ANNALS OF SURGERY
Vol. 232, No. 3, 430–441

Postoperative Bile Duct Strictures: Management and Outcome in the 1990s

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Objective

To describe the management and outcome after surgical reconstruction of 156 patients with postoperative bile duct strictures managed in the 1990s.

Summary Background Data

The management of postoperative bile duct strictures and major bile duct injuries remains a challenge for even the most skilled biliary tract surgeon. The 1990s saw a dramatic increase in the incidence of bile duct strictures and injuries from the introduction and widespread use of laparoscopic cholecystectomy. Although the management of these injuries and short-term outcome have been reported, long-term follow-up is limited.

Methods

Data were collected prospectively on 156 patients treated at the Johns Hopkins Hospital with major bile duct injuries or postoperative bile duct strictures between January 1990 and December 1999. With the exception of bile duct injuries discovered and repaired during surgery, all patients underwent preoperative percutaneous transhepatic cholangiography and placement of transhepatic biliary catheters before surgical repair. Follow-up was conducted by medical record review or telephone interview during January 2000.

Results

Of the 156 patients undergoing surgical reconstruction, 142 had completed treatment with a mean follow-up of 57.5 months. Two patients died of reasons unrelated to biliary tract disease before the completion of treatment. Twelve patients (7.9%) had not completed treatment and still had biliary stents in place at the time of this report. Of patients who had completed treatment, 90.8% were considered to have a successful outcome without the need for follow-up invasive, diagnostic, or therapeutic interventional procedures. Patients with reconstruction after injury or stricture after laparoscopic cholecystectomy had a better overall outcome than patients whose postoperative stricture developed after other types of surgery. Presenting symptoms, number of stents, interval to referral, prior repair, and length of postoperative stenting were not significant predictors of outcome. Overall, a successful outcome, without the need for biliary stents, was obtained in 98% of patients, including those requiring a secondary procedure for recurrent stricture.

Conclusions

Major bile duct injuries and postoperative bile duct strictures remain a considerable surgical challenge. Management with preoperative cholangiography to delineate the anatomy and placement of percutaneous biliary catheters, followed by surgical reconstruction with a Roux-en-Y hepaticojejunostomy, is associated with a successful outcome in up to 98% of patients.

A stricture of the biliary tree can be one of the most difficult challenges that a surgeon can face. If unrecognized or managed improperly, life-threatening complications, such as biliary cirrhosis, portal hypertension, and cholangitis, can develop. The causes of benign bile duct strictures include inflammatory conditions such as chronic pancreatitis, biliary calculi, or biliary tract infection. Primary sclerosing cholangitis, a biliary tract disease of unknown cause, is also an important cause of bile duct strictures. However, the vast majority of benign bile duct strictures occur after surgery on the gallbladder or biliary tree.

The widespread use of laparoscopic cholecystectomy (LC) has dramatically increased the incidence of bile duct

Presented at the 120th Annual Meeting of the American Surgical Association, April 6–8, 2000, The Marriott Hotel, Philadelphia, Pennsylvania.
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Accepted for publication April 2000.

injuries and strictures associated with cholecystectomy.[1–5] The early management and short-term results after surgical management of these injuries were previously reported and appear excellent.[6–11] Long-term follow-up, however, is limited. The goal of this report is to describe the surgical management and provide outcome analysis for postoperative bile duct strictures and major bile duct injuries treated during the 1990s.

METHODS

Data were collected prospectively on all patients with a postoperative bile duct stricture or major bile duct injury treated with definitive reconstructive biliary surgery at the Johns Hopkins Hospital between January 1, 1990, and December 31, 1999. Major bile duct injuries included all transections or partial lacerations of the common hepatic duct, common bile duct, or major segmental ducts at the porta hepatis. Minor leaks from the cystic duct or gallbladder bed were excluded. Postoperative bile duct strictures included patients with strictures after open or laparoscopic cholecystectomy, common bile duct exploration, bile duct anastomosis, or injury to the biliary tree associated with another abdominal surgery or trauma. Patients with bile duct strictures from benign inflammatory processes such as chronic pancreatitis, gallstones, stenosis of the sphincter of Oddi, biliary tract infections, duodenal ulcers, or primary sclerosing cholangitis, as well as strictures from malignant causes, were excluded.

Clinical Management

Between January 1, 1990, and December 31, 1999, 196 patients with postoperative major bile duct injuries or strictures were treated at the Johns Hopkins Hospital. Forty patients (20%) were managed exclusively by radiographic techniques, leaving 156 patients who underwent biliary reconstruction; they form the basis of this report. In 11 patients (6%), the original surgery resulting in a bile duct injury or stricture was performed at the Johns Hopkins Hospital. The remaining 145 patients were referred after having their original surgery elsewhere. Patients referred from outside hospitals were initially managed with percutaneous transhepatic cholangiography and placement of percutaneous biliary catheters. When the injury or stricture was at or near the bifurcation, both the right and left hepatic ductal systems were accessed with transhepatic catheters. When major bile duct injuries included an ongoing biliary leak, percutaneous drainage of bile collections or ascites was performed as indicated. Surgical reconstruction was generally performed as an elective procedure. If there was evidence of ongoing bile leak or sepsis, a period of 4 to 6 weeks was generally allowed to pass, with the aim of reducing inflammation. In these cases, patients were discharged when clinically stable and were readmitted for definitive repair.

Surgical management in all cases consisted of a Roux-en-Y hepaticojejunostomy. The proximal hepatic duct was identified and mobilized in the cephalad direction. The preoperative biliary catheters were exchanged for larger soft Silastic stents. After stent placement, a Roux-en-Y jejunal limb, generally 40 to 60 cm long, was prepared for the biliary-enteric anastomosis. The anastomosis was performed as an end-to-side hepaticojejunostomy using interrupted absorbable sutures, with the transhepatic stent placed through the anastomosis. In cases involving more than one major duct, individual anastomoses were generally performed. The perianastomotic area was drained with closed-suction drains.

In the immediate postoperative period, the Silastic stents were connected to external drainage. On postoperative day 4 or 5, a cholangiogram was performed. If the study was satisfactory, the stents were internalized, and the hospital course was completed under the direction of the surgical staff.

Bile duct injuries that occurred at the Johns Hopkins Hospital and were recognized during surgery were repaired during the same procedure. In all but one instance, reconstruction with a Roux-en-Y hepaticojejunostomy was performed with intraoperative placement of a transhepatic stent. The final patient underwent repair at the initial operation with an end-to-end ductal anastomosis over a T tube. Patients at Johns Hopkins with injuries discovered in the immediate postoperative period were managed with percutaneous cholangiography and stent placement, as described for referred patients.

In the months after discharge, the Silastic stents were exchanged on a routine 2- to 3-month basis by the interventional radiology staff. The overall length of postoperative stenting was determined by the treating surgeon based on the location of injury, the patient's clinical course, and the follow-up cholangiographic studies. A biliary manometric perfusion study or a 2-week clinical trial with the stent positioned above the anastomotic site, or both, was often completed before stent removal.[12] The length of postoperative stenting, calculated from the date of definitive repair at Johns Hopkins until the date of final stent removal, was defined as short term ($<$4 months), intermediate (4–9 months), or long term ($>$9 months).

Data Collection

Data were collected prospectively on all patients, including demographics, clinical presentation, management at Johns Hopkins, and follow-up treatment. Treatment was considered complete at the time of removal of all biliary stents. The length of follow-up was calculated from the date of definitive surgical repair. Outcome assessments were completed through January 2000 on all patients based on direct patient contact or hospital records.

The patient's current status was rated subjectively as excellent if there were no symptoms attributable to the

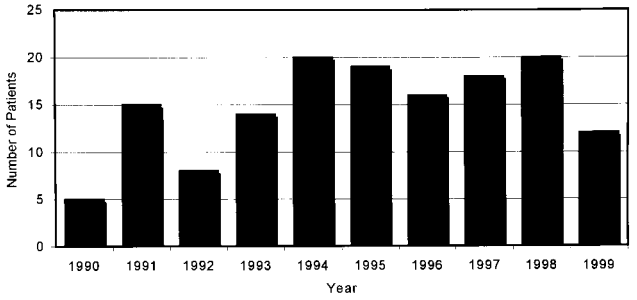

Figure 1. Year of presentation of postoperative bile duct strictures and major bile duct injuries for definitive surgical repair.

biliary tract injury or reconstruction, or good if mild symptoms, not requiring invasive investigation or treatment, were present. Patients classified as either excellent or good were considered to be treatment successes. Patients were considered to be treatment failures if an invasive investigational or therapeutic procedure, either radiologic or surgical, was necessary to treat ongoing symptoms or stricture recurrence. These definitions are consistent with earlier reports from our institution.[11,13]

Data Analysis

Comparisons between groups of patients were made using analysis of variance; chi-square statistics, including the Fisher exact test; and the Student *t* test as appropriate. Actuarial statistics were generated using the Mantel-Cox technique. Results are reported as mean ± standard deviation or median. Significance was accepted at the 5% level.

RESULTS

Patient Characteristics, Prior Management, and Presentation

A total of 156 patients underwent surgical reconstruction during the 1990s (Fig. 1). The mean age was 43 ± 15 years (range 15–83) (Fig. 2). One hundred twenty patients (77%) were female. The racial distribution in the series was 121 whites (77.6%), 23 blacks (14.7%), and 9 other ethnicity (5.7%).

One hundred forty-five patients (93%) had their original surgery at an outside institution. As summarized in Table 1, the original surgical procedure in these patients consisted of LC (109 patients, 75.2%), open cholecystectomy (27 patients, 18.6%), open cholecystectomy with common bile duct exploration (4 patients, 2.8%), or other abdominal surgery or trauma (5 patients, 3.4%) In 27 patients (18.6%), the biliary injury was discovered during the original surgery and the surgeon elected to proceed with immediate surgical reconstruction. There was no difference in the frequency with which the injury was recognized at the original surgery between patients undergoing LC (20/109, 18.4%) or open cholecystectomy (7/27, 25.9%). The immediate reconstructions included primary end-to-end bile duct repairs in 14 of the 27 patients (51.9%), hepatojejunostomy in 10 patients (37.0%), and choledochoduodenostomy in 3 patients (11.1%).

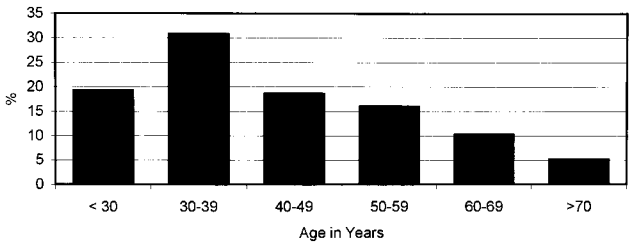

Figure 2. Age distribution of patients with postoperative bile duct strictures or major bile duct injuries for definitive surgical repair.

Thirty-three patients (28.0%) had their injury or stricture discovered after the original surgery and underwent surgical repair at an outside hospital before referral. Significantly fewer patients with injury recognized in the postoperative period after LC had an attempt at repair before referral than patients with open cholecystectomy or another operation (21.3% vs 48.3%, $P < .01$). Patients with original LC also had exploratory laparotomy without attempted repair before referral more often than after the other procedures (18.0% vs. 2.9%, $P < .05$).

In total, 60 patients (41.4%) had undergone previous attempts at surgical repair before referral. Eight patients (5.5%) had more than one attempt at repair before referral to Johns Hopkins. Patients with injury after LC were significantly more likely not to have had any attempt at repair before referral than non-LC patients (64.2% vs. 41.7%, $P < .05$). In contrast, patients who underwent open cholecystectomy with postoperative stricture or injury were more likely to have had a repair attempt (63.0% vs. 36.4%, $P < .01$) than other patients in the series.

The time interval for referral to Johns Hopkins from the patient's original surgery was 1 day to 44 years (median 3 months) for the 145 referred patients. The interval was less than 1 month in 57 patients (39.3%) and more than 12 months in 49 patients (33.8%). Twenty patients (13.8%) had undergone their original surgery before January 1990.

At the time of referral, 49 patients (31.4%) had an ongoing biliary leak in the form of biliary ascites, biliary peritonitis, biloma, abscess, or an external biliary fistula (Table 2). Another 42 patients (26.9%) had obstructive jaundice; 50 patients (32.1%) had cholangitis. Two patients (1.3%) were asymptomatic at the time of referral after percutaneous stenting but were referred for definitive surgical repair.

Patients referred after LC with or without prior repair were more likely to have a biliary leak (37.3% vs. 13.2%, $P < .01$) and less likely to have cholangitis (22.9% vs. 60.5%, $P < .001$) than other patients. The opposite was true of patients after open cholecystectomy with or without prior repair. These patients at referral generally had symptoms of cholangitis (63.0% vs. 25.6%, $P < .001$) and seldom had signs of a biliary leak (14.8% vs. 34.9%, $P < .05$).

Table 1. PRIOR MANAGEMENT OF 145 PATIENTS REFERRED WITH POSTOPERATIVE BILE DUCT STRICTURES

		Original Surgery			
	Total	Lap. Chole.	Open Chole.	Open Chole. With CBDE	Other or Trauma
Total	145 (100.0%)	109 (75.2%)	27 (18.6%)	4 (2.8%)	5 (3.4%)
Repair at initial surgery	27 (18.6%)	20 (18.3%)	7 (25.9%)	0 (0.0%)	0 (0.0%)
End-to-end ductal	14 (51.9%)	10 (50.0%)	4 (57.1%)		
Hepaticojejunostomy	10 (37.0%)	8 (40.0%)	2 (28.6%)		
Choledochoduodenostomy	3 (11.1%)	2 (10.0%)	1 (14.3%)		
Injury recognized in the postoperative period	118 (81.4%)	89 (81.7%)	20 (74.1%)	4 (100.0%)	5 (100.0%)
Attempt at repair before referral	33 (28.0%)	19 (21.3%)*	10 (50.0%)	1 (25.0%)	3 (60.0%)
End-to-end ductal	7 (21.2%)	7 (36.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hepaticojejunostomy	23 (69.7%)	12 (63.2%)	10 (100.0%)	1 (100.0%)	0 (0.0%)
Cholecystojejunostomy	3 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (100.0%)
Exploratory laparotomy without repair	17 (14.4%)	16 (18.0%)†	1 (5.0%)	0 (0.0%)	0 (0.0%)
No repair	85 (58.6%)	70 (64.2%)‡	10 (37.0%)	3 (75.0%)	2 (40.0%)
Total with repair	60 (41.4%)	39 (35.8%)	17 (63.0%)§	1 (25.0%)	3 (60.0%)
Total with more than one repair	8 (5.5%)	5 (4.6%)	3 (11.1%)	0 (0.0%)	0 (0.0%)

CBDE, common bile duct exploration.
* $P < .01$, laparoscopic cholecystectomy vs. others.
† $P < .05$, laparoscopic cholecystectomy vs. others.
‡ $P < .05$, laparoscopic cholecystectomy vs. others.
§ $P < .01$, open cholecystectomy vs. others.

Eleven patients (6%) underwent biliary reconstruction after sustaining an injury to their bile duct at Johns Hopkins. The original surgery at Johns Hopkins was LC in nine patients (82%) and another abdominal operation (hepatic resection, transhiatal esophagectomy) in two patients (18%). Nine patients (82%) had injuries that were recognized and repaired at their original surgery. In all but one of these patients (whose injury was repaired with a primary end-to-end ductal repair over a T tube), surgical reconstruction was accomplished by Roux-en-Y hepaticojejunostomy with placement of a transhepatic stent. In patient 10, jaundice developed in the early postoperative period after LC. Biliary transection was confirmed with percutaneous transhepatic cholangiography, and a percutaneous transhepatic stent was placed. The patient underwent definitive repair during the same hospital stay. In the final patient, obstructive jaundice developed 3 months after LC with an otherwise uncomplicated surgical and postoperative course. This patient underwent percutaneous transhepatic cholangiography that demonstrated a stricture. A percutaneous transhepatic stent was placed and a Roux-en-Y hepaticojejunostomy was performed.

Management

Among all 156 patients, the level of obstruction or injury to the biliary tree was classified as Bismuth 1 in 7 patients (4.5%), Bismuth 2 in 63 patients (40.4%), Bismuth 3 in 46 patients (29.5%), Bismuth 4 in 25 patients (16.0%), and Bismuth 5 in 7 patients (4.5%). An isolated right hepatic duct transection was found in eight patients (5.1%). Injuries associated with LC were more complex than those from other surgeries. The injuries associated with LC had a higher Bismuth level (Bismuth 3, 4, 5) or included an isolated hepatic duct injury in 74 patients (62.7%), whereas only 11 (40.7%) of the patients undergoing open cholecystectomy sustained such complex injuries ($P < .05$) (Fig. 3). Similarly, the complexity of injury from LC was also significantly greater than from all other procedures (62.7% vs. 31.6%, $P < .001$).

The number of transhepatic stents used ranged from one to four. One stent was used in 58 patients (37.2%), two stents in 89 patients (57.1%), three stents in 8 patients (5.1%), and four stents in 1 patient (0.6%). Patients having reconstruction after LC were less likely to have only one stent (32.2% vs. 52.6%, $P < .01$). In contrast, injury or stricture from other abdominal surgery or trauma was substantially more likely to require only one stent (85.7% vs. 34.9%, $P < .01$). The length of postoperative stenting was greater than 9 months in 89 patients (62.7%), 4 to 9 months in 30 patients (20.0%), and less than 4 months in 23 patients (16%).

Outcomes

There was one death in the postoperative period secondary to a pulmonary embolus, for a perioperative death rate of 0.6%. One patient died of advanced esophageal carcinoma before completing his treatment at 2 months after

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

		Original Surgery			
	Total	Lap. Chole.	Open Chole.	Open Chole. With CBDE	Other or Trauma
Total	156 (100.0%)	118 (75.6%)	27 (17.3%)	4 (2.6%)	7 (4.5%)
Presenting symptoms					
Jaundice	42 (26.9%)	34 (28.8%)	6 (22.2%)	0 (0.0%)	2 (28.6%)
Biliary leak	49 (31.4%)	44 (37.3%)*	4 (14.8%)†	1 (25.0%)	0 (0.0%)
Cholangitis	50 (32.1%)	27 (22.9%)‡	17 (63.0%)§	3 (75.0%)	3 (42.9%)
Asymptomatic after stenting	2 (1.3%)	2 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Recognized during surgery	13 (8.3%)	11 (9.3%)	0 (0.0%)	0 (0.0%)	2 (28.6%)
Level of obstruction					
Bismuth 1	7 (4.5%)	4 (3.4%)	3 (11.1%)	0 (0.0%)	0 (0.0%)
Bismuth 2	63 (40.4%)	40 (33.9%)	13 (48.1%)	4 (100.0%)	6 (85.7%)
Bismuth 3	46 (29.5%)	38 (32.2%)	8 (29.6%)	0 (0.0%)	0 (0.0%)
Bismuth 4	25 (16.0%)	21 (17.8%)	3 (11.1%)	0 (0.0%)	1 (14.3%)
Bismuth 5	7 (4.5%)	7 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Isolated IRHD	8 (5.1%)	8 (6.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Use of stents					
1	58 (37.2%)	38 (32.2%)¶	11 (40.7%)	3 (75.0%)	6 (85.7%)**
2	89 (57.1%)	71 (60.2%)	16 (59.3%)	1 (25.0%)	1 (14.3%)
3	8 (5.1%)	8 (6.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
4	1 (0.6%)	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

CBDE, common bile duct exploration; IRHD, isolated right hepatic duct.
* $P < .01$; laparoscopic cholecystectomy vs. others.
† $P < .05$; open cholecystectomy vs. others.
‡ $P < .0001$; laparoscopic cholecystectomy vs. others.
§ $P < .0002$; open cholecystectomy vs. others.
¶ $P < .01$; laparoscopic cholecystectomy vs. others.
** $P < .01$; other abdominal surgery or trauma vs. others.

surgery. His biliary tract injury did not contribute to his death.

Excluding the two patients who died before completion of treatment, follow-up was obtained in 153 of 154 patients through January 2000. Eleven patients (7.1%) remained stented at that time and had therefore not completed treatment. The lengths of stenting in these patients were 14, 11, 8, 7, 6, 6, 4, 4, 4, 1, and 1 month after reconstruction. Five patients (3.2%) died during the follow-up period unrelated to biliary tract disease. All were considered to have had a successful outcome. Follow-up for these patients was extended up to the time of final contact with each patient. The length of follow-up for patients completing treatment (n = 142) was 11 to 119 months (mean 57.5 months, median 54.7 months). The only patient lost to follow-up was doing well 3 months after her surgery. This patient returned to her country of residence and received all her remaining treatment abroad. Without follow-up to the date of stent removal, this patient is considered not to have completed treatment.

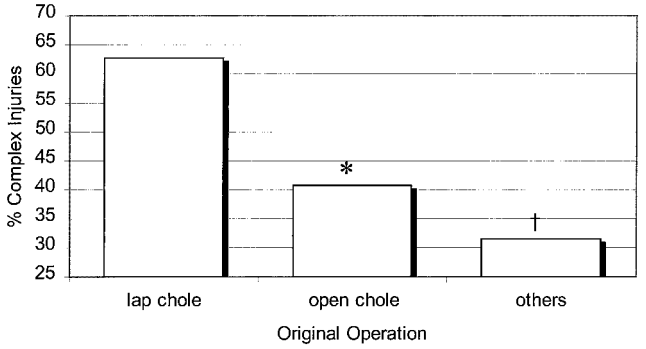

Figure 3. The complexity of bile duct injury. Patients undergoing original laparoscopic cholecystectomy had a significantly higher percentage of complex injuries (Bismuth 3, 4, 5 or isolated hepatic duct) than patients undergoing open cholecystectomy ($P < .05$) or all other surgical procedures ($P < .001$).

The overall outcome of 142 patients with surgical reconstruction who completed treatment was excellent in 101 patients (71.1%) and good in 28 (19.7%). This represents an overall success rate of 90.8% (Table 3). The actuarial success for different initial surgeries is depicted in Figure 4. The success rate for patients initially undergoing abdominal surgery other than cholecystectomy or trauma was substantially worse than for those who initially underwent LC, open cholecystectomy, or open cholecystectomy with common bile duct exploration (33.3% vs. 92.9%, $P < .001$). Moreover, the overall success rate associated with injury during

Table 3. OUTCOME OF DEFINITIVE SURGICAL TREATMENT OF POSTOPERATIVE BILE DUCT STRICTURES OR MAJOR INJURIES

		Original Surgery			
	Total	Lap. Chole.	Open Chole.	Open Chole. With CBDE	Other or Trauma
Total	142 (100.0%)	107 (75.4%)	25 (17.6%)	4 (2.8%)	6 (4.2%)
Outcome					
Success	129 (90.8%)	101 (94.4%)*	23 (92.0%)	3 (75.0%)	2 (33.3%)†
Excellent	101 (71.1%)	83 (77.6%)‡	13 (52.0%)§	3 (75.0%)	2 (33.3%)¶
Good	28 (19.7%)	18 (16.8%)	10 (40.0%)	0 (0.0%)	0 (0.0%)
Failure	13 (9.2%)	6 (5.6%)*	2 (8.0%)	1 (25.0%)	4 (66.7%)†

CBDE, common bile duct exploration.
* $P < .05$; laparoscopic cholecystectomy vs. others.
† $P < .0001$; other abdominal operation or trauma vs. others.
‡ $P < .01$; laparoscopic cholecystectomy vs. others.
§ $P < .05$; open cholecystectomy vs. others.
¶ $P < .0001$; other abdominal operation or trauma vs. others.

LC in our series was significantly better than that observed in patients referred after all other original surgeries (94.4% vs. 80.0%, $P < .05$).

There were 13 failures (9.2%) after surgical reconstruction at our institution, occurring at 1, 2, 8, 12, 12, 13, 14, 21, 25, 26, 56, 59, and 86 months after completing treatment and stent removal (mean 25.8 months, median 14 months). Factors potentially predicting outcome are listed in Table 4. Five of the 13 patients in whom reconstruction failed (38.5%) had undergone a repair before referral to Johns Hopkins. Outcomes were analyzed with respect to the presence of previous repair, symptoms, level of obstruction, number of stents, length of stenting, and interval to referral. Other than the type of original surgery referred to above, there was no significant difference with respect to any of these factors.

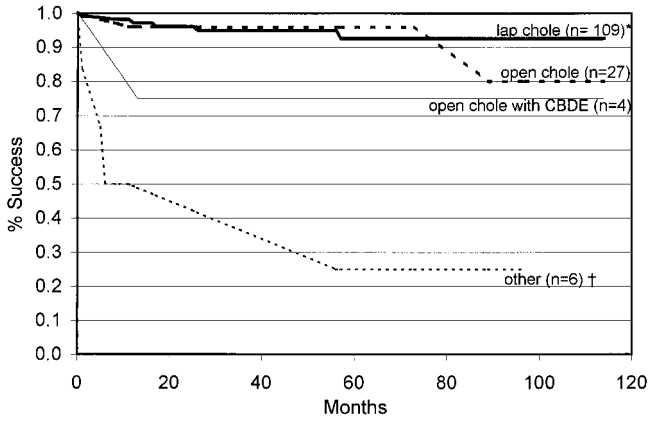

Figure 4. Actuarial success of surgical repair in patients with postoperative bile duct injury or stricture after various original surgeries. The success rate for patients undergoing laparoscopic cholecystectomy was significantly better (*$P < .05$) than for patients undergoing all other original surgeries. The success rate for patients originally undergoing other abdominal surgeries or trauma was significantly worse ($P < .002$) than patients undergoing all other original procedures. (CBDE, common bile duct exploration.)

Of the 13 patients with failed reconstruction, 1 patient underwent a surgical revision of his hepaticojejunostomy at 25 months and had an excellent result at 85 months of total follow-up. The remaining 12 patients were managed by percutaneous dilatation, achieving excellent or good results in 9 patients with follow-up of 19, 26, 38, 62, 74, 76, 85, 99, and 118 months after their original reconstruction. Three patients required long-term biliary stents to prevent symptoms of biliary obstruction or cholangitis at 30, 37, and 67 months of follow-up. Thus, of the 142 patients who completed therapy, including subsequent interventional procedures, a successful outcome was achieved in 139 patients (97.9%).

DISCUSSION

A postoperative bile duct stricture is a serious and potentially devastating complication that usually occurs as a result of a technical mishap associated with cholecystectomy. In the current environment of outpatient or short-stay LC, the occurrence of a major bile duct injury can be an overwhelming emotional as well as financial and healthcare disaster.[14] During the past decade, the incidence and mechanisms of such injuries have been well defined.[1–6,15] Also, several series have described the successful management of bile duct injuries by surgical, radiologic, and endoscopic techniques.[6–11,15–19] The results of long-term follow-up, however, after management of bile duct injuries and strictures in the era of LC are limited.

Bile duct injuries occurred with cholecystectomy long before the introduction of LC. The incidence of major bile duct injury in a series of more than 42,000 open cholecystectomies performed in the United States analyzed by

Table 4. FACTORS PREDICTING OUTCOME AFTER SURGICAL REPAIR OF POSTOPERATIVE BILE DUCT STRICTURES OR MAJOR INJURIES

Predictors of Outcome	Failure/Total (%)	P
Total	13/142 (9.2%)	
No previous repair	8/83 (9.6%)	NS
Previous repair	5/59 (8.5%)	NS
End-to-end ductal	1/20 (5.0%)	
Hepaticojejunostomy	3/33 (9.1%)	
Choledochoduodenostomy	0/3 (0.0%)	
Cholecystojejunostomy	1/3 (33.3%)	
Presenting symptoms		NS
Jaundice	3/39 (7.7%)	
Bile leak	3/45 (6.7%)	
Cholangitis	6/48 (12.5%)	
Asymptomatic after stenting	0/2 (0.0%)	
Recognized during surgery	1/8 (12.5%)	NS
Interval to referral		NS
<1 month	2/48 (4.2%)	
1–12 months	3/34 (8.8%)	
>12 months	7/49 (14.3%)	
Level of obstruction		NS
Bismuth 1 and 2	8/64 (12.5%)	
Bismuth 3, 4, and 5	4/70 (5.7%)	
IRHD	1/8 (12.5%)	
Use of stents		NS
1	7/55 (12.7%)	
2	6/79 (7.6%)	
3	0/7 (0.0%)	
4	0/1 (0.0%)	
Length of stenting		NS
Short (0–4 months)	0/23 (0.0%)	
Intermediate (4–9 months)	3/30 (10.0%)	
Long (>9 months)	10/89 (11.2%)	

IRHD, isolated right hepatic duct.

Roslyn et al[20] was found to be 0.2%. In a review by Strasberg et al[5] of more than 25,500 open cholecystectomies reported in the literature since 1980, major bile duct injuries were reported in 0.3% of patients. Since the introduction of LC, however, the incidence of major bile duct injuries has increased. Surveys encompassing thousands of patients from multiple hospitals have demonstrated a bile duct injury rate for LC of 0.4% to 0.6%.[1–5,21] It had been hoped, as most surgeons passed through the LC learning curve, that the incidence of injury would decline. Unfortunately, an analysis by Wherry et al[4] of more than 10,000 LCs performed at United States military institutions after reaching a "steady state" in the procedure showed no significant improvement over an initial report from the same institutions.[3] Similarly, the results of a nationwide audit in New Zealand demonstrated that despite increasing experience with LC, the incidence of iatrogenic bile duct injury remained stable.[22] Therefore, we can assume that bile duct strictures and injuries will continue to be a problem well into the new millennium.

Although the short-term consequences of major bile duct injury and stricture are significant,[14] it is the long-term outcome after repair that serves as the primary determinant of the successful treatment of this problem. It was well established in the pre-LC era that excellent long-term results could be obtained in tertiary-care centers specializing in the management of these problems.[13,23–28] In most series, successful outcomes were reported in 80% to 95% of patients, with follow-up usually in excess of 5 years. Whether the excellent results after the surgical management of bile duct strictures associated with open cholecystectomy can be extrapolated to patients sustaining bile duct injuries during LC has yet to be determined. Some have suggested that the mechanism of bile duct injury during LC, the complex nature of many of these injuries, and the frequent association with significant inflammation and fibrosis secondary to sustained, unrecognized bile leakage may result in poorer long-term results.[5,6,29,30] Further, the high percentage of these patients who have undergone unsuccessful surgery, often performed by the primary laparoscopic surgeon, may lead to a poorer outcome.

Evidence for the latter hypothesis was provided by the analysis performed by Stewart and Way,[31] who analyzed the records of 85 patients who underwent a total of 112 biliary repairs. The series included 64 bile duct injury repairs 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: the performance of preoperative cholangiography, the choice of surgical repair, the details of the surgical repair, and the experience of the surgeon performing the repair. The importance of preoperative delineation of anatomy was defined clearly: 96% of procedures in which cholangiograms were not obtained before surgery were unsuccessful, and 69% of repairs were not successful when the cholangiographic data were incomplete. When cholangiographic data were complete, the initial repair was successful in 84% of patients. The type of repair was also of significant importance in influencing outcome. A primary end-to-end ductal repair over a T tube was unsuccessful in all patients in whom a complete transection of the bile duct had taken place, whereas 63% of Roux-en-Y hepaticojejunostomies were successful. Attempts at repair by the primary surgeon were successful in only 17% of cases, and in no patient was a secondary repair by the primary surgeon successful. If the first repair was performed by a tertiary-care biliary surgeon, the success rate was 94%.

Despite these concerns, a significant body of data with short-term follow-up is available suggesting that the outcomes of surgical treatment of bile duct injuries or strictures associated with LC are likely to be comparable with those from earlier series. A 1997 report from our institution reported on the management and outcome of 89 patients with a major laparoscopic bile duct injury. Both surgical reconstruction and balloon dilatation were used, as indicated by

the clinical presentation and cholangiographic findings. Evaluation of 52 patients completing treatment after surgical reconstruction showed a success rate of 92%. The success rate for 25 patients completing treatment with balloon dilatation was 64%. However, the mean length of follow-up in that series was only 33.4 months in the surgical group.

The current series adds to the body of literature supporting the conclusion that outcomes of surgical reconstruction of major bile duct injuries and strictures remain excellent, even in the era of LC. This study comprised 156 patients managed at our institution with surgical reconstruction during the 1990s. All patients were initially managed with percutaneous transhepatic cholangiography and placement of percutaneous biliary catheters. Percutaneous cholangiography is essential in defining the anatomy of the proximal extrahepatic bile ducts to be used in reconstruction. The use of percutaneous biliary catheters not only allows immediate control of sepsis or leaks associated with the injury, but also facilitates surgical reconstruction.

The overall success rate in this series of all 142 patients who completed treatment after surgical reconstruction is 90.8%. When patients undergoing biliary reconstruction for injuries or strictures associated with LC were compared with those with injuries from open cholecystectomy, open cholecystectomy with bile duct exploration, or other abdominal operations or trauma, the overall success rate was significantly better (94.4% for LC vs. 80.0% for other procedures). This is despite the fact that the injuries associated with LC tended to be more complex, with a higher Bismuth classification (Bismuth 3.45), and a greater incidence of bile leak. The length of follow-up in the current series has been extended from our past report and now approaches a mean of almost 5 years (57.5 months).

Analysis of the outcomes of these patients suggests that the presence of a previous repair, symptoms such as cholangitis, jaundice, or biliary leak, the level of obstruction, the number of stents necessary, the length of stenting, and the interval from the initial surgery to eventual referral did not influence the long-term outcome. Further, in the 12 patients in whom initial surgical reconstruction was a failure (9.2%), management with percutaneous balloon dilatation was successful in 9. Therefore, the overall success rate in this series approaches 98%.

These results should not be interpreted to mean that repair of bile duct injuries is no longer a significant clinical problem. The cost of management of these patients can be substantial.[14] Further, these results were obtained at a tertiary center with a primary focus on complex pancreatic and hepatobiliary surgery. These results may, therefore, reflect our substantial experience in the management of these patients and may not be achievable at other hospitals. A recent analysis of complex, high-risk gastrointestinal surgical procedures performed in Maryland, based on publicly available statewide discharge data, demonstrated that increased hospital experience was associated with a marked decrease in the hospital death rate, shorter lengths of stay, and lower hospital charges.[32] Although long-term outcomes were not available from that analysis, it seems likely that successful long-term results may also be observed with increased surgical experience. The importance of having a tertiary biliary tract surgeon perform the biliary reconstruction was also demonstrated in the analysis by Stewart and Way.[31]

Another analysis from our institution has demonstrated improvement in hospital outcomes associated with implementation of a clinical pathway.[33] In this analysis, patients undergoing hepaticojejunostomy for either malignant or benign obstruction were compared during two periods. In the first period, the patients were managed according to standard surgical management and surgeon preference. During the second period, a clinical pathway was implemented to standardize treatment, in hopes of improving outcomes. Analysis demonstrated that total length of stay, hospital charges, and hospital death rate were all reduced after the clinical pathway was implemented. Although these results also reflect only short-term outcomes, similar standard approaches applied to patient management after the initial hospital stay may be useful in optimizing long-term results.[12]

In conclusion, the optimal management of patients with major bile duct injuries and strictures in the current era remains surgical reconstruction. The first step in management is percutaneous transhepatic cholangiography to define the proximal bile duct anatomy and the placement of transhepatic biliary catheters to relieve obstruction or control biliary leaks. Surgical reconstruction with the Roux-en-Y hepaticojejunostomy is associated with an overall success rate of more than 90%, with follow-up approaching 5 years. If initial surgical management fails, secondary therapy, usually with balloon dilatation, results in a successful outcome in virtually all patients. Finally, these data appear to support the concept of regionalization of care of patients with major bile duct injuries to centers with significant surgical experience and institutional expertise in hopes of improving short-term and long-term outcomes.

Acknowledgments

The authors thank the surgical house staff and the surgical nurses of the Johns Hopkins Hospital for their skill and devotion; the institution's interventional radiologists for their expertise and technical abilities; and Lori E. Barrick for her assistance in preparing the manuscript.

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Discussion

DR. LAWRENCE W. WAY (San Francisco, California): This report shows that the challenging technical problems posed by bile duct injuries can be successfully handled by surgeons thoroughly experienced in complex hepatobiliary surgery. But what are the keys to success? Dr. Lillemoe described his management protocol, and other articles such as one we wrote several years ago (*Arch Surg* 1995;130:1123), spell out the avoidable factors that contribute to a poor surgical result. Nevertheless, it is not really possible to relate verbally the technical nuances on which operative success ultimately hinges. That consists of so-called "procedural knowledge," learned and displayed primarily in the operating room—in the performance itself. This is why operative surgery cannot be taught primarily through books or lectures; why the essence of success in complex operations is inevitably missing in articles on surgical technique; and why the good results in a series like this cannot usually matched by surgeons inexperienced in this kind of work, even though they may possess a similar amount of native technical ability.

I would like to ask the authors about the timing of the reparative operation. In my opinion, the ideal is to operate when the anatomic diagnosis has been made and the patient has been prepared—preferably within days of the index operation, before the inflammatory reaction is fully developed or infection can set in. Further delay would be indicated principally to control established infection by percutaneously draining the bile duct or a hilar collection. One still hears the old, outdated recommendation that an obstructed bile duct should be left as such for a while in order to dilate, but dilatation is an uncommon outcome of that tactic, which is potentially quite dangerous.

Thus, my formula is to operate when the patient is stable and free of infection, which may be within a few days but is rarely more than a few weeks. I noted that you mentioned timing of surgery in the manuscript, and I wonder whether you would expand on your views?

PRESENTER DR. KEITH D. LILLEMOE (Baltimore, Maryland): Dr. Way has really pointed out an important element of patient management. But really the timing of repair depends on how a patient presents. In a patient who has undergone a laparoscopic cholecys-

tectomy in which the injury was not recognized at the original operation and develops a bile leak, we feel strongly that percutaneous transhepatic cholangiography and stent placement should be performed to control the bile leak. A period of time is then allowed for the patient to recover from the local inflammation associated with the bile leak. Usually, even without placement of a percutaneous drain, biliary stenting can control the bile leak. The patient's sepsis and peritonitis will resolve and the patient will return to a state of relative wellbeing. We then usually time the operation within 2 to 3 weeks after gaining control of the fistula.

In patients who had a laparoscopic cholecystectomy in which there is no bile leak and the duct is simply clipped off, or if the leak is controlled with an intraoperatively placed drain, we will agree with you that early operation is appropriate. We do not feel that there is any advantage to allowing the system to dilate.

DR. WILLIAM C. MEYERS (Worcester, Massachusetts): Dr. Lillemoe and colleagues have just provided us with the best long-term data to date on the outcomes of patients with laparoscopic and other bile duct injuries after repair at a center of excellence. The excellent results are important documentation of how to manage these patients properly and what to advise patients, physicians, and others with respect to anticipated long-term outcomes.

Several of the authors' points deserve special emphasis: the importance of preoperative transhepatic mapping of the extent of injury (it is usually naive to think otherwise); the importance of the Roux-en-Y technique even when a primary repair seems achievable; and third, the excellent results to be expected even after multiple previous attempts at repair.

We have seen similar results in 40 laparoscopic bile duct-injured patients repaired before 1990 and now followed compulsively for over 10 years. All 40 patients have been followed with ultrasounds, liver function tests, as well as reported symptoms. On the basis of this experience, I have several questions about your series.

First, we have noticed a correlation of vague symptoms despite normal tests, with the filing of lawsuits, as well as resolution of these symptoms after resolution of the legal claims. Can you comment on any medicolegal influence you might have noticed on the outcomes of your patients?

Second, why the better outcomes with lap-chole repairs as opposed to the other repairs? Is this a function of your better expertise? These excellent results seem puzzling since lap-chole injuries are often higher and more complex than the others.

Third, we have had to perform a number of liver resections for particularly high biliary injuries. Have you had to do this?

Finally, what about the 37 patients managed exclusively by radiologic methods? Most of those type patients in our series ended up coming to surgery. What about your series with respect to this?

DR. LILLEMOE: Dr. Meyers asked about the patient's symptoms with respect to legal action by the patient. Obviously, we are all aware that a lot of these patients do end up in some form of litigation and many of them may try to extend their period of pain and suffering at least until resolution. We do not have data available concerning the frequency of lawsuits in our patients so we cannot correlate lawsuits with symptoms. We are about to perform a quality of life survey of these patients to really look at outcomes with respect to symptoms and long-term problems that they may have—essentially how this injury has affected their life. Hopefully in that questionnaire we will be able to correlate the existence of legal action with symptoms.

Why were the results after laparoscopic cholecystectomy injury better than open cholecystectomy? As you noted, despite the fact that laparoscopic cholecystectomy injuries were more complex, with a higher probability of bile leak and a higher level of injury, there really was no difference between the two types of cholecystectomy with respect to outcome. Furthermore, when you compared lap-chole patients with all other types of injuries, the results were significantly better. I do think that some patients with laparoscopic cholecystectomy injury are easier to take care of, particularly if the injury is at a lower Bismuth level and the injury is referred early before the development of a bile leak and associated inflammation takes place. On the other hand, high injuries, at or above the bifurcation, require careful, meticulous technique, and perhaps we have gotten better over the last few years as we have seen more of these injuries.

We have not needed to perform a liver resection in any of these patients. We all recognize that sometimes the right hepatic artery can be injured during the course of the initial operation, but we have had no cases where any of the liver parenchyma has needed to be resected.

With respect to balloon dilatation, a few years ago at the Southern Surgical Association, we presented our initial experience with laparoscopic bile duct injuries and reported a 62% success rate in a limited 2- to 3-year follow-up. We have recently completed another analysis of those 37 patients that you referred to who were managed nonoperatively. The results still continue to show a better than 50% success rate with the mean length of follow-up increased to about 5 years. As you have noted, though, some of these patients will eventually require surgical reconstruction.

Obviously for any patient to be a candidate for balloon dilatation, biliary enteric continuity must be present. That means they have to have had some form of an anastomosis, either an end-to-end repair or a hepaticojejunostomy, performed prior to referral. As you can see, in our series we have had 12 failures; nine of those patients have had a successful result from balloon dilatation. So we would not rule out this form of management in appropriately selected patients.

DR. JOHN TERBLANCHE (Cape Town, South Africa): Two anatomical comments. This (slide) is to remind the audience of John Northover's work of some 2 decades ago (*Br J Surg* 1979;66:378–384). He demonstrated the excellent blood supply to the bile duct above in the liver and below in the pancreas. His important finding was the tenuous blood supply to the supraduodenal bile duct from tiny 9 o'clock and 3 o'clock arteries that can so easily be damaged. The point to make is that prevention is the best form of treatment.

The second anatomical point is one that I learned from Bernard Launois of Rennes in France. In performing liver resections, the use of his posterior intrahepatic approach to the bile ducts is helpful (*Surg Gynecol Obstet* 1992;74:155–158). I have found that in bile duct stricture repair with a high lesion, approaching it using a similar approach has made it much easier to access the bile ducts intrahepatically. I wonder whether you have used this approach? It certainly has helped me.

My other question relates to stents. It is not clear to me why you use postoperative stents when you have performed a satisfactory anastomosis?

DR. LILLEMOE: I would like to thank Dr. Terblanche and acknowledge his contributions. I have used that slide in every chapter I have ever written about bile duct strictures.

We have not needed to use the intrahepatic approach. I know there are a number of people who strongly advocate the Hepp-Couinaud or segment 4 approach, but we still find that even in those patients who have had previous reconstruction, with meticulous millimeter-by-millimeter dissection we can get an adequate length of duct to perform a mucosa-to-mucosa anastomosis. We do find that preoperatively placed stents facilitate that dissection by allowing us to more easily mobilize the duct in a proximal fashion.

In terms of the use of postoperative stents, we obviously like the stents in the immediate postoperative period to control any biliary leaks that might take place. The length of postoperative stenting is quite variable. We really like to see what the anastamosis looks like postoperatively with a good overwire cholangiogram. We also use supplemental information provided by the biliary manometric flow studies or a clinical trial before we remove these stents.

You can ask Dr. Cameron why some of our group wait a year to take the stents out. He has a great story, but in general we feel that the stents are helpful during that period of time in which maximal healing and fibrosis takes place. Although they are a pain for some patients, most tolerate them pretty well.

DR. JOHN L. CAMERON (Baltimore, Maryland): Briefly, the first patient I repaired with a transhepatic biliary stent was in 1969, and I didn't know how long to leave the stent in. The patient disappeared and ended up in Baltimore City Jail. At 1 year, a prison guard looked at the stent and said, "What is this thing?" The patient didn't answer quickly, so the guard pulled it out. That patient did well subsequently, so I figured the prison guard must have known something. So we have used 12 months for many years after that as the length of postoperative stenting.

DR. ALAN G. JOHNSON (Sheffield, United Kingdom): I am interested in your use of stents preoperatively and postoperatively. Preoperatively, do you put the stent across the stricture or do you rely on draining above the stricture? We would prefer not to put a stent through the stricture if we are going to operate quite soon.

Postoperatively we try not to use a stent at all if there is a good mucosal suture, and I am surprised that you use them routinely. But I wonder if it depends on the time of repair—if the fibrosis has already matured, a stent is unnecessary, but a stent may be needed if active inflammation is still present at the time of the anastomosis. This may relate to how long it has been since the damage occurred.

Finally, have you costed this complication? We have estimated that in the U.K. National Health Service, £500 ($750) has to be added to the cost of every cholecystectomy to pay for the treatment and litigation costs of bile duct damage—that is 50% on top of the cost of the primary operation.

DR. LILLEMOE: With respect to where we leave the stents preoperatively, initially we try to get the stent into the biliary tree above the site of transection to totally direct the bile flow to the outside, so that the leak will be controlled and the patient's peritonitis and sepsis will resolve.

However, before the patient is taken to the operating room we will make sure that the radiologist pushes that stent below the level of the transection into the subhepatic space. This makes it so much easier to identify the transected duct by finding the plastic stent extending out into the free space.

We use stents in every patient regardless of the timing of the reconstruction. But again, I realize there are excellent results reported with short-term or even no stenting. This is simply our institutional philosophy, and we have become very comfortable with it.

In terms of the costs, we have looked at the costs of these injuries in a prior report. These injuries can be significant additions to patients' short-term medical expenses. But hopefully most of these patients are not going to fall into the situation where they require repeated treatments, or develop long-term problems which may even require liver transplantation, which has been suggested by some individuals.

DR. CARLOS A. PELLEGRINI (Seattle, Washington): Dr. Lillemoe, obviously your data and the flavor of the discussion today indicate that the outcome is heavily dependent on the experience of the team caring for the patient with this kind of injury. Could you outline briefly what would be your advice for the average surgeon who, while doing a laparoscopic cholecystectomy, notices that he or she has transected the bile duct high up? What should that individual do? How should the patient be managed?

DR. LILLEMOE: Unfortunately, most data—including Dr. Meyers' data and our previous report—show that only about 20% to 25% of laparoscopic cholecystectomy injuries are recognized at the time of the original operation.

I have been faced with the question you ask, being called by a surgeon in the operating room who has cut the duct and has not yet opened the patient, and calls to ask me what to do. First, if you know what to do or if you have someone immediately available who knows how to do a good reconstruction, the best time to fix it is at that time. Although we are not proud of it, we have had a good success in fixing bile duct injuries occurring at our institution that were recognized at the initial operation.

If the surgeon does not feel comfortable or does not feel that he or she has the technical ability to repair the injury, I urge them to place some form of a catheter, like a catheter that would be used for an intraoperative cholangiogram, into the transsected duct, and place a clip across it so that you get a controlled fistula. Then place a closed suction drain in the area and wake the patient up, explain the situation to them, and then transfer the patient to us the next morning. The biliary catheter can be used by our interventional radiologists to perform a cholangiogram, and will facilitate percutaneous access. The patient can then be taken to the operating room within a few days, have the construction done without having to go through all the problems of bile peritonitis that might have otherwise been encountered.

DR. JOHN G. HUNTER (Atlanta, Georgia): Dr. Lillemoe, I always attributed your superb results to a policy of waiting until the inflammatory response had resolved before repairing bile duct injuries, yet I heard today that you often repair biliary injuries immediately. Did any of the 12 patients that developed anastomotic strictures undergo immediate repair?

DR. LILLEMOE: I really don't have available data looking at the relationship between outcome and the timing of repair. I should clarify for Dr. Hunter that most patients are not taken to the operating room immediately. Certainly in patients with a bile leak,

it takes a week or so to really control the leak, so allowing time for recovery, most injuries associated with a leak are delayed for 4 to 6 weeks before they have their repair. It is really only in the situation when there is no bile leak or it is well-controlled with an operatively placed drain that we operate immediately.

DR. GORAN B. KLINTMALM (Dallas, Texas): Taking a cue from liver transplantation, I have for the last several years put patients like these on a small dose of steroids postreconstruction for 3 months, trying to minimize any possible fibrosis. I just wonder if you had any comments or thoughts about that.

DR. LILLEMOE: We have not used steroids to try to decrease the inflammatory response in any patient. Nor do we have any data on patients who may have been on steroids for another reason. So I really can't comment based on any data to support their use.