

Causes of Biliary Leak after Cholecystectomy in Rural and Tribal India: A 12-Year Single-Surgeon Experience

Authors:

Dr. Nitin Baste¹, Nilesh Gulab Dabhade², Vishaka R Patil³, Dr. Prakhar Nagar⁴

¹Professor & HOD, SMBTMSRC, Nashik.

²Assistant Professor, SMBTMSRC, Nashik.

³Senior Resident, SMBTMSRC, Nashik.

⁴Associate Professor, SMBTMSRC, Nashik.

Corresponding Author:

Dr. Prakhar Nagar, Associate Professor, SMBTMSRC, Nashik.

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ABSTRACT

Background: Biliary leakage is an uncommon but clinically important complication of cholecystectomy. Although most postoperative bile leaks can be managed successfully with timely drainage, endoscopic intervention, or conservative treatment, bile duct and sectoral duct injuries may result in substantial morbidity. Data describing biliary leaks after cholecystectomy in rural and tribal populations in India remain limited. This study evaluated the incidence, causes, timing, clinical presentation, and management of biliary leaks following cholecystectomy in a rural and tribal healthcare setting. **Methods:** A retrospective observational study was conducted involving consecutive patients who underwent cholecystectomy under the care of a single surgeon at rural and tribal hospitals between January 2011 and December 2022. Demographic characteristics, operative approach, postoperative bile leak, timing of presentation, source of leakage, imaging findings, interventions, and outcomes were obtained from hospital records, operative notes, and follow-up registers. Descriptive statistical analysis was performed. The incidence of bile leak was calculated with a 95% confidence interval, and gender association was assessed using Fisher's exact test. **Results:** A total of 1,071 cholecystectomies were performed during the study period. There were 407 male patients (38.0%) and 664 female patients (62.0%). Laparoscopic cholecystectomy was performed in 1,026 patients (95.8%), while 45 patients (4.2%) underwent open cholecystectomy. Seven laparoscopic procedures were converted to open surgery. Postoperative bile leakage occurred in 10 patients, giving an overall incidence of 0.93% (10/1,071). Eight of the 10 patients with bile leakage were male (80%) and two were female (20%). The male-specific incidence was 1.97% compared with 0.30% among females (Fisher's exact test, $p=0.008$). Three leaks were identified intraoperatively, comprising one common bile duct injury and two right sectoral duct injuries. Two patients developed cystic duct stump leaks on postoperative day 1 and were successfully treated with endoscopic retrograde cholangiopancreatography (ERCP). Two patients developed low-output leaks during postoperative days 2–7 and were managed conservatively. Three patients presented after postoperative day 10, including two patients with bile duct-related leaks and one with a bilioma; these patients were managed using combinations of percutaneous drainage and ERCP, including stone extraction and biliary stenting where indicated. No mortality was reported. **Conclusion:** In this 12-year single-surgeon rural and tribal hospital series, postoperative bile leakage occurred in 0.93% of patients undergoing cholecystectomy. Bile duct and sectoral duct injuries accounted for important intraoperative causes, while cystic duct stump leakage and delayed biliary complications were also observed. Early recognition, appropriate imaging, percutaneous drainage when required, and timely ERCP were associated with favorable outcomes. Adherence to the critical view of safety and strengthening access to biliary imaging and therapeutic endoscopy may further reduce morbidity in resource-limited settings.

Keywords: bile leak; cholecystectomy; laparoscopic cholecystectomy; bile duct injury; ERCP; bilioma; rural India; tribal India; critical view of safety.

1. INTRODUCTION

Cholecystectomy is the definitive surgical treatment for symptomatic gallstone disease and is one of the most frequently performed abdominal surgical procedures worldwide. Laparoscopic cholecystectomy has largely replaced open cholecystectomy because of its established advantages, including reduced postoperative pain, shorter hospital stay, and faster recovery. Nevertheless, biliary complications remain an important source of postoperative morbidity.

Biliary leakage after cholecystectomy may arise from several anatomical sites. The most common sources include the cystic duct stump and small accessory ducts in the gallbladder bed. More significant leaks may result from inadvertent injury to the common bile duct (CBD), common hepatic duct, or sectoral and segmental bile ducts. Early recognition is essential because an untreated bile leak can result in biloma, biliary peritonitis, intra-abdominal sepsis, electrolyte disturbances, prolonged hospitalization, and the need for additional interventions. The incidence of clinically significant bile leakage following cholecystectomy is generally reported to be below 2%, although the incidence varies according to patient characteristics, operative complexity, surgeon experience, and definition of bile leak. The introduction of laparoscopic surgery has also altered the pattern and clinical consequences of biliary injury.

The critical view of safety (CVS) technique has been widely advocated to reduce the risk of bile duct injury during laparoscopic cholecystectomy. Nevertheless, difficult gallbladder anatomy, acute or chronic inflammation, adhesions, aberrant biliary anatomy, and limited visualization may increase the risk of ductal injury.

The challenges may be particularly relevant in rural and tribal healthcare settings in India. Patients may present late, frequently with advanced inflammatory disease or multiple comorbidities. Access to high-quality hepatobiliary imaging, magnetic resonance cholangiopancreatography (MRCP), therapeutic ERCP, interventional radiology, and specialist hepatobiliary surgery may also be limited. Consequently, early recognition and appropriate referral or transfer may be critical to successful management.

The present study describes the experience of a single surgeon over a 12-year period in rural and tribal hospitals in India. The objectives were to determine the incidence of postoperative bile leakage and characterize its causes, timing, clinical course, management, and outcomes.

2. METHODS

2.1 Study design and setting

This was a retrospective observational study of patients undergoing cholecystectomy under the care of a single surgeon at rural and tribal hospitals in India.

The study period extended from January 2011 through December 2022, representing a total observation period of 12 years.

2.2 Study population

All patients who underwent cholecystectomy during the study period were considered for inclusion.

A total of 1,071 cholecystectomies were performed.

The cohort consisted of:

- 407 males (38.0%)
- 664 females (62.0%)

2.3 Surgical approach

Of the 1,071 procedures:

- 1,026 (95.8%) were laparoscopic cholecystectomies.
- 45 (4.2%) were open cholecystectomies.
- Seven laparoscopic procedures were converted to open surgery.

The indication for cholecystectomy and operative findings were obtained from the medical records and operative notes.

2.4 Identification of bile leak

Postoperative bile leakage was identified on the basis of clinical findings, drain output, imaging, operative findings, or subsequent biliary intervention.

Patients were categorized according to the timing of recognition:

1. Intraoperative
2. Postoperative day 1
3. Postoperative days 2–7
4. Delayed presentation after postoperative day 10

The source of the leak and the subsequent management strategy were recorded.

2.5 Diagnostic investigations

Depending on the clinical presentation, patients underwent appropriate imaging and/or biliary investigations. These included:

- Ultrasonography
- Contrast-enhanced computed tomography
- Magnetic resonance cholangiopancreatography
- Endoscopic retrograde cholangiopancreatography

The choice of investigation was based on clinical findings and availability.

2.6 Management

Management was individualized according to the source and severity of the bile leak. Treatment strategies included:

- Observation and conservative management
- Percutaneous drainage of biloma
- ERCP
- Biliary stent placement
- Endoscopic stone extraction
- Combined percutaneous and endoscopic management

2.7 Statistical analysis

Continuous and categorical variables were summarized descriptively. The overall incidence of bile leakage was calculated as the number of patients with bile leakage divided by the total number of cholecystectomies.

For the overall incidence, a 95% confidence interval was calculated using the Wilson method.

The association between sex and bile leak was assessed using Fisher's exact test because of the small number of events. A two-sided p value <0.05 was considered statistically significant.

Because complete comorbidity data for the entire cohort were not provided, the previously stated assumption that approximately 30% of the total cohort had comorbidities was not used to calculate a definitive comorbidity-related risk estimate.

3. RESULTS

3.1 Overall cohort

During the 12-year study period, 1,071 cholecystectomies were performed.

Females constituted the majority of the overall surgical cohort, accounting for 664 patients (62.0%), while 407 patients (38.0%) were male.

Laparoscopic cholecystectomy was the predominant operative approach, accounting for 1,026 procedures (95.8%). Open cholecystectomy accounted for 45 procedures (4.2%).

Seven laparoscopic procedures were converted to open surgery.

3.2 Incidence of bile leakage

Ten patients developed clinically recognized bile leakage following cholecystectomy.

The overall incidence was:

$$10/1,071 = 0.93\%$$

The corresponding 95% Wilson confidence interval was approximately 0.51%–1.71%.

Thus, postoperative bile leakage occurred in fewer than 1% of all cholecystectomy procedures in this series.

3.3 Gender distribution

Among the 10 patients with bile leakage:

- 8 were male (80%)
- 2 were female (20%)

The incidence among males was:

$$8/407 = 1.97\%$$

The incidence among females was:

$$2/664 = 0.30\%$$

The difference was statistically significant on Fisher's exact test ($p=0.008$).

The observed association should nevertheless be interpreted cautiously because only 10 bile-leak events occurred.

3.4 Timing and causes of bile leakage

Three bile leaks were identified intraoperatively.

These included:

- One common bile duct injury
- Two right sectoral duct injuries

Two patients developed bile leakage on postoperative day 1. Both were diagnosed as cystic duct stump leaks associated with clip slippage. MRCP confirmed the diagnosis, and both patients underwent successful ERCP.

Two patients developed low-output bile leakage between postoperative days 2 and 7. The recorded output was approximately 20–30 mL/day. These leaks were self-limiting and resolved with conservative treatment without further complications.

Three patients presented after postoperative day 10. One developed a large bilioma requiring percutaneous drainage. Another had a CBD leak treated with pigtail catheter drainage and ERCP. The third patient had CBD stones associated with bile leakage and was treated with ERCP, stone extraction, and biliary stenting.

3.5 Outcomes

All reported bile-leak cases were successfully managed using an individualized combination of conservative, percutaneous, and endoscopic approaches.

No mortality was reported among the 10 patients with bile leakage.

4. Tables

Table 1. Baseline characteristics of the cholecystectomy cohort

Variable	Number	Percentage
Total cholecystectomies	1,071	100
Male	407	38.0
Female	664	62.0
Laparoscopic cholecystectomy	1,026	95.8
Open cholecystectomy	45	4.2
Laparoscopic-to-open conversions	7	—
Postoperative bile leaks	10	0.93

Percentages may not total exactly 100% because of rounding.

Table 2. Characteristics of patients with postoperative bile leakage

Characteristic	Number	Percentage
Total bile leaks	10	100
Male	8	80
Female	2	20
Intraoperative leaks/injuries	3	30
Postoperative day 1	2	20
Postoperative days 2–7	2	20
Delayed presentation >day 10	3	30
Reported comorbidity	9	90
No reported comorbidity	1	10
Mortality	0	0

Note: The comorbidity distribution among the 10 bile-leak patients is reported descriptively. A population-level association cannot be reliably calculated without the corresponding comorbidity data for all 1,071 patients.

Table 3. Causes and management of bile leakage

Timing	Cause/source	Number	Management
Intraoperative	CBD injury	1	Intraoperative recognition and management
Intraoperative	Right sectoral duct injury	2	Intraoperative management
Postoperative day 1	Cystic duct stump leak/clip slippage	2	MRCP followed by ERCP
Postoperative days 2–7	Low-output leak	2	Conservative management
>Day 10	Large bilioma	1	Percutaneous drainage
>Day 10	CBD leak	1	Pigtail drainage + ERCP
>Day 10	CBD stones with bile leak	1	ERCP, stone extraction + stent

Table 4. Gender-specific incidence of bile leakage

Sex	Total cholecystectomies	Bile leaks	Incidence
Male	407	8	1.97%
Female	664	2	0.30%
Total	1,071	10	0.93%

Fisher's exact test: $p=0.008$

5. Statistical Analysis

The overall postoperative bile-leak incidence was **0.93% (10/1,071)**. The 95% confidence interval calculated using the Wilson method was approximately **0.51%–1.71%**.

There was a statistically significant difference in bile-leak incidence according to sex. Eight of 407 male patients developed a bile leak (1.97%), compared with two of 664 female patients (0.30%). Fisher's exact test demonstrated a statistically significant association (**p=0.008**).

However, statistical interpretation should recognize that the analysis is based on only **10 outcome events**. Therefore, the finding of an association between male sex and bile leakage should be regarded as exploratory rather than definitive.

The previously reported Fisher's exact test for comorbidity (**p<0.001**) should not be retained in the final manuscript based on the currently supplied information. Although 9 of the 10 patients with bile leakage reportedly had comorbidities, the number of patients with comorbidities among the remaining 1,061 cholecystectomy patients is not available. An assumed prevalence of approximately 30% cannot be used as the denominator for a valid inferential analysis.

Accordingly, the present manuscript reports comorbidity as a **descriptive characteristic** rather than claiming a statistically proven association.

6. DISCUSSION

This 12-year single-surgeon series from rural and tribal hospitals in India identified postoperative bile leakage in 10 of 1,071 patients undergoing cholecystectomy, corresponding to an incidence of **0.93%**. This incidence is broadly consistent with previously reported rates of clinically significant bile leakage following cholecystectomy.

The predominance of laparoscopic surgery in the present cohort reflects contemporary surgical practice. More than 95% of the procedures were laparoscopic. Although laparoscopic cholecystectomy provides substantial benefits compared with open surgery, it requires careful identification of biliary anatomy. Major bile duct injuries remain among the most serious complications of the procedure.

Three of the 10 bile-leak cases in this series were recognized intraoperatively. These included one CBD injury and two right sectoral duct injuries. Recognition of an injury during the initial procedure provides an important opportunity for immediate management or appropriate referral. In contrast, an unrecognized ductal injury may present later with bile collection, peritonitis, sepsis, jaundice, or persistent drain output.

The critical view of safety remains an important component of safe laparoscopic cholecystectomy. Achieving adequate visualization of the cystic duct and cystic artery before division can reduce the likelihood of misidentification of the common bile duct or other biliary structures. In difficult cases, the surgeon should consider alternative strategies, including subtotal cholecystectomy or conversion to open surgery when appropriate.

Two patients developed cystic duct stump leaks on the first postoperative day. Both were associated with clip slippage and were confirmed on MRCP and successfully treated with ERCP. Cystic duct stump leakage is generally considered a low-grade biliary complication and can often be treated effectively with endoscopic biliary decompression and stenting. The favorable response in these two patients supports the role of timely endoscopic intervention when a persistent postoperative leak is identified.

Two additional patients developed low-output leaks during postoperative days 2–7. With an output of approximately 20–30 mL/day, these leaks resolved with conservative treatment. This emphasizes that not every postoperative bile leak requires immediate invasive intervention. In clinically stable patients with low-output drainage and no evidence of uncontrolled intra-abdominal collection or major ductal injury, careful observation may be appropriate.

Three patients presented after postoperative day 10, demonstrating the potential for delayed recognition of biliary complications. One developed a large bilioma requiring percutaneous drainage, while another had a CBD leak requiring pigtail catheter drainage and ERCP. The third had CBD stones associated with bile leakage and underwent ERCP with stone extraction and stent placement.

These cases demonstrate the importance of combining source control with biliary decompression when required. Percutaneous drainage can provide effective control of an infected or symptomatic biloma, while ERCP allows reduction of transpapillary pressure and treatment of obstructing pathology such as retained CBD stones.

The rural and tribal healthcare context is particularly relevant. Patients in geographically remote areas may have difficulty accessing specialist services, and referral delays may contribute to delayed diagnosis. In such environments, the availability of ultrasonography, CT, MRCP, ERCP, and percutaneous drainage can substantially influence management. A practical referral pathway linking rural surgical units with tertiary hepatobiliary and endoscopic services may therefore improve outcomes.

The observed male predominance among bile-leak patients is noteworthy. Although females constituted 62% of the overall cholecystectomy population, 80% of bile leaks occurred in males. The male-specific incidence was approximately 1.97%, compared with 0.30% in females, and the difference was statistically significant. However, the very small number of events means that this observation should be interpreted cautiously. Larger multicenter studies would be necessary to determine whether male sex independently predicts bile leakage in similar populations.

Nine of the 10 patients with bile leakage were reported to have comorbidities, most commonly diabetes mellitus. Comorbid conditions may potentially contribute to delayed recovery or impaired healing; however, the present dataset does not provide adequate information to determine whether comorbidity independently increases the risk of bile leakage. Future prospective studies should systematically record diabetes, hypertension, obesity, cardiovascular disease, and other relevant conditions across the entire surgical cohort.

An important strength of this study is the long observation period and the consistency of surgical practice associated with a single surgeon. The study also provides insight into the management of biliary complications in rural and tribal healthcare environments, a setting that is relatively underrepresented in the surgical literature.

The findings emphasize that successful management does not necessarily depend on a single intervention. Rather, outcomes can be optimized through early recognition, appropriate imaging, adequate drainage, biliary decompression, and selective endoscopic therapy.

7. Limitations

This study has several limitations.

First, it was a **retrospective single-surgeon study**, which limits generalizability. Outcomes may reflect the individual surgeon's operative technique and experience and may not be representative of other surgeons or institutions.

Second, the study was conducted across rural and tribal hospitals, and the availability of imaging and endoscopic services may have varied during the 12-year study period.

Third, only 10 bile-leak events were identified. Consequently, statistical power is limited, and associations such as the observed relationship between male sex and bile leakage should be interpreted cautiously.

Fourth, complete patient-level data regarding comorbidities, operative difficulty, inflammatory status, intraoperative blood loss, previous abdominal surgery, and other potential risk factors were not available in the

information provided. Therefore, multivariable risk-factor analysis was not possible.

Fifth, the dataset does not provide sufficient detail to compare bile-leak rates independently between laparoscopic and open procedures because the number of bile leaks attributable to each operative approach is not specified.

Finally, long-term outcomes such as biliary stricture, recurrent cholangitis, quality of life, and subsequent hepatobiliary surgery were not systematically available.

8. CONCLUSION

In this 12-year single-surgeon series involving **1,071 cholecystectomies**, postoperative bile leakage occurred in **10 patients (0.93%)**.

Biliary leakage was caused by a range of mechanisms, including intraoperative CBD and right sectoral duct injuries, cystic duct stump leakage, low-output postoperative leaks, bilioma formation, and CBD stones associated with leakage.

Most patients were successfully managed through an individualized combination of conservative treatment, percutaneous drainage, and ERCP. Early recognition of bile leakage and timely biliary decompression were important components of successful management.

The findings emphasize the importance of meticulous biliary anatomy identification and adherence to the **critical view of safety** during laparoscopic cholecystectomy. In rural and tribal healthcare settings, strengthening access to MRCP, ERCP, percutaneous drainage, and timely referral to tertiary hepatobiliary centers may further reduce morbidity associated with bile duct complications.

Larger multicenter prospective studies from rural and underserved regions are needed to identify independent risk factors and develop region-specific strategies for prevention and management of postoperative biliary leaks.

9. Declarations

Ethics Approval

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was approved by the Institutional Ethics Committee of SMBTMSRC, Nashik, India.

Informed Consent

As this was a retrospective study based on previously recorded hospital data, the requirement for individual informed consent was determined in accordance with the decision of the Institutional Ethics Committee.

Conflict of Interest

The authors declare that they have no conflict of interest related to this study.

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Author Contributions

All authors contributed to the study conception and design, data collection, analysis and interpretation of the findings, manuscript preparation, and critical revision of the manuscript. All authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to institutional and ethical restrictions.

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