

Original Research Article

Predictors of primary biliary patency loss following biliary-enteric reconstruction for iatrogenic bile duct injury: a retrospective cohort study from a tertiary referral center in Mexico

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Received: 07 July 2026

Revised: 16 July 2026

Accepted: 27 July 2026

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ABSTRACT

Background: Iatrogenic bile duct injury is one of the most serious complications associated with cholecystectomy. Although its incidence is low, its clinical impact is substantial due to the associated morbidity and mortality, the need for complex reconstructive procedures, and the significant deterioration in patients' quality of life.

Methods: A retrospective cohort study was conducted. Patients who underwent biliary-enteric reconstruction for iatrogenic bile duct injury at a tertiary care center from 2018 to 2022. The primary outcome was loss of primary biliary patency during follow-up. Univariate analysis was performed to identify factors associated with this outcome, using statistical package for the social sciences (SPSS) 25.

Results: A total of 73 patients were included. Primary biliary patency was achieved in 49 patients (67.1%), whereas 24 patients (32.9%) developed loss of primary biliary patency. Postoperative bile leak occurred in 22 patients (30.1%). On univariate analysis, postoperative bile leak was significantly associated with loss of primary biliary patency (OR 14.33; 95% CI 4.30–47.78; $p < 0.001$). SG3 classification showed a trend toward association with loss of primary biliary patency, although statistical significance was not reached (OR 2.27; 95% CI 0.83–6.19; $p = 0.110$). According to the Cho classification, 52 patients (71.2%) achieved favorable outcomes (grades A–B).

Conclusions: Postoperative bile leak was significantly associated with loss of primary biliary patency following biliary-enteric reconstruction for iatrogenic bile duct injury. Early identification of this complication may allow closer surveillance strategies and timely detection of reconstructive failure.

Keywords: Bile duct injury, Biliary-enteric reconstruction, Hepaticojejunostomy, Bile leak, Biliary patency, Iatrogenic injury

INTRODUCTION

Iatrogenic bile duct injury is one of the most serious complications associated with cholecystectomy. Although its incidence is low, its clinical impact is substantial due to the associated morbidity and mortality, the need for complex reconstructive procedures, and the significant deterioration in patients' quality of life. The introduction

of laparoscopic cholecystectomy has altered the profile of these injuries, resulting in a higher frequency of proximal bile duct injuries and more complex anatomical patterns compared with traditional open surgery.¹

Biliary-enteric reconstruction with Roux-en-Y hepaticojejunostomy is considered the standard treatment for complex bile duct injuries. When performed in

specialized centers by experienced hepatopancreatobiliary surgeons, this procedure can achieve high long-term success rates. Nevertheless, a substantial proportion of patients develop late complications, including anastomotic stricture, recurrent episodes of cholangitis, the need for additional interventional procedures, and loss of biliary patency.^{2,3}

The assessment of outcomes following biliary reconstruction has historically been heterogeneous. To standardize outcome measurement and reporting, Cho and colleagues proposed specific criteria for evaluating biliary patency and clinical outcomes after surgical repair, thereby allowing more uniform comparisons among institutions and patient cohorts.^{4,9}

Several factors have been associated with unfavorable outcomes following biliary-enteric reconstruction. These include the anatomical complexity of the injury, the extent of biliary confluence involvement, the presence of concomitant vascular injuries, the timing of surgical repair, and early postoperative complications. However, the available evidence remains limited, and predictors of loss of biliary patency have not yet been clearly established.⁵⁻⁷

The identification of variables associated with reconstructive failure is of direct clinical relevance, as it may facilitate individualized follow-up strategies, improve the early detection of complications, and ultimately enhance long-term outcomes in patients undergoing biliary reconstruction. Furthermore, the experience of referral centers remains essential for understanding the factors that influence outcomes in this complex patient population.⁸

Therefore, the aim of the present study was to identify factors associated with loss of primary biliary patency following biliary-enteric reconstruction for iatrogenic bile duct injury in a cohort of patients treated at a tertiary referral center.

METHODS

A retrospective cohort study was conducted in patients who underwent biliary-enteric reconstruction for iatrogenic bile duct injury at High Specialty Medical Unit No. 25 of the Mexican Social Security Institute (IMSS), Monterrey, Nuevo León, Mexico, between January 2018 and December 2022. The inclusion criteria were patients older than 18 years who underwent reconstructive surgery. Patients with incomplete medical records or insufficient information to determine the outcomes of interest were excluded.

Study variables

Demographic, clinical, anatomical, and surgical variables were collected from institutional medical records. Bile duct injuries were classified according to the Strasberg and Bismuth classification systems, as appropriate, based on

the anatomical characteristics documented in the operative reports. Variables analysed included sex, age, injury classification, surgical complexity (SG2 or SG3), type of reconstruction performed, presence of postoperative bile leak, and biliary patency during follow-up.

Surgical technique

Biliary reconstruction was performed by surgeons experienced in hepatopancreatobiliary surgery. Roux-en-Y hepaticojejunostomy was the preferred reconstructive procedure. In selected cases involving complex hilar injuries, portoenterostomy was performed. All procedures were carried out by different attending hepatopancreatobiliary surgeons working at the institution during the study period.

Follow-up

Patients were followed through clinical, biochemical, and imaging assessments according to institutional protocols. Follow-up duration was calculated from the date of reconstructive surgery to the last recorded clinical evaluation. The cohort had a mean follow-up of 30.56 ± 25.86 months, with a median follow-up of 26 months (interquartile range, 4–55 months).

Outcomes

The primary outcome was loss of primary biliary patency following biliary-enteric reconstruction. Clinical outcomes were evaluated using the criteria proposed by Cho and colleagues for the standardized reporting of outcomes after treatment of bile duct injuries.⁴ These criteria classify clinical evolution into four categories (A–D) according to the maintenance of biliary patency, the need for additional procedures, and the occurrence of complications during follow-up. Although the Cho classification was used to describe overall clinical outcomes, the primary endpoint of the present study was loss of primary biliary patency, defined according to the clinical and radiological findings documented during follow-up.

Postoperative bile leak was defined as the presence of biliary output through abdominal drains or the identification of an intra-abdominal biliary collection during the early or intermediate postoperative period following biliary-enteric reconstruction.

Analysis

Categorical variables were described using absolute frequencies and percentages. Continuous variables were summarized using measures of central tendency and dispersion. Univariate analysis was performed to identify factors associated with loss of primary biliary patency. The strength of association was expressed as odds ratios (ORs) with 95% confidence intervals (95% CIs). Statistical significance was defined as a *p* value <0.05. Statistical

analyses were performed using the institutional database created for the study.

RESULTS

A total of 73 patients underwent biliary-enteric reconstruction for iatrogenic bile duct injury between January 2018 and December 2022. Most patients were female (86.3%) (Table 1).

Table 1: Clinical and surgical characteristics of the cohort (n=73).

Variables	N (%)
Female sex	63 (86.3)
Male sex	10 (13.7)
SG2 classification	43 (58.9)
SG3 classification	30 (41.1)
Roux-en-Y hepaticojejunostomy	71 (97.3)
Portoenterostomy	2 (2.7)
Postoperative bile leak	22 (30.1)
No bile leak	51 (69.9)
Primary biliary patency achieved	49 (67.1)
Loss of primary biliary patency	24 (32.9)

According to the surgical complexity classification, 43 patients (58.9%) were classified as SG2 and 30 patients (41.1%) as SG3. Biliary-enteric reconstruction was performed using Roux-en-Y hepaticojejunostomy in 71 patients (97.3%), whereas 2 patients (2.7%) required portoenterostomy because of complex hilar injuries.

Postoperative bile leak occurred in 22 patients (30.1%). During follow-up, primary biliary patency was achieved in 49 patients (67.1%), whereas 24 patients (32.9%) developed loss of primary biliary patency.

Mean follow-up was 30.56 ± 25.86 months, with a median follow-up of 26 months (interquartile range [IQR], 4–55 months).

Anatomical distribution of bile duct injuries

Strasberg E3 injuries represented the most frequent category (31.5%), followed by Strasberg E4 (19.2%) and E2 injuries (16.4%). In addition, injuries classified according to the Bismuth and Bismuth-Corlette systems were documented in patients with complex hilar involvement (Table 2).

The predominance of proximal injuries reflects the complexity of cases referred to this tertiary referral center for reconstructive management.

Factors associated with loss of primary biliary patency

A univariate analysis was performed to identify factors associated with loss of primary biliary patency (Table 3).

Table 2: Anatomical distribution of bile duct injuries.

Classifications	N (%)
Strasberg E1	6 (8.2)
Strasberg E2	12 (16.4)
Strasberg E3	23 (31.5)
Strasberg E4	14 (19.2)
Bismuth I	6 (8.2)
Bismuth II	3 (4.1)
Bismuth III	2 (2.7)
Bismuth IV	6 (8.2)
Bismuth-Corlette I	1 (1.4)

Table 3: Factors associated with loss of primary biliary patency.

Variables	OR	95% CI	P value
SG3 versus SG2	2.27	0.83–6.19	0.110
Postoperative bile leak	14.33	4.30–47.78	<0.001

SG3 classification showed a trend toward an association with loss of primary biliary patency (OR 2.27; 95% CI 0.83–6.19), although statistical significance was not reached ($p=0.110$).

In contrast, the occurrence of postoperative bile leak was significantly associated with loss of primary biliary patency (OR 14.33; 95% CI 4.30–47.78; $p<0.001$).

Association between postoperative bile leak and loss of primary biliary patency

Among the 22 patients who developed postoperative bile leak, 16 (72.7%) subsequently experienced loss of primary biliary patency, whereas only 6 patients (27.3%) maintained biliary patency (Table 4).

Table 4: Association between postoperative bile leak and loss of primary biliary patency.

Variables	Primary biliary patency	Loss of biliary patency	Total
Bile leak	6	16	22
No bile leak	43	8	51
Total	49	24	73

OR=14.33 (95% CI 4.30–47.78); $p<0.001$

In contrast, among the 51 patients without postoperative bile leak, only 8 (15.7%) developed loss of biliary patency during follow-up.

These findings demonstrate a clinically relevant association between early postoperative bile leak and subsequent failure of biliary-enteric reconstruction.

Patients who developed postoperative bile leak showed a substantially higher rate of loss of primary biliary patency

during follow-up compared with those without bile leak (72.7% versus 15.7%; OR 14.33, 95% CI 4.30–47.78; $p < 0.001$).

Clinical outcomes according to the Cho classification

Thirty-seven patients (50.7%) achieved a grade A outcome, and 15 patients (20.5%) achieved a grade B outcome. In contrast, 18 patients (24.7%) were classified as grade C and 3 patients (4.1%) as grade D (Table 5).

Overall, 52 patients (71.2%) achieved favourable outcomes (grades A–B), whereas 21 patients (28.8%) had unfavourable outcomes (grades C–D).

These results suggest satisfactory overall effectiveness of biliary-enteric reconstruction performed at a specialized tertiary referral center, despite the fact that approximately one-third of patients developed loss of primary biliary patency during follow-up.

Table 5: Clinical outcomes according to the Cho criteria.

Cho classifications	N (%)
Grade A	37 (50.7)
Grade B	15 (20.5)
Grade C	18 (24.7)
Grade D	3 (4.1)
Total	73 (100)
Overall clinical outcome	
Outcomes	
Favorable (A–B)	52 (71.2)
Unfavorable (C–D)	21 (28.8)

DISCUSSION

Biliary-enteric reconstruction remains the standard treatment for complex iatrogenic bile duct injuries. Nevertheless, loss of primary biliary patency continues to represent one of the major obstacles to achieving favorable long-term outcomes. In the present cohort, approximately one-third of patients developed loss of primary biliary patency during follow-up. The principal finding of this study was the identification of postoperative bile leak as a factor significantly associated with this outcome.

Reported success rates following biliary-enteric reconstruction in specialized centers vary across studies but generally range from 70% to 90% when repair is performed by experienced hepatopancreatobiliary teams.^{2,3} In our series, primary biliary patency was achieved in 67.1% of patients. Although this rate is slightly lower than those reported in some contemporary series, it should be interpreted in the context of the anatomical complexity of our cohort, which was characterized by a high proportion of proximal injuries and referrals to a tertiary referral center.

Several studies have demonstrated that injury complexity influences reconstructive outcomes. Proximal injuries, particularly those involving the biliary confluence, are associated with a higher risk of anastomotic stricture and the need for additional interventions during follow-up.^{5–7} In our study, SG3 classification showed a trend toward an association with loss of primary biliary patency; however, this relationship did not reach statistical significance. It is possible that the sample size limited the ability to detect significant differences within this subgroup.

The most relevant finding of the present study was the strong association observed between postoperative bile leak and subsequent loss of primary biliary patency. Patients who developed bile leak had a significantly greater likelihood of experiencing reconstructive failure during follow-up. From a pathophysiological perspective, bile leak may reflect technical difficulties during anastomotic construction, impaired local vascularization, or inflammatory processes capable of promoting fibrosis and progressive stricture formation. Although the available literature has identified multiple factors associated with unfavorable outcomes, limited information exists regarding the specific role of early postoperative bile leak as a prognostic marker of long-term biliary patency.^{5,6}

Our findings support the concept that postoperative bile leak should be considered not only an early postoperative complication but also a potential indicator of increased risk for subsequent deterioration of biliary-enteric reconstruction. From a clinical standpoint, identification of these patients may justify more intensive surveillance strategies, including clinical, biochemical, and imaging follow-up aimed at the early detection of anastomotic stricture or loss of biliary patency.

In addition to the assessment of primary biliary patency, application of the criteria proposed by Cho and colleagues allowed a more comprehensive evaluation of long-term clinical outcomes. More than 70% of patients achieved favourable outcomes (grades A–B), supporting the overall effectiveness of biliary-enteric reconstruction when performed at a specialized tertiary referral center. The use of standardized reporting systems facilitates comparisons among studies and contributes to a more accurate interpretation of outcomes across different institutions.^{4,9}

Institutional experience represents another important factor when interpreting these results. Several authors have demonstrated that specialized referral centers achieve superior reconstructive outcomes and lower reintervention rates compared with lower-volume hospitals.⁸ Although the present study did not specifically evaluate the impact of surgical volume, the observed outcomes support the role of early referral to centers with expertise in hepatopancreatobiliary surgery.

This study has limitations inherent to its retrospective single-center design. Data collection depended on the quality of available medical records, and the sample size

limited the ability to identify associations of smaller magnitude. Furthermore, it was not possible to uniformly evaluate potentially relevant variables such as associated vascular injuries, exact timing of repair, or specific technical aspects of reconstruction. Nevertheless, the cohort represents the experience of a national referral center and includes a follow-up period sufficient to assess clinically meaningful outcomes after biliary reconstruction.

CONCLUSION

Postoperative bile leak was significantly associated with loss of primary biliary patency following biliary-enteric reconstruction for iatrogenic bile duct injury. This finding suggests that the occurrence of early bile leak may identify patients at increased risk of reconstructive failure during follow-up.

The use of the Cho criteria complemented the assessment of biliary patency by providing a standardized evaluation of long-term clinical outcomes. Early identification of high-risk patients may support closer surveillance strategies and contribute to improved outcomes following biliary-enteric reconstruction.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the Surgery Department of UMAE Hospital No. 25.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Escobar-González A, Saavedra-Flores DR, Álamo-Hernández MV, García-Félix IG. Predictors of primary biliary patency loss following biliary-enteric reconstruction for iatrogenic bile duct injury: a retrospective cohort study from a tertiary referral center in Mexico. *Int Surg J* 2026;13:1322-6.