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Bile duct injury repairs: Progressive outcomes in a tertiary referral center

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ABSTRACT

Background: Bile duct injury during laparoscopic cholecystectomy persists as a significant problem in general surgery, resulting in complex injuries, arterial damage, and post repair strictures.
Methods: We performed a retrospective analysis between 2 eras of bile duct injury repairs: 1987 to 2001 ($n = 58$) and 2002 to 2016 ($n = 52$) using logistic regression analyses to assess presentation, repair complexity, and outcomes.
Results: No differences in demographics, incidence of cholecystitis, conversion, time to presentation, level of injury, or arterial injury were identified. The second era had an increase in patient age, transhepatic catheter use, prior repair, and utilization of complex repairs. This approach resulted in equivalent complications and mortality rates with increased resource utilization but a lesser incidence of post-repair strictures ($P = .004$). Regression modeling correlated strictures to prior operative repairs (OR 4.25; $P = .016$) and a protective effect of repairs performed in the second era (OR 0.23; $P = .045$).
Conclusion: The second era identified a decreasing trend of attempted repairs by referring surgeons but an increase in transhepatic catheters and complex repairs resulting in lesser rates of post-repair stricture. Final regression modeling confirmed increased operative experience decreased post-repair stricture reaffirming the benefits of early identification and referral of bile duct injuries to an experienced hepatobiliary surgeon at a specialty center.

Introduction

The overall incidence of iatrogenic bile duct injuries has remained stable but remains consistently somewhat greater with laparoscopic cholecystectomy (0.2%–1.5%) compared with the open operative approach (0.1%–0.2%).[1–4] The misidentification of the critical structures appears to be the principal etiology of bile duct injuries, when visualization is obscured by inflammation, adhesions, fibrosis, or hemorrhage, which results in ligation, division, or even thermal injury to major ductal or vascular structures.[1,5–7] Bile duct injuries vary from leaks of minor ducts, such as the ducts of Luska, to the more devastating major vasculo-biliary injuries that can lead to substantial morbidity and even mortality.[8–12] The management of these same bile duct injuries can vary from simple endoscopic stenting to major biliary-enteric resections/anastomoses with vascular reconstruction, liver resection, or in extreme cases even liver transplantation.[1,3,13]

Over the last few decades, numerous classification systems have been created to define and communicate the extent of bile duct injuries. These classification schemas evolved from the original Bismuth system that was created to describe chronic bile duct strictures into the current multi-level systems of Strasberg, Hannover, and the modified Bismuth-Strasberg classification.[8,14–16] No matter which classification system is used to describe an injury, those occurring at the hilar plate or those associated with a concomitant vasculo-biliary injury are recognized as the most complex and challenging to manage and repair.[17] Failure or even

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delay in the recognition of concomitant vasculo-biliary injury or further misguided operative intervention to repair such injuries can lead to even more serious adverse or further iatrogenic sequela.[2,13,17,18] Current surgical philosophy advocates immediate referral of patients with a bile duct injury to high-volume, specialty centers with experienced hepatobiliary surgeons for management and definitive operative repair.[19–23]

Prior studies have concluded that attempted repairs of bile duct and/or vascular injuries by the primary operative surgeon at the time of the sentinel laparoscopic cholecystectomy have a greater incidence of failed repairs and subsequent complications.[13,17,18] A study by Koffron et al implicated unrecognized vascular injuries as a major etiology of post repair, biliary-enteric strictures.[18,20] The recognition of this association then extends into the controversy surrounding the optimal timing for definitive repair. A recent study by Gouma et al identified early repair as having inferior outcomes to delayed or "late" reconstructive operations for bile duct injuries.[19] Our current study evaluates these clinical questions in the setting of a large series of bile duct injury repairs across 2 consecutive eras, managed by a single surgeon at a tertiary referral center.

Methods

The current study was designed as a retrospective analysis of 2 consecutive and contiguous cohorts to evaluate the evolution of an operative approach to bile duct injuries by a single, hepatobiliary surgeon at a tertiary referral center. This study was performed after approval by our institutional review board.

Data collection

Data were collected through a retrospective chart review process involving all hard copy and electronic medical records of each patient. The database was analyzed to evaluate our experience in the management and operative approach to bile duct injuries referred to a tertiary center between 2 consecutive and contiguous eras. Between 1987 and 2001, 58 patients with bile duct injuries were managed; while 52 patients were managed between 2002 and 2016. Medical records reviewed included the index admission, as well as any subsequent readmissions or outpatient procedures. Data gathered included medical histories, index operative notes, diagnostic imaging, including hepatobiliary iminodiacetic acid scans, magnetic resonance cholangiopancreatography, endoscopic cholangiopancreatography, percutaneous transhepatic cholangiography (PTC), and any formal hepatic artery angiography. Additionally, all initial and definitive operative repair reports were reviewed, as were all short- and long-term clinic outpatient appointments. Patient demographics included patient age, sex, race, medical comorbidities, and preoperative body mass index. Clinical data included the preoperative diagnosis for the index cholecystectomy, the presence of cholecystitis, the patient referral source (whether it was internal or an outside hospital referral), time from injury to recognition, time from injury to definitive repair, method of definitive diagnosis, conversion to open procedure, attempted repair by the primary cholecystectomy surgeon, Bismuth classification of injury, and the presence or absence of any concomitant vasculo-biliary injury. Postoperative outcomes were also reviewed, including intensive care utilization, duration of hospital stay, all associated complications utilizing the Clavien-Dindo (I-V) classification system, and the incidence of post-repair stricture. As the principle, regional referral center for bile duct injuries and complicated biliary issues, our group has continued to follow these patients through their postoperative courses and then yearly with a mean follow-up of 32 months.

Definition of post-repair stricture

A post-repair stricture was defined as either a symptomatic patient (right upper quadrant pain, fevers, chills, jaundice, pruritus, or increased transaminases) or a clinically asymptomatic patient with a critical radiologic stenosis (>40%) of the repair on postoperative imaging (computed tomography [CT], magnetic resonance imaging [MRI], or PTC). Intervention for post-repair stricture was initiated by the presence of an asymptomatic radiologic but clinically relevant stricture (>40%) or the presence of symptoms of cholangitis. Initial management of all post-repair strictures included PTC placement or PTC upsizing, balloon dilation, and interventional stenting. Reoperation was reserved for persistence or recurrence after nonoperative, radiologic intervention.

Definition of bile duct repairs

Simple repairs

These operative procedures included hepaticojejunostomy repairs for single-duct, multi-duct, or spatulated, dual-duct anastomoses to a 60 cm Roux-en-Y limb.

Complex repairs

In this study, a complex repair was defined by the use of a Rodney-Smith reconstruction comprised of a longitudinal incision into the left lateral ductal system for creation of an elongated single orifice to create the hepaticojejunostomy anastomosis at the level of the hilar injury. This repair was utilized in the presence of an isolated left ductal injury or a predominantly left-sided ductal injury with inclusion of the right ductal system. The second complex repair utilized in this study was the Kasai portoenterostomy **.** The Kasai portoenterostomy was performed in injuries that had completely obliterated the normal anatomic structures of the biliary bifurcation and biliary radicals distal to the level of the hilar plate. The hepaticojejunostomy of the Kasai portoenterostomy was created using the residual fibrous margin of the hilar plate, the liver capsule, or any residual viable duct after completion of a sharp operative debridement of the devitalized ductal structures. The Kasai portoenterostomy anastomosis was constructed using a large, single orifice of jejunum from a 60 cm Roux-en-Y limb to the remnant liver and biliary structures.

Patient and operative management

Era 1: 1987 to 2001

In era 1, a substantial proportion of patients were referred or transferred after having undergone an operative conversion and attempted repair by the primary outside surgeon. This era was marked by a high utilization of endoscopic cholangiopancreatographies to confirm obstruction, leakage, or visualization of free flowing, open ductal structures. After transfer, all patients were evaluated with dual contrast CT for evaluation of undrained or residual perihepatic collections or abscess. When present, all fluid collections were drained percutaneous by interventional radiology. During this era, patients were managed selectively with PTC catheters with the majority also undergoing formal hepatic arteriography.

After wide percutaneous drainage, patients were discharged and subsequently readmitted for elective repair, usually 6 weeks after their final drainage intervention. At the time of definitive repair, the patients were explored, vascular anatomy examined, and the biliary anatomy was sharply debrided to healthy viable ducts. Ductal debridement frequently required excision of approximately 1 centimeter of damaged or nonviable duct. The biliary enteric anastomosis was performed under magnification using interrupted

Table I
Demographics of bile duct injuries during 2 eras of operative management at a tertiary referral center

	Era 1 1987–2001	Era 2 2002–2016	*P* value
Number of patients	58	52	
Age (y)	45.4	51.21	.047
Caucasian	79%	64%	.065
Male	22%	37%	.082
BMI	31.2	31.2	.993
Cholecystitis	35%	50%	.119
Conversion to open exploration	38%	23%	.092
Prior operative repair	43%	17%	.004
Time to definitive repair (d)	220.4	121.1	.482
Bismuth grade (%)			
I	8	4	.126
II	16	14	
III	10	6	
IV	13	23	
V	11	5	
Arterial injury	14%	27%	.086
PTC placement	26%	60%	< .001

BMI, body mass index.

5-0 or 6-0 PDS with reconstruction around the PTC catheter or utilizing internal stents made of a short segment of a pediatric feeding tube catheter secured across the anastomosis to the posterior wall of the anastomosis.

Era 2: 2002 to 2016

In this era, the majority of patients were referred and transferred immediately after a ductal injury was identified. Once transferred, patients were managed with triphasic CT for evaluation of undrained fluid collections or perihepatic abscess and for assessment of vascular anatomy on the arterial phase and the venous phase of a hepatic angiogram for any evidence of concomitant vasculo-biliary injury. Any clearly identified vascular injury or disruption was then followed by a formal hepatic angiogram. Vascular reconstruction for a major vascular injury was considered futile after 72 hours. In this era, PTC catheters were used widely. After definitive drainage, patients were discharged and then readmitted for elective repair approximately 6 weeks after discharge.

In this later era, similar to the first cohort, all patients were explored, vascular anatomy examined, and the biliary structures were sharply debrided to viable duct. This part of the operation frequently required a 1-cm debridement or resection of damaged or nonviable duct. Recognition of concomitant vasculo-biliary or the presence of multi-ductal injuries distal to the hilar plate were managed with either an extended left bile duct exposure and lateral incision of the left duct system to create a lateral “Rodney-Smith” hepaticojejunostomy; in the case of complete destruction or necrosis of the extrahepatic biliary system to a level distal to the hilum, the repair was accomplished by a Kasai portoenterostomy. The Kasai portoenterostomy anastomosis was performed under magnification using interrupted 5-0 or 6-0 PDS drained with a PTC or a short segment of a pediatric feeding tube catheter secured across the posterior anastomotic wall. All patients with PTC catheters had post repair cholangiograms through their existing catheters at 6 weeks before removal. Long-term follow-up included 6-month and yearly laboratory evaluations.

Statistical analysis

An outcome analysis was performed between 2 groups based on the year of management and definitive repair of the bile duct injury.

Table II
Outcomes of operative repairs of bile duct injuries after 2 eras of operative management at a tertiary referral center

	Era 1 1987–2001	Era 2 2002–2016	*P* value
Number patients	58	52	
Complex operation	19%	46%	.002
ICU stay (d)	0.09	0.2	.036
Duration of stay (d)	8.3	14.7	.031
Complications	14%	27%	.086
Mortality	2%	4%	.130
Post repair stricture	29%	8%	.004

ICU, intensive care unit.

Fifty-eight patients with bile duct injuries occurring between 1987 and 2001 were identified and grouped into Era 1, and 52 patients with injuries occurring between 2002 and 2016 were grouped into Era 2. Patient demographics, medical management, operative approaches, and outcome data were collected. Logistic regression analysis was performed for the primary clinical outcome of post-repair stricture. Statistical analysis was performed using STATA analytics (Statacorp, College Station, TX). During the analysis, concern over small sample size required performance of 2 robustness checks. The first robustness check estimated our recurrence regression with only a binary variable for prior operations, and for the second era of operations (2002–2016) our estimates were very similar to those in the larger regression and definitive repair. In the second robustness check, we calculated linear probability models, and again, our results are similar to logistic regression.

Results

The study population consisted of 110 patients: 78 (71%) were male and 78 were white (71%) with an average Bismuth injury level of grade III. (Table I). Four (3.6%) of the 110 bile duct injuries occurred in our tertiary center, and the remaining 106 (96.4%) patients were transferred from outside facilities, after recognition of a bile duct injury during a laparoscopic cholecystectomy. In era 1 (1987–2001), 58 patients were managed with a bile duct injury, and in era 2 (2002–2016), 52 patients were transferred and managed. The second era saw a substantial increase in patient age ($P = .047$), whereas no other differences were identified in patient demographics or clinical presentation across the 2 eras of bile duct repairs, including sex, race, body mass index, incidence of cholecystitis, arterial injury, or distribution of Bismuth grade injuries (Table I).

The second era had a lesser incidence of bile duct repairs attempted by an outside surgeon before referral (43% vs 17%; $P = .004$). Injuries occurring during the second era were treated with a greater utilization of PTC catheters (59% vs 26%; $P < .001$) and complex surgical repairs (46% vs 19%; $P = .002$) as is defined in the methods section. Clinical outcomes in the second era required an increase in both ICU utilization ($P = .036$) and overall hospital stay ($P = .031$) (Table II). Despite the increased use of PTC catheters and complex surgical repairs, there were equivalent rates of complications ($P = .086$) and no increase in mortality (5% vs 2%; $P = .130$). The second era resulted in a decrease in the post-repair stricture rate (8% vs 29%; $P = .004$) (Table II).

Regression analysis identified several risk factors impacting the duration of stay, including increased patient age ($P = .022$) and a level V Bismuth injury ($P = .019$). In a separate regression analysis of post-repair stricture, a prior attempt to repair by the outside surgeon (OR 4.24; $P = .016$) was predictive of restricture, whereas repairs performed in the second era (OR 0.23; $P = .045$) were protective (Table III).

Table III
Logistic regression analysis for post-repair stricture between 2 eras of bile duct injury repairs

	OR	Std err	*P* value
Age at repair	1.008	0.016	.602
Caucasian	0.673	0.454	.557
BMI	1.072	0.057	.187
Bismuth grade			
	0.615	0.585	.609
	0.645	0.684	.679
	0.756	0.841	.802
	0.585	0.717	.662
Arterial injury	1.122	0.971	.888
PTC placed	0.860	0.551	.814
Prior operative repair	4.246	0.653	.016
Complex repair	0.787	0.169	.773
Repair date	0.232	0.061	.045

BMI, body mass index: *OR,* odds ratio; *Std err,* standard error.

Discussion

Bile duct injuries are an unfortunate but well recognized complication of cholecystectomy, whether performed laparoscopically, robotically, or even by an open approach.[1–3] After the early era of laparoscopic cholecystectomy, the incidence of bile duct injury has remained stable between 0.22% to 1.3%.[10,11,22] This increased incidence of bile duct injury after a laparoscopic cholecystectomy remains greater than the 0.1% to 0.2% incidence associated with open cholecystectomy. Unfortunately, iatrogenic bile duct injuries are associated with considerable morbidity (31%–43%),[4,5,22] including recurrent bile leak, intra-abdominal abscess, liver infarction, wound infection, cholangitis, sepsis, and even death from liver failure or cirrhosis, with an overall mortality rate of 1.7%.[7,13,17,18,22]

A major contributing factor to this morbidity and mortality is the incidence of concomitant vasculo-biliary injury.[1–18,22] The reported incidence of hepatic arterial injury associated with bile duct injuries during laparoscopic cholecystectomy varies between 7% and 63% with the greatest incidence associated with grade III to V injuries.[13,17] The most common arterial injury during laparoscopic cholecystectomy is to the right hepatic artery, whether it is the anterior or posterior segmental branch of the right hepatic artery or the main branch.[17,18,22] More serious injuries, such as those to the common hepatic and proper hepatic artery and portal vein injuries, have been reported.[17,18] An injury to the right hepatic or common hepatic artery can lead to acute hepatic infarction in approximately 10% of patients and often long-term hepatic atrophy.[7,13,17,22] Management of an acute arterial injury can include ligation, division, and thrombosis and can even lead to pseudo-aneurysm formation.[17,18] Pseudo-aneurysms can be the most challenging and can be managed with any one of several options, including non-operative monitoring, embolization, ligation, or primary repair.

Major devascularization or massive infarction of the liver is the most devastating complication of vasculo-biliary injuries, and in extreme circumstances, hepatic resection with biliary-enteric diversion or even liver transplantation may be required.[8,13,17,22] Fortunately, the majority of patients do not require such extreme approaches and can be managed with more standard, biliary-enteric repairs. This reality underscores the critical nature of understanding, describing, and communicating the anatomy of bile duct and the injured segments among referring surgeons and specialized hepatobiliary surgeons at tertiary referral centers. The Bismuth-Strasberg Classification synthesizes the original Bismuth system designed for chronic biliary strictures with the body of work of Strasberg.[10,11,17,22] This system includes the following: type A: cystic or duct of Luschka leak; type B: aberrant right duct injury with no leak; type C: aberrant right duct with leak; type D: partial injury to the common hepatic duct with leak; type E: complete bile duct transection with the following subclassifications: E1: injury >2cm from bifurcation; E2: injury <2cm from the bifurcation; E3: injury at the confluence; E4: injury resulting in separated ducts; and E5: common duct injury in conjunction with a transected aberrant right hepatic artery.[10,11,17,22]

The current study evaluated the presentation and management of patients referred to our center with bile duct injuries after laparoscopic cholecystectomy over a nearly 30-year period. When the cohort was divided into 2 distinct eras, with the exception of increasing age, the patient demographics and clinical presentation of the bile duct injury were similar, but there was a significant decrease in the incidence of attempted repairs by the referring surgeon prior to transfer during the second era. Despite this decrease in the incidence of conversion, exploration, and attempted repair, there was no increase in the level of injury or concomitant arterial injury identified. During the second era, our standard approach shifted to the routine use of PTC catheters and the utilization of previously defined, complex operative repairs, including the Rodney-Smith procedure and the Kasi portoenterostomy. These practice changes, in conjunction with increasing clinical experience, culminated in a statistically significant decrease in the rate of post-repair bile duct strictures. Post-repair bile duct strictures are known complications of bile duct injury repairs with considerable variable incidence among reported series.[13,20,23] Several authors have confirmed that these cases are often associated with unrecognized, concomitant, vasculo-biliary injuries. Koffron and colleagues identified a 61% incidence of a clinically relevant arterial injury associated with the presence of a stricture resulting from the repair of a post bile duct injury with hepaticojejunostomies.[18] This study and others have correlated biliary ischemia and in particular early ischemia as an independent risk for post-repair stricture.[13,17,18,22,23] When post repair strictures do occur, they can often be treated successfully by serial dilations with PTC placement, upsizing, balloon choledochoplasty, or intraluminal stenting without resulting in substantial morbidity or recurrent stricture. Only when all nonoperative approaches are exhausted are patients considered for a reoperative approach.

The greatest risk associated with delayed or unrecognized vasculo-biliary or asymptomatic recurrent stricture is the development of secondary biliary cirrhosis. The incidence of post-stricture biliary cirrhosis is not negligible and has been reported in at least 1 series to be as great as 8%, with the only appropriate or definitive therapy being liver transplantation.[13,21] This possibility then brings to light the last controversial question of the timing of a definitive repair. The opinion of our group has been that the performance of delayed repairs may provide an opportunity to better assess and manage ischemic tissue, allowing a surgeon to better evaluate marginally perfused bile duct tissue; this possibility may affect the extent of excision and the type of repair performed, subsequently affecting the incidence of post-repair stricture. In the final regression analysis of our surgical experience, the most important variable in decreasing the incidence of post-repair stricture was the extent of surgeon experience; this occurred in the context of decreased operative intervention by the referring surgeons, increased utilization of PTC catheters, and the adoption of more complex operative l repairs performed in a delayed elective fashion after at least 6 weeks of percutaneous drainage.

In conclusion, the current study reaffirms and even strengthens the recommendations that the standard of care is that all bile duct injuries should be referred to experienced hepatobiliary surgeons in a tertiary referral center.[13,23]

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