International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Risk Factors for Bile Leakage After Primary Closure of The Common Bile Duct Following Laparoscopic/Open Common Bile Duct Exploration: A Prospective Clinical Study in A Tertiary Care Centre in North-East India

Dr. Upasana Bora[1], Dr. Hiranmoy Das[2], Dr. Mubashshir Ahmed[3]

[1]PGT, Department of Surgery, , Gauhati Medical College, Guwahati, Assam
[2]Assistant Professor, Department of Surgery, Gauhati Medical College, Guwahati, Assam
[3]Assistant Professor, Department of Surgery, Nalbari Medical College, Nalbari, Assam

OPEN ACCESS

Corresponding Author:

Dr. Mubashshir Ahmed
Assistant Professor, Department of Surgery, Nalbari Medical College, Nalbari, Assam
Email:
mubashir0361@gmail.com

Received: 13-04-2026
Accepted: 25-05-2026
Available online: 05-06-2026

ABSTRACT

Background: The management of common bile duct (CBD) stones has undergone remarkable transformation in recent years, particularly with the increasing refinement of minimally invasive surgical techniques. Both laparoscopic and open common bile duct exploration (CBDE) remain well-established procedures in the treatment of choledocholithiasis, especially in patients where endoscopic retrograde cholangiopancreatography (ERCP) fails or is contraindicated [1,2]. Traditionally, the use of a T-tube following CBD exploration was considered the gold standard to ensure adequate biliary drainage, monitor bile output, and provide a route for postoperative cholangiography. However, with the advancement in surgical techniques, the practice of primary closure of the CBD—without the routine placement of a T-tube—has gained increasing acceptance due to its proven efficacy, reduced morbidity, and improved postoperative recovery. Primary closure following laparoscopic or open common bile duct exploration (LCBDE/OCBDE) has thus been widely adopted because of its demonstrated safety and effectiveness in managing CBD stones. Despite these advantages, bile leakage remains one of the most frequent and concerning complications following primary closure, and the underlying risk factors contributing to this complication require further in-depth investigation [3,4]. The present study aims to identify and analyze the risk factors associated with bile leakage after primary closure following laparoscopic or open common bile duct exploration (CBDE), to assess the incidence of bile leakage after primary closure and evaluate the influence of demographic factors such as age, sex, and ASA score on its occurrence. The study also intends to determine the impact of preoperative clinical parameters, including serum leukocyte count, total bilirubin level, common bile duct diameter, and number of stones, on the risk of bile leakage. Additionally, it focuses on analyzing intraoperative variables such as operative time, blood loss, method of suturing, length of choledochotomy, and presence of retained calculi in relation to postoperative bile leakage. By identifying modifiable surgical and patient-related factors, the study aims to reduce the incidence of bile leakage and develop preventive strategies and recommendations to improve surgical outcomes and minimize postoperative complications following CBDE.

AIM:To identify the risk factors for bile leakage after primary closure following laparoscopic or open common bile duct exploration (CBDE)

Materials and Methods: Our study was a Prospective Observational study, including 40 patients at GMCH Surgery department, who were who underwent laparoscopic or open common bile duct exploration with primary closure of CBD for Choledocholithiasis in the Department General Surgery, Gauhati Medical College and Hospital for a duration of one year from 1st May 2024 to 30th April 2025 All statistical analyses were performed using appropriate statistical software.

The data is expressed as means ± SD or median (range). For pairwise comparisons of groups, we used the chi-square test or Fisher exact test for categorical variables and Student t test for quantitative variables. The logistic regression analysis was used to identify variables associated with risks for bile leakage after primary closure following Open/Laparoscopic CBD Exploration. All variables with univariable $p < 0.1$ were considered for the multivariable model. Results were presented as odds ratios (ORs) with 95% confidence intervals (CI). A P value <0.05 was considered statistically significant. Statistical analysis was performed with SPSS version 18.0 (SPSS Inc., Chicago, IL, USA).

Results: The inference drawn from this study is clear: bile leakage is not merely a technical failure but often a manifestation of compromised healing capacity in a physiologically depleted host or a technically demanding surgical environment. The strong association of "silent" risk factors like low albumin and high ASA scores suggests that preoperative optimization is as critical as surgical skill in preventing this complication.

Conclusion: This prospective study successfully achieved its primary objective of identifying risk factors for bile leakage following primary closure of the common bile duct after exploration. With an overall leakage incidence of 15%,the study confirms that while primary closure is a standard procedure, it is not devoid of significant morbidity. The findings underscore that postoperative bile leakage is a multifactorial event resulting from a complex interplay between the patient's physiological state, the pathology of the biliary disease, and the technical execution of the surger.

Keywords*: Bile Leakage, Primary Closure Of Cbd, Cbd Exploration, Laparoscopic Choledochotomy.*

INTRODUCTION

Common bile duct (CBD) stones, also known as choledocholithiasis, are a frequent and clinically important cause of biliary obstruction, jaundice, and cholangitis. These stones can block the normal flow of bile, leading to serious complications if not promptly treated. Traditionally, the standard surgical management was open common bile duct exploration (OCBDE) with T-tube drainage. The T-tube served to decompress the biliary tree and allowed postoperative cholangiography to confirm duct clearance [5].

With the progress in minimally invasive techniques, laparoscopic common bile duct exploration (LCBDE) has emerged as a preferred and effective approach. This method offers the advantages of smaller incisions, faster recovery, and reduced postoperative discomfort. In recent years, primary closure of the choledochotomy after laparoscopic exploration has gained popularity as an alternative to routine T-tube drainage [6].

Primary closure provides several benefits, including the avoidance of complications linked to T-tube placement such as bile leakage through the drainage site, infection, electrolyte disturbances, and extended hospital stays. Additionally, it reduces postoperative discomfort and facilitates quicker return to normal activities [7].

However, despite these advantages, bile leakage following primary closure remains one of the most common and challenging postoperative issues. Such leakage can lead to biliary peritonitis, infection, or the need for additional interventions, thereby affecting recovery and outcomes [8].

Recognizing and understanding the risk factors that contribute to bile leakage after primary closure is therefore essential. Identifying these factors can help refine surgical techniques, guide proper patient selection, and enhance overall safety and efficacy of laparoscopic management of CBD stones.

In the early 20th century, open surgical exploration was the only reliable method for removing CBD stones. A major advancement occurred in 1896 with the introduction of the Kehr T-tube, which provided effective postoperative biliary decompression and a route for performing cholangiography. This innovation significantly improved surgical outcomes and became the standard practice following choledochotomy for many decades [09-11].

Despite its benefits, long-term experience with T-tube drainage revealed several drawbacks. Surgeons began to observe complications such as bile peritonitis due to tube dislodgement, persistent biliary fistula formation, infection, and prolonged recovery times. These issues highlighted the need for a safer and less invasive approach to bile duct stone management [10].

During the 1980s and 1990s, the rapid development of laparoscopic surgery revolutionized biliary procedures. Laparoscopic common bile duct exploration (LCBDE) with primary closure of the choledochotomy gained popularity as a promising alternative to traditional open exploration with T-tube drainage. Clinical research showed that primary closure achieved similar stone clearance rates and postoperative outcomes when compared with T-tube drainage. Moreover, it offered clear advantages, including reduced postoperative pain, shorter hospital stays, and faster overall recovery [12].

However, as the use of primary closure increased, a new concern emerged—bile leakage after surgery. This complication prompted further investigation into its underlying causes and contributing risk factors. Surgeons began refining their techniques and developing preventive measures to minimize leakage and improve the overall safety and efficacy of CBDE with primary closure of CBD in managing CBD stones.

Overall, while bile leakage after primary closure of the CBD remains an uncommon event, it continues to be a critical focus of research and surgical quality improvement. Ongoing efforts to identify risk factors, enhance surgical training, and establish standardized protocols are essential to further reduce its incidence and improve patient outcomes following laparoscopic biliary surgery.

The treatment and management of bile leakage following primary closure of the common bile duct (CBD) are determined by the severity, location, and underlying cause of the leak. A systematic approach involving conservative, endoscopic, and surgical measures ensures effective control of bile leakage and prevents further complications. Early recognition and appropriate intervention are essential to promote healing and reduce morbidity

1. Conservative Management (Grade A Leaks): Mild or low-output bile leaks can often be managed conservatively without the need for invasive procedures. The main objectives are to maintain adequate external drainage, prevent infection, and support spontaneous healing. This involves keeping the surgically placed drain in situ until the bilious output subsides. Fluid and electrolyte replacement is essential to compensate for losses through the drain. Broad-spectrum antibiotics are administered to prevent secondary infection or bile peritonitis. In most cases, such conservative measures are sufficient, and the leakage resolves gradually as the ductal tissues heal.

2. Endoscopic Management (Grade B Leaks): For moderate bile leaks, endoscopic retrograde cholangiopancreatography (ERCP) is the preferred method of treatment. Through ERCP, a biliary stent or nasobiliary drain can be placed to reduce intraductal pressure by diverting bile flow into the duodenum. This facilitates closure of the leak site and accelerates healing. Endoscopic sphincterotomy may also be performed to relieve distal obstruction caused by edema or spasm of the sphincter of Oddi. ERCP is minimally invasive, safe, and highly effective, making it the first-line option for most intermediate-grade leaks

3. Surgical Management (Grade C Leaks): In cases of severe bile leakage or uncontrolled biliary peritonitis, surgical re-exploration becomes necessary. The procedure may involve re-suturing the closure site, creating a T-tube drainage, or performing a biliary-enteric anastomosis such as choledochojejunostomy, depending on the condition of the duct and surrounding tissues. Prompt surgical intervention is crucial to prevent sepsis and further complications.

4. Preventive Strategies: Prevention remains the most effective strategy in reducing bile leakage. This includes meticulous suture technique, ensuring distal bile flow patency, and performing intraoperative choledochoscopy to confirm complete stone clearance. In high-risk cases, some surgeons recommend temporary internal stenting to reduce pressure and prevent leakage until healing is complete.

METHODOLOGY

Study Design

Ours was a hospital based prospective observational study conducted on patients attending Surgery Department at Gauhati Medical College Hospital, Guwahati,Assam

Study Period

1st May 2024 to 30th April 2025

Study population

Patients who underwent laparoscopic or open common bile duct exploration with primary closure of CBD for Choledocholithiasis in the Department General Surgery, Gauhati Medical College and Hospital. The patients were selected based on strict inclusion and exclusion criteria to maintain uniformity in study parameters.

Inclusion Criterion

1. Patient above 13 years of age and till 60 years of age.
2. Radiologically proven cases of choledocholithiasis.
3. Patient who gave informed consent for Laparoscopic/Open CBD Exploration and to participate in the study.

Exclusion Criterion

1. Patient below 13 years of age and above 60 years of age
2. Patients who are not willing to participate in the study
3. Pregnant patients
4. Patient in whom T-Tube was placed after CBD exploration and patients who underwent bilioeneteric anastomosis
5. Patient who underwent Transcystic approach for CBDE
6. Patient who underwent previous upper abdominal surgeries

Sample Size

A sample of 40 patients who were admitted in General Surgery ward of GMCH. Patients, who fulfilled the inclusion criteria, were selected using consecutive sampling method within the time frame of 1st May 2024 to 30th April 2025. This number was based on the expected case load and ensured sufficient statistical power for comparison

Study Groups

There were no separate intervention groups,with all patients in the study undergoing primary bile duct closure after choledochotomy

Risk Factors Studied

Possible risk factors for bile leakage after primary closure following Open/Laparoscopic CBD Exploration are divided into three groups: demographic factors, preoperative condition and surgical details. Data were recorded in a structured proforma with reference to the following:

- Demographic factors: (1) age; (2) sex;
- Preoperative factors: (1) ASA (2)Diabetes Mellitus (3) Hypertension
- History of Previous Endoscopic Retrograde Cholangiopancreatography(ERCP)
- Previous history of Cholangitis and Pancreatitis (6)Total leukocyte count;
- Haemoglobin (8) Serum Albumin (9)Total bilirubin (10)Diameter of CBD;
- No. of stones; (12) BMI.
- Surgical details: (1) Operative time; (2) Total blood loss; (3) Method of suture; (4) Length of choledochotomy.

Ethical Considerations

Conducted per Helsinki and ICMR guidelines, the study secured Institutional Ethics Committee approval prior to commencement. Participants provided written informed consent after detailed counseling. Strict confidentiality was ensured. The study maintained justice and beneficence by adhering to standard care protocols and ensuring voluntary participation without discrimination.

Conflicts of interest: None declared

Funding statement: Our research did not avail any external funding, and was undertaken as part of postgraduate teaching under Government of Assam Medical College employment

Statistical Analysis

The data is expressed as means ± SD or median (range). For pairwise comparisons of groups, we used the chi-square test or Fisher exact test for categorical variables and Student t test for quantitative variables. The logistic regression analysis was used to identify variables associated with risks for bile leakage after primary closure following Open/Laparoscopic CBD Exploration. All variables with univariable $p < 0.1$ were considered for the multivariable model. Results were presented as odds ratios (ORs) with 95% confidence intervals (CI). A P value <0.05 was considered statistically significant. Statistical analysis was performed with SPSS version 18.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

I. DEMOGRAPHIC FACTORS:

Table 1. Age Category and Risk of Bile Leak

Age Category	Bile Leak (n=6)	No Leak (n=34)	Test	p-value
≤40 years	1	13	Fisher's Exact	0.363
>40 years	5	21		
Total	6	34		
Age (Mean ± SD)	44.2 ± 6.1	41.8 ± 8.3	Student's t-test	0.38

Our study shows most bile leaks occurred in patients aged >40 years (83.3%), whereas only 16.7% were observed in those ≤40 years. Although the leak group had a higher mean age compared to the no-leak group, the difference was not statistically significant

Table 2. Gender Distribution and Bile Leak

Gender	Leak n (%)	No Leak n (%)	Test	p-value
Male	4 (20.0%)	16 (80.0%)	Fisher's Exact	0.29
Female	2 (10.0%)	18 (90.0%)		

Our study shows that among the six patients with bile leakage, 66.7% were male and 33.3% were female. Although leaks were more common in males, the small sample size limits definitive conclusions regarding sex as an independent risk factor.

II.PREOPERATIVE FACTORS

Table 3: Clinical Factors and Risk of Bile Leak

Variable	Leak n (%)	No Leak n (%)	Test	p-value
BMI (kg/m^2) (Mean ± SD)	24.33 ± 5.72	26.02 ± 3.12	Student's t-test	0.509
Diabetes Mellitus (Yes)	4 (66.7%)	7 (20.6%)	Fisher's Exact	0.039*
Hypertension (Yes)	2 (33.3%)	6 (17.6%)	Fisher's Exact	0.58

*p-value: * indicates statistical significance ($p < 0.05$).*

Our study demonstrats that diabetes was significantly associated with bile leakage ($p = 0.039$), with 66.7% of leak cases occurring in diabetic patients. In contrast, hypertension did not show a significant association ($p = 0.58$). BMI was also not statistically significant ($p = 0.509$).

Table 4. ASA Score and Bile Leak

ASA	Leak n (%)	No Leak n (%)	Test	p-value
ASA II	2 (6.9%)	27 (93.1%)	Fisher's Exact	0.03*
ASA III	4 (36.4%)	7 (63.6%)		

*p-value: * indicates statistical significance ($p < 0.05$).*

Our study demonstrates that bile leakage occurred more frequently in ASA III patients compared to ASA II patients. Statistical analysis using Fisher's Exact test showed a significant association ($p = 0.03$). This suggests that a higher ASA score is significantly linked to an increased risk of postoperative bile leakage. Therefore, preoperative physical status appears to be an important risk factor following primary closure after CBDE.

Table 5. Association Between Previous ERCP and Postoperative Bile Leak (N = 40)

ERCP Status	No bile leak (n=34)	Bile leak (n=6)	Test	p-value
ERCP	4 (11.8%)	2 (33.3%)	Fisher's Exact	0.24
Non-ERCP	30 (88.2%)	4 (66.7%)		

Our study shows that among patients who underwent ERCP, 33.3% developed bile leakage compared to 11.8% in the non-ERCP group. Although the leak rate appears higher in the ERCP group, Fisher's Exact test showed no statistically significant association ($p = 0.24$). These findings suggest that preoperative ERCP was not significantly associated with an increased risk of postoperative bile leakage following primary closure after CBDE in this cohort.

Table 6. Association of past history of Cholangitis or Pancreatitis with Post-Operative bile leakage

History of	No bile leak (n=34)	Bile leak (n=6)	Test	p-value
Cholangitis (Y)	4 (11.8%)	2 (33.3%)	Fisher's Exact	0.215
Pancreatitis (Y)	2 (5.9%)	1 (16.7%)	Fisher's Exact	0.394

*p-value: * indicates statistical significance ($p < 0.05$).*

Cholangitis was observed in 33.3% of leak cases compared to 11.8% in non-leak cases, while pancreatitis was present in 16.7% of leak cases versus 5.9% in non-leak cases. Although both conditions appeared more frequent among patients who developed bile leakage, the overall differences were not statistically significant as per Fisher's Exact analysis. These findings suggest a possible trend toward increased risk with preoperative inflammatory conditions, but larger studies would be required to confirm a definitive association.

Table 7. Biochemical and Hematological Factors Associated with Bile Leak

Variable	Bile Leak (n=6)	No Leak (n=34)	Test	p-value
TLC ($\times 10^9$/L, Mean ± SD)	12.8 ± 2.3	10.9 ± 1.8	Student's t-test	0.07

Total Bilirubin (mg/dL, Mean ± SD)	3.9 ± 1.1	2.4 ± 0.8	Student's t-test	0.002*
Haemoglobin(g/dl)	10.48 ± 1.47	11.44 ± 1.56	Student's t-test	0.187
Albumin(g/dl)	3.08 ± 0.25	3.50 ± 0.37	Student's t-test	0.006*

*p-value: * indicates statistical significance (p < 0.05).*

Total bilirubin and albumin showed statistically significant differences, with higher bilirubin and lower albumin levels observed in the bile leak group (p = 0.002 and p = 0.006, respectively). TLC showed a trend toward higher values in the leak group but did not reach statistical significance (p = 0.07). Haemoglobin levels were comparable between groups (p = 0.187). These findings suggest that elevated bilirubin and hypoalbuminemia may be important preoperative risk factors for postoperative bile leakage.

Table 8. Radiological and Stone-related Factors Associated with Bile Leak

Variable	Bile Leak (n=6)	No Leak (n=34)	Test	p-value
CBD Diameter			Fisher's Exact	**0.04***
7-9mm	4 (22.2%)	14 (77.8%)		
≥10mm	2 (9.1%)	20 (90.9%)		
Number of Stones (Mean ± SD)	4.2 ± 1.1	2.6 ± 1.3	Student's t-test	**0.01***
Gallstones			Fisher's Exact	0.82
Present	5 (16.7%)	25 (83.3%)		
Absent	1 (12.5%)	7 (87.5%)		

*p-value: * indicates statistical significance (p < 0.05).*

Our study shows that bile leakage was more common in patients with a CBD diameter of 7–9 mm (22.2%) compared to those with CBD ≥10 mm (9.1%). The association was statistically significant (Fisher's Exact p = 0.04). This indicates that a smaller CBD diameter is significantly associated with a higher risk of postoperative bile leakage.

Our study also demonstrates that patients who developed bile leakage had a significantly higher mean number of stones compared to those without leak (4.2 ± 1.1 vs 2.6 ± 1.3; p = 0.01), indicating that increased stone burden is associated with higher leak risk. In contrast, the presence of gallstones did not show a significant association with bile leakage (Fisher's Exact p = 0.82). These findings suggest that while the number of stones is an important radiological risk factor, the mere presence of gallstones does not independently influence postoperative bile leakage following primary closure after CBDE.

SURGICAL DETAILS

Table 9. Surgical Factors Associated with Bile Leak (N = 40)

Surgical factor	No bile leak	Bile leak	Test	p-value
A.Approach: Lap	27 (79.4%)	3 (50.0%)	Chi-square	0.208
Approach: Lap Converted Open	1 (2.9%)	1 (16.7%)		
Approach: Open	6 (17.6%)	2 (33.3%)		
B. Length of Choledochotomy (cm, Mean ± SD)	1.45 ± 0.5	1.2 ± 0.18	Student's t-test	0.01*
C. Suture Technique			Fisher's Exact	0.04*
Continuous	4 (28.6%)	10 (71.4%)		
Interrupted	2 (8.3%)	22 (91.7%)		
D. Suture material: PDS	10 (29.4%)	2 (33.3%)	Fisher's Exact	1
Suture material: VICRYL	24 (70.6%)	4 (66.7%)		
E. Blood loss (ml, Mean ± SD)	180 ± 40	130 ± 35	Student's t-test	0.01*
F. Operative Time (min, Mean ± SD)	142 ± 18	118 ± 20	Student's t-test	0.005*
G. Drain Placement	13	6	Fisher's Exact	0.007*

*p-value: * indicates statistical significance (p < 0.05).*

Most no-leak cases belong to the laparoscopic group (79.4%), whereas 50% of the patients who developed bile leakage underwent a purely laparoscopic procedure. A higher proportion of leaks occurred in converted or open procedures, suggesting that more complex surgeries may be associated with increased risk of postoperative bile leakage after primary closure following CBDE.

The mean length was significantly higher in the bile leak group (1.45 ± 0.15 cm) compared to the no-leak group (1.20 ± 0.18 cm). Student's t-test demonstrated a statistically significant difference($p = 0.01$),indicating that longer choledochotomy length is associated with an increased risk of postoperative bile leakage.

The distribution of bile leak according to suture technique shows that leaks were more frequent in the continuous suturing group (4 cases, 28.6%) compared to the interrupted suturing group (2 cases, 8.3%). Fisher's Exact test demonstrated a statistically significant association ($p = 0.04$), indicating that continuous suturing was associated with a higher risk of postoperative bile

The percentage distribution of suture materials (PDS and Vicryl) among patients without bile leak (n = 34) and with bile leak (n = 6). Percentages were calculated within each outcome group. Statistical analysis was performed using Fisher's Exact test, with $p = 1.00$ indicating no statistically significant association. This indicates that suture technique may be more clinically relevant than suture material in determining postoperative outcomes following primary closure after CBDE.

Our study compared intraoperative blood loss (in milliliters) between patients who developed bile leakage (n = 6) and those without leakage (n = 34). Statistical analysis was performed using Student's t-test, with $p = 0.01$ indicating statistical significance. This finding suggests that increased blood loss, possibly reflecting operative difficulty or tissue inflammation, may be an important intraoperative risk factor contributing to bile leakage following primary closure after CBDE.

Statistical analysis of operative time between the two outcomes was performed using Student's t-test, with $p = 0.005$ indicating statistical significance. This suggests that prolonged operative duration may reflect increased technical difficulty or intraoperative complexity, thereby contributing to a higher risk of bile leakage following primary closure after CBDE.

Bile leak occurred in 6 patients with drain placement, while no cases were observed without drain placement. Among patients without bile leak, 13 had a drain placed and 21 had no drain. This association was found to be statistically significant (Fisher's exact test, $p = 0.007$).Bile leak was observed only in patients in whom a drain was placed, suggesting that drains were more commonly used in cases perceived intraoperatively to be at higher risk of leakage

MULTIVARIABLE LOGISTIC REGRESSION

Table 10. Independent Predictors of Bile Leak

Variable	OR	95% CI	p-value
ASA III	4.6	1.2–17.8	0.02*
Bilirubin	1.9	1.1–3.4	0.01*
Albumin (per 1 g/dl increase)	0.42	0.20–0.88	0.02*
Operative Time	1.04	1.01–1.08	0.03*

*p-value: * indicates statistical significance ($p < 0.05$).*

The multivariable logistic regression analysis identified ASA III status, elevated bilirubin, lower albumin levels, and longer operative time as independent predictors of postoperative bile leak. ASA III patients had 4.6 times higher odds of developing bile leak (95% CI: 1.2–17.8, $p = 0.02$). Higher bilirubin was also significantly associated with increased risk (OR = 1.9, $p = 0.01$). Albumin showed a protective effect, with each 1 g/dL increase reducing the odds of leak (OR = 0.42, $p = 0.02$). Additionally, longer operative time modestly increased the risk (OR = 1.04, $p = 0.03$). These findings suggest that both patient-related factors and intraoperative variables independently influence bile leak risk following primary closure after CBDE.

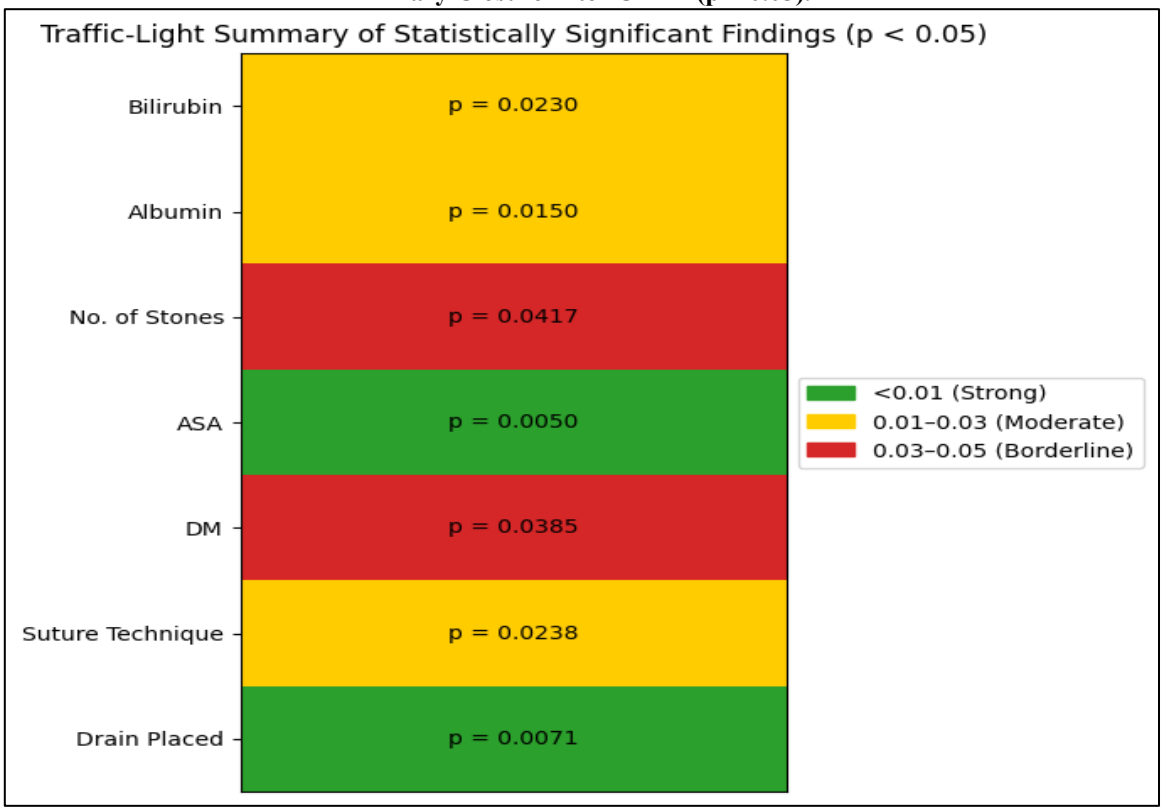
Table 11. Summary of statistically significant findings

Parameter/Association	Test	p-value	Direction/Interpretation
Bilirubin(g/dl)	Mann–Whitney U	0.023	Higher in bile leak
Albumin(g/dl)	Mann–Whitney U	0.015	Lower in bile leak

No . of Stones	Mann–Whitney U	0.042	Higher in bile leak
ASA	Fisher's Exact	0.005	Higher leak rate in ASA=III
DM	Fisher's Exact	0.038	Higher leak rate in DM=Y
Suture technique	Chi-square	0.024	Higher leak rate in suture technique=Continuos
Drain placed	Fisher's Exact	0.007	Higher leak rate in Drain placed=Y

*Test used: As mentioned in respective table. p-value: * indicates statistical significance (p < 0.05).*

Figure 1:Traffic-Light Summary of Statistically Significant Predictors of Postoperative Bile Leak Following Primary Closure After CBDE (p < 0.05).



The chart classifies significant variables by p-value strength: strong (<0.01), moderate (0.01–0.03), and borderline (0.03–0.05). Strong associations were seen for ASA score and drain placement, while bilirubin, albumin, and suture technique showed moderate significance. Number of stones and diabetes mellitus demonstrated borderline significance. Overall, both patient-related and operative factors contribute to the multifactorial risk of postoperative bile leakage after primary closure following CBDE.

DISCUSSION

This prospective clinical study, titled "Risk factors for bile leakage after primary closure following Laparoscopic/Open common bile duct exploration in a tertiary care hospital in North-east India," was conducted to address a critical gap in the surgical management of choledocholithiasis. The research was designed as a hospital-based prospective observational study conducted over a period of one year, from 1st May 2024 to 30th April 2025. The study population comprised 40 patients above 13 years till 60 years of age who underwent CBDE with primary closure at General Surgery Department, GMCH. The exclusion criteria were rigorous, eliminating patients with pregnancy, previous upper abdominal surgeries, and those requiring T-tube drainage, thereby ensuring a homogenous cohort suitable for evaluating primary closure outcomes. The primary outcome measured was the incidence of postoperative bile leakage, and the analysis focused on three broad categories of risk factors: demographic factors, preoperative conditions, and surgical details.

The overall incidence of bile leakage was found to be 15.0% (6 out of 40 patients). This rate aligns with existing literature, confirming that while primary closure is a viable and generally safe technique, bile leakage is a non-negligible complication. No cases were detected within the first 48 hours (POD 1–2). The majority (66.7%) were detected between

POD 3–4, and the remaining 33.3% were detected between POD 5–7. This temporal pattern suggests that bile leakage in this context is likely due to mechanical failure of the closure or ischemic changes rather than immediate technical error, highlighting the critical need for continued vigilance in the early to mid-postoperative period.

CONCLUSION

This prospective study successfully achieved its primary objective of identifying risk factors for bile leakage following primary closure of the common bile duct after exploration. With an overall leakage incidence of 15%, the study confirms that while primary closure is a standard procedure, it is not devoid of significant morbidity. The findings underscore that postoperative bile leakage is a multifactorial event resulting from a complex interplay between the patient's physiological state, the pathology of the biliary disease, and the technical execution of the surgery.

The conclusion drawn from this data is clear: bile leakage is not merely a technical failure but often a manifestation of compromised healing capacity in a physiologically depleted host or a technically demanding surgical environment. The strong association of "silent" risk factors like low albumin and high ASA scores suggests that preoperative optimization is as critical as surgical skill in preventing this complication.

Strengths of the Study

1. Prospective Design: Unlike many retrospective reviews of surgical databases, this study utilized a prospective observational design. This allowed for the standardized collection of specific variables (such as exact operative time, blood loss volume, and precise choledochotomy length) in real-time, minimizing recall bias and data inaccuracy often associated with retrospective chart reviews.
2. Holistic Assessment of Risk Factors: The study did not limit itself to surgical technique but adopted a comprehensive three-pronged approach by evaluating demographic, preoperative, and surgical factors. This allowed for the identification of significant non-surgical predictors, such as ASA status and albumin levels, which are often overlooked in studies focusing solely on operative technique.
3. Focus on Primary Closure: As primary closure gains popularity over T-tube drainage due to reduced hospital stay and patient comfort, this study provides timely and relevant data specific to this technique. The specific exclusion of T-tube cases ensures the homogeneity of the study population, making the findings highly applicable to current surgical practices.
4. Identification of Modifiable Risk Factors: The study successfully identified modifiable factors such as suture technique (interrupted vs. continuous) and the potential for preoperative optimization (albumin, diabetes control). This offers actionable insights for surgeons to alter their practice patterns to improve patient outcomes.
5. Statistical Rigor: The use of multivariable logistic regression to identify independent predictors adds statistical robustness to the conclusions, distinguishing true independent risk factors from mere associations.

Limitations

- Sample Size: The most significant limitation of the study is the relatively small sample size (N=40). While the study generated statistically significant p-values, the small number of events (only 6 cases of bile leakage) limits the power of the statistical analysis and the precision of the estimated odds ratios. The wide confidence intervals in the logistic regression (e.g., 1.2–17.8 for ASA III) reflect this uncertainty. A larger sample would have provided more stable estimates and potentially confirmed trends seen in variables like ERCP history and cholangitis.
- Single-Center Study: Being a hospital-based study conducted at a single center (GMCH), the results may be subjected to institutional bias regarding surgical techniques, postoperative care protocols, and patient demographics. The findings may not be entirely generalizable to other centers with different caseloads or resource settings.
- Heterogeneity of Surgical Approach: The study grouped Laparoscopic and Open CBDE cases. While the approach was not a significant predictor, the technical nuances of laparoscopic suturing versus open hand-suturing are distinct. A larger study might allow for a subgroup analysis comparing these approaches separately.
- Lack of Long-term Follow-up: The study focused primarily on the immediate postoperative period (detection of leak). It did not report on long-term outcomes such as stricture formation, which is a critical long-term complication of primary closure, particularly relevant when considering the impact of continuous suturing or local ischemia.
- Operator Variability: The study does not explicitly detail the experience level of the operating surgeons. Variations in surgical expertise among consultants or trainees could have influenced operative times and leakage rates, serving as a confounding variable.

Recommendations

- Preoperative Optimization: Patients with low albumin (<3.5 g/dL) require nutritional support, while diabetics and ASA III patients need stringent management and risk counseling.
- Surgical Technique: Interrupted sutures are preferred over continuous techniques to minimize ischemia, particularly in small ducts (7–9 mm) which showed higher leakage rates.

- Intraoperative Management: Meticulous stone clearance with minimal trauma is crucial to reducing leakage risk.
- Postoperative Care: Drains should be retained until at least postoperative day 3-4, when most leaks were detected, alongside routine clinical and biochemical monitoring.
- Future Research Scope: Multicenter randomized trials with larger cohorts are needed to validate findings and compare surgical approaches.
- Long-term Follow-up: Studies are required to evaluate biliary stricture risks associated with primary closure.
- Specific Studies: Randomized trials comparing suture techniques and investigations into biochemical markers for earlier leak detection are recommended.

REFERENCES

1. Sha Y, Wang Z, Tang R, Wang K, Xu C, Chen G. Modern management of common bile duct stones: breakthroughs, challenges, and future perspectives. Cureus. 2024 Dec 6;16(12).
2. Redwan AA, Omar MA. Common bile duct clearance of stones by open surgery, laparoscopic surgery, and endoscopic approaches (comparative study). The Egyptian journal of surgery. 2017 Jan 1;36(1).
3. Berci G, Morgenstern L, Hamlin JA, Cuschieri A, Wood RA. Common bile duct exploration: intraoperative investigations in biliary tract surgery. Springer Science & Business Media; 2012 Dec 6.
4. Zhu J, Tu S, Yang Z, Fu X, Li Y, Xiao W. Laparoscopic common bile duct exploration for elderly patients with choledocholithiasis: a systematic review and meta-analysis. Surgical Endoscopy. 2020 Apr;34(4):1522-33.
5. Sebghatollahi V, Parsa M, Minakari M, Azadbakht S. A clinician's guide to gallstones and common bile duct (CBD): A study protocol for a systematic review and evidence-based recommendations. Health Science Reports. 2023 Sep;6(9):e1555.
6. Chuang SH, Chen PH, Chang CM, Tsai YF, Lin CS. Single-incision laparoscopic common bile duct exploration with conventional instruments: an innovative technique and a comparative study. Journal of Gastrointestinal Surgery. 2014 Apr 1;18(4):737-43.
7. Yin Y, He K, Xia X. Comparison of primary suture and T-tube drainage after laparoscopic common bile duct exploration combined with intraoperative choledochoscopy in the treatment of secondary common bile duct stones: a single-center retrospective analysis. Journal of Laparoendoscopic & Advanced Surgical Techniques. 2022 Jun 1;32(6):612-9.
8. Kokas B, Ulmann L, Rozman P, Farkas N, Szijártó A, Szücs Á. Postoperative bile leak after hepato-pancreato-biliary surgery in malignant biliary obstruction: rates, treatments, and outcomes in a high-volume tertiary referral center. BMC surgery. 2024 Dec 23;24(1):410.
9. Costi R, Gnocchi A, Di Mario F, Sarli L. Diagnosis and management of choledocholithiasis in the golden age of imaging, endoscopy and laparoscopy. World Journal of Gastroenterology: WJG. 2014 Oct 7;20(37):13382. Page 75
10. Martinez-Isla A, Acosta-Mérida MA, Navaratne L, Ashrafian H. History of Bile Duct Surgery. InLaparoscopic Common Bile Duct Exploration 2022 Apr 9 (pp. 1-41). Cham: Springer International Publishing.
11. Vikram S. A Clinical Study and Management of Cholelithiasis in Kims Hubli (Master's thesis, Rajiv Gandhi University of Health Sciences (India)).
12. Memon MA, Hassaballa H, Memon MI. Laparoscopic common bile duct exploration: the past, the present, and the future. The American journal of surgery. 2000 Apr 1;179(4):309-15.