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The Application of a New Model for Disease Classification in Minimally Invasive Treatment of Concomitant Cholecystolithiasis and Choledocholithiasis

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AIM: There is no consensus regarding the minimally invasive treatment method for concomitant cholecystolithiasis and choledocholithiasis. Therefore, this study aimed to develop a universal classification system for minimally invasive surgeries, thereby supporting development of consensus in guidelines for diagnosing choledocholithiasis.
METHODS: This retrospective study included 1044 consecutive patients with concomitant cholecystolithiasis and choledocholithiasis who underwent different minimally invasive surgical treatments at the Zhongnan Hospital of Wuhan University, China, between January 2014 and April 2021. To identify the key factors influencing the choice of different minimally invasive surgical procedures, clinical data for all hospitalized patients were analyzed. The patients were followed up through outpatient visits or telephonic calls at 1 week, 6 weeks, 3 months, 6 months, and 1 year or immediately if symptoms developed following discharge from the hospital. This information was integrated in the form of a new disease classification model, and the optimal treatment approaches were screened.
RESULTS: A significant correlation was observed between the choice of minimally invasive surgical procedures and the concomitant common bile duct (CBD) ($p < 0.001$), stone size ($p < 0.001$), or stone number ($p < 0.001$). A new clinical classification model was developed for patients with concomitant gallbladder (GB) and CBD stones based on the CBD diameter, stone sizes, and stone numbers, and the patients were sorted into Type I, II, III, and IV, respectively. Three invasive surgical methods were performed in patients with type I patients, revealing the laparoscopic cholecystectomy + Laparoscopic Transcystic Common Bile Duct Exploration (LC + LTCBDE) method as a preferred option for these patients. Furthermore, five surgical methods were performed on patients with type II CBD stones, demonstrating LC + LTCBDE as the viable option for these patients. Additionally, among the four minimally invasive surgical methods applied in patients with type III, the LC + laparoscopic choledochotomy for common bile duct exploration (LCCBDE) + Duodenoscope or LC + LCCBDE + primary closure demonstrated favorable results in this group of patients. Among the three methods applied in type IV patients, LC + laparoscopic choledocholithotomy and T-tube drainage (LCTD) were found to be more favorable.
CONCLUSIONS: In summary, this novel and simple clinical classification system, which is based on CBD diameter, stone sizes, and stone numbers, can assist clinicians in selecting a minimally invasive treatment approach for managing concomitant GB and CBD stones.

Keywords: laparoscopy; duodenoscopy; choledochoscopy; common bile duct stones; retrospective cohort study

Introduction

Cholelithiasis is a common condition worldwide, affecting up to 20% of the adult population, with >20% of affected people developing symptoms or complications. Recent population-based studies indicate a prevalence of 5% to 13.9% [1–3]. Over the past 20 to 30 years, the management of concomitant gallbladder (GB) and common bile duct (CBD) stones have advanced significantly. Before the advent of laparoscopic and endoscopic methods, open cholecystectomy combined with CBD exploration was the standard method for treating patients with CBD stones [4,5].

With the rapid development in endoscopic retrograde cholangiopancreatography (ERCP), laparoscopy, and other relevant technologies, laparoscopic removal of bile duct stones has become increasingly common. Laparoscopic common bile duct exploration (LCBDE) demonstrates significant advantages over endoscopic and open surgical procedures, such as shorter hospital stays, decreased postoperative pain, and enhanced cosmetic outcomes [6,7]. However, LCBDE needs high technical expertise and involves extensive instrumental manipulation, such as balloon dilators, guidewires, catheters, and baskets, along with laparoscopic suturing of the CBD. The primary concerns associated with LCBDE include the risks of bile duct injury, postoperative bile leakage, and stricture formation [7,8].

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Several clinical guidelines have been developed for the management of choledocholithiasis, but they differ in quality and methodological rigor. They offer varying perspectives on vital clinical issues, such as the diagnosis of biliary calculi, management approaches for various biliary stones, the role of ERCP, and the treatment of complex calculi, which confuse physicians. For instance, a 2017 guideline indicated a lack of high-quality evidence to demonstrate the superiority of perioperative ERCP over LCBDE regarding efficacy, mortality, or morbidity. In contrast, a 2018 guideline recommended ERCP as the primary approach for patients with common bile duct stones (CBDS). Similarly, the 2019 ESGE guideline strongly endorsed a two-stage ERCP surgical approach for CBDS patients, citing insufficient evidence in terms of the safety and efficacy of LCBDE. A 2021 guideline also recommended the two-stage ERCP approach. However, these guidelines acknowledge that LCBDE was linked to a shorter hospital stay compared to the two-stage ERCP approach and that surgery was often reserved for refractory CBDS patients [9–12].

The emergence of ERCP combined with endoscopic sphincterotomy (EST) has made endoscopic stone removal the preferred option for patients with CBD and GB stones before cholecystectomy [13,14]. However, this technique is associated with high complication rates (19%), failure rates (10–15%), and mortality rates (3%) [5,15–17]. These complications include pancreatitis, perforation, blooding, sepsis, and even death; furthermore, the procedure can compromise the sphincter of Oddi, disrupting the physiological barrier function and elevating the risk of cholangitis due to duodenobiliary reflux [16].

For stone extraction through ERCP, starting with endoscopic papillary large balloon dilation (EPLBD) followed by EST as a backup in case of cannulation failure is not recommended. This strategy increases the number of cannulations attempts and increase the risk of complications, such as post-ERCP pancreatitis. Although studies have shown no statistically significant difference between EPLBD and EST in stone clearance efficiency or preservation of Oddi sphincter function, EPLBD is relatively more recommended [18,19]. In the surgical management of LCBDE, the transcystic (TC) route is considered as the gold standard. However, a study has showed a greater preference for the transduodenal (TD) approach due to its broader surgical field, a superior pathway for treating recurrence stones, and alleviated bile leakage [7]. Advancements in technology, such as the SpyGlass™ Discover cholangioscope (Boston Scientific) with a 3.5-mm outer diameter, have allowed for percutaneous or laparoscopic gallbladder puncture for CBD exploration and CBDS retrieval. Moreover, it guides the treatment of refractory CBD stones not amenable to traditional endoscopic approaches, decreasing surgical risks, major postoperative complications, and hospital stays. A retrospective case series demonstrated an 89% success rate for intraoperative laparoscopic transcystic CBDS treatment with SpyGlass™ Discover during cholecystectomy, with any major complications [20].

The ideal treatment for choledocholithiasis should be simple, accessible, reliable, minimally invasive, and cost-effective. However, the optimal minimally invasive treatment for concurrent GB and CBD stones remains unknown, no standard protocol or clinical classification criteria established. Currently, there is six minimally invasive techniques used for stones removal, including two-stage methods using a laparoscope and duodenoscope, a one-stage approach combining laparoscopy with intraoperative choledochoscopy, and three mirror schemes (combining laparoscopy, choledochoscopy, and intraoperative duodenoscope or gastroscopy).

The primary controversies focus on T-tube placement during LCBDE [6]. The effectiveness of one-stage versus two-stage management, and the choice between EST and endoscopic papillary balloon dilatation (EPBD) remains undetermined. Furthermore, the timing of ERCP, either preoperative or intraoperative, remain undetermined. Advocates of the two-stage ERCP followed by the laparoscopic cholecystectomy (LC) approach argue it is less invasive because CBD dissection is unnecessary [21,22]. In contrast, advocates of the single-stage LCBDE approach indicate its advantages of requiring only a single procedure is necessary [23].

Due to a lack of consensus regarding the minimally invasive treatment method for concomitant GB and CBD stones, therapeutic guidelines should be suggested for each case [7,13,24]. Additionally, no universal classification system for concomitant GB and CBD stones occurs that is clinically valuable and useful in guiding the selection of the best minimally invasive treatment approach. Therefore, to address this gap, we conducted a single-center retrospective cohort study involving 1044 eligible patients with concomitant GB and CBD stones who underwent minimally invasive surgery. Furthermore, we developed a disease classification model based on the inside diameter of the CBD, the maximum stone size, and the stone number. This clinical classification system, along with the analysis of the clinical characteristics and treatment strategies, was utilized to determine the optimal minimally invasive treatment method for each patient type to reduce residual stones and recurrence while improving therapeutic efficacy.

Our findings revealed a strong consensus in recommendations for diagnosing choledocholithiasis. However, significant differences were observed in the guidelines addressing treatment and preventive management. These variations were particularly evident in the timing of treatment, patient selection for ERCP, and methods for treating complex stone cases. Furthermore, some recommendations lacked supporting evidence or relied on inappropriate citations. As previously indicated, the quality of guidelines for diagnosing and treating choledocholithiasis varied widely, both across different guidelines and even within various domains of the same guideline [9–12].

Materials and Methods

Study Participants

This single-center study included 1044 consecutive patients with GB and CBD stones who underwent various minimally invasive surgical treatments at Zhongnan Hospital of Wuhan University China, between January 2014 and April 2021. The inclusion criteria for patient selection included diagnosis of cholelithiasis with choledocholithiasis confirmed via imaging modalities (e.g., ultrasound, computed tomography (CT), Magnetic Resonance Imaging (MRI)), aged between 18 to 80 years, with no gender restriction, no prior history of upper abdominal surgery, American Society of Anesthesiologists (ASA) physical status classification of below Class 4 [25], and no significant cardiovascular (e.g., myocardial infarction, unstable angina) or pulmonary diseases (e.g., chronic obstructive pulmonary disease, asthma). We excluded patients who had acute cholecystitis, acute cholangitis, concurrent stones in the third-order intrahepatic duct or smaller branches, acute pancreatitis, history of upper abdominal surgery, uncorrectable coagulopathy, ASA class 4 or 5 diseases [25], and open CBD exploration.

Clinical data included demographics (age, gender), clinical presentation, ASA grade, preoperative liver function tests, CBD size and number, CBD diameter, imaging findings, stone distribution, type of surgery, stone clearance outcomes, postoperative morbidity, mortality, conversion rates to open surgery, operative time, postoperative hospital stay, procedural cost, hospitalization charges, postoperative complications, and short-term therapeutic efficacy. This study design adhered to the Declaration of Helsinki and relevant Chinese regulations. Furthermore, this study was approved by the Ethical Committee of Zhongnan Hospital of Wuhan University (Scientific Ethics Quick Review Number: 2023274K), and informed consent has been obtained from the patients.

Assessing the Distribution and Size of the Stones and CBD Diameter

Doppler ultrasound (US), computed tomography (CT), and magnetic resonance cholangiopancreatography (MRCP) were collectively used to assess the number and size of stones, as well as the diameter of the CBD before the surgery. The number and size of the stones were determined based on intraoperative findings. Additionally, a nutritional risk assessment and an evaluation of liver function grade and reserve were performed for each patient.

Surgical Procedures

Combining Laparoscope with Duodenoscope

We applied two approaches combining laparoscope with duodenoscope: the two-stage approach preoperative endoscopic retrograde cholangiopancreatography + laparoscopic cholecystectomy (Pre-ERCP + LC) and the one-stage Intraoperative endoscopic retrograde cholangiopancreatography + laparoscopic cholecystectomy (IO-ERCP + LC) method. A detailed surgical plan was developed based on the preoperative evaluation, with the goal of complete stone removal. In the Pre-ERCP + LC approach, LC was performed as soon as technically feasible, typically 48 to 72 hours after ERCP/EST or EPBD. In the one-stage method (IO-ERC + LC), ERCP/EPBD was performed using a guidewire via the TC route, followed by LC. Intraoperative cholangiography (IOC) was used in both methods to confirm complete stone removal from the CBD.

Combining Laparoscopy with Intraoperative Choledochoscopy

The one-stage method (LC + LCBDE) was performed under general anesthesia, with the patient positioned in a head-up, left-tilted supine position. LCBDE was categorized into Laparoscopic Transcystic Common Bile Duct Exploration (LTCBDE), which removed the stone through the TC route, and laparoscopic choledochotomy for common bile duct exploration (LCCBDE), which removed stone through the TD route. In LTCBDE, following adequate exposure to the CBD, a longitudinal incision was made in the junction of the cystic duct and the CBD. The "basket in catheter" technique was initially used. In cases of failure to retrieve stones after 3 attempts, choedochoscopy was performed. IOC confirmed the complete CBD clearance. If stones could not be removed or if the common hepatic or intrahepatic bile ducts were difficult to inspect through cystic duct choledochoscopy, the cystic duct incision could be extended 2 to 3 mm along the confluence, and possibly further along the long axis of the bile duct. During the procedure, using separation forceps to forcibly expand the incision was avoided, as this process could tear the bile duct wall. A 3-mm choledochoscope was inserted through an operating hole under the costal margin or xiphoid process at the right midclavicular line to explore the CBD and remove the stones. For larger stones, hydroelectric or holmium laser lithotripsy was employed to fragment the stone before removal.

In LCCBDE, stones were extracted through laparoscopic choledochotomy, with the placement of a laparoscopic choledocholithotomy and T-tube drainage (LCTD) or LCCBDE + primary closure of the incision. In LCTD, complete clearance of the distal CBD was confirmed when the wire basket passed into the duodenum through the ampulla of Vater. An appropriately sized T-tube was introduced through the epigastric port and placed in the choledochotomy, with saline injected to examine leakage. The T-tube was commonly removed 6 to 8 weeks later, after routine cholangiography confirmed the absence of residual stones in the CBD. In the LCCBDE + primary closure, the CBD was primarily closed using absorbable sutures after confirmation of complete CBD clearance, simultaneous with the choledochotomy.

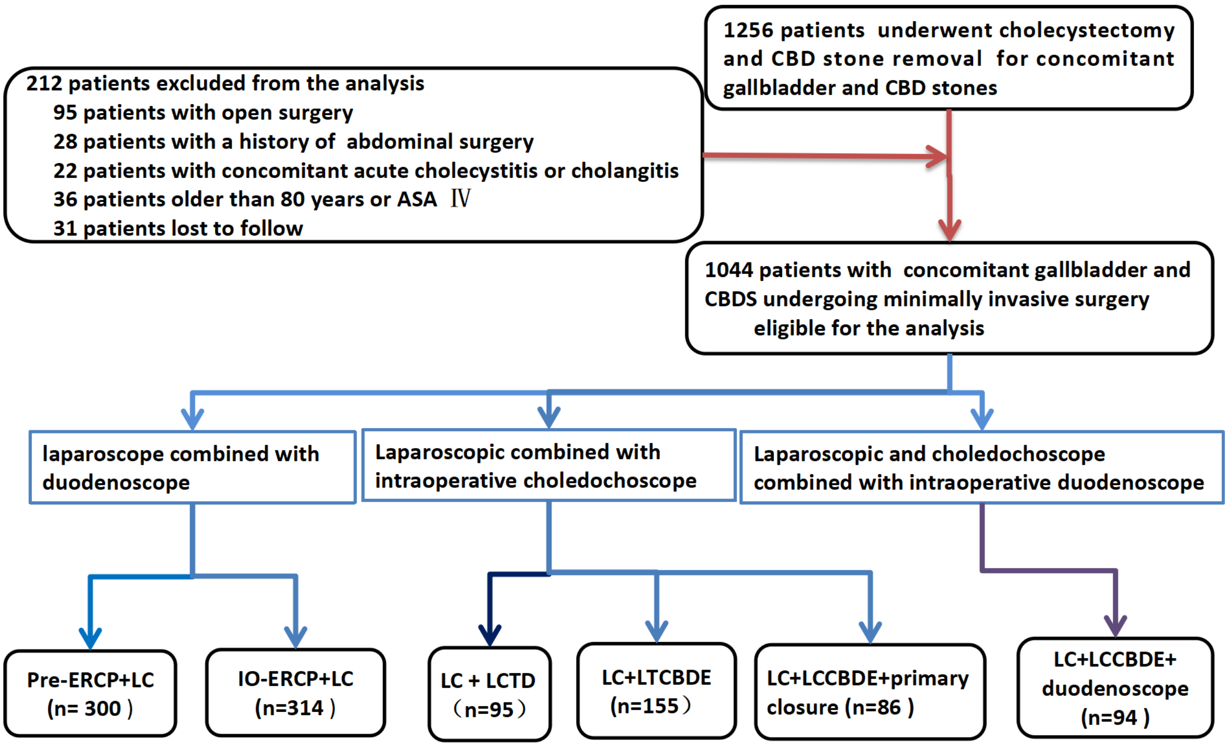

Fig. 1. A flow chart of patient selection and treatment modalities. ASA, American Society of Anesthesiologists; CBD, common bile duct; CBDS, common bile duct stones; LC, laparoscopic cholecystectomy; Pre-ERCP, preoperative endoscopic retrograde cholangiopancreatography; IO-ERCP, Intraoperative endoscopic retrograde cholangiopancreatography; LCCBDE, laparoscopic choledochotomy for common bile duct exploration; LCTD, laparoscopic choledocholithotomy and T-tube drainage; LTCBDE, Laparoscopic Transcystic Common Bile Duct Exploration.

Combining Laparoscopy and Choledochoscopy with the Intraoperative Duodenoscope

In the LC + LCCBDE + Duodenoscope method, conventional LC was initially performed. After this, the CBD was dissected, and the stones were extracted using a basket under choledochoscopic control. Once the stones were cleared, a guidewire was advanced through the CBD into the duodenum. The endoscopist then inserted a flexible duodenoscope orally, advancing it to the duodenum. Following this, an endoscopic nasobiliary drainage tube was inserted into the CBD using the "railroad" technique with a guidewire. Finally, a cholangiogram was conducted via the nasobiliary drainage tube to confirm complete clearance of the bile duct, and the CBD incision was primarily closed with absorbable sutures.

Follow-up

All patients were followed up through outpatient visits and telephone consultations at 1 week, 6 weeks, 3 months, 6 months, and 1-year post-discharge, or sooner if symptoms developed. During the 6-week telephone follow-up evaluation, overall satisfaction was assessed using a verbal rating scale ranging from 0 (not satisfied) to 3 (very satisfied), with intermediate scores of 1 (partially satisfied) and 2 (satisfied).

Furthermore, transabdominal US and liver function tests were performed at the 3-month outpatient follow-up to assess the status of the CBD. Immediate stone clearance was defined as the complete removal of stones during the procedure. Final stone clearance was defined as the removal of residual stones after the operation using a stone basket under choledochoscopy or holmium laser lithotripsy. Postoperative residual stones were defined as stones that remained and could not be removed via nonoperative approaches confirmed by US, CT, or MRCP at 3 months after surgery.

Statistical Analysis

Patient demographics and baseline characteristics, including stone number, size, location, treatment method, duration of surgery, postoperative hospital stay, and average expenses, were presented as counts, and the group differences were analyzed using the Chi-square test or Fisher's exact test. Clinical data were assessed for normality using Shapiro-Wilk (S-W) tests.

Continuous variables were expressed as the mean ± standard deviation (SD) or the median and compared using ANOVA or the Kruskal-Wallis H test. For the post hoc method following the ANOVA test, Turkey 's Honestly Significant Difference (HSD) Test was employed when equal variances were assumed. However, the Games-Howell Post

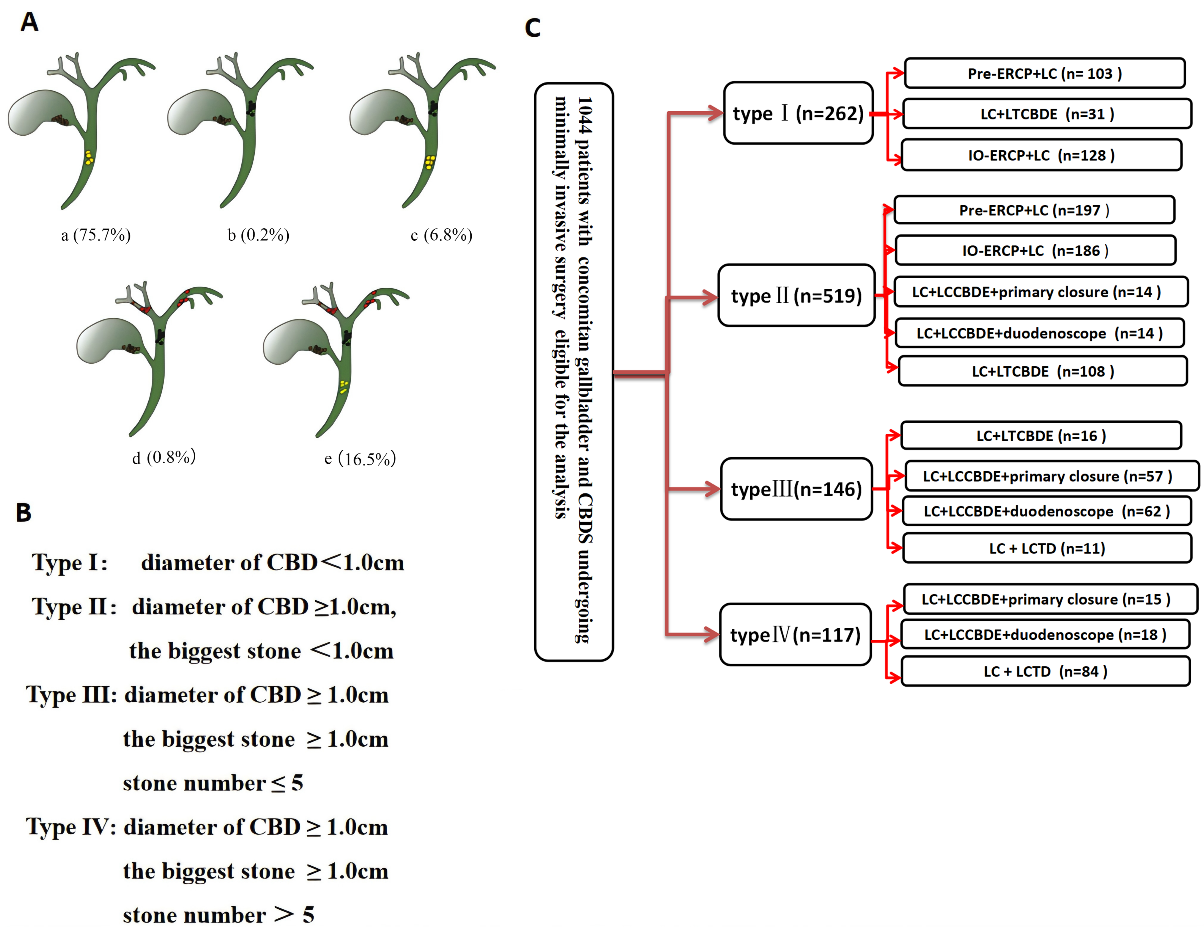

Fig. 2. The distribution of CBD stones and the clinical classification. (A) The distribution of CBD stones. a: stones located in the CBD; b: stones confined to the common hepatic duct; c: stones located in the CBD and the common hepatic duct; d: stones located in the common hepatic duct together with the hepatic duct and/or its second-order branches; e: stones located in both the extrahepatic and hepatic ducts. (B) Classification of gallbladder (GB) and CBD stones based on CBD diameter and stone size and number. (C) The cases and minimally invasive procedures for each type based on our clinical classification. A graph was created using Adobe Illustrator CC 2020 (Version 24.0 for Windows, Adobe Systems Incorporated, San Jose, CA, USA).

Hoc Test was applied when equal variances were not assumed. For the Kruskal-Wallis H test, Bonferroni Correction was used for post hoc analysis. Moreover, Student's t test or the Mann-Whitney test was used in the case of pairwise group comparison.

Associations between clinical prognosis and variables such as age, gender, weight, alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL), γ-glutamy transpeptidase (γ-GT), alkaline phosphatase (ALP), were analyzed using univariate and multivariate logistic regression. Statistical significance was determined as a p value of less than 0.05. These statistical analyses were conducted using Statistical Package for the Social Sciences (SPSS 24.0 for Windows, IBM, Chicago, IL, USA), and figures were created using Adobe Illustrator CC 2020 (Version 24.0 for Windows, Adobe Systems Incorporated, San Jose, CA, USA).

Results

Comparison of Baseline Characteristics and Treatment Modalities

This study initially recruited 1256 patients with concomitant GB and CBD stones. Of these, 212 patients were excluded due to various reasons. The remaining 1044 patients who underwent one of 6 minimally invasive treatments and met the inclusion criteria, were finally included. These treatment protocols were retrospectively compared. No significant differences were found among the 6 groups regarding age, gender, ASA classification, body mass index (BMI), clinical presentation, or liver markers (ALT, AST, TBIL, γ-GT, and ALP) ($p > 0.05$) (**Supplementary Table 1**). The intervention modalities were performed as follows: Pre-ERCP + LC was performed in 300 patients, IO-ERCP with a guidewire via TC and simultaneous LC in 314 patients, LC + LTCBDE in 155 patients, LC + LCCBDE + primary closure in 86 patients, LC + LCCBDE + Duodenoscope in 94 patients, and LC + LCTD in 95 patients (Fig. 1).

Table 1. The diameter of CBD, stone number, and stone size were significantly correlated with selecting minimally invasive surgical procedures.

Operative tactics	Cases	Diameter of CBD (mm)	Maximal stone size (mm)	Number of stones ≤5	Number of stones >5
Pre-ERCP + LC	300	10.0 (8.0, 13.0)[a,b,c,d]	7.0 (5.0, 11.0)[a,b,c,d]	209 (69.7%)	91 (30.3%)[b,c,d]
IO-ERCP + LC	314	11.0 (9.0, 13.0)[e,f,g]	7.0 (4.0, 10.0)[e,f,g]	220 (70.1%)	94 (29.9%)[f,g,h]
LC + LCCBDE + Duodenoscope	94	14.0 (13.0, 16.0)[i]	11.0 (8.0, 14.0)[i]	55 (58.5%)	39 (41.5%)[i,j,k]
LC + LCTD	95	18.0 (14.0, 20.0)[l,m]	15.0 (14.0, 18.0)[l,m]	10 (10.5%)	85 (89.5%)[l,m]
LC + LTCBDE	155	13.0 (11.0, 15.0)[n]	11.0 (9.0, 15.0)[n]	118 (76.1%)	37 (23.9%)
LC + LCCBDE + primary closure	86	14.5 (14.0, 16.0)	13.0 (10.8, 15.0)	64 (74.4%)	22 (25.6%)
H value		385.650	393.609		
Chi-square value				143.360	
p value		<0.001	<0.001	<0.001	

[a]: Pre-ERCP + LC vs LC + LCCBDE + Duodenoscope, $p < 0.05$; [b]: Pre-ERCP + LC vs LC + LCTD, $p < 0.05$; [c]: Pre-ERCP + LC vs LC + LTCBDE, $p < 0.05$; [d]: Pre-ERCP + LC vs LC + LCCBDE + primary closure, $p < 0.05$; [e]: IO-ERCP + LC vs LC + LCCBDE + Duodenoscope, $p < 0.05$; [f]: IO-ERCP + LC vs LC + LCTD, $p < 0.05$; [g]: IO-ERCP + LC vs LC + LTCBDE, $p < 0.05$; [h]: IO-ERCP + LC vs LC + LCCBDE + primary closure, $p < 0.05$; [i]: LC + LCCBDE + Duodenoscope vs LC + LCTD, $p < 0.05$; [j]: LC + LCCBDE + Duodenoscope vs LC + LTCBDE, $p < 0.05$; [k]: LC + LCCBDE + Duodenoscope vs LC + LCCBDE + primary closure, $p < 0.05$; [l]: LC + LCTD vs LC + LTCBDE, $p < 0.05$; [m]: LC + LCTD vs LC + LCCBDE + primary closure $p < 0.05$; [n]: LC + LTCBDE vs LC + LCCBDE + primary closure, $p < 0.05$.

Distribution of CBD Stones

Analysis of CBD stones distribution revealed 5 distinct patterns, with 75.7% of the stones located in the CBD and 0.2% confined to the common hepatic duct. Furthermore, 6.8% of the stones were found in both the CBD and the common hepatic duct, and 0.8% were located in the common hepatic duct together with the hepatic duct and/or its second-order branches. Finally, 16.5% of the stones were distributed in both the extrahepatic and hepatic ducts (Fig. 2A).

Comparison of Stone Characteristics among Patients Undergoing Various Minimally Invasive Surgical Procedures

We assessed the stone characteristics of patients undergoing different surgical procedures based on CBD diameter, maximum stone size and stone number (Table 1). The Post-ERCP/EST or EPBD + LC group included only 5 cases, with no stone observed in their CBD before surgery. These patients were not examined through MRCP due to certain factors, including fixation of the internal bone with a steel plate or other reasons. After undergoing LC, the patients returned to the hospital with acute cholangitis and subsequently underwent post-ERCP/EST or EPBD treatment. Therefore, data obtained from this group were excluded from the stone characteristic analysis.

The median CBD diameter and maximum stone size were smaller in the Pre-ERCP + LC and IO-ERCP + LC groups than in the other groups, with no differences observed between the two groups ($p > 0.05$). The LC + LCTD group indicated the largest median CBD diameter and the maximum stone size among all groups.

There were no substantial differences in the median CBD diameter and maximum stone size between the LC + LCCBDE + Duodenoscope and the LC + LCCBDE + primary closure groups ($p > 0.05$). The median CBD diameter was greater than 10 mm in all patients within the LC + LCCBDE + Duodenoscope, LC + LTCBDE, LC + LCCBDE + primary closure, and LC + LCTD groups. Furthermore, the maximum stone size was less than 2.0 cm in all groups except the LC + LCTD group.

Regarding stone number, no substantial differences were found between the ≤5 and >5 subgroups within the Pre-ERCP + LC and IO-ERCP + LC groups ($p > 0.05$). However, stone numbers typically exceeded 5 in the LC + LCTD group. In comparison, the proportion of patients with stones ≤5 is higher in the LC + LTCBDE, LC + LCCBDE + Duodenoscope, and LC + LCCBDE + primary closure groups.

Classification of Concomitant GB and CBD Stones

To identify the critical factor influencing the choice of different minimally invasive surgical procedures, logistic regression analysis was performed. The six different minimally invasive surgical procedures were applied as the dependent variable (excluding Post-ERCP/EST or EPBD + LC because of the small case numbers), while clinical features and stone characteristics, including gender, age, BMI, liver function, CBD diameter, stone number, and stone size were included as independent variables.

Univariate and multivariate logistic regression analysis revealed a significant correlation, indicating that CBD diameter, stone number, and stone size were independent risk factors affecting clinical prognosis ($p < 0.05$, Table 2). Therefore, selection of surgical procedures was guided by CBD diameter, stone number, and maximal stone size.

Furthermore, based on CBD diameter, stone size, and stone number, a new clinical classification was developed for pa-

Table 2. The correlation analysis between the CBD diameter, stone number, and stone size.

Characteristics	Univariate analysis					Multivariate analysis				
	Odds Ratio (95% CI)	B	SE	Wald	p value	Odds Ratio (95% CI)	B	SE	Wald	p value
Gender										
Female	Reference									
Male	1.203 (0.732–1.978)	0.185	0.254	0.531	0.493					
Age	1.010 (0.992–1.028)	0.010	0.009	1.238	0.269					
Diameter of CBDS (mm)	1.285 (1.206–1.370)	0.252	0.033	59.625	<0.001	1.142 (1.048–1.243)	0.136	0.045	9.255	0.002
Stone size (mm)	1.371 (1.260–1.491)	0.316	0.043	54.533	<0.001	1.201 (1.083–1.333)	0.198	0.055	13.071	<0.001
Stone number										
Single	Reference					Reference				
Multiple	6.872 (2.441–19.351)	1.928	0.528	13.317	<0.001	4.628 (1.581–13.545)	1.532	0.548	7.817	0.005
Weight (kg)	0.999 (0.976–1.021)	–0.001	0.011	0.015	0.903					
ALT (U/L)	0.999 (0.997–1.001)	–0.001	0.001	1.060	0.322					
AST (U/L)	0.999 (0.996–1.001)	–0.002	0.001	1.288	0.274					
TBIL (mmol/L)	1.000 (0.996–1.003)	0.000	0.002	0.002	0.959					
ALP (U/L)	1.001 (0.999–1.002)	0.001	0.001	1.379	0.254					
γ-GT (U/L)	1.000 (0.999–1.001)	0.000	0.000	0.165	0.711					

ALP, alkaline phosphatase; γ-GT, γ-glutamy transpeptidase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; TBIL, total bilirubin; CI, confidence interval.

tients with concomitant GB and CBD stones (Fig. 2B): Type I: CBD diameter $<$1.0 cm; Type II: CBD diameter $\geq$1.0 cm and maximal stone $<$1.0 cm; type III: CBD diameter $\geq$1.0 cm, maximal stone $\geq$1.0 cm, and stone number $\leq$5; type IV: CBD diameter $\geq$1.0 cm, maximal stone $\geq$1.0 cm, and stone number $>$5. Utilizing this classification, 262 type I patients, 519 type II patients, 146 type III patients, and 117 type IV patients underwent 3, 5, 4, and 3 kinds of minimally invasive surgery, respectively (Fig. 2C).

LC + LTCBDE can be an Optimum Treatment Option for Type I Patients

To identify the optimal minimally invasive treatments, we evaluated surgical results, postoperative complications, and follow-up complications for each type of procedure. Vital assessment indicators included the incidence of serious complications, residual stones, relapse rates, surgical success rate, average expense, and postoperative hospital stay durations.

For type I patients, three minimally invasive treatments were performed. Among 103 patients who underwent Pre-ERCP + LC, 96 patients had successful ERCP followed by cholecystectomy after a median interval of 3 days (range 1–8 days). However, 7 patients showed unsuccessful ERCP; 4 patients out of them converted to IO-ERCP + LC after 2–4 days, while 2 required open surgery because of duodenum perforation or bleeding. Additionally, 1 patient received open surgery due to severe gallbladder inflammation.

In the IO-ERCP + LC group, 128 patients were considered for the procedure, and 123 patients successfully underwent intraoperative EPBD with guidewire insertion from the cystic duct through the CBD to the duodenum, followed by simultaneous LC. Moreover, 3 patients needed surgical adjustments because of the anatomical variation or gallbladder duct obstruction, which involved dissecting and cutting the gallbladder duct at its confluence with the common bile duct to insert the guidewire. The other two patients required conversion to open surgery because of severe gallbladder inflammation.

The comparison between the Pre-ERCP + LC and IO-ERCP + LC groups showed no substantial variations in CBD stone clearance, conversion to open surgery, mortality, and intraoperative blood loss ($p > 0.05$, Table 3). However, the IO-ERCP + LC group exhibited significantly lower average cost, shorter postoperative hospitalization, reduced postoperative serum amylase level, and fewer total complications than those in the Pre-ERCP + LC group ($p < 0.05$). Furthermore, with the application of a 3-mm thin choledochoscope, 31 patients underwent LC + LTCBDE. This group of patients demonstrated superior outcomes, including lower average costs, shorter postoperative hospital stays, reduced operative time, and fewer total complications compared to the Pre-ERCP + LC and IO-ERCP + LC groups ($p < 0.001$). However, no significant differences were observed in surgical success rates or CBDS clearance among the three groups ($p > 0.05$). These results suggest that LC + LTCBDE is the most suitable for treating type I patients due to reduced surgical times, shorter hospital stays, and lower average costs.

LC + LTCBDE is the Most Suitable Option for Treating Type II Patients

Five minimally invasive treatments were performed for type II patients (Fig. 2C). Among 197 patients who underwent Pre-ERCP + LC, 11 patients experienced a failed ERCP, including 3 patients requiring conversion to open surgery due to duodenum perforation or bleeding and an-

Table 3. LC + LTCBDE is the viable treatment option for type I CBD stones.

	Pre-ERCP + LC (n = 103)	IO-ERCP + LC (n = 128)	LC + LTCBDE (n = 31)	F value	Chi-square value	H value	p value
Preoperative indicators							
Age	56.6 ± 10.2	57.6 ± 11.1	57.0 ± 9.7	0.216			0.806
Gender (female)	59 (57.3%)	78 (60.9%)	19 (61.3%)		0.361		0.835
ASA grade (<3)	60 (58.3%)	69 (53.9%)	20 (64.5%)		1.278		0.528
Body mass index	26.8 ± 3.6	26.8 ± 3.6	27.7 ± 5.3	0.364			0.696
Medical history							
Diabetes	18 (17.5%)	13 (10.2%)	5 (16.1%)		Fisher		0.232
Hypertension	17 (16.5%)	22 (17.2%)	6 (19.4%)		0.136		0.934
Liver function							
TBIL (μmol/L)	58.3 ± 26.2	62.5 ± 25.1	65.6 ± 25.1	1.296			0.275
ALT level (U/L)	202.2 ± 89.0	194.4 ± 77.8	180.4 ± 80.4	0.861			0.424
AST level (U/L)	163.3 ± 63.0	160.4 ± 67.9	163.0 ± 82.1	0.057			0.945
γ-GT (U/L)	317.7 ± 104.5	327.1 ± 118.5	293.0 ± 121.3	1.145			0.320
ALP (U/L)	259.4 ± 108.1	263.9 ± 96.8	228.7 ± 115.2	1.450			0.236
Surgical results							
Average expenses	34,688.1 ± 3291.5	31,039.8 ± 1970.9[a]	25,785.7 ± 2020.3[b,c]	166.520			<0.001
Postoperative hospital stay (days)	6.0 (5.0, 9.0)	3.0 (2.0,5.0)[a]	2.0 (2.0, 3.0)[b,c]			75.790	<0.001
Intra-operative blood loss (mL)	10.0 (5.0, 20.0)	10.0 (5.0, 20.0)	10.0 (5.0, 20.0)			0.333	0.847
Operative time (minutes)	124.4 ± 20.4	89.3 ± 24.6[a]	69.0 ± 16.7[b,c]	107.280			<0.001
CBDS clearance	101 (98.1%)	126 (98.4%)	30 (96.8%)		Fisher		0.674
Operation success rates	96 (93.2%)	123 (96.1%)	30 (96.8%)		Fisher		0.605
ERCP failure	7 (6.8%)	0 (0.0%)[a]			Fisher		0.001
Mortality	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Postoperative complications							
Uprising serum amylase	82 (79.6%)	31 (24.2%)[a]	0 (0.0%)		98.062		<0.001
Bile leakage	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Bleeding	1 (1.0%)	0 (0.0%)	0 (0.0%)		Fisher		0.511
Perforation	1 (1.0%)	0 (0.0%)	0 (0.0%)		Fisher		0.511
Cholangitis	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Pleural effusion	1 (1.0%)	0 (0.0%)	0 (0.0%)		Fisher		0.511
Pneumonia	1 (1.0%)	0 (0.0%)	0 (0.0%)		Fisher		0.511
T-tube displacement	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Multiple organ failure	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Follow-up complications							
Stone recurrence	5 (4.9%)	6 (4.7%)	2 (6.5%)		Fisher		0.847
Stricture of CBD	0 (0.0%)	0 (0.0%)	0 (0.0%				
Reflux cholangitis	1 (1.0%)	1 (0.1%)	0 (0.0%)		Fisher		1.000
Total complication	92 (89.3%)	38 (29.7%)[a]	2 (6.5%)		108.331		<0.001

[a]: PreERCP + LC vs IO-ERCP + LC, $p < 0.05$; [b]: Pre-ERCP + LC vs LC + LTCBDE, $p < 0.05$; [c]: IO-ERCP + LC vs LC + LTCBDE, $p < 0.05$.

other 3 patients requiring conversion due to severe inflammation and adhesion during laparoscopic cholecystectomy. The median postoperative hospital stays for this group was 7 days, with a stone-free rate of 96.9%. Complications were found in 168 patients, including increased postoperative serum amylase, stone recurrence, and reflux cholangitis. Specifically, the postoperative serum amylase was elevated in 157 patients, and 19 patients experienced recurrent bile duct stones at least 1 year after surgery.

In the IO-ERCP + LC group, 186 patients underwent the procedure, with 6 patients converted to open surgery due to severe inflammation and adhesion during laparoscopic cholecystectomy. The median postoperative hospital stay in this group was 3.5 days, with a stone-free rate of 97.3%. Postoperative serum amylase levels were increased in 49 patients, and 23 experienced recurrent bile duct stones at least 1 year after surgery.

Furthermore, LC + LTCBDE was conducted in 108 patients, with 3 patients converted to open surgery because

Table 4. LC + LTCBDE is more suitable for treating patients with type II CBD stones.

	Pre-ERCP + LC (n = 197)	IO-ERCP + LC (n = 186)	LC + LCCBDE + Duodenoscope (n = 14)	LC + LTCBDE (n = 108)	LC + LCCBDE + primary closure (n = 14)	F value	Chi-square value	H value	p value
Preoperative indicators									
Age	56.1 ± 13.0	52.8 ± 14.2	50.6 ± 13.6	53.2 ± 14.8	57.6 ± 10.8	2.030			0.089
Gender (female)	112 (56.8%)	119 (64.0%)	8 (57.1%)	63 (58.3%)	7 (50.0%)		2.739		0.602
ASA grade (<3)	101 (51.3%)	98 (52.7%)	9 (64.3%)	67 (62.0%)	8 (57.1%)		4.130		0.389
Body mass index	25.7 ± 3.9	26.4 ± 3.6	25.2 ± 2.7	26.3 ± 3.6	25.4 ± 4.3	1.377			0.241
Medical history									
Diabetes	31 (15.7%)	32 (17.2%)	3 (21.4%)	25 (23.1%)	2 (14.3%)		Fisher		0.552
Hypertension	34 (17.3%)	41 (22.0%)	3 (21.4%)	29 (26.9%)	3 (21.4%)		Fisher		0.386
Liver function									
TBIL (μmol/L)	66.8 ± 26.1	65.8 ± 20.7	66.6 ± 23.5	71.3 ± 28.7	74.2 ± 21.2	1.131			0.352
ALT level (U/L)	217.2 ± 91.1	231.1 ± 93.1	193.5 ± 86.0	220.2 ± 87.1	230.4 ± 90.8	0.985			0.415
AST level (U/L)	186.4 ± 83.5	190.8 ± 85.2	209.9 ± 72.9	204.7 ± 80.6	233.6 ± 140.3	1.331			0.271
γ-GT (U/L)	390.8 ± 107.2	378.8 ± 111.1	412.0 ± 159.6	375.5 ± 114.4	387.4 ± 124.7	0.654			0.624
ALP (U/L)	332.2 ± 91.6	315.4 ± 90.7	337.2 ± 60.2	309.5 ± 86.7	344.0 ± 114.6	1.702			0.148
Surgical results									
Average expenses	36,841.9 ± 4836.3	32,781.5 ± 1553.3[a]	33,078.7 ± 3575.9	24,075.4 ± 3787.5[c,e,f,g]	34,078.5 ± 3464.8[d]	168.748			<0.001
Postoperative hospital stay (d)	7.0 (6.0, 9.5)	3.5 (3.0, 6.0)[a]	3.5 (3.0, 6.0)[b]	3.0 (2.0, 5.0)[c,e,f,g]	5.5 (4.0, 7.0)[d]			199.226	<0.001
Intra-operative blood loss (mL)	20.0 (20.0, 50.0)	20.0 (20.0, 50.0)	30.0 (17.5, 50.0)	20.0 (20.0, 50.0)	30.0 (17.5, 50.0)			2.261	0.688
Operation time (min)	116.8 ± 34.4	108.0 ± 35.6[a]	108.1 ± 36.1[b]	100.4 ± 36.6[c,e,f,g]	107.0 ± 36.4[d]	3.974			0.003
CBDS clearance	191 (97.0%)	181 (97.3%)	13 (92.9%)	103 (95.4%)	13 (92.9%)		Fisher		0.409
Operation success rates	186 (94.4%)	180 (96.8%)	14 (100%)	105 (97.2%)	14 (100%)		Fisher		0.703
Mortality	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Postoperative complications									
Uprising serum amylase	157 (79.7%)	49 (26.3%)[a]	3 (21.4%)[b]	0 (0.0%)[c]	0 (0.0%)[d]		226.620		<0.001
Bile leakage	0 (0.0%)	0 (0.0%)	1 (7.1%)	2 (1.9%)	1 (7.1%)		Fisher		0.001
Bleeding	2 (1.0%)	2 (1.1%)	0 (0.0%)	0 (0.0%)	1 (7.1%)		Fisher		0.219
Perforation	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		Fisher		1.000
Cholangitis	0 (0.0%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	1 (7.1%)		Fisher		0.003
Pleural effusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Pneumonia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
T-tube displacement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Multiple organ failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Follow-up complications									
Stone recurrence	19 (9.6%)	23 (12.4%)	2 (14.3%)	11 (10.2%)	2 (14.3%)		Fisher		0.811
Stricture of CBD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Reflux cholangitis	2 (1.0%)	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		Fisher		0.829
Total complication	168 (85.3%)	73 (39.2%)[a]	5 (35.7%)[b]	13 (12.0%)[c]	5 (35.7%)[d]		171.119		<0.001

[a]: PreERCP + LC vs IO-ERCP + LC, $p < 0.05$; [b]: Pre-ERCP + LC vs LC + LCCBDE + Duodenoscope, $p < 0.05$; [c]: Pre-ERCP + LC vs LC + LTCBDE, $p < 0.05$; [d]: Pre-ERCP + LC vs LC + LCCBDE + primary closure, $p < 0.05$; [e]: IO-ERCP + LC vs LC + LTCBDE, $p < 0.05$; [f]: LC + LCCBDE + Duodenoscope vs LC + LTCBDE, $p < 0.05$; [g]: LC + LTCBDE vs LC + LCCBDE + primary closure, $p < 0.05$.

Table 5. LC + LCCBDE + Duodenoscope or LC + LCCBDE + primary closure approach is acceptable for treating patients with type III CBD stones.

	LC + LTCBDE	LC + LCCBDE + Duodenoscope	LC + LCTD	LC + LCCBDE + primary closure	F value	Chi-square value	H value	p value
	(n = 16)	(n = 62)	(n = 11)	(n = 57)				
Preoperative indicators								
Age	55.3 ± 10.8	58.4 ± 13.1	51.0 ± 10.6	56.8 ± 12.6	1.215			0.307
Gender (female)	11 (68.8%)	30 (48.4%)	5 (45.5%)	25 (43.9%)		3.158		0.368
ASA grade (<3)	10 (62.5%)	42 (67.7%)	7 (63.6%)	35 (61.4%)				0.920
Body mass index	23.9 ± 2.7	23.3 ± 2.5	23.8 ± 1.4	24.2 ± 2.3	1.528			0.210
Medical history								
Diabetes	2 (12.5%)	7 (11.3%)	1 (9.1%)	8 (14.0%)		Fisher		0.975
Hypertension	3 (18.8%)	9 (14.5%)	1 (9.1%)	11 (19.3%)		Fisher		0.828
Liver function								
TBIL (μmol/L)	72.8 ± 20.7	81.0 ± 18.4	79.0 ± 21.9	84.3 ± 23.7	1.304			0.276
ALT level (U/L)	219.6 ± 56.1	226.6 ± 67.7	179.8 ± 34.6	212.9 ± 54.7	2.056			0.109
AST level (U/L)	188.8 ± 56.3	215.3 ± 47.9	207.2 ± 38.2	192.7 ± 58.3	2.263			0.084
γ-GT (U/L)	347.1 ± 91.6	361.8 ± 62.6	379.5 ± 99.7	369.8 ± 87.4	0.497			0.685
ALP (U/L)	277.0 ± 56.4	298.0 ± 59.4	277.6 ± 89.0	282.0 ± 69.0	0.886			0.450
Surgical result								
Average expenses	28,764.0 ± 5361.9	38,964.9 ± 1785.5	41,823.8 ± 3783.2	33,562.3 ± 4862.6	39.144			<0.001
Postoperative hospital stay (d)	3.0 (2.0, 5.0)	4.5 (3.8, 6.0)[a]	9.0 (6.0, 13.0)[b,d]	5.0 (4.5, 7.5)[c,e]			40.664	<0.001
Intra-operative blood loss (mL)	25.0 (10.0, 37.5)	30.0 (10.0, 60.0)	40.0 (20.0, 60.0)	30.0 (10.0, 50.0)			3.303	0.347
Operation time (min)	141.1 ± 19.8	135.4 ± 24.0[a]	102.7 ± 17.3[b]	125.8 ± 25.8[c]	7.542			<0.001
CBDS clearance	15 (93.8%)	54 (87.1%)	10 (90.9%)	56 (98.2%)		Fisher		0.093
Operation success rates	14 (87.5%)	59 (95.2%)[a]	11 (100%)[b]	56 (98.2%)[c]		Fisher		0.207
Mortality	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		Fisher		0.185
Postoperative complications								
Uprising serum amylase	0 (0.0%)	6 (9.7%)	0 (0.0%)	0 (0.0%)		Fisher		0.060
Bile leakage	0 (0.0%)	0 (0.0%)	1 (9.1%)	2 (3.5%)		Fisher		0.123
Bleeding	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Perforation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Cholangitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)		Fisher		0.575
Pleural effusion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Pneumonia	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
T-tube displacement	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Multiple organ failure	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Follow-up complications								
Stone recurrence	2 (12.5%)	3 (4.8%)	1 (9.1%)	3 (5.3%)		Fisher		0.463
Stricture of CBD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Reflux cholangitis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Total complication	2 (12.5%)	9 (14.5%)	2 (18.2%)	6 (10.5%)		Fisher		0.787

[a]: LC + LCCBDE + Duodenoscope vs LC + LTCBDE, $p < 0.05$; [b]: LC + LTCD vs LC + LTCBDE, $p < 0.05$; [c]: LC + LCCBDE + primary closure vs LC + LTCBDE, $p < 0.05$; [d]: LC + LCTD vs LC + LCCBDE + Duodenoscope, $p < 0.05$; [e]: LC + LCCBDE + primary closure vs LC + LCTD, $p < 0.05$.

Table 6. LC + LCTD can be a first-line treatment for patients with type IV CBD stones.

	LC + LCCBDE + primary closure (n = 15)	LC + LCCBDE + Duodenoscope (n = 18)	LC + LCTD (n = 84)	F value	Chi-square value	H value	*p* value
Preoperative indicators							
Age	58.6 ± 9.9	51.9 ± 16.6	53.2 ± 11.2	1.917			0.167
Gender (female)	9 (60.0%)	8 (44.4%)	39 (46.4%)		1.039		0.595
ASA grade (<3)	10 (66.7%)	11 (61.1%)	62 (73.8%)		1.312		0.519
Body mass index	22.9 ± 1.9	23.8 ± 2.6	22.6 ± 3.3	1.092			0.339
Medical history							
Diabetes	2 (13.3%)	2 (11.1%)	9 (10.7%)		Fisher		0.898
Hypertension	3 (20.0%)	3 (16.7%)	10 (11.9%)		Fisher		0.568
Liver function							
TBIL (μmol/L)	85.7 ± 25.1	67.7 ± 20.7	71.8 ± 28.4	2.088			0.129
ALT level (U/L)	192.8 ± 48.5	174.2 ± 67.1	201.4 ± 60.7	1.522			0.223
AST level (U/L)	189.1 ± 71.6	220.3 ± 56.9	185.0 ± 60.2	2.469			0.089
γ-GT (U/L)	387.5 ± 127.5	365.6 ± 119.8	423.5 ± 123.5	1.914			0.152
ALP (U/L)	392.0 ± 135.3	320.1 ± 82.4	313.5 ± 82.7	2.307			0.120
Surgical result							
Average expenses	41,866.8 ± 4009.2	41,068.0 ± 3218.6	40,395.3 ± 3909.8	1.046			0.355
Post-hospitalization time (d)	5.0 (4.0, 6.0)[a]	5.0 (4.0, 7.3)	10.0 (8.3, 14.8)[b]			59.721	<0.001
Intra-operative blood loss (mL)	30.0 (10.0, 50.0)	25.0 (10.0, 40.0)	30.0 (20.0, 50.0)			4.456	0.108
Operation time (min)	128.5 ± 20.3	146.5 ± 21.3	144.1 ± 25.6	2.871			0.061
CBDS clearance	13 (86.7%)[a]	17 (94.4%)	65 (77.4%)[b]		Fisher		0.229
Conversion to open surgery	2 (13.3%)	3 (16.7%)	5 (6.0%)		Fisher		0.155
Mortality	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Postoperative complications							
Uprising serum amylase	0 (0.0%)	3 (16.7%)	0 (0.0%)		Fisher		0.005
Bile leakage	1 (6.7%)	0 (0.0%)	4 (4.8%)		Fisher		0.608
Bleeding	0 (0.0%)	1 (5.6%)	1 (1.2%)		Fisher		0.486
Perforation	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Cholangitis	1 (6.7%)	0 (0.0%)	0 (0.0%)		Fisher		0.128
Pleural effusion	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Pneumonia	0 (0.0%)	0 (0.0%)	1 (1.2%)		Fisher		1.000
T-tube displacement	0 (0.0%)	0 (0.0%)	2 (2.4%)		Fisher		1.000
Multiple organ failure	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Follow-up complications							
Stone recurrence	2 (13.3%)	3 (16.7%)	6 (7.1%)		Fisher		0.229
Stricture of CBD	0 (0.0%)	0 (0.0%)	0 (0.0%)				
Reflux cholangitis	0 (0.0%)	1 (5.6%)	0 (0.0%)		Fisher		0.282
Total complication	4 (26.7%)	8 (44.4%)	14 (16.7%)		Fisher		0.035

[a]: LC + LCCBDE + Duodenoscope vs LC + LCCBDE + primary closure, $p < 0.05$; [b]: LC + LCTD vs LC + LCCBDE + primary closure, $p < 0.05$.

of severe inflammatory adhesion. In this group, the median postoperative hospital stay was 3.0 days. However, recurrent bile duct stones were observed in 11 patients 1 year after surgery, with a total complication rate of 12.0%.

Additionally, 14 patients underwent LC + LCCBDE + primary closure, and another 14 underwent LC + LCCBDE + Duodenoscope. Among all minimally invasive treatments, there were no substantial differences in CBD stone clearance, operation success rates, mortality, stone recurrence, or intraoperative blood loss ($p > 0.05$, Table 4). The Pre-ERCP + LC group showed longer postoperative hospital stay, increased serum amylase levels, and higher total complications than in the other groups, suggesting care while using the Pre-ERCP. Compared to all other groups, the LC + LTCBDE demonstrated the lowest total complications, operative time, and average cost. The IO-ERCP + LC group exhibited similar outcomes regarding surgical success rates, operative time, and total complications to those of the group concerning, but had higher average cost and longer postoperative hospital stays than the LC + LTCBDE.

These results suggest LC + LTCBDE as the preferred option for treating type II patients. Pre-ERCP + LC and IO-ERCP + LC were performed before 2020; however, LC + LTCBDE became more frequent after the introduction of cholangioscopy, emphasizing its significance in modern settings.

LC + LCCBDE + Duodenoscope or LC + LCCBDE + Primary Closure Approach is Viable Option for Treating Patients with Type III CBD Stones

Four minimally invasive treatments were conducted for patients with type III CBD stones. Baseline indicators demonstrated no substantial differences among the groups (Table 5). At this medical center, ERCP is not usually selected for patients with common bile duct stones larger than 1 centimeter. Therefore, laparoscopic surgery was performed in various groups, including LC + LTCBDE (16 cases), LC + LCCBDE + primary closure (57 cases), LC + LCCBDE + Duodenoscope (62 cases) and LC + LCTD (11 cases).

In the LC + LTCBDE group, operation times were longer due to the need for intraoperative lithotripsy for stones larger than 1 centimeter. However, this group exhibited shorter postoperative hospital stays and the lowest average costs among all 4 groups. Furthermore, no significant difference was found in CBD stone clearance, intraoperative blood loss, or mortality among the 4 laparoscopic surgery CBD stone groups ($p > 0.05$).

The LC + LCTD group showed the longest postoperative hospital stays and highest average costs than the other groups, as patients were not discharged until the T-tube was clamped. The LC + LCCBDE + primary closure and LC + LCCBDE + Duodenoscope groups had similar surgical outcomes and complication rates, though a slight increase was observed in the risk of bile leakage. These results suggest that both LC + LCCBDE + Duodenoscope or LC + LCCBDE + primary closure approach is viable options for treating patients with type III CBD stones, providing comparable effectiveness and safety.

LC + LCTD can be a Viable Option for Treating Patients with Type IV CBD Stones

Three minimally invasive treatments were performed for patients with type IV CBD stones. Out of the total selected, 18 patients underwent LC + LCCBDE + Duodenoscope, with 3 patients converted to open surgery due to challenges in clearing the stones. LC + LCCBDE + primary closure was conducted in 15 patients, of which 2 patients were converted to LCTD, and 3 were converted to open surgery due to challenges in clearing the stones. LC + LCTD was conducted in 84 patients, with 5 patients converted to open surgery due to challenges in clearing the stones.

No significant differences were found among the three groups regarding average cost, blood loss, operation time, or mortality ($p > 0.05$, Table 6). However, the LC + LCTD group demonstrated lower CBD stone clearance rates and longer postoperative hospitalization stays than the other groups. This outcome is due to the larger stone sizes and higher stone numbers in the LC + LCTD group, making it a viable option for such cases.

Additionally, we observed higher stone numbers and larger stone sizes in the LC + LCTD group than in the LC + LCCBDE + Duodenoscope and LC + LCCBDE + primary closure groups. The maximum stone size in the LC + LCCBDE + Duodenoscope and LC + LCCBDE + primary closure groups was less than 1.5 cm, whereas in the LC + LCTD group, stones are often larger than or equal to 1.5 cm, and the stone number was greater. Importantly, the LC + LCTD group showed fewer total complications than the LC + LCCBDE + Duodenoscope and LC + LCCBDE + primary closure groups. Therefore, LC + LCTD is the more appropriate option for treating type IV patients, especially those with larger and numerous CBD stones.

Discussion

There is controversy regarding the optimal minimally invasive treatment strategy for patients with concomitant cholecystolithiasis and choledocholithiasis, with several different methods available for stone removal [13]. The choice of surgical approach is based on various factors [5,26]. In this study, we summarized six surgical options for treating concomitant cholecystolithiasis and choledocholithiasis. The primary techniques included the single-stage approach of LCBDE + LC and the two-stage approach of ERCP stone removal followed by LC. The specific methods are as follows. (1) Laparoscopy combined with intraoperative choledochoscopy (LC/LCBDE). LCBDE involves stone removal via either the TC or TD route. For the TD route, two options exist: LCTD, which requires T-tube placement, and LC + LCCBDE + primary closure which does not need T-tube placement. (2) Laparoscopy combined with duodenoscopy (three patterns): a preoperative ERCP with EST or EPBD followed by LC (Pre-ERCP + LC); intraoperative ERCP and EST or EPBD using the rendezvous technique during LC (IO-ERCP + LC); or postoperative ERCP with EST or EPBD after LC (Post-ERCP/EST or EPBD + LC). (3) Laparoscopy and choledochoscopy combined with intraoperative duodenoscope (LC + LCCBDE + Duodenoscope). This study evaluated the advantages and disadvantages of each treatment option to establish an optimal minimally invasive treatment model, offering a clearer direction for future clinical guidelines.

To assess the primary factor affecting the selection of different minimally invasive surgical procedure, we performed logistic regression analysis. Since there were only 5 cases of post-ERCP/EST or EPBD + LC, and this treatment was used as a remedial measure when no stones were found in the CBD before surgery, it was not considered an ideal treatment model for CBD stones and was excluded for the subsequent analysis. Therefore, we examined six minimally invasive surgical procedures, excluding post-ERCP/EST or EPBD + LC, as the dependent variable, while clinical features (including stone characteristics) served as the independent variables. We found that the choice of surgical procedures primarily depended on the CBD diameter, stone number, and stone size. Initially, we predicted that the bilirubin levels might also impact the choice of surgical procedures; however, it was strongly associated with the stone incarcerated. Since incarcerated CBD stones were often accompanied by acute cholangitis, these cases were excluded from the analysis. This exclusion likely explains why bilirubin level did not impact the choice of surgical procedures. Additionally, our analysis demonstrates that the choice of surgical procedures is independent of the stone location within the CBD. Therefore, we developed a classification model for the disease, dividing all patients with concomitant cholecystolithiasis and choledocholithiasis into four types, defined by CBD diameter, maximum stone size, and stone number.

To establish an optimal minimally invasive treatment model for managing concomitant cholecystolithiasis and choledocholithiasis, we compared the advantages and disadvantages of various approaches for CBD stone removal based on a four-type classification system. Crucial indicators such as the incidence rate of serious complications, residual stones, relapse, surgical success rate, average expense, and postoperative hospital stay were considered in screening the optimal procedures. For type I patients, three minimally invasive treatment approaches, including Pre-ERCP + LC, IO-ERCP + LC and LC + LTCBDE, were utilized. Among these methods, LC + LTCBDE was found to be the best strategy due to shorter surgical duration, reduced hospital stays, and lower postoperative serum amylase levels. In our practice, CD dilatation has not been adopted due as some anatomical challenges. Certain configurations of the CD/CBD junction make it impossible to fully dilate the duct, and dilating the intramural part of the CD may be undesirable due to the risk of CBD disruption.

For type II cases, 5 minimally invasive treatment approaches were utilized. The optimal surgical method primarily depends on whether the gallbladder neck canal is unobstructed and whether a slender choledochoscopy can pass through the confluence of the cystic duct and the common bile duct after a slight incision. If the cystic duct was unobstructed and sufficiently larger to pass a slender choledochoscopy, the LC + LTCBDE group is recommended as the preferred treatment method due to its lowest average cost and shortest hospital stay. Especially, with the recent advancement in choledochoscopy, the emergence of increasingly slender choledochoscopy and more efficient lithotripsy devices have further improved the efficacy and feasibility of this method.

For patients where the cystic duct is not obstructed but its diameter is not sufficient to pass a slender choledochoscop, IO-ERCP + LC is recommended technique. If it is obstructed, LC + LCCBDE + primary duct-closure is considered the preferred for stone clearance. For type III cases, 4 treatment options were analyzed, with LC + LCCBDE + Duodenoscope found to be the most appropriate treatment option. For type IV cases, 3 minimally invasive treatment approaches were utilized, with LC + LCTD identified as an ideal treatment approach.

For patients with a maximum stone size of less than 1.0 cm and a CBD diameter of less than 1.0 cm, whether Pre-ERCP + LC and IO-ERCP with a guidewire via TC + LC is the better option has been highly controversial. Previously, Pre-ERCP was the standard therapeutic procedure. While it is effective and generally safe, it poses significant risks, including severe perforation, massive bleeding, and permanent destruction of the Oddi sphincter, which can lead to long-term complications, such as intestinal content reflux, biliary tract inflammation, and stone recurrence [27–30]. However, limited EST + EPBD has been suggested as a more reasonable alternative procedure. In this real-world study, EPBD was only performed in selected patients, i.e., patients with an altered anatomy or coagulopathy because of a higher incidence of post-ERCP pancreatitis in the Pre-ERCP + LC group. In addition, Pre-ERCP has many limitations: during LC, 12.9% of patients who underwent preoperative endoscopic CBD clearance still had residual stones [31]. These stones could either be retained (due to false-negative ERCP or incomplete stone extraction) or form new stones (as GB stones migrate into the CBD during the interval before LC). Furthermore, this technique requires two anesthesia sessions and potentially two hospital admissions, leading to extended hospital stays and higher costs.

Conversely, current evidence supports IO-ERCP with a guidewire via TC + LC as superior alternative to Pre-ERCP. This approach avoids the need for cutting the sphincter of Oddi, is a one-stage procedure, and is most cost-effective. Notably, no cases of post-EPBD pancreatitis were observed in patients receiving IO-ERCP with a guidewire via TC + LC. Furthermore, this approach is technically simpler because of wire guidance, with a 100% ERCP success rate in our study, compared to 91.3% for Pre-ERCP + LC. However, 2 patients with ERCP failure in the Pre-ERCP group successfully managed using IO-ERCP with a guidewire via TC. Moreover, the Pre-ERCP groups also exhibited higher complication rates and severity, with most cases of ERCP requiring conversion to open surgery because of serious complications. These observations indicate that IO-ERCP with a guidewire via TC is a viable approach for patients with a maximum stone size of less than 1.0 cm and CBD diameter of less than 1.0 cm. However, Pre-ERCP + LC should be applied with caution, especially for managing type III patients, given its higher risk implications and extended recovery.

For cases with a maximal stone size of less than 1.0 cm, and a CBD diameter greater than 1.0 cm, LTCBDE showed cost effectiveness over IO-ERCP with a guidewire via TC, without significant differences in the duration of hospital stay, operation time, CBD stone clearance, surgical success rate, or complication rates [17]. Currently, LCBDE can be conducted with the TC (LTCBDE) or choledochotomy (LCCBDE) approaches. In the LCCBDE method, the CBD integrity is compromised due to the incision. The LTCBDE employs the cystic duct to reach the CBD, thereby minimizing incision-related complications, such as postoperative bile leakage [32,33]. This makes LTCBDE a viable approach compared to the choledochotomy incision. Importantly, a crucial advantage of the TC approach is its preservation of both the CBD and the sphincter of the duodenal papilla [32].

Our results confirmed that LTCBDE is the most secure and effective surgical technique with low morbidity rates. It eliminates the need for choledochotomy, and avoids the use of a T-tube, along with the potential complications that may arise thereafter. These results are supported by other studies [33–35]. Additionally, the anatomical features of the cystic duct favor LTCBDE. The cystic duct serves as a functional sphincter, with a wider diameter at its confluence with the hepatic duct compared to the CBD. The cystic duct can dilate to a diameter of 1 cm or more, particularly at the confluence, creating a favorable condition for conducting LTCBDE. However, the success of the TC approach depends on the anatomy of the cystic duct, such as its diameter and the bifurcation angle with the hepatic ducts. If the stone bulk is large or the cystic duct is blocked, complete clearance of the CBD cannot be achieved via the TC method [17,33]. Additionally, many patients had stones in the supracystic portion of the CBD which pose challenges for removal via the TC route. In our study, the success rate for LTCBDE was 88.5%. Therefore, in case of LTCBDE failure, LCCBDE + Duodenoscope serves as a reasonable alternative.

Compared to LTCBDE, LCCBDE + Duodenoscope has the disadvantage of requiring an incision over the CBD, additional equipment, and higher costs. However, this approach offers a higher success rate compared to LTCBDE and avoids the need for a T-tube, as needed in LCTD. LCCBDE + primary closure is similar to LCCBDE + Duodenoscope but poses the greatest risk of delayed bile leakage. Therefore, LTCBDE is an ideal approach for treating CBD stones in patients with a maximum stone size of less than 1.0 cm and a CBD diameter greater than 1.0 cm. LCCBDE + Duodenoscope could be a preferred alternative when LTCBDE fails. However, LTCBDE is not recommended when the internal CBD diameter is less than 1.0 cm because of the risk of CBD stricture.

For patients with a maximum stone size of greater than 1.0 cm and a stone number less than 5, LTCBDE has several technical limitations. Factors contributing to the failure of this approach include unfavorable cystic duct anatomy, stones larger than >0.6 cm in diameter, or a large stone number. For this purpose, we modified the approach by slitting the cystic duct and creating a 3–5 mm opening at the superior and inferior margins of its confluence. This change supported the insertion of choledochoscope into the cystic duct without the need for balloon dilation. Using this approach, we effectively eliminated CBD stones larger than 6 mm in diameter in a single procedure. However, CBD stones larger than 10 mm remained challenging to remove, even with stone fragmentation and prolonged operative time [33].

In the one-stage method, the utilization of three endoscopes as adjunct tools demonstrated superior efficacy and safety [36]. This method offered several advantages as discussed below: Firstly, by avoiding EST, this approach mitigated the risk of pancreatitis post-ERCP while preserving the functionality of the Oddi sphincter. Secondly, compared to LTCBDE, the tri-endoscopic approach showed a greater success rate, especially for larger stones and anatomically complex cases. Lately, unlike LCTD, this method eliminated T-tube requirements, reducing related complications. While effective, the LCCBDE + primary closure approach poses a higher risk of delayed bile leakage compared to the LCCBDE + Duodenoscope, which offered a higher success rate but required additional equipment and higher costs. Therefore, the combined tri-endoscopic approach is the ideal treatment for patients with CBD stones larger than 1.0 cm and fewer than 5 stones.

However, achieving complete clearance of the CBD using LTCBDE, LC + LCCBDE + primary closure, or LC + LCCBDE + Duodenoscope becomes difficult when the maximum stone size exceeds 2.0 cm, and the stone number is greater than 5. The presence of multiple large stones in a dilated CBD elevates the difficulty and time of removal using LTCBDE. Our results confirm that retained stones are more frequently observed in the LC + LCCBDE + primary closure and LC + LCCBDE + Duodenoscope groups compared to the LCTD group. These observations underscore the significance of selecting the most suitable approach based on patient-specific factors.

LCTD showed superior outcomes compared to LC + LCCBDE + primary closure and LC + LCCBDE + Duodenoscope, primarily due to its reduced postoperative stone retention rate. While LCTD requires the use of a T-tube, the ability to completely remove the stone and prevent retained stone is crucial for success. Therefore, LCTD is the preferred approach for type IV CBD patients, especially for those with stone sizes larger than 2.0 cm or more than 5 stones.

Some researchers prioritize LCBDE over ERCP in young patients. Others propose for single-stage therapy only in patients classified as ASA I or II, utilizing ERCP with sphincterotomy for those with significant comorbidities. However, evidence supports the safety and effectiveness of LCBDE in geriatric individuals [35]. Zhu *et al.* [37] demonstrated no significant difference in treatment outcomes between younger and older individuals undergoing transcystic LCBDE. Wu *et al.* [38] published similar findings following choledochotomy. Additionally, LCBDE has demonstrated substantial advantages in the bariatric population [39], highlighting that characteristics such as age, gender, and BMI should not exclude patients from undergoing LCBDE via choledochotomy. Instead, criteria such as the diameter of CBD, stone number, and stone size should guide the selection of minimally invasive surgeries.

The timing of early ERCP in the treatment of cholelithiasis pancreatitis remains a controversial subject, with different opinions across guideline [11,12,40]. Regarding the simultaneous use of ERCP and cholecystectomy, most guidelines support the "ERCP combined with laparoscopic cholecystectomy" approach for treating "patients with both choledocholithiasis and cholecystolithiasis". However, there is controversy about whether ERCP should be performed at the same time as cholecystectomy [11,12,40].

There are significant differences in recommendations across guidelines for the treatment of choledocholithiasis, particularly regarding the role of ERCP as a treatment method for managing complex stone case. While similar lithotripsy methods are proposed for managing challenging cholelithiasis, the guidelines usually lack detailed instructions on method selection and specific indications. Contrary to the variation in treatment recommendations, there is consensus across different guidelines regarding diagnosing biliary calculi, with minimal discrepancies. However, when it comes to treatment, substantial variation arises, particularly regarding the timing of ERCP. This lack of consensus is a major contradiction, compounded by the poor quality of evidence supporting several of these recommendations.

Conclusions

In summary, we have developed a novel, and simple clinical classification system based on CBD diameter, stone size, and stone number. This classification system aims to guide surgeons in selecting the optimal minimally invasive treatment approach for individual patients, thereby reducing residual stones, minimizing relapse, and improving therapeutic efficacy. This study is limited by its single-center design, and it temporarily lacks external validation, which may limit the generalizability of this system across different medical settings and populations. Furthermore, regional variations in healthcare practices could also impact its applicability. Additionally, as a retrospective study, case selection was based on specific criteria during data collection. This approach can lead to the exclusion of ineligible cases or those with missing clinical information, exacerbating selection bias. Furthermore, incomplete clinical records pose challenges in ensuring the reliability and quality of the data. To overcome these challenges, we devised a clear and clinically consistent inclusion and exclusion criteria based on the research objectives. We employed a random sampling method to define the scope and duration of the cases analyzed, minimizing selection bias. Additionally, we secured a sufficient sample size to enhance the statistical power of the study. Baseline participant characteristics, such as age, gender, and underlying medical conditions were recorded to enable adjustments for potential selection biases in later analyses. Moreover, appropriate matching techniques were applied to further mitigate selection bias. Furthermore, this retrospective study relies on existing medical records and data, without the ability to pre-control variables. It may hinder the ability to establish causality and increase the likelihood of lower data quality, rendering the findings more susceptible to chance and bias. Ultimately, larger prospective studies with extensive sample sizes are needed to validate the applicability of this clinical classification system.

Abbreviations

LC, laparoscopic cholecystectomy; IOC, intraoperative cholangiography; CBD, common bile duct; GB, gallbladder; LCBDE, laparoscopic common bile duct exploration; ERCP, endoscopic retrograde cholangiopancreatography; Pre-ERCP, preoperative endoscopic retrograde cholangiopancreatography; EPBD, endoscopic papillary balloon dilatation; LCTD, laparoscopic choledocholithotomy and T-tube drainage; LCCBDE, laparoscopic choledochotomy for common bile duct exploration; ALT, alanine aminotransferase; AST, aspartate aminotransferase; TBIL, total bilirubin; ALP, alkaline phosphatase; γ-GT, γ-glutamy transpeptidase.

Availability of Data and Materials

The data and materials are contained in this article. If readers would like more data on the article, please contact the authors.

Author Contributions

Conceived and designed the study: QYL and YSX. Performed the study: QYL, YWL, YSX, PPL, JWL, DKS, and LHX. Wrote the paper: QYL, YWL and YSX. All authors have been involved in revising it critically for important intellectual content. All authors gave final approval of the version to be published. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study design adhered to the Declaration of Helsinki and relevant Chinese regulations. Furthermore, this study was approved by the Ethical Committee of Zhongnan Hospital of Wuhan University (Scientific Ethics Quick Review Number: 2023274K), and informed consent has been obtained from the patients.

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Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.62713/aic.3771.

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