analyses were performed using SPSS 26.0 (IBM) and GraphPad Prism 8.0 (GraphPad). Data were presented as mean  $\pm$  standard deviation (SD) for normally distributed

continuous variables, median with interquartile range (IQR) for non-normally distributed data, and counts with percentages [n (%)] for categorical variables. The normality of all continuous data was assessed using the Shapiro-Wilk test. Between-group comparisons for baseline characteristics and postoperative outcomes were conducted using independent-samples t-tests for normally distributed data or the Mann-Whitney U test for non-normally distributed data, and the  $\chi^2$  test or Fisher's exact test for categorical variables, as appropriate. For within-group comparisons of pre- and postoperative laboratory measurements, paired-samples t-tests (for normally distributed data) or the Wilcoxon signed-rank test (for non-normally distributed data) were applied.

To identify independent risk factors for a poor prognosis, univariate logistic regression analyses were first performed for all candidate preoperative and intraoperative variables. Variables with a  $P$  value  $< 0.05$  in the univariate analyses were selected as candidates for inclusion in the multivariable logistic regression model. The final multivariate analysis was constructed using the enter method, where all candidate variables were included simultaneously. We deliberately avoided automated stepwise (forward or backward) selection procedures to prevent the issues of model instability, inflated Type I error rates, and overfitting. The goodness-of-fit of the final multivariate model was assessed using the Hosmer-Lemeshow test, which indicated a good fit ( $P = 0.42$ ). Multicollinearity among the independent variables was evaluated using the Variance Inflation Factor (VIF), and all VIF values were below 2.0, suggesting no significant multicollinearity. For the regression analysis, selected continuous variables were dichotomized based on clinical cut-off points to facilitate the interpretation of odds ratios (OR). The results of the regression were reported as adjusted ORs with 95% confidence intervals (CIs). All reported  $P$  values were two-tailed, and significance was set as  $P < 0.05$ .

#### **Results**

##### *Comparison of general data between the two groups*

The two groups showed no significant differences in age, sex, BMI, smoking history, alcohol consumption history, family history of choleli-

**Table 1.** Baseline characteristics of the study groups [n (%)]

Variable	Control (n = 59)	Observation (n = 59)	$\chi^2$	P
Age			2.170	0.141
$\geq 60$	33 (55.93)	25 (42.37)		
< 60	26 (44.07)	34 (57.63)		
Sex			0.137	0.712
Male	33 (57.63)	25 (42.37)		
Female	26 (44.07)	34 (55.93)		
BMI			0.042	0.837
$\geq 24 \text{ kg/m}^2$	16 (27.12)	17 (28.81)		
< 24 $\text{kg/m}^2$	43 (72.88)	42 (71.19)		
Smoking history			0.155	0.694
Yes	20 (33.90)	18 (30.51)		
No	39 (66.10)	41 (69.49)		
Alcohol consumption history			0.038	0.845
Yes	20 (33.90)	19 (32.20)		
No	39 (66.10)	40 (67.80)		
Family history of cholelithiasis			0.371	0.542
Yes	7 (11.86)	5 (8.47)		
No	52 (88.14)	54 (91.53)		
Comorbid hepatolithiasis			0.187	0.665
Yes	13 (22.03)	15 (25.42)		
No	46 (77.97)	44 (74.58)		
Biliary stricture			0.314	0.575
Yes	23 (38.98)	26 (44.07)		
No	36 (61.02)	33 (55.93)		
Comorbid hypertension			0.336	0.562
Yes	19 (32.20)	22 (37.29)		
No	40 (67.80)	37 (62.71)		
Comorbid diabetes mellitus			0.063	0.802
Yes	9 (15.25)	10 (16.95)		
No	50 (84.75)	49 (83.05)		
Comorbid CHD			0.565	0.452
Yes	11 (18.64)	8 (13.56)		
No	48 (81.36)	51 (86.44)		
Comorbid other conditions			0.076	0.782
Yes	7 (11.86)	8 (13.56)		
No	52 (88.14)	51 (86.44)		
CBD diameter			0.550	0.458
$\geq 15 \text{ mm}$	24 (40.68)	28 (47.46)		
< 15 mm	35 (59.32)	31 (52.54)		
Maximum stone diameter in the CBD			1.990	0.158
$\geq 10 \text{ mm}$	21 (35.59)	14 (23.73)		
< 10 mm	38 (64.41)	45 (76.27)		

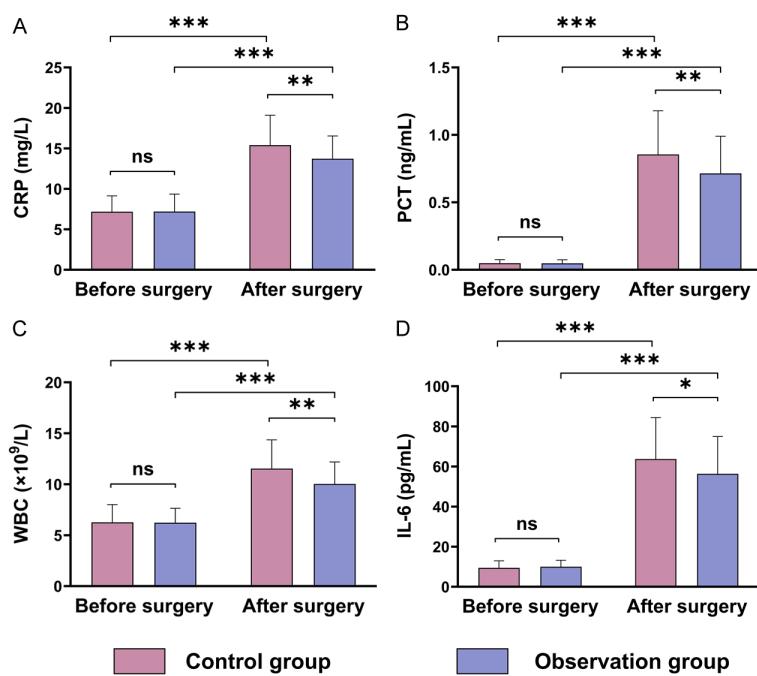
Note: CHD: coronary heart disease, CBD: common bile duct.

thiasis, presence of comorbid hepatolithiasis, biliary stricture, presence of comorbid hypertension, CHD, and diabetes mellitus, CBD diam-

eter, or maximum CBD stone size, indicating the two groups were well-matched and comparable ( $P > 0.05$ ; **Table 1**).

**Table 2.** Comparison of clinical efficacy between the two groups [n (%)]

Group	Significantly effective	Effective	Ineffective	Total effective rate
Control (n = 59)	16 (27.12)	32 (54.24)	11 (18.64)	48 (81.36)
Observation (n = 59)	26 (44.07)	30 (50.85)	3 (5.08)	56 (94.92)
$\chi^2$		7.017		
P		0.030		



**Figure 2.** Comparison of inflammatory and stress indicators between the two groups before and after surgery. A. CRP. B. PCT. C. WBC. D. IL-6. CRP, C-reactive protein; PCT, Procalcitonin; WBC, White blood cells; IL-6, Interleukin-6; ns, Not significant; \*P < 0.05; \*\*P < 0.01; \*\*\*P < 0.001.

#### Comparison of clinical efficacy between the two groups

The total clinical effective rate was 81.36% in the control group and 94.92% in the observation group, with the observation group showing a significantly higher total effective rate than the control group ( $P < 0.05$ ; **Table 2**).

#### Comparison of liver function indicators and synthetic markers between the two groups

Before surgery, no significant differences were observed between the two groups in terms of TBIL, ALP, GPT, ALB, TP, or PA ( $P > 0.05$ ; **Figure 1**). After surgery, both groups showed elevated levels of TBIL, ALP, and GPT ( $P < 0.05$ ), while levels of ALB, TP, and PA decreased significantly in both groups ( $P < 0.05$ ). The control group exhibited significantly higher TBIL and GPT lev-

els compared to the observation group ( $P < 0.05$ ), and also showed a more pronounced reduction in ALB, TP, and PA levels than the observation group ( $P < 0.05$ ).

#### Comparison of inflammatory and stress indicators between the two groups

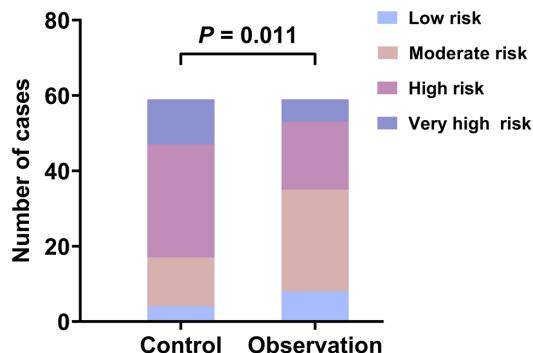
No significant differences were observed between the two groups in terms of preoperative CRP, PCT, WBC, or IL-6 levels ( $P > 0.05$ ; **Figure 2**). Postoperatively, all indicators increased in both groups, with the control group demonstrating significantly higher values than the observation group ( $P < 0.05$ ).

#### Comparison of postoperative VTE risk distribution between the two groups

In the observation group, postoperative risk stratification was as follows: low risk in 8 patients (13.6%), moderate risk in 27 (45.8%), high risk in 18 (30.5%), and very high risk in 6 (10.2%). Corresponding proportions in the control group were 4 (6.8%), 13 (22.0%), 30 (50.8%), and 12 (20.3%) (**Figure 3**). The observation group exhibited a significantly more favorable distribution of VTE risk grades than the control group ( $P = 0.011$ ).

#### Comparison of surgical and recovery outcomes between the two groups

Compared to the control group, the observation group exhibited significantly shorter surgical time, reduced intraoperative blood loss, earlier time to gas passage, earlier time to first feeding, shorter length of hospital stay, and lower hospital costs (all  $P < 0.05$ ; **Figure 4**).



**Figure 3.** Comparison of postoperative VTE risk grade distribution between the observation and control groups. VTE, Venous thromboembolism.

#### Comparison of postoperative complications and recurrence between the two groups

The total incidence of postoperative complications was 25.4% in the control group, including 4 cases of acute pancreatitis, 5 cases of acute cholangitis, 3 cases of bleeding, and 3 cases of perforation. In the observation group, the total complication rate was significantly lower, at 10.2%, with 3 cases of acute pancreatitis, 1 case of acute cholangitis, 1 case of bleeding, and 1 case of perforation ( $P < 0.05$ ; **Table 3**). Additionally, the recurrence rate of CBDS was significantly higher in the control group (8 cases) compared to the observation group (2 cases) ( $P < 0.05$ ).

#### Univariate analysis of prognostic factors in GS complicated with CBDS

Based on the presence or absence of postoperative complications and recurrence, patients from the observation and control groups were reclassified into a good prognosis group (85 cases) and a poor prognosis group (33 cases). Univariate analysis revealed significant differences between the two groups in age, BMI, intrahepatic bile duct stones, duodenal diverticula, CBD wall thickness, and SOD ( $P < 0.05$ ; **Table 4**).

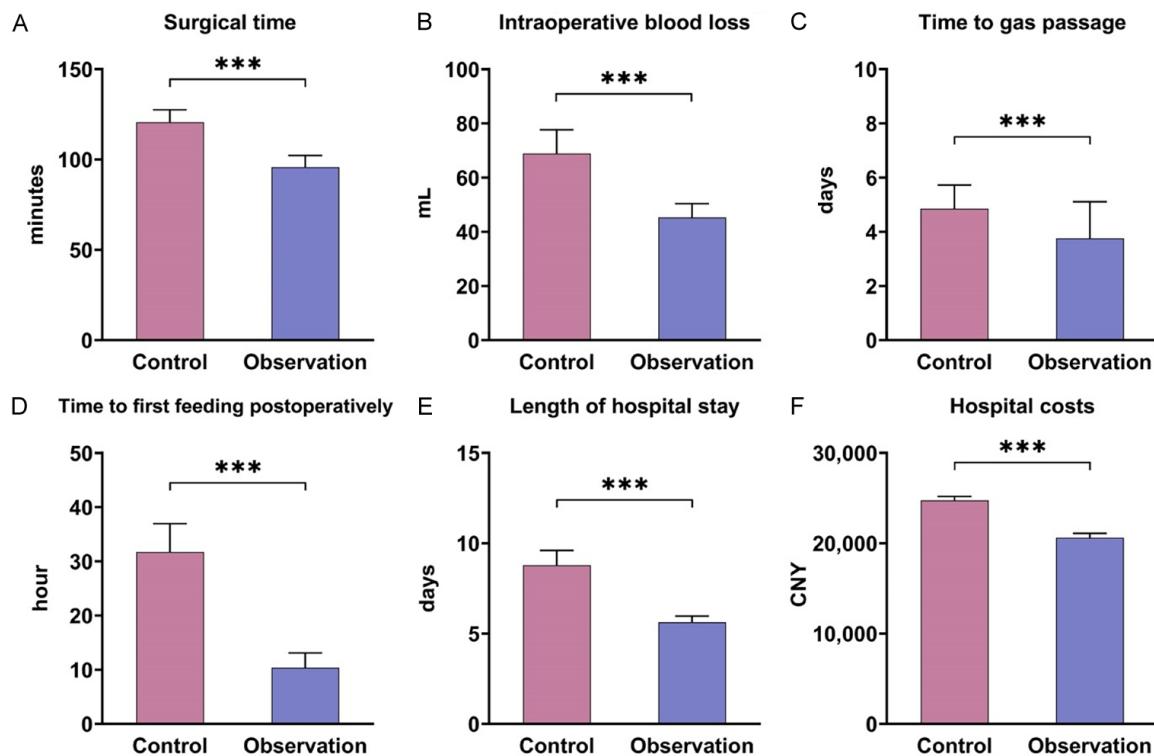
#### Multivariate analysis of prognosis in GS complicated with CBDS

Subsequent multivariate logistic regression analysis identified age  $\geq 60$  years, BMI  $\geq 24$  kg/m $^2$ , CBD wall thickness  $\geq 6$  mm, and SOD as independent risk factors for poor prognosis ( $P < 0.05$ ; **Table 5**).

#### Discussion

GS with concomitant CBDS represents a prevalent clinical entity often necessitating complex surgical management, which significantly prolongs hospitalization, increases medical burden, and elevates the risk of long-term complications [13]. Our study demonstrates that LC+LCBDE with primary closure and double-J biliary stent placement yields outcomes superior to those achieved with traditional T-tube drainage. The observed advantages, including enhanced clinical efficacy, attenuated inflammatory response, accelerated recovery, and reduced complications, underscore the potential of this approach as a viable alternative in selected patients.

The primary closure with double-J biliary stent group demonstrated a superior total clinical efficacy rate compared to the T-tube drainage group, a finding consistent with recent comparative studies [14]. The double-J biliary stent facilitates internal biliary drainage, preserves physiological biliary conditions, enhances cholecototomy healing, and maintains bile flow, thereby reducing the risks of cholangitis and pancreatitis. These factors collectively contribute to improved stone clearance and symptom relief, establishing the procedure as a safe and effective alternative in suitable patients. Regarding postoperative hepatic metabolism, the T-tube group exhibited more pronounced liver function impairment and a greater suppression of synthetic function compared to the double-J biliary stent group. In hepatobiliary surgery, elevated TBIL suggests impaired bilirubin excretion, increased ALP indicates biliary damage or obstruction, and rising GPT reflects hepatocellular injury and inflammation [15]. Concurrently, reductions in ALB, TP, and PA levels are indicative of impaired hepatic synthetic function and systemic nutritional stress following surgical intervention [16]. The observed disparity is consistent with previous reports of delayed biochemical and functional recovery with external drainage [17]. This is likely attributable to bile diversion, which disrupts the enterohepatic circulation, leading to bile salt dysregulation, gut flora translocation, and endotoxin absorption. These factors collectively intensify hepatic inflammation and metabolic stress, further suppressing protein synthesis [18]. In contrast, the double-J biliary stent maintains physiological bile flow into the intestine, supporting bile salt



**Figure 4.** Comparison of surgical and recovery outcomes between the observation and control groups. A. Surgical time. B. Intraoperative blood loss. C. Time to gas passage. D. Time to first feeding postoperatively. E. Length of hospital stay. F. Hospital cost. \*\*\* $P < 0.001$ .

**Table 3.** Postoperative complications and recurrence at 12-month follow-up [n (%)]

Outcome	Overall (n = 118)	Control Group (n = 59)	Observation Group (n = 59)	P
Composite endpoint events	33 (27.97)	23 (38.98)	8 (16.95)	0.002
Complications	23 (19.49)	15 (25.42)	6 (10.17)	0.030
Acute pancreatitis	7 (5.93)	4 (6.78)	3 (5.08)	
Acute cholangitis	6 (5.08)	5 (8.47)	1 (1.69)	
Bleeding	6 (5.08)	3 (5.08)	1 (1.69)	
Perforation	4 (3.39)	3 (5.08)	1 (1.69)	
CBDS recurrence	10 (8.47)	8 (13.56)	2 (3.39)	0.047

Note: CBDS: common bile duct stones.

recycling and reducing biliary pressure, which may decrease bacterial reflux, alleviate metabolic stress, and better preserve hepatic synthetic function [5, 19]. These biochemical and functional outcomes highlight the advantage of double-J biliary stent drainage in preserving hepatobiliary homeostasis, reducing postoperative stress, and supporting nutritional-metabolic recovery.

Following LC+LCBDE, a transient elevation in inflammatory markers is commonly observed due to surgical stress [20, 21]. Consistently wi-

th this, our study found that the postoperative rise in inflammatory and stress indicators was notably less pronounced in the primary closure with double-J biliary stent group than in the T-tube drainage group. This attenuated inflammatory response can be attributed to several factors related to the T-tube technique: the additional choledochotomy and suturing required for its fixation increase operative trauma and duration, thereby potentiating the innate immune response and the release of pro-inflammatory cytokines such as IL-6, which in turn stimulates the synthesis of CRP and PCT

**Table 4.** Comparison of preoperative and intraoperative variables between patients with good and poor prognosis [n (%)]

Variable	Good Prognosis (n = 85)	Poor Prognosis (n = 33)	$\chi^2$	P
Age $\geq$ 60 years	35 (41.18)	23 (69.70)	7.737	0.005
BMI $\geq$ 24 kg/m <sup>2</sup>	18 (21.18)	15 (45.45)	6.955	0.008
Intrahepatic bile duct stones	15 (17.65)	13 (39.39)	6.212	0.013
Duration of initial illness $\geq$ 7 d	12 (14.12)	7 (21.21)	0.886	0.347
Duodenal diverticula	7 (8.24)	9 (27.27)	5.816	0.016
Biliary infections	7 (8.24)	5 (15.15)	1.245	0.265
History of biliary surgery	10 (11.76)	8 (24.24)	4.232	0.091
CBD wall thickness $\geq$ 6 mm	32 (37.65)	22 (66.67)	8.065	0.005
Number of CBDS $\geq$ 5	42 (49.41)	22 (66.67)	2.851	0.091
CBD diameter $\geq$ 15 mm	19 (22.35)	11 (33.33)	1.512	0.219
Maximum diameter of CBDS $\geq$ 10 mm	24 (28.24)	11 (33.33)	0.296	0.586
SOD	10 (11.76)	10 (30.30)	5.804	0.016

Note: BMI: body mass index, CBD: common bile duct, CBDS: common bile duct stones, SOD: sphincter of Oddi dysfunction.

**Table 5.** Multivariate logistic regression analysis of factors associated with poor prognosis in patients with GS and CBDS

Variable	B	SE	Wald $\chi^2$	P	OR (95% CI)
Age ( $\geq$ 60 years vs. $<$ 60 years)	1.38	0.55	2.51	0.012	3.980 (1.351-11.722)
BMI ( $\geq$ 24 kg/m <sup>2</sup> vs. $<$ 24 kg/m <sup>2</sup> )	1.75	0.62	2.83	0.005	5.758 (1.710-19.390)
Intrahepatic bile duct stones (Yes vs. No)	0.61	0.59	1.05	0.295	1.848 (0.586-5.830)
Duodenal diverticula (Yes vs. No)	1.35	0.70	1.93	0.053	3.845 (0.981-15.068)
CBD wall thickness ( $\geq$ 6 mm vs. $<$ 6 mm)	2.32	0.62	3.73	< 0.001	10.220 (3.017-34.620)
SOD (Yes vs. No)	1.63	0.68	2.40	0.016	5.094 (1.351-19.201)
Intercept	-4.22	0.75	-5.60	< 0.001	0.015 (0.003-0.065)

Note: BMI: body mass index, CBD: common bile duct, SOD: sphincter of Oddi dysfunction. Variable assignment for regression analysis: For all categorical variables, the former category was assigned as 1 (e.g., Age: 1 =  $\geq$  60 years, 0 =  $<$  60 years; BMI: 1 =  $\geq$  24 kg/m<sup>2</sup>, 0 =  $<$  24 kg/m<sup>2</sup>; Intrahepatic bile duct stones: 1 = Yes, 0 = No; Duodenal diverticula: 1 = Yes, 0 = No; CBD wall thickness: 1 =  $\geq$  6 mm, 0 =  $<$  6 mm; SOD: 1 = Yes, 0 = No).

[21, 22]. Moreover, the T-tube itself carries a risk of bile microleakage, inducing local chemical peritonitis and amplifying systemic inflammation [23, 24], while external drainage disrupts biliary homeostasis and exacerbates the surgical stress response [24]. In contrast, primary closure with a double-J biliary stent minimizes duct injury and bile leakage risk. By immediately restoring biliary continuity and providing internal decompression, it promotes a quicker return to physiologic conditions, thereby lowering acute inflammatory and stress responses [5, 25]. This reduction in inflammation underscores the benefits of reduced surgical trauma and superior anatomic restoration, which collectively support a more favorable clinical recovery.

Venous thromboembolism (VTE) is a common and severe postoperative complication [12]. In

patients undergoing LC+LCBDE, the postoperative VTE risk profile reflects the intensity of surgical trauma and the consequent systemic hypercoagulable state. Our analysis indicated a more favorable VTE risk profile in patients undergoing primary closure with Double-J internal drainage compared to those receiving T-tube drainage. This finding aligns with the established consensus that less invasive surgical approaches are associated with a reduced risk of VTE [8, 26]. The underlying mechanisms may include the avoidance of an additional choledochotomy and T-tube placement, leading to reduced surgical trauma and an attenuated inflammatory response, thereby suppressing excessive coagulation activation. Furthermore, the internal drainage approach, by avoiding external tubes and associated discomfort, facilitates earlier postoperative ambulation, thereby reducing venous stasis and mitigating

VTE risk through multiple synergistic pathways [3].

Primary closure with Double-J internal drainage demonstrated advantages in multiple surgical and recovery metrics, supporting its use over T-tube drainage [5]. These superior outcomes result from omitting the T-tube fixation process, which better preserves biliary integrity and function while reducing local trauma and inflammation, thereby collectively enhancing recovery and reducing costs. Furthermore, this approach was associated with a lower incidence of post-operative complications and stone recurrence [22, 27, 28]. This benefit is attributed to the maintenance of biliary continuity, minimal interference with the sphincter of Oddi, and a consequent reduction in infection risk. In contrast, T-tube drainage disrupts normal biliary flow and pressure dynamics, acts as a potential nidus for infection and inflammation, thereby increasing the risk of cholangitis, pancreatitis, and stone recurrence. By restoring native anatomy and ensuring unimpeded bile flow, primary closure with internal drainage effectively decreases reflux-related infections and associated complications [5, 22, 29], underscoring its clinical advantages in the LC+LCBDE procedure.

Multivariate analysis in our study identified age  $\geq 60$  years, BMI  $\geq 24$  kg/m<sup>2</sup>, CBD wall thickness  $\geq 6$  mm, and SOD as independent risk factors for adverse postoperative outcomes, which is consistent with the findings of prior studies [30, 31]. A thickened CBD wall, often resulting from chronic inflammation and fibrosis due to prolonged stone friction or recurrent cholangitis, increases surgical difficulty and impedes tissue healing, thereby serving as a reliable indicator of both procedural complexity and patient prognosis [32, 33]. Furthermore, SOD was also identified as a significant predictor of adverse outcome. As the key regulator of bile flow and a barrier against duodenal reflux, SOD dysfunction disrupts biliary drainage, alters hydrodynamic stability, and promotes bacterial colonization and stone formation, thereby increasing the risk of recurrence [34-36]. Consequently, the assessment of SOD function adds a valuable dimension to prognostic evaluation, complementing the goal of stone clearance with the objective of restoring functional biliary drainage to mitigate long-term recurrence risk.

This study has several strengths, including a comprehensive comparison of two distinct CBD management techniques, evaluating outcomes from short-term recovery (e.g., operative time and inflammatory markers) to one-year complication and recurrence rates. The use of multivariate regression to identify risk factors adds clinical relevance by supporting personalized treatment decisions. Furthermore, standardized surgical protocols and rigorous statistical adjustments enhance the validity of the results. Limitations involve its retrospective, single-center design, which remains prone to selection bias despite statistical controls. The sample size (n = 118) offers limited power for detecting rare adverse events, and the 12-month follow-up is too short to evaluate long-term stent efficacy or recurrence. Future studies should conduct multicenter randomized trials to strengthen evidence, extend follow-up beyond five years, and incorporate advanced imaging or functional assessment to improve patient selection. Economic and quality-of-life comparisons would further aid clinical evaluation.

### Conclusion

In patients with GS combined with CBDS, biliary obstruction and infection may lead to severe complications such as cholangitis or pancreatitis. LC+LCBDE with primary closure and double-J biliary stent insertion yields superior outcomes to T-tube drainage, offering higher therapeutic efficacy, faster recovery, fewer complications, and reduced medical costs. Benefits include maintained physiologic biliary drainage, lower risk of infection, and preservation of enterohepatic circulation. Key predictors of adverse outcome included age  $\geq 60$  years, BMI  $\geq 24$  kg/m<sup>2</sup>, CBD wall thickness  $\geq 6$  mm, and SOD. This approach aligns with Enhanced Recovery After Surgery (ERAS) principles and is recommended for suitable patients, whereas individualized management should be tailored for high-risk cases. Further multicenter prospective studies are warranted to validate results.

### Disclosure of conflict of interest

None.

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