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Laparoscopic Cholecystectomy-Related Bile Duct Injuries

A Health and Financial Disaster

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Objective
This study was designed to evaluate the total costs associated with repair of laparoscopic cholecystectomy (LC)-related bile duct injuries.

Summary Background Data
The popularity of LC with both patients and surgeons is such that this procedure now exceeds open cholecystectomy by a ratio of approximately 4 to 10:1. However, costs associated with LC-related injuries, particularly regarding treatment patterns, have up to now not been explored fully.

Methods
The complete hospital and interventional radiology (IR) billing records for 49 patients who have completed treatment for laparoscopic cholecystectomy-related bile duct injuries were divided into 8 categories. These records were totaled for comparison of costs between patient groups that experienced different injuries and treatment patterns.

Results
Patients with LC-related bile duct injuries were billed a mean of $51,411 for all care related to repair of their bile duct injury. Patients incurred an average of 32 days of inpatient hospitalization and 10 outpatient care days. Postoperative treatment included long-term chronic biliary intubation averaging 378 days. Two patients (4%) died as a result of their LC-related complications. Patients with bile duct injuries that were recognized immediately at the time of the initial surgery ultimately experienced a total cost for their repair and hospitalization of 43% to 83% less than for patients in whom recognition of the injury was delayed ($p < 0.019$ to 0.070). In addition, the total hospitalization and outpatient care days was reduced by as much as 76% with early recognition of an iatrogenic injury.

Conclusions
Repair of cholecystectomy-related bile duct injuries can run 4.5 to 26.0 times the cost of the uncomplicated procedure and carries a significant mortality rate. Intraoperative recognition of such an injury with immediate conversion to an open procedure for definitive repair can result in significant cost savings and relates directly to a decreased morbidity, mortality, length of hospitalization, and number of outpatient care days.

Iatrogenic injuries occurring during cholecystectomy are the most common cause of bile duct trauma.[1,2] The incidence of bile duct injury after open cholecystectomy (OC) ranges from 0.06% to 0.21%.[3,4] Laparoscopic cholecystectomy, first introduced in 1990 by Dubois et al.,[5] has undergone rapid development and acceptance, leading both surgeons and patients to believe that this procedure is superior to OC, both in terms of complication rates and overall results.[6–8] However, there have been numerous reports citing a significant increase in the occurrence of common bile duct injuries associated with laparoscopic cholecystectomy (LC), ranging from 0.30% to 0.60%.[9,10]

The treatment of cholecystectomy-related bile duct injuries, particularly those occurring during laparoscopic surgery, is a significant issue for the following reasons:

1. The number of LC procedures performed now exceeds OC by a ratio of approximately 4 to 10:1.[11,12]
2. Because there are more than 500,000 cholecystectomies performed per year in the United States,[13] the present complication rate of 0.30% to 0.60%[9,10] potentially could yield 1500 to 3000 patients annually with significant ductal injuries.
3. The minimally invasive nature of LC may broaden the indications for cholecystectomy, further increasing the total number of procedures performed per year.
4. Common bile duct injuries can be notoriously difficult to treat and may require multiple costly surgical or interventional procedures, or both.[14]
5. Adequate treatment of common bile duct injuries may require up to a year of postoperative stenting,[14,15] thus resulting in significant long-term morbidity.
6. Nonmonetary issues such as hospitalization time, travel, and loss in quality of life can be significant, thus accentuating the long-term overall morbidity.

Reports on treatment of postcholecystectomy complications are numerous.[6,8,14,16–18] However, none have explored the equally significant issues of the costs associated with these injuries. We therefore present our findings on the costs associated with the complete treatment of LC-related bile duct injuries in 49 patients.

METHODS

From August 1990 to May 1995, 79 patients with bile duct injuries resulting from LC were treated at the Johns Hopkins Hospital. Seventy-four of these patients were referred from outside institutions. The 49 patients who have completed their treatment are the focus of this study. This group consisted of 39 women with a mean age of 38 years (range, 23 to 60 years) and 10 men with a mean age of 55 years (range, 25 to 72 years). Twenty of these patients were referred to in other articles.[16,19]

The surgical and interventional treatment of these patients is described in detail in other reports.[14–16,19] In summary, patients with suspected bile duct injuries were evaluated initially with computed tomography. All bilomas were treated by percutaneous catheter drainage. Percutaneous transhepatic cholangiography subsequently was performed to define the location, extent, and nature of the injury. Patients with a cystic duct stump leak or common bile duct stricture of minimal-to-moderate severity underwent percutaneous biliary drainage (PBD) followed by chronic biliary intubation with a large bore (14F to 16F) silicone catheter. Patients with a common bile duct transection, ligation, or severe laceration or stricture were treated with PBD followed by surgical creation of a Roux-en-Y hepaticojejunostomy. Preoperative endoscopic retrograde cholangiopancreatography was not used in this patient group because of our surgeons' routine practice of converting percutaneously placed biliary drainage catheters into large caliber internal–external silicone stents during the Roux-en-Y hepaticojejunostomy repair. Follow-up treatment in this second group of patients also consisted of long-term stenting with one to three silicone catheters (depending on ductal anatomy). Catheters were removed as indicated by clinical and radiologic findings, including successful completion of a clinical trial or biliary manometric perfusion test or both.[19]

The complete departmental and hospital billing records were obtained for each patient in this study. These records included all hospital charges and professional fees billed to the patients from the time of their initial clinic visit or admission for surgery or intervention until 1 month after the removal of their biliary stents. Inclusive were all related outpatient visits for chronic biliary tube care. Charges then were placed into one of seven categories as follows:

1. Hospital room—inclusive of all charges for inpatient admission fees, daily room charges, and interventional radiology (IR) room charges for outpatient procedures such as routine biliary tube changes.
2. Laboratory fees—inclusive of all charges for any laboratory-based tests such as chemistry, hematology, bacteriology, virology, fungal testing, blood bank, venipuncture, and arterial blood gases.
3. Pharmacy—inclusive of all charges for drugs, intravenous fluids, and blood products.
4. Surgery and anesthesia—inclusive of all profes-

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sional fees billed for by the Departments of Surgery and Anesthesia, hospital charges for same, surgical suite and recovery room charges, and costs for surgical and anesthesia equipment (*e.g.*, operating room instrument trays, disposable gas delivery systems).
5. Interventional radiology—inclusive of all professional fees and hospital charges for all IR equipment used (*e.g.*, catheters, guidewires, drainage catheters, balloons for cholangioplasty, biliary stents).
6. Diagnostic radiology—inclusive of all professional and hospital fees for radiology studies conducted outside the IR section such as computed tomography, plain film, and ultrasound.
7. Consultations—inclusive of hospital and professional fee charges emanating from other services for formal consultation or procedures or both (*e.g.*, endoscopy, pathologic interpretation of specimens, electrocardiogram interpretation).

Charges for each patient were totaled and categorized. Unrelated hospital admissions were not included. Patients were categorized further into one of five groups based on the nature of their injury and course of treatment as follows:

1. Laparoscopic cholecystectomy at outside institution resulting in major bile leak, referred to this institution for reparative surgery.
2. Laparoscopic cholecystectomy at outside institution resulting in major bile leak, referred to this institution after failed attempt at reparative surgery.
3. Laparoscopic cholecystectomy at outside institution resulting in bile duct stricture, referred to this institution for reparative surgery.
4. Laparoscopic cholecystectomy at outside institution resulting in bile duct stricture, referred to this institution after failed attempt at reparative surgery.
5. Laparoscopic cholecystectomy at this institution, intraoperative complication recognized, and immediate conversion to OC with definitive repair.

A one-tailed Student's t test was used to evaluate the significance of the differences in total charges between the five groups. The p values of 0.05 or less were considered significant.

RESULTS

Forty-nine patients underwent definitive repair for postcholecystectomy bile duct injuries, which included 32 bile duct strictures, 11 bile duct transections, 2 bile duct ligations, and 4 bile duct leaks or lacerations. Percutaneous transhepatic cholangiography followed by PBD was performed initially in all patients except those patients in group E, who underwent intraoperative biliary intubation after conversion from a laparoscopic to an OC procedure. Forty-one patients (84%) subsequently were treated by a hepaticojejunostomy with Roux-en-Y loop reconstruction, 1 patient (2%) was treated with primary ductal repair over a T-tube, 6 patients (12%) were treated with percutaneous cholangioplasty and chronic biliary intubation, and 1 patient (2%) with a minor bile leak required only short-term percutaneous biliary diversion. Two patients (one in group A and one in group B) died after extended intensive care admissions (18 and 68 days, respectively) from sepsis and multiorgan system failure before reparative surgery could be performed. Initial primary treatment by surgical or interventional means was followed up in the remaining 47 patients with long-term biliary intubation with large bore silicone catheters (mean, 16 F; range, 8–20 F).

Routine biliary tube changes were performed at 4- to 8-week intervals or whenever patient's symptoms suggested tube obstruction, cholangitis, or bacteremia. Patients underwent chronic biliary intubation for a mean of 378 days (range, 58 to 847 days). If two patients with unusually long periods of biliary intubation (806 and 847 days) are excluded, then the period is reduced to a mean 359 days. Patients experienced a mean of 32 days (range, 1 to 184) of inpatient hospitalization and 10 days (range, 0 to 31 days) of outpatient care during the course of their treatment. If the two patients with unusually long periods of care (192 and 131 total days) are excluded, then the mean number of inpatient days is reduced to 18 (mean outpatient days remain at 10).

A summary of the categoric and total charges is given in Table 1. Hospital room charges ranged from $400 to $500 per day for routine floor care and $1000 to $1200 per day for intensive care with an overall mean of $11,439, comprising 22.3% of the total bill. Combined mean laboratory and pharmacy charges were $2124 and $2211, respectively. Surgery and anesthesia professional fees, hospital, and supply charges were combined into one category. The mean surgical and anesthesia charges were $7474, accounting for 14.5% of the total bill.

The IR charges were separated from those accrued by diagnostic radiology. The IR professional fees ran a mean of $22,626. These charges comprised the major component of the total cost at 44.0%, reflecting extensive preoperative and outpatient follow-up care provided by this service. Diagnostic radiology charges were a relatively minor component (4.7%) at a mean of $2400. Miscellaneous charges comprised 4.4% of the total charges, running a mean of $2282. During the course of their hospitalization, patients required an average of two consultations with other services such as Medicine, Gastroenterology, and Cardiology. These consultations were a relatively small component of the total charges (1.7%), running a mean of $854.

Overall, total mean charges for this group of patients

Table 1. CHARGES FOR BILE DUCT INJURY REPAIR*

	Inpatient/ Outpatient† (days)	Room Charges	Laboratory	Pharmacy	Surgery/ Anesthesia	CVIR	Diagnostic Radiology	Consultations	Miscellaneous	Total
LC (%)	32/10	11,439 (22.3)	2124 (4.1)	2211 (4.3)	7474 (14.5)	22,626 (44.0)	2400 (4.7)	854 (1.7)	2282 (4.4)	51,141

* All monetary values are means and in U.S. dollars.
† Inpatient days (days hospitalized)/outpatient days for follow-up care.
CVIR = cardiovascular/interventional radiology; LC = laparoscopic cholecystectomy.

was $51,411; however, if the two patients with extended care of 131 and 192 days, respectively, are not included, then the mean cost of definitive bile duct repair after LC-related injury is reduced by 8.2% to $42,391. The mean age of the female patients (38 years) was significantly younger ($p < 0.005$) than that of the male patients (55 years); however, the cost of repair in the female group was greater, averaging $54,599 *versus* $49,183 in the male group. Collections for all professional fees combined and IR averaged 51% and 53%, respectively.

Costs for ductal repair based on the nature of the injury and course of treatment are listed in Table 2. Those patients experiencing a bile duct injury with major bile leak followed by a delayed and failed surgical repair (group B) experienced a significantly greater mean cost ($130,345) than did patients in the other four groups (mean range, $22,565 to $43,501) ($p < 0.019$ to 0.039). Patients who experienced a bile duct injury that was recognized immediately and repaired definitively (group E) experienced a significantly decreased overall cost ($22,565 *vs.* $39,571 to $130,345) ($p < 0.019$ to 0.070) than did patients in groups A through D.

DISCUSSION

Open cholecystectomy traditionally has been considered to be the gold standard for surgically treatable gallbladder disease; however, it also can be associated with a 3- to 4-day hospital stay, significant postoperative pain, and a 6- to 8-week recovery period. Numerous reports on LC have cited decreased overall hospitalization time (1.2 to 1.3 *vs.* 3.7 days), decreased postoperative pain, and decreased at-home recovery time (8 days *vs.* 43 days),[8,20] sparking unprecedented enthusiasm for this procedure. Unfortunately, any perceived cost savings associated with LC *versus* OC have not been realized.[7,8] In fact, Bass et al.,[7] in their cost-effectiveness model, noted that the similar costs for these two procedures hold true only if the risk for bile duct injury, among other factors, is not greater for the laparoscopic *versus* OC.[7] Because it has been established that, at least at the present time, LC is associated with a greater risk of bile duct injury than is OC,[3,4,9,10] then it is important to establish the costs (both monetarily and intangible) associated with this complication.

Our study shows that bile duct injuries associated with

Table 2. COMPARISON OF TYPE OF INJURY AND REPAIR TO OVERALL COST OF REPAIR

Group	Cost* Mean	Cost* Range	p Value†
A: Outside LC, major bile leak repair at JHH	43,507	7570–68,649	Group A *vs.* B: 0.039 Group A *vs.* E: 0.028
B: Outside LC, major bile leak, repair at JHH after other surgery	130,345	27,134–305,013	Group B *vs.* C 0.034 Group B *vs.* D 0.034 Group B *vs.* E 0.019
C: Outside LC, bile duct stricture, repair at JHH	39,725	17,745–70,294	Group C *vs.* E 0.050
D: Outside LC, bile duct stricture, repair at JHH after other surgery	39,571	2858–89,192	Group D *vs.* E 0.070
E: JHH LC, CBD injury, immediate repair	22,565	8300–35,770	—

* Values are given in U.S. dollars.
† Only significant p values are shown.
LC = laparoscopic cholecystectomy; JHH = Johns Hopkins Hospital; CBD = common bile duct.

LC costs an average of $51,411 to facilitate and complete a durable repair.[19] If the two patients with unusually lengthy hospital admissions are excluded, the mean cost is decreased by 8.2% to $42,391, still hardly an insignificant figure. When divided by gender, the age of the patients differed significantly. The mean age of the female patients was 17 years younger than their male counterparts ($p < 0.005$). In addition, female patients outnumbered male patients almost 4 to 1, reflecting the relative prevalence of gallbladder disease in females. Interestingly, cost of repair in the younger female group (mean, $54,599) was greater than in the older male group (mean, $49,183), thus increased patient age did not contribute to greater overall hospitalization costs as might be expected.

The charges for IR services exceeded all other categories and accounted for a mean of 44.0% of the total cost of the bile duct repair. These charges included such procedures as preoperative percutaneous transhepatic cholangiography, PBD (48% of patients required two or more PBD catheters), biloma drainage, and postoperative biliary tube care during an extended period of biliary intubation, which averaged 378 days. Patients averaged 12.9 interventional radiologic procedures during their course of therapy. Room charges for patients, which consisted of admission fees and all inpatient room fees, accounted for the second greatest component of the total expenses at 22.3%. Patients averaged 32 days (range, 1 to 192 days) of inpatient hospitalization and 10 days for outpatient follow-up care. Combined charges for the surgical and anesthesia services accounted for the third greatest component of the total cost averaging 14.5%, but individually were relatively small components of the total cost.

A cost that our patients did not incur was that associated with diagnostic and interventional endoscopic procedures. The use of endoscopy in the evaluation of patients with suspected LC injuries clearly has been shown.[7,13] In addition, the use of endoscopic sphincterotomy, stenting, and balloon dilatation in patients with post-LC-related biliary tract leaks and strictures also has been reported.[19,21] The use of endoscopic *versus* percutaneous techniques remains at the discretion of the referring physician. Literature comparing the costs of these two techniques is presently unavailable.

The relation between the cost of repair, the nature of the injury, and how that injury was treated is listed in Table 2. Patients in group B (*i.e.,* those with a major bile duct leak and a failed attempt at reparative surgery) experienced significantly greater mean costs and longer hospitalizations than did patients in the other four groups. This group of patients generally was more sick (secondary to bile peritonitis and sepsis) and more debilitated after their two prior operations. Patients in groups A, C, and D all experienced similar costs for bile duct repair, which averaged approximately 31% of the costs of group B. On the contrary, patients who experienced a bile duct injury that was recognized immediately and treated successfully experienced overall costs significantly less (17% to 57%) than did patients in any of the other four groups. These findings indicate that patients experience fewer costs for repair of an LC-related bile duct injury when that injury is recognized immediately and treated successfully. Patients may not benefit from attempts at reparative surgery in institutions that do not have the experience required to treat these complex injuries. Not only do these patients experience the trauma of an unnecessary procedure, but also the additional expense (a cost for which we could not account) associated with that operation.

Another factor that must be addressed is the cost associated with treatment of the 10% to 30% of patients who will, even under the best of circumstances, restricture after surgical or percutaneous intervention.[19,22] The majority of these failures will occur within 2 years; however, because recurrent strictures can occur up to 20 years after the initial procedure,[22] the true total cost incurred by our group of patients with LC-related bile duct injuries never may be appreciated fully.

In addition to the definable medical expenses seen in this group of patients, we also have been enlightened as to significant other costs associated with bile duct injury and repair for which we could not readily account. These include 1) patient's lost wages during periods of hospitalization and recovery; 2) lost wages from the spouse or significant other during periods when accompanying the patient to the hospital; 3) day care expenses for children while a parent was hospitalized as an inpatient or required an outpatient procedure, and 4) supplies for outpatient chronic biliary tube care and oral antibiotic therapy. An intangible cost that we could not tabulate, and arguably the most important, is the significant loss in quality of life associated with repair of a bile duct injury. In addition, we are aware of numerous patients in litigation for recovery of damages; however, exact figures were not available. The costs associated with the litigation, workman's compensation, monetary rewards, and changes in malpractice premiums easily could surpass the total cost of a bile duct repair and warrant further study.

This study illustrates that cholecystectomy-related bile duct injuries are disastrous both healthwise and monetarily. In accountable monetary terms, repair of a bile duct injury, which typically requires a well-coordinated, multidisciplinary approach, can run 4.5 to 26.0 times the cost of an uncomplicated LC.[7,8] Although surgical intervention is required in the majority (86%) of cases, the interventional radiologist ultimately can spend a very significant amount of time devoted to the care of this group of patients. Although one rightfully can argue that the cost of repair of a bile duct injury largely is dependent on the technique used, a survey of the literature would

suggest that the combined multidisciplinary approach used by this institution widely is accepted.[15,23–25]

Laparoscopic cholecystectomy is here to stay. Complication rates typically decrease to an "acceptable" rate after a rather steep learning curve.[11] This study serves to bring to light the tremendous expenses incurred as a result of a bile duct injury. In addition, the benefits associated with immediate recognition of a bile duct injury and subsequent conversion to an open procedure to facilitate a definitive repair have been shown.

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