Referral Pattern, Management, and Long-Term Results of Laparoscopic Bile Duct Injuries: A Case Series of 44 Patients

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Key words: *laparoscopic cholecystectomy; bile duct injury; management strategy; long-term results.*

Summary. *Background and Objective. The incidence of bile duct injuries (BDIs) after laparoscopic cholecystectomy (LC) is higher than after open cholecystectomy, and the management of these lesions is still controversial. This study analyzed diagnostic and management strategies as well as long-term outcomes after BDI.*

Material and Methods. A prospective database of patients with BDIs at the Clinic of Surgery was maintained during the 8-year period (2000–2007). The long-term results were evaluated during 2008–2010, after 36- to 120-month follow-up (median, 84 months).

Results. In our series, 21 patients (48%) presented with minor and 23 (52%) with major BDIs. The overall incidence of BDIs was 0.24%. In 92% of cases in the minor BDI group, endoscopic stenting resulted in a good outcome. Major BDIs were treated by immediate, early, or delayed surgery depending on the timeliness of diagnosis and presence of biliary sepsis and/or cholangitis. The mean estimated time to failure after the initial treatment in the minor BDI group was significantly longer when compared with the major BDI group (114.3 vs. 81.8 months, log-rank test P=0.048). The hazard ratio of initial treatment failure after major versus minor BDIs was 6.06 (95% CI, 1.01–17.59). The mean estimated time to develop a biliary stricture after immediate, early, and delayed reconstructions was not different (P>0.05 in pairwise comparisons by log-rank test).

Conclusions. Minor BDIs are best served by endoscopy, while surgical repair may be an efficient option when injury is diagnosed intraoperatively. The timing of reconstruction after major BDIs does not portend a different outcome; consequently, every attempt to achieve infection control should be warranted. Referral to a tertiary care center should be encouraged to facilitate a proper classification of preoperative injuries and multidisciplinary approach.

Introduction

Gallstone disease is one of the most common digestive health problems (1). Laparoscopic cholecystectomy (LC) represents the gold standard of surgical treatment of gallstone disease and is one of the most commonly performed elective procedures in general surgery. It is preferred over open cholecystectomy due to faster patient return to normal activity, lesser postoperative pain, shorter length of hospital stay, and better cosmetic effect (2). However, it is associated with a higher incidence of biliary injuries as compared with the open procedure. This incidence appears to be up to 4 times higher than that of open cholecystectomy, and it has remained stable in large surveys (3, 4) with a reported incidence of 0.1%–2% for laparoscopic (5, 6) versus 0.4%–0.86% for open cholecystectomy (5, 7–9). Subsequent procedures (surgical and/or endoscopic) are almost inevitable and bear high socioeconomic costs. These injuries are a disaster for both the patient and the surgeon because of associated morbidity and prolonged hospitalization; they result in impaired survival and nearly 3 times higher risk of death (10). The aim of this study was to explore the potential determinants of iatrogenic bile duct injury (BDI) and to analyze management strategies and their influence on long-term outcomes.

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Material and Methods

Data Collection and Study Population

A prospective database of patients with sustained BDIs following LC and managed at the Clinic of Surgery, Hospital of Lithuanian University of Health Sciences, Lithuania, between January 1, 2000, and December 31, 2007, was maintained in accordance with the guidelines of the Regional Ethics Committee.

This report analyses injuries and strictures incurred in association with LC, irrespective of whether the operation was completed laparoscopi-

cally or converted to an open procedure. Bile duct injury was defined as any clinically evident damage to the integrity of biliary system occurring at any time during LC. Ultrasonography and endoscopic retrograde cholangiopancreatography (ERCP) were carried out in all patients as indicated for diagnosis and classification of the bile duct injury or biliary stricture before management. Computed tomography (CT), magnetic resonance cholangiopancreatography (MRCP), and/or percutaneous transhepatic cholangiography (PTC) were performed as indicated. For practical purposes, BDI was classified as minor or major, depending on the nature of the lesion as described by Tsalis et al. (11). The Strasberg classification for more detailed analysis of bile duct injuries was used (12). Accordingly, minor BDI was defined as any injury occurring without major tissue loss and without the occurrence of associated stricture (Strasberg types A to D); major BDI was defined as any disruption (ligation, resection) of the common hepatic duct, common bile duct, or major segmental duct at the hepatic porta (Strasberg types E1–E5).

Intraoperatively recognized bile duct injuries were repaired by choledocho-choledochostomy or hepaticojejunostomy Roux-en-Y. In cases where BDIs were diagnosed postoperatively, every patient was first considered for endoscopic retrograde cholangiopancreatography (ERCP) and nonsurgical treatment by endoscopic stenting. Those who failed endoscopic therapy were scheduled for surgical repair. A Roux-en-Y end-to-side hepaticojejunostomy was the procedure of choice for reconstruction.

Demographics, referring surgeon's management and perioperative diagnostic strategy, grade of BDI, type of surgical reconstruction, and long-term outcomes were analyzed. Patients were followed up at the Outpatient Department, Hospital of Lithuanian University of Medical Sciences, from 2008 to 2010. Follow-up ranged from 36 to 120 months (median, 84 months) after the repair of BDI. Ultrasonography was used to evaluate the dilation of bile ducts; liver enzyme and bilirubin levels were assessed.

Anastomotic strictures were confirmed by ERCP, MRCP, and/or PTC as indicated. Patients requiring a postoperative intervention for the management of recurrent strictures were considered as treatment failures.

Data Analysis

Comparison between groups was done using the χ^2 statistics, Mann Whitney *U* test, Student *t* test, Nelson-Aalen plot of the cumulative hazard, log-rank test, and 2-sample test of proportions as appropriate using SPSS® for Windows release 14.0 (SPSS, Chicago, Illinois, USA). Results are reported as mean (SD), ranges, or percentages of the appropriate denominator. Significance was accepted at the 5% level.

Results

The study population comprised 44 patients, 30 women (68%) and 14 men (32%), with a mean age of 54.2 years (SD, 16.5; range, 23 to 77 years), treated for BDIs after LC during the 8-year period. In 11 cases (25%), BDI during LC occurred at our department, while the remaining 33 patients (75%) were referred to us with the suspected BDI after LC performed elsewhere.

Incidence of Bile Duct Injuries During Laparoscopic Cholecystectomy

According to the database of our University Hospital, there were 4438 LCs performed for acute and chronic cholecystitis at our department during the study period. The overall incidence of BDI was 0.24% (11 patients); the incidence of major injuries was 0.11% (5 patients). The incidence of BDI was 0.62% in acute and 0.11% in chronic cholecystitis patients.

Bile Duct Injuries According to the Strasberg Classification

Minor BDIs occurred in 21 patients (48%), presenting with bile leak from a cystic duct stump or tangential main bile duct lesion without major tissue loss, classified as Strasberg type A to D. The remaining 23 patients (52%) experienced major BDIs, including the complete transection or resection of the common hepatic duct below or at the confluence (Table 1).

Table 1. Type of Bile Duct Injury According to the Strasberg Classification

Type of Injury	No. of Patients	Incidence, %	Total, n (%)
Minor bile duct injuries			21 (48)
A	4	10	
D	17	38	
Major bile duct injuries			23 (52)
E1	1	2	
E2	21	48	
E4	1	2	

Recognition of Bile Duct Injuries

In our study, 8 BDIs (18%) were diagnosed during the index surgery. In 29 (66%) of cases, BDI was diagnosed during the early postoperative period (within the first 10 days), when patients presented with the typical signs and symptoms of bile duct transection and/or occlusion. Seven patients (16%) had a late manifestation of bile duct obstruction, weeks and months after the LC (Table 2).

Table 2. Clinical Presentation of Bile Duct Injuries Over Time

Recognition of Bile Duct Injury	Incidence n (%)	Clinical Presentation	Rate n (%)
During operation	8 (18)	–	8 (18)
Early postoperative	29 (66)	Jaundice Biliary fistula (drains) Biloma Biliary sepsis	7 (16) 10 (22) 6 (14) 6 (14)
Late postoperative	7 (16)	Jaundice/bile duct stricture Cholangitis	2 (5) 5 (11)
Total	44 (100)		44 (100)

Management Strategies

Management of Minor Bile Duct Injuries

Minor BDIs (n=21) were treated by surgical or endoscopic approach depending on the type of injury and timing of diagnosis. Twelve patients (57%) were treated by endoscopic stenting with plastic stents at our department. In 11 patients (92%), endoscopic procedures were effective and resulted in good poststenting outcomes. One patient (8%) required repeated endoscopic procedures, including stent replacement and stricture dilation. Finally hepaticojejunostomy was performed. The remaining 9 patients (43%) with minor BDI were treated surgically (open or laparoscopic): suture of small tangential bile duct lesions (type D, 3 patients), ligation of accessory bile duct (type A, 1 patient), and repair of lacerated common bile duct over a T-tube after conversion (5 patients).

Management of Major Bile Duct Injuries

Immediate Surgery. The major BDI was diagnosed during the initial surgery in 3 cases. Conversion and biliary reconstruction was performed in all cases. A primary end-to-end repair over a T-tube was attempted in 1 case in a regional hospital by a general surgeon. It resulted in a biliary stricture and subsequent reconstruction 9 months later. In the remaining 2 cases, conversion and hepaticojejunostomy were performed by a specialist hepatobiliary surgeon.

Early Surgery. Seven patients in an early surgery group presented with jaundice and were referred to our hospital. The complete proximal obstruction of the extrahepatic biliary tree was confirmed with no signs of bile leak or biliary sepsis. An end-to-side hepaticojejunostomy was performed in all cases by a specialist hepatobiliary surgeon.

Delayed Surgery. The delayed surgery group comprised 13 patients. BDI was suspected or confirmed within the first few days after LC in majority of cases. However, intraperitoneal bile leak and local or generalized biliary sepsis precluded early reconstructive surgery. Laparoscopic or transcutaneous drainage of intraperitoneal/subhepatic collections was followed by delayed hepaticojejunostomy in all cases. The strategy of major BDI reconstruction is summarized in Table 3.

Hospital Stay

Although LC is now considered a one-day or even outpatient procedure, the mean hospital stay of patients with bile duct injury was 18 days (SD, 13; range, 5–91 days).

Patients with minor BDIs treated by endoscopic stenting had a significantly shorter hospital stay (mean, 7 days; SD, 1 day), when compared with the patients who suffered major BDIs (mean, 19 days; SD, 12 days) ($P<0.05$). There were no statistical differences in the inhospital stay comparing the immediate (mean, 18 days; SD, 11 days), early (mean, 17 days; SD, 13 days), and delayed surgery groups (mean, 19 days; SD, 12 days). The mortality rate after endoscopic/surgical repair or reconstruction was 0%.

Long-Term Results

Having prospectively examined all the patients at the outpatient department 36–120 months after the initial stenting or repair, 5 patients (11%) with treatment failure were identified. Only 2 of these patients were clearly symptomatic (recurrent cholangitis, biliary pain, jaundice), while others presented with nonspecific symptoms. However, all the patients had significantly elevated bilirubin levels and liver enzymes (Table 4).

The mean estimated time to failure after initial treatment in the minor BDI group was 114.3 months (95% CI, 105.7–122.9), whereas it was 81.8 months (95% CI, 64.1–99.5) in the major BDI group, and the difference was significant (log-rank

Table 3. Reconstruction Strategy in Major Bile Duct Injuries According to the Timing of Diagnosis

Type of Reconstruction	Major Bile Duct Injuries (n=23)			
	Immediate Reconstruction n=3 (13%)		Early Reconstruction n=7 (30%)	Delayed Reconstruction n=13 (57%)
Initial, n (%)				
Hepaticojejunostomy	2 (67)	0	7 (100)	13 (100)
Choledocho-choledochostomy	0	1 (33)	0	0
Repeated, n (%)				
Hepaticojejunostomy	0	1 (33)	2 (28)	4 (31)

Table 4. Laboratory Tests as a Tool For Recognition of Possible Treatment Failures at Follow-Up

Blood Serum Measurement	Patients' Group		*P*
	Uncomplicated Course n=39 (89%)	Suspected Failure n=5 (11%)	
Total bilirubin, μmol/L	10.4 (4.1)	19.3 (11.1)	<0.05
Direct bilirubin, μmol/L	2.5 (1.0)	6.0 (3.2)	<0.01
Alanine aminotransferase, U/L	25.3 (12.1)	65.0 (46.9)	<0.01
Aspartate aminotransferase, U/L	27.9 (7.6)	52.2 (18.9)	<0.01
Alkaline phosphatase, U/L	79.8 (30.2)	291.0 (109.2)	<0.01
Gamma-glutamyl transferase, U/L	29.3 (15.3)	525.2 (268.8)	<0.01

Values are mean (SD).

test P=0.048). The hazard ratio of initial treatment failure after major versus minor BDIs was 6.06 (95% CI, 1.01–17.59). A plot of the cumulative hazard of initial treatment failure by the minor and major BDI groups is presented in Fig. 1.

The long-term results of surgical management of major BDIs showed that 1 of 3 patients who were reconstructed immediately after BDIs developed biliary strictures at 9 months. In the early surgery group, 2 patients (28%) developed biliary strictures and were scheduled for repeated surgery 24 and 36 months after the initial reconstruction. In the delayed surgery group, 4 patients (31%) developed biliary strictures and were re-reconstructed after a mean of 23 months (SD, 18 months) (Table 3).

The mean estimated time to develop a biliary stricture after the immediate reconstruction was 62.3 months (95% CI, 19.6–105.1); after early reconstruction, 89.1 months (95% CI, 64.4–113.9); and after delayed reconstruction, 74.9 months (95% CI, 49.1–100.7). There was no significant difference in developing the strictures between groups with the different timing of reconstruction (P>0.05 in all pairwise comparisons by log-rank test). A plot of the cumulative hazard of initial repair failure by timing of reconstruction after major BDIs is presented in Fig. 2.

The mortality rate after repeated reconstructive surgery was 0%.

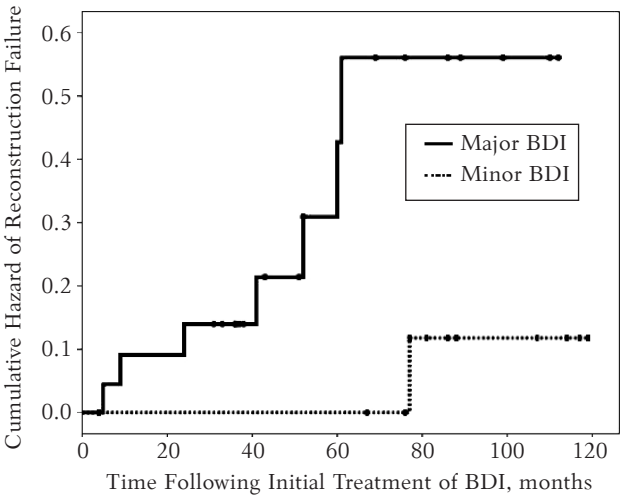

Fig. 1. Nelson-Aalen plot of the cumulative hazard of initial treatment failure after minor bile duct injuries (BDI) (N=21) compared with major bile duct injuries (N=23)

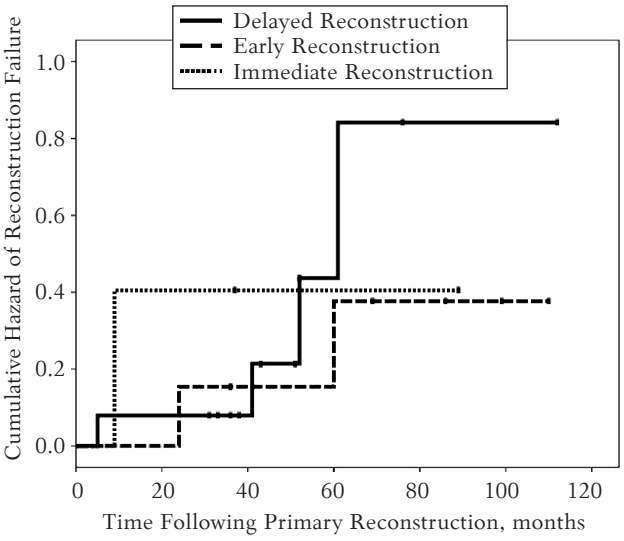

Fig. 2. Nelson-Aalen plot of the cumulative hazard of stricture development following reconstruction after major bile duct injuries (N=23)
Timing of surgery depended on the timeliness of diagnosis and presence of biliary sepsis: immediate reconstruction (3 patients), the bile duct injury was diagnosed during index operation; early reconstruction (7 patients), the bile duct injury was diagnosed postoperatively with the totally occluded proximal bile duct without biliary sepsis; and delayed reconstruction (13 patients), after the initial management of biliary sepsis, biloma, and/or cholangitis.

Discussion

With the introduction of laparoscopic cholecystectomy, the incidence of BDIs and associated bile duct strictures has increased 2 to 4 times when compared with open cholecystectomy. The reported incidence of BDIs after LC ranges from 0.1% to 2%. According to our data, the overall incidence of BDIs during LC was 0.24%, similar to other reports (13). However, the overall rate of BDIs after LC in Lithuania remains unknown.

Risk Factors

Many factors have been incriminated to impel BDI during LC. These are mainly anatomical misidentification of the cystic duct, unusual anatomical

variations, lack of experience, technical difficulties, poor visualization of the operative field, acute and/or chronic inflammation of the gallbladder, and excessive hemorrhage (14, 15). Other risk factors include older age and male gender (7). In our study, acute inflammation of the gallbladder was associated with an increased risk (0.62%) of BDIs. Although the results did not reach the statistically significant difference, there was a clear pattern showing the higher prevalence of BDIs in clinical situations associated with acute inflammation. On the other hand, no potential risk factors are identified in up to 80% of the patients with BDI (4, 7).

We believe that the most important factor in preventing a biliary injury is a proper identification of the anatomy and meticulous surgical technique. The basic principles to avoid BDIs were described by Strasberg et al. as "critical view of safety" (12) and Lord Ganesha's sign by Tantia et al. (5). Proper education of surgical residents identifying and interpreting the anatomical structures of the Calot's triangle may further reduce the incidence of BDIs.

Recognition of Bile Ducts Injuries

Timely diagnosis and appropriate treatment of BDI are of paramount importance in preventing the life-threatening complications, such as cholangitis, biliary cirrhosis, portal hypertension, and end-stage liver disease, and death.

Our data support the observation that most BDIs are not recognized at the time of the index operation. In our study, out of the 44 patients, only 8 (18%) were timely diagnosed and underwent an immediate repair. This number is considerably lower than that reported in the literature (16, 17). According to the report of Zvonimir et al., 33% of BDIs were recognized intraoperatively, and the most common type of iatrogenic BDI was a complete transection, accounting for 42% of cases (18). In another report, 46% of injuries were recognized intraoperatively (4).

The early presentation of BDIs after LC is often nonspecific in patients reporting vague abdominal pain, persistent nausea, vomiting, and low-grade fever. Patients who develop delayed symptoms due to a biliary stricture typically present with jaundice and cholangitis. According to our data, approximately two-thirds (66%) of cases were diagnosed within 10 days after the surgery. Similarly, as reported by Winslow et al., in 72 patients, in whom injuries were recognized postoperatively, 36 (51%) became evident within the first postoperative week (19).

Imaging studies, such as ultrasonography and CT scan, and MRCP studies play an important role in the initial evaluation of patients with suspected BDI. These studies will identify the presence of intraabdominal collections or ascites. In most cases of bile duct transection, ERCP will demonstrate only a normal-sized distal bile duct up to the site of total obstruction; delineation of the proximal anatomy is usually not possible. Percutaneous transhepatic cholangiography or magnetic resonance cholangiopancreatography is necessary for the proper diagnosis and staging of the injury. PTC may sometimes be advantageous not only defining the proximal anatomy, but also allowing the placement of percutaneous biliary catheters to decompress the biliary tree in the presence of cholangitis.

Treatment Options

Endoscopic Approach. Every patient suspected of having a BDI after laparoscopic cholecystectomy should undergo cholangiography. Repair of a BDI without defining the anatomy usually fails. Stewart and Way noted that 96% of repairs performed without a preoperative cholangiogram were unsuccessful (20). ERCP is now readily available and technically feasible. If a tangential bile duct injury or a cystic duct leak is identified, placement of a transampullary stent will control the leak and provide definitive treatment (20, 21). According to our data, 21 patients with Strasberg type A and D injuries were identified at ERCP. Twelve patients were managed endoscopically by transpapillary stenting, and only one patient developed a bile duct stricture in the long run and, subsequently, underwent surgical reconstruction. Recently, Weber et al. reported the long-term results of endoscopic therapy in patients with BDIs and found it effective in 91.6% of cases, particularly in patients with peripheral bile duct leakage and bile duct strictures (22). To our knowledge, endoscopic management is an appropriate treatment option in minor BDIs when the continuity of the biliary tract is retained.

Surgical Treatment. Unfortunately, major BDIs result in the complete transection or resection of bile ducts. In our study, Strasberg type E BDIs were present in 52% of patients, similarly as reported by others (19). A Roux-en-Y hepaticojejunostomy provides the optimal reconstruction (17, 19) with up to 78.0% of good postoperative results (23). We utilize 3 different scenarios in the management of major BDIs: immediate surgery (at the time of initial operation); 2) early surgery (proximal bile duct is completely obstructed, no bile leak); and 3) delayed surgery (presence of cholangitis, biliary sepsis).

The management of intraoperatively recognized BDI depends on the nature, type of injury, and local expertise. The injury should preferably be repaired by a biliary surgeon. When the injury is recognized in the early postoperative period and is not associated with bile leak or biliary sepsis, early reconstruction may be considered. In both cases, there is a safe possibility to close and send a patient to a referral hospital, in case a biliary surgeon is not

available. Otherwise, the control of biliary sepsis and establishment of biliary drainage are the primary goals (24). Bile duct reconstruction is not an urgent procedure and should be delayed for approximately 6–8 weeks. Reconstruction in the presence of biliary sepsis or cholangitis portends a statistically poorer outcome (15).

Stewart and Way performed a multivariate analysis of 307 major BDIs following LC to show that the timing of repair was not important. Instead, success correlated with eradication of intra-abdominal infection, preoperative cholangiography, proper surgical technique, and repair by a biliary surgeon (25).

Similarly, the success of repair was not different in our patients with different reconstruction scenarios.

Overall repeated reconstruction was needed in 30.4% of our patients, 7 months to 4 years after initial reconstruction. Winslow et al. reported a secondary repair in 22% of earlier reconstructed patients (19), while others reported a postreconstruction stricture rate of 29.5% (18).

The success of biliary reconstruction depends on the possibility to achieve 6 major goals: adequately vascularized, tension free, mucosa-to-mucosa, widely patent, and precisely constructed anastomosis draining all the parts of the liver (19). Carroll et al. reported a successful outcome rate of 79% after surgery performed by a referral surgeon, as opposed to 27% when performed by a primary surgeon (26). Multidisciplinary management in a tertiary care center with experienced hepatobiliary surgeons and availability of skilled interventional radiologists and endoscopists may offer the best options to optimize treatment.

Conclusions

Based on our data, acute inflammation or tissue scaring does play a role as a potentially hazardous factor facilitating bile duct injuries during laparoscopic cholecystectomy; however, the majority of injuries are being executed while operating on "normal" tissues. Minor bile duct injuries are best served by endoscopy, while surgical repair may be an efficient option when injury is diagnosed intraoperatively. The timing of reconstruction after major bile duct injuries does not portend different outcomes; consequently, every attempt to achieve infection control should be warranted. Referral to a tertiary care center should be encouraged to facilitate a proper classification of preoperative injuries, to enable a multidisciplinary approach, and further to improve treatment of outcomes.

Acknowledgments

G.B and S.P. equally contributed to this article.

Statement of Conflict of Interest

The authors state no conflict of interest.

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