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Major Bile Duct Injuries During Laparoscopic Cholecystectomy

Follow-Up After Combined Surgical and Radiologic Management

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Objective
The authors provide the results of follow-up evaluation after combined surgical and radiologic management of 89 patients with major bile duct injuries during laparoscopic cholecystectomy.

Summary Background Data
The incidence and mechanism of injury of major bile duct injuries during laparoscopic cholecystectomy has been clearly defined. Furthermore, a number of series have described the management of these injuries by surgical, endoscopic, and radiologic techniques with excellent short-term results. Long-term follow-up data, however, are lacking in the management of these injuries.

Methods
Data were collected prospectively on 89 patients treated at a single institution with major bile duct injuries after laparoscopic cholecystectomy managed between July 1, 1990, and July 1, 1996. Patients referred with injuries underwent early percutaneous transhepatic cholangiography and biliary drainage. Based on the cholangiographic appearance and clinical situation, patients were managed by either percutaneous balloon dilatation or surgical reconstruction with a Roux-en-Y hepaticojejunostomy with transanastomotic stenting. Follow-up was obtained by personal interview during October 1996.

Results
Two patients died without an attempt at definitive therapy. Both deaths were caused by sepsis and multisystem organ failure present at the time of transfer to the authors' institution. The remaining 87 patients were managed initially by either balloon dilatation (N = 28) or surgical reconstruction (N = 59). Ten patients have not completed treatment and still have biliary stents in place. Evaluation of 25 patients completing treatment after balloon dilatation (mean follow-up, 27.8 months) showed a success rate of 64%. Evaluation of 52 patients completing treatment after surgical reconstruction (mean follow-up, 33.4 months)

showed a success rate of 92%. All failures were managed successfully by either surgical reconstruction or balloon dilatation.

Conclusions

Major bile duct injuries can be managed successfully by combined surgical and radiologic techniques. This series provides, for the first time, significant follow-up on a large number of patients with overall success rates of 64% after balloon dilatation and 92% after surgical reconstruction. The combination of surgery and balloon dilatation resulted in a successful outcome in 100% of patients treated.

Laparoscopic cholecystectomy has altered dramatically the management of patients with cholelithiasis. This procedure has rapidly gained acceptance as the treatment of choice for most patients with symptomatic gallstones because of the minimal pain and disability associated with the procedure. However, compared to open cholecystectomy, the incidence of bile duct injury appears to be increased, resulting in significant morbidity, high financial costs, and a major increase in litigation.[1-3] In the past few years, the incidence[4-10] and the mechanisms[2,11-13] of bile duct injury during laparoscopic cholecystectomy have been well defined. A number of series describing the management of bile duct injuries after laparoscopic cholecystectomy by surgical,[1,2,11,14-18] endoscopic,[18-21] and percutaneous techniques[22,23] have been reported with excellent short-term results. At this point, however, long-term follow-up data are lacking. The goal of this report is to evaluate the outcome of combined surgical and radiologic management of major bile duct injuries after laparoscopic cholecystectomy with respect to long-term follow-up.

CLINICAL MATERIAL AND METHODS

Data were collected prospectively on all patients treated at The Johns Hopkins Hospital for major bile duct injuries before July 1, 1996. All patients had undergone laparoscopic cholecystectomy for treatment of benign biliary tract disease. Major bile duct injuries included transections or partial lacerations of the common hepatic or common bile duct or major segmental ducts injured at the porta hepatis. Cystic duct leaks or bile leaks from the gallbladder bed after laparoscopic cholecystectomy were excluded. Bile duct injuries after open cholecystectomy and other upper abdominal operations were also excluded.

A total of 89 patients were managed during this period. In seven patients (7.9%), the injury occurred during laparoscopic cholecystectomy at The Johns Hopkins Hospital, whereas the remaining 82 patients were referred after injury at an outside hospital. The initial management of all the patients referred with a bile duct injury consisted of a percutaneous transhepatic cholangiogram and placement of percutaneous biliary catheters. In those patients with injuries at or near the hepatic bifurcation, both the right and left hepatic ductal systems were accessed with transhepatic catheters. In patients with ongoing biliary leaks, percutaneous drainage of bile collections or ascites was also performed as indicated. It is our practice in such patients to control the biliary leak and associated sepsis and then allow a period for resolution of the associated inflammation. In many cases, after control of the bile leak, the patient was discharged to home and returned for definitive repair at a later date.

In those patients in whom biliary-enteric continuity was intact and percutaneous dilatation and stenting was an option, the decision to pursue this alternative *versus* surgical repair was based on the clinical assessment of the surgeon and interventional radiologist. If the option of percutaneous dilatation and stenting was chosen, the need for repeat dilatation, the length of stenting, and the decision to abandon this technique in favor of surgical reconstruction again was based on the clinical judgment of the treating surgeon and radiologist.

Surgical management consisted of a Roux-en-Y hepaticojejunostomy. All procedures were performed electively with one to three biliary catheters placed before surgery to facilitate the operative procedure.[24] After identification and mobilization of the proximal hepatic duct, the preoperative catheters were exchanged for larger soft silastic stents. A Roux-en-Y limb of jejunum, 50 to 60 cm in length, was created, and an end-to-side hepaticojejunostomy was performed with the stents placed through the anastomosis.

The anastomoses were performed routinely with interrupted absorbable suture with the Roux limb placed in a retrocolic position. The perianastomotic area was drained with closed suction drains. In the immediate postoperative period, the stents were left to external drainage. At postoperative day 4 or 5, a cholangiogram was performed,

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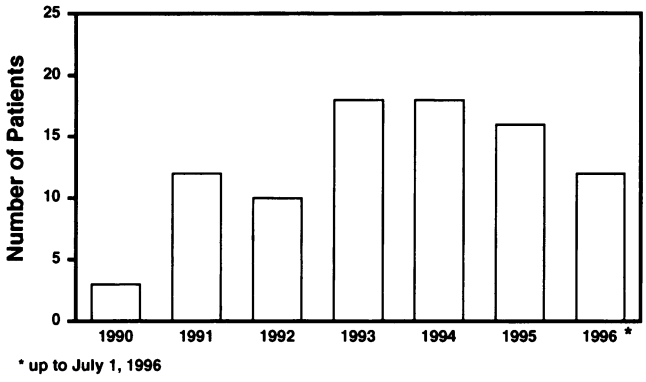

Figure 1. Year of presentation of major bile duct injuries after laparoscopic cholecystectomy (* represents through July 1, 1996).

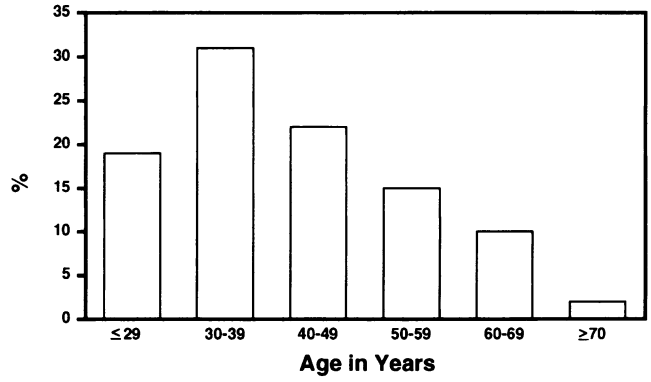

Figure 2. Age distribution of patients with major bile duct injuries after laparoscopic cholecystectomy.

and if the study was satisfactory, the stents were internalized, and the patient's hospital course was completed as directed by the surgical staff. The silastic stents were changed routinely on an outpatient basis every 2 to 3 months. The length of postoperative stenting was determined by the treating surgeon based on the clinical scenario, the location of the injury, and the follow-up cholangiographic appearance. In most patients, a biliary Whitaker study[25] and 2-week clinical trial with the stent positioned above the anastomosis were completed before stent removal.

A patient's treatment was considered complete at the time of removal of all biliary stents. The length of follow-up was considered from the time of the patient's definitive surgical or radiologic procedure. Follow-up evaluation results were obtained by review of the patient's Johns Hopkins Hospital and Outpatient Center medical records and/or by personal telephone interview conducted during October 1996. Outcome was assessed subjectively by history with symptoms of abdominal pain, fever, chills, and jaundice being noted. The results of any diagnostic evaluation or therapeutic procedures performed after completion of the treatment were recorded and confirmed by hospital records.

Patients' current status was rated subjectively as excellent if they had no symptoms attributable to their biliary tract injury or reconstruction and rated good if mild symptoms, not requiring invasive investigation or treatment, were present. Patients classified as either excellent or good were considered to be a treatment success. Patients were considered to be a treatment failure if a second therapeutic procedure, either surgical or radiologic, was necessary to treat ongoing symptoms or stricture recurrence. These definitions were consistent with an earlier report from this institution.[26]

Statistical comparisons were made using Student's t test and Fisher's exact test as appropriate. Actuarial success rates were analyzed by the Mantel–Cox technique. A p value of <0.05 was considered statistically significant.

RESULTS

Patient Characteristics, Prior Management, and Presentation

Eighty-nine patients with major bile duct injuries have been treated at The Johns Hopkins Hospital since the initial patient was referred in August 1990 (Fig. 1). Seventy-two patients (81%) were female. The average age of the patients was 41.2 years (range, 22–78 years; Fig. 2). Eighty-two patients (92.9%) had undergone laparoscopic cholecystectomy at an outside hospital and were referred with a presumed or confirmed bile duct injury (Table 1). In 26 patients (31%), the bile duct injury had been recognized at the time of laparoscopic cholecystec-

Table 1. PRIOR MANAGEMENT OF 82 PATIENTS REFERRED WITH MAJOR BILE DUCT INJURIES

Management	No. (%)
Injury recognized at time of laparoscopic cholecystectomy	26 (31)
Repair at initial operation	26 (100)
End-to-end ductal	14 (54)
Hepaticojejunostomy	12 (46)
Injury recognized in postoperative period	56 (69)
Attempt at repair prior to referral	18 (32)
End-to-end ductal	6 (33)
Hepaticojejunostomy	12 (67)
Exploratory laparotomy for bile leak without repair	9 (16)
Total prior attempts at repair	44 (54)
End-to-end ductal	20 (45)
Hepaticojejunostomy	24 (55)
Total prior laparotomy	53 (65)

tomy, and the patient was converted to an open procedure. Management at that time consisted of an end-to-end primary ductal anastomosis in 14 (54%) of the 26 patients, whereas in the other 12 patients, a biliary-enteric anastomosis was constructed. In 56 patients, the injury was not recognized at the time of laparoscopic cholecystectomy. In 18 of these patients, at least 1 attempt at biliary reconstruction was made before referral. These procedures included 6 end-to-end primary repairs and 12 biliary-enteric reconstructions. One patient had undergone two laparotomies for attempt at repair. In that patient, a hepaticojejunostomy was constructed when an injury was recognized at the time of laparoscopic cholecystectomy, followed 1 week later by a second laparotomy in an attempt to repair an ongoing biliary leak.

Nine additional patients had undergone laparotomy for a biliary leak with external drainage without attempt at reconstruction. In one patient, two laparotomies were performed and in another patient, a partial left hepatic lobectomy was performed for hepatic ischemia due to a concomitant vascular injury. In total, 44 (54%) of 82 patients referred from outside hospitals had undergone an attempt at repair, whereas 53 (65%) of the 82 patients had undergone at least 1 laparotomy in an attempt to manage the injury.

The interval from laparoscopic cholecystectomy to referral to The Johns Hopkins Hospital ranged from 1 day to 48 months with a mean of 7.7 months for all 82 patients referred. The interval was <1 month in 35 patients (43%) and longer than 12 months in 13 patients (16%). In 31 patients (38%), an ongoing biliary leak (bile ascites or peritonitis, a biloma or abscess, or an external fistula) was present at the time of referral. In 30 patients (37%), obstructive jaundice was the primary reason for referral, whereas in 18 patients (22%), cholangitis was the major indication. All patients referred with cholangitis had undergone an attempt at biliary reconstruction before referral. In the remaining three patients, a biliary stent (two percutaneous transhepatic and one endoscopic) had been placed after a cholangiogram, which had showed a biliary injury. These patients were referred without active cholangitis or jaundice for definitive management of the injury.

Seven patients underwent biliary reconstruction after laparoscopic cholecystectomy performed at Johns Hopkins. In five of these seven patients (71%), the injury was recognized at the time of laparoscopic cholecystectomy, and the patient was converted to an open procedure. In four patients, reconstruction with a Roux-en-Y hepaticojejunostomy with intraoperative placement of transhepatic silastic stents (one stent, three patients; two stents, one patient) was performed. In the fifth patient, a primary end-to-end ductal anastomosis over a T-tube was completed. Jaundice developed in the sixth patient in the early postoperative period, who then underwent percutaneous transhepatic cholangiography, which showed complete obstruction of the common hepatic duct. A transhepatic biliary catheter was placed, and definitive repair was performed during the same hospitalization. The final patient presented with obstructive jaundice 3 months after a laparoscopic cholecystectomy performed for acute cholecystitis. Her initial operative procedure and postoperative course had been uncomplicated. At the time of her presentation, she underwent a percutaneous transhepatic cholangiogram, and a Roux-en-Y hepaticojejunostomy was performed for a bile duct stricture.

Management

Percutaneous transhepatic cholangiography was performed and percutaneous biliary catheters were placed shortly after admission in all patients referred with suspected bile duct injuries. In 31 patients (38% of patients referred), an ongoing biliary leak was shown. In those patients without prior external drainage of the leak, percutaneous drainage of bile ascites or a bile collection was performed. In only one patient was early operation necessary to drain an infected bile collection.

There were two deaths in the series for an overall mortality of 2.2%. Both patients were older men (ages 62 and 72) who were septic with multisystem organ failure secondary to ongoing biliary leaks at the time of transfer to The Johns Hopkins Hospital. The first patient had undergone a hepaticojejunostomy and a second laparotomy to repair an ongoing bile leak before referral. The second patient had undergone two laparotomies for intra-abdominal sepsis due to a bile leak, but no biliary reconstruction had been attempted. Both patients underwent successful percutaneous transhepatic cholangiography and placement of biliary catheters, and the biliary leak appeared to be controlled. No intra-abdominal collections were seen on computed tomogram scan. Both patients died from multisystem organ failure without a surgical procedure being performed. In all other patients, the leak and associated biliary sepsis was controlled. Thirteen patients (45%) presenting with a bile leak eventually were discharged after referral and subsequently readmitted for definitive surgical reconstruction at a mean of 4.7 weeks (median, 5 weeks; range, 2–6 weeks). There were no deaths in any of the 87 patients undergoing definitive management at The Johns Hopkins Hospital either by surgical reconstruction or percutaneous dilatation during the immediate post-treatment period or throughout the follow-up period.

In 28 (32%) of the 87 surviving patients, percutaneous dilatation and stenting was performed as the initial attempt at definitive management (Table 2). All 28 patients had undergone a prior attempt at bile duct repair, therefore representing 64% of patients referred with a prior biliary

Table 2. PREVIOUS REPAIR, PRESENTING SYMPTOMS, LEVEL OF OBSTRUCTION, AND USE OF STENTS

	Balloon Dilatation (N = 28) [no. (%)]	Surgical Reconstruction (N = 59) [no. (%)]
Previous repair	28* (100)	15 (25)
End-to-end ductal	11 (39)	9 (60)
Biliary-enteric	17 (61)	6 (40)
Presenting symptoms		
Jaundice	11 (39)	21 (36)
Biliary leak	8 (29)	21 (36)
Cholangitis	8 (29)	10 (17)
None	1 (4)	2 (3)
Recognized at laparoscopic cholecystectomy	—	5 (8)
Level of obstruction		
Bismuth 1	6† (21)	3 (5)
Bismuth 2	12 (43)	20 (34)
Bismuth 3	6 (21)	21 (36)
Bismuth 4	3 (11)	7 (12)
Bismuth 5	1 (4)	3 (5)
Isolated RHD	—	5 (8)
Use of stents (no.)		
1	15 (54)	20 (34)
2	11 (39)	36 (61)
3	2 (7)	3 (5)
Dilatations (no.)		
1	18 (64)	—
2	8 (29)	—
3+	2 (7)	—

RHD = right hepatic duct.
* $p < 0.001$ *vs.* surgical repair.
† $p < 0.05$ *vs.* surgical repair.

reconstruction. These prior repairs consisted of an end-to-end duct repair in 11 patients (39%) and a hepaticojejunostomy in 17 patients (61%). Eleven (39%) of the 28 patients presented with obstructive jaundice, 8 patients (29%) with a biliary leak, and 8 (29%) with episodes of cholangitis. One patient was asymptomatic after percutaneous drainage at an outside hospital. The interval from injury to referral ranged from 1 week to 40 months (mean, 7.8 months; median, 2 months). Twelve patients were referred at 1 month or less after injury. The level of the injury with respect to the confluence of the hepatic ducts, as described by Bismuth,[27] is listed in Table 2. The number of stents and the number of dilatations performed also are included in Table 2.

In 59 (68%) of the surviving 87 patients, the initial definitive management consisted of surgical biliary reconstruction. Only 15 (25%) of these patients had undergone an attempt at repair before treatment at Johns Hopkins. The previous repairs consisted of nine end-to-end ductal repairs (60%) and six hepaticojejunostomies (40%). Twenty-one (36%) of the 59 patients presented with a biliary leak, 21 patients (36%) presented with obstructive jaundice, 10 (17%) with cholangitis, and 2 (3%) were asymptomatic after stenting at an outside hospital. In five patients, the duct injury was recognized during surgery at the time of laparoscopic cholecystectomy at Johns Hopkins. The interval from injury to management (excluding intraoperatively recognized injuries) ranged from 1 day to 48 months (mean, 6.3 months; median, 1 month). The Bismuth level of injury and the number of stents used during the reconstruction are listed in Table 2.

The two groups of patients undergoing balloon dilatation and surgical reconstruction were similar by most parameters. Patients undergoing balloon dilatation were more likely to have undergone a previous attempt at repair ($p < 0.001$) and to have a lower (Bismuth 1) level of injury ($p < 0.05$).

The length of postoperative stenting was determined in all patients and was defined as short-term (<4 months), intermediate (between 4 and 9 months), and long-term (9 months or longer). In seven patients, all <1 year after surgery, the stents are still in position and therefore the total length of stenting cannot be determined. In 6 (12%) of the remaining 52 patients, the length of stenting was classified as short-term, in 11 patients (21%), the stenting was continued for an intermediate period, and in 35 patients (67%), the long-term stenting was maintained for longer than 9 months. The longest period of postoperative stenting was 14 months.

Outcome

Current follow-up as of October 1996 is available for 86 of 87 surviving patients. The follow-up period for all patients ranges from 4 to 75 months (mean, 31.4 months; median, 28.5 months). At this time, 10 patients (11%) have not completed their course of treatment and have biliary stents in place. Three patients have undergone percutaneous biliary dilatation with their initial dilatation 4, 9, and 10 months ago. Seven patients not completing treatment have undergone biliary reconstruction and currently are 4, 5, 6, 7, 8, 8, and 9 months after the procedure. The only patient lost to follow-up was doing well when last seen as an outpatient 4 months after stent removal and 16 months after a hepaticojejunostomy.

The current status of the 25 patients who have completed therapy after balloon dilatation as their *initial* therapy has been excellent (N = 12) and good results (N = 4) in 16 patients, representing an overall success rate of 64% (Table 3). The actuarial success for balloon dilatation as an initial treatment is shown in Figure 3. The range of follow-up is from 4 to 64 months with a mean follow-up of 27.8 months and a median follow-up of 23

Table 3. OUTCOME FOLLOWING INITIAL TREATMENT OF MAJOR BILE DUCT INJURY*

	Balloon Dilatation	Surgical Reconstruction
Number	25	52
Outcome		
Success	16 (64%)†	48 (92%)
Excellent	12 (48%)‡	41 (79%)
Good	4 (16%)	7 (13%)
Failure	9 (36%)†	4 (8%)
Predictors of outcome (no. of failures/total patients)		
Previous repair	9/25	3/12
End-to-end ductal	4/10	2/8
Hepaticojejunostomy	5/15	1/4
None	—	1/40**
Presenting symptom		
Jaundice	1/9	3/21
Biliary leak	6/8§	2/27
Cholangitis	2/7	0/9
Bismuth class		
1 and 2	3/16	1/20
3, 4, 5	6/8‖	2/27
RHD	—	1/5
Interval to referral		
≤1 month	7/11	1/16
>1 month	2/14¶	3/36

RHD = right hepatic duct.
* Includes only 77 patients completing treatment.
† $p < 0.002$ *vs.* surgical reconstruction.
‡ $p < 0.01$ *vs.* surgical reconstruction.
§ $p < 0.05$ *vs.* jaundice/cholangitis.
‖ $p < 0.05$ *vs.* Bismuth 1 and 2.
¶ $p < 0.05$ *vs.* ≤1 month.
** $p < 0.05$ *vs.* previous repair.

months. There have been nine failures of percutaneous dilatation for a 36% failure rate. Factors potentially predicting outcome are listed in Table 3. In five of these patients, the original outside repair had been a hepaticojejunostomy, whereas in the four other failures, an end-to-end ductal anastomosis had been performed. Presentation with a bile leak, a Bismuth classification of level 3 injury or higher, and an interval to referral of <1 month appeared to be predictors of a poor outcome. The interval from initial dilatation to failure ranged from 4 to 17 months (mean, 8.2 months; median, 6 months). Eight of the nine patients subsequently have undergone surgical biliary reconstruction at Johns Hopkins. The ninth failure was managed by repeat percutaneous dilatation at a center closer to his home with excellent results.

The current status of the 52 patients completing therapy after surgical reconstruction as the initial management is an excellent outcome in 41 patients and good results in 7 patients for an overall success rate of 92% (48 of 52 patients) (Table 3). The actuarial success for surgical repair as an initial therapy is shown in Figure 3. The success rate for surgical repair was significantly better than for balloon dilatation ($p < 0.002$). The range of follow-up is from 4 to 75 months with a mean follow-up of 33.4 months and a median follow-up of 29 months. There have been four failures of surgical management occurring at 8, 13, 21, and 27 months. Factors potentially predicting outcome are listed in Table 3. Three of the four failures had undergone a repair before referral to Johns Hopkins. The Bismuth classification was level 2 in one patient and level 4 in two patients. The remaining patient had an injury that was an isolated transected right hepatic duct and had presented with a bile leak. Three of the four failures were managed by percutaneous dilatation with excellent or good results in all three patients with follow-up of 17, 22, and 39 months. The fourth patient underwent a revision of his hepaticojejunostomy and has had an excellent result at 22 months of follow-up.

The length of postoperative stenting was of intermediate length in two of the patients who did not respond to surgical repair and long-term in the remaining two patients. The length of stenting was not significant as a predictor of outcome.

As discussed above, all patients who failed their initial management with either balloon dilatation or surgical reconstruction currently are considered a treatment success after a second procedure. Therefore, of the 77 patients who have completed therapy, including both primary management and additional treatment for an unsuccessful initial result, a successful outcome has been achieved in 100% of patients. In 28 patients who completed therapy after balloon dilatation, performed as either initial therapy or as therapy after a failed hepaticojejunostomy performed at this institution, an overall success rate of 68% was seen (mean follow-up, 27.7 months; median follow-up, 22.5 months). Similarly, a total of 61 patients have

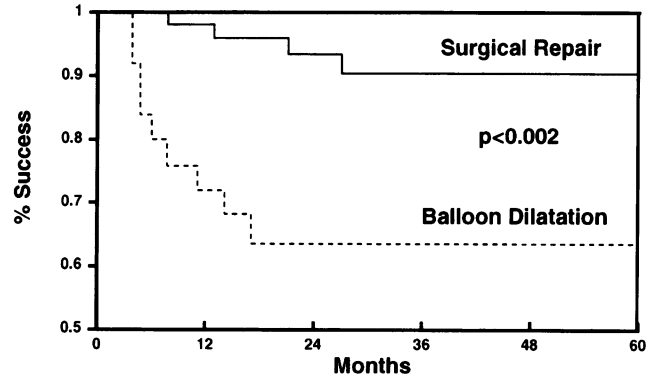

Figure 3. Actuarial success rate for surgical repair and balloon dilatation as the initial treatment for bile duct injuries after laparoscopic cholecystectomy. The difference is highly statistically significant ($p < 0.002$).

completed therapy after surgical reconstruction either as a primary therapy or after failed dilatation with a successful outcome in 93% (mean follow-up, 33.2 months; median follow-up, 29 months). The overall success rate associated with surgical repair was statistically better than that observed with percutaneous dilatation (<0.002).

DISCUSSION

Since its introduction in the late 1980s, laparoscopic cholecystectomy has gained widespread acceptance among surgeons and the public and has essentially replaced open cholecystectomy as the treatment of choice for symptomatic gallstones. Compared with open cholecystectomy, laparoscopic cholecystectomy is associated with less postoperative pain, a shorter hospital stay, earlier return to work, and a better cosmetic outcome.[28] Unfortunately, compared to open cholecystectomy, laparoscopic cholecystectomy appears to be associated with an increase in the incidence of bile duct injuries. Before the introduction of laparoscopic cholecystectomy, the incidence of major bile duct injury was considered to be 2 to 3 injuries per 1000 procedures.[13,29,30] Roslyn et al.[30] analyzed the results of more than 42,000 open cholecystectomies performed in the United States in 1989 and found the incidence of bile duct injury to be 0.2%. In a review by Strasberg et al.[13] of more than 25,500 open cholecystectomies reported in the literature since 1980, major bile duct injury was reported in 0.3% of patients.

The incidence of bile duct injury during laparoscopic cholecystectomy has varied from large single institution series without a single biliary injury[31–34] to surveys encompassing thousands of patients from multiple hospitals with the incidence of injury reported as high as 0.9%.[4–10,35] The review by Strasberg et al.[13] of more than 124,000 laparoscopic cholecystectomies reported in the literature found the incidence of major bile duct injury to be 0.5%. It had been hoped, as most surgeons passed through the "learning curve" of laparoscopic cholecystectomy, that the incidence of injury would decline. Unfortunately, a recent "steady-state" report of more than 10,000 cases at U.S. military institutions by Wherry and colleagues[10] has shown no significant improvement over the initial report from the same institutions.[9]

As experience in the management of laparoscopic bile duct injuries has been gained, the mechanisms of injury have been established. Misidentification of anatomy appears to be the most common cause of laparoscopic bile duct injury. The most common scenario, initially described by Davidoff et al.[11] at Duke as the "classic" injury, involves mistaking the common bile duct for the cystic duct. The structure then is clipped and divided. Further retraction of the gallbladder will lead to a second higher injury with division of the common hepatic duct often as it approaches the bifurcation. This second ductal injury often is described in the operative note as being a "second cystic duct" or "an accessory duct." In some cases, the right hepatic artery also is injured during this process. If the proximal hepatic duct is not secured adequately with clips, a bile leak develops with the patient presenting in the early postoperative period with bile ascites or peritonitis. This injury is particularly devastating in that a complete transection of the biliary tree virtually removes any possibility of nonoperative management by either endoscopic or transhepatic technique and mandates the need for surgical reconstruction of the biliary tree to establish biliary-enteric drainage. In a series also reported from Duke by Branum et al.,[16] this classic injury occurred in 24 (63%) of 38 patients. Other less common mechanisms of injury include a "tenting injury" in which the common bile duct is pulled laterally at the time of occlusion of the cystic duct and caught in the clip, thermal injuries due to injudicious use of cautery or laser, excessive application of clips to control bleeding in the area of the triangle of Calot, and, finally, injuries to an aberrant or low-inserting right hepatic duct.

Regardless of the nature of the injury, the majority of biliary injuries are not recognized during the initial laparoscopic cholecystectomy. In their initial series, Davidoff et al.[11] from Duke found that in all 12 patients with major bile duct injuries, the injury was not recognized at the time of laparoscopic cholecystectomy. In the current series, fewer than one third of injuries were recognized at the original operation, although in five of seven patients at our own institution, the injury was recognized and repaired successfully at the original laparoscopic procedure. The failure to recognize an injury at the time of laparoscopic cholecystectomy and the high incidence of bile leakage in the postoperative period with resultant sepsis and associated periportal inflammation can complicate greatly the management of these patients.

The management of laparoscopic bile duct injuries has been well defined by a number of authors.[1,2,11,14–23] We believe that a patient with a suspected major bile duct leak should not undergo immediate operation but rather be evaluated completely before operative management is considered. A computed tomogram scan is useful in showing the presence of an intraperitoneal bile leak by displaying either bile ascites or a "biloma." Endoscopic retrograde cholangiography usually is readily available to confirm the presence of an injury. However, in the classic injury involving bile duct transection, the retrograde cholangiogram will only show a "cutoff" of the common bile duct below the level of the cystic duct. It is essential, therefore, that percutaneous transhepatic cholangiography be performed to define the exact location and nature of the injury as well as to define the anatomy of the proximal biliary tree, which will be used for reconstruction. Percu-

taneous transhepatic biliary catheters should be placed to control the bile leak, and percutaneous drainage of the intraperitoneal bile collection should be performed as indicated. This management usually will result in immediate improvement of the patient. In many cases, this management will allow the patient to be discharged to home for a period of a few weeks before surgical repair to allow resolution of the inflammation and adhesions associated with the bile leak. The standard operation for reconstruction of a major bile duct injury after laparoscopic cholecystectomy is a Roux-en-Y hepaticojejunostomy. The transection of the bile duct and associated resection of a segment of the duct usually precludes any attempt at primary end-to-end ductal anastomosis.

Using this or a similar management course, a number of centers have reported excellent early results in the management of laparoscopic bile duct injuries.[1,2,11,14–23] In most series, surgical management has been necessary in the majority of cases. Selected patients, however, have been reported who have been managed successfully entirely by endoscopic or percutaneous technique.[18–23] Asbun et al.[2] at The Lahey Clinic reported their preliminary experience in the management of 15 repairs with a successful outcome in all patients at a median follow-up of 10 months.[2] In contrast, of the 38 patients with complex major bile duct injuries managed at the Duke Medical Center, 5 patients required reoperation and 1 patient required balloon dilatation for persistent or subsequent problems.[16] Long-term outcome is not available in either of these series.

Three other series stand out for both the number of patients treated and their analysis of results. Perhaps the best analysis of data from a large number of patients is that provided by Stewart and Way[36] who analyzed the treatment of 88 patients who sustained bile duct injuries during laparoscopic cholecystectomy. In this report, the records of 85 patients who underwent a total of 112 biliary repairs were reported. The series included 64 reparative operations performed by the primary surgeon or a surgeon of comparable experience as well as 46 surgical reconstructions performed on 45 patients by tertiary care biliary surgeons. Four factors determined the success or failure of treatment in their series. These factors were the performance of preoperative cholangiography, the choice of surgical repair, the details of the operative technique, and the experience of the surgeon performing the repair. The importance of preoperative delineation of the anatomy is defined clearly, because 96% of procedures in which cholangiograms were not obtained before surgery were unsuccessful and 69% of repairs were unsuccessful when the cholangiographic data were incomplete. When cholangiographic data were complete, the initial repair was successful in 84% of patients. The type of repair also was of significant importance in influencing outcome. A primary end-to-end ductal repair over a T-tube was unsuccessful in all of those patients in which a complete transection of the bile duct had taken place, whereas 63% of Roux-en-Y hepaticojejunostomies were successful. Dilatation and stenting was unsuccessful as a primary treatment in all 3 patients in whom it was performed and successful in only 7 (27%) of 26 patients in whom it was attempted after previous operative repair. Attempts at repair performed by the primary surgeon were successful in only 17% of cases and in no case was a secondary repair successful. In those patients in which the first repair was performed by a tertiary care biliary surgeon, a 94% success rate was obtained.

A multicenter report by Woods et al.[18] from the Virginia Mason Clinic in Seattle, Washington, the Lahey Clinic in Burlington, Massachusetts, and the Mayo Clinic in Rochester, Minnesota, have reported the management of 81 patients with biliary tract injuries occurring during laparoscopic cholecystectomy.[18] This series included 66 patients with major ductal strictures, leaks, or transections. In this report, a similar high rate of failure (94% for biliary-enteric bypass) was observed after repair outside of the referral center. Conversely, all patients managed by reoperation (N = 29) at the tertiary center and 10 of 11 patients managed by endoscopic stenting had a successful result. Unfortunately, in neither the series by Stewart and Way[36] or the multicenter report by Woods et al.[18] was long-term follow-up provided.

Perhaps the longest follow-up available after the management of major bile duct transections is reported by Bergman et al.[21] from the Netherlands in which 15 patients sustaining major bile duct injury were reconstructed with a Roux-en-Y hepaticojejunostomy. At a median follow-up of 25 months (range, 6–38 months) 5 (33%) of the 15 patients required subsequent transhepatic balloon dilatation or reconstruction with a secondary hepaticojejunostomy.

A number of series have provided excellent long-term results in the management of bile duct strictures occurring before the laparoscopic era.[26,37–42] In most series, successful outcomes are reported in 80% to 95% of patients. Whether the results of repair of bile duct strictures after open cholecystectomy are transferable directly to the patients sustaining laparoscopic bile duct injuries is unclear. It has been suggested that laparoscopic bile duct injuries may have a less satisfactory outcome because of both the more complex nature of many of the injuries and the frequent association with significant inflammation and fibrosis secondary to the bile leakage. Furthermore, the high percentage of failed operations performed before referral to a tertiary biliary tract surgical center may lead to a poorer outcome.

The results of the current analysis provide, for the first time, significant follow-up in a large number of patients

with laparoscopic bile duct injuries undergoing both surgical reconstruction and nonoperative percutaneous balloon dilatation. These patients represent a heterogeneous group of patients, including those in whom the injury took place at our own institution, patients who were referred before any attempt at repair, and patients referred after attempts at biliary reconstruction. In total, 54% of the patients referred from outside hospitals had undergone an attempt at repair before referral. Active ongoing biliary leak was present in 38% and sepsis due to cholangitis was present in 22% of patients at the time of referral to our institution. The patients referred to our center with injuries were all managed with combined radiologic and surgical management. Preoperative imaging of the biliary tree by way of the percutaneous transhepatic route and placement of biliary stents were performed in all patients. Subsequent management was based on the clinical scenario and cholangiographic appearance with patients selected accordingly for either primary management by radiologic balloon dilatation or surgical repair.

Follow-up to the present time was obtained by direct patient contact in 86 of 87 surviving patients and ranged from 4 to 75 months with a mean of 31.4 months and a median of 28.5 months. Primary nonoperative management with balloon dilatation was associated with an overall success rate of 64%. In contrast, primary surgical management with hepaticojejunostomy was associated with a success rate of 92%. Although this difference was statistically significant, we do not conclude that this study directly favors one treatment option over the other. Patients undergoing balloon dilatation all had undergone a previous attempt at repair, and in a number of the cases, the balloon dilatation option was aborted in favor of surgery before completion of a full treatment course. Fortunately, the 13 failures (9 dilatation failures and 4 surgical failures) were all salvaged by secondary management. Therefore, using combined surgical and radiologic management, 100% of patients have achieved a successful outcome at the time of this evaluation.

Although the follow-up in this series is substantial, continued surveillance and follow-up will be necessary. Pitt et al.[37] in their analysis of factors influencing the outcome after repair of postoperative bile duct strictures in the prelaparoscopic era have reported that only 68% of recurrent strictures will have developed by 3 years after repair. If this analysis, derived from open cholecystectomy data, can be applied to the current series, the long-term success rate of balloon dilatation would be approximately 50% and of surgical reconstruction would be 86%. These projected results are almost identical to those reported previously from this institution from the open cholecystectomy era.[26]

The small number of failures in this series does not allow indepth statistical analysis with respect to factors influencing outcome. Three of the four surgical failures did occur after a failed early repair at an outside institution, and two of the four patients required reconstruction to be performed above the level of the hepatic duct bifurcation. Our analysis would, however, suggest that patients presenting with an ongoing bile leak, referred at 1 month or earlier after injury, and patients with injuries located at the level of the hepatic duct bifurcation or higher are more likely to fail attempts at balloon dilatation.

The significance of delayed management of patients with laparoscopic bile duct injuries can be evidenced by the fact that there were two deaths in the series. In both patients, ongoing biliary leaks persisted despite two surgical interventions having been performed at the initial hospital for each patient. Both patients were older and had persistent sepsis and multisystem organ failure at the time of transfer. Despite achieving adequate percutaneous drainage of the biliary tree, as well as drainage of all potential foci of intra-abdominal sepsis, the patients died because of the advanced state of their disease despite maximal supportive care.

Finally, the results of this series, as well as those of previous reports,[18,36] would suggest that success rates in excess of 90% can be achieved at tertiary referral centers for complex biliary tract surgery. These results far exceed those available after repair of these injuries by less experienced surgeons,[18,36] although it could be argued that the true denominator is not known because successful repairs outside tertiary referral centers often go unreported. It would appear, however, as with other complex surgical procedures,[43,44] that major bile duct injuries can be managed best at centers with a high-volume experience.

In conclusion, the optimal management of patients with laparoscopic bile duct injury requires a multidisciplinary approach. Percutaneous transhepatic cholangiography to define the proximal anatomy and the placement of transhepatic biliary catheters to relieve biliary obstruction or control biliary leaks is the first step in management. The decision to proceed with percutaneous balloon dilatation *versus* operative management is determined by the nature and location of the injury and the clinical scenario. This study provides, for the first time, follow-up evaluation results in a significant number of patients undergoing both treatment regimens. With mean follow-ups in excess of $2\frac{1}{2}$ years, percutaneous balloon dilatation is associated with an overall success rate of 64% and biliary reconstruction with a Roux-en-Y hepaticojejunostomy is associated with an overall success rate of 92%. The combined surgical and radiologic management should result in a successful outcome after laparoscopic bile duct injuries in virtually all patients.

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Discussion

DR. WILLIAM C. MEYERS (Worcester, Massachusetts): Thank you, Dr. Cameron, Dr. Copeland, Members, and Guests. I agree with you, Dr. Cameron, that you've assembled the finest group of gastrointestinal surgeons in the country and the continent.