ENDOSCOPY

Assessment of Need for Repeat ERCP During Biliary Stent Removal After Clinical Resolution of Postcholecystectomy Bile Leak

Nayantara Coelho-Prabhu, MD[1] and Todd H. Baron, MD, FASGE[1]

OBJECTIVES: **In patients who have undergone endoscopic retrograde cholangiopancreatography (ERCP) with biliary stent placement for postcholecystectomy bile leak there is limited evidence to support the repeat ERCP at the time of stent removal. Esophagogastroduodenoscopy (EGD) with biliary stent removal may suffice. The aim of this study was to describe the clinical course of patients who underwent biliary stent placement for a postcholecystectomy bile leak and determine whether repeat ERCP is necessary.**

METHODS: **We identified all adult patients who underwent biliary stent placement for postcholecystectomy bile leak from 1 January 1996 to 31 October 2008. Demographic data, cholecystectomy details, and procedural data were collected, specifically focusing on closure of the bile leak. Time to resolution of leak was calculated, up to either the date of the first repeat ERCP that demonstrated no persistent leak or the date of removal of any radiologically placed percutaneous drain, whichever came first.**

RESULTS: **Sixty-four patients underwent repeat ERCP with biliary stent removal. The median time to repeat ERCP was 36 days (interquartile range (IQR) 26–48). Fifty-seven (89%) patients had resolved the leak by time of repeat ERCP. Of those in whom the leak had not resolved, 6 had a repeat exam within 14 days of stent placement; 4 of these resolved the leak by day 39. There were no procedure-related complications in the ERCP group. Thirteen patients underwent EGD with stent removal after a median of 29 days (IQR 23–38). None had adverse events, with a median follow-up of 38 months. Overall, the median time to resolution of biliary leak was 33 days (IQR 22–44). Importantly, repeat ERCP altered the management in only one patient in whom bile duct stones were found.**

CONCLUSIONS: **Patients with uncomplicated postcholecystectomy bile leak who have clinically resolved their leak do not require cholangiography at the time of stent removal. In these patients, EGD with stent removal at 4–6 weeks seems to be sufficient and significantly less expensive.**

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INTRODUCTION

Bile leak after cholecystectomy is common and has a significant impact on patients' quality of life (1) and finances (2–4). The incidence of bile leak after open cholecystectomy is about 0.5% (5,6). However, the incidence of bile leak is significantly higher after laparoscopic cholecystectomy (7–9). It continues to be an important complication even past the initial "learning curve" phase with the introduction of laparoscopic cholecystectomy (10).

Postcholecystectomy bile leak is most often managed using endoscopic retrograde cholangiopancreatography (ERCP). Endoscopic management strategies include biliary sphincterotomy (11–13), biliary stent placement (14,15), nasobiliary tube placemernt (12,15), or a combination of these (16,17). Nasobiliary tube placement is less often used because of patient discomfort and the possibility of premature dislodgment. Endoscopic biliary stent placement is as efficacious as biliary sphincterotomy (18) and has fewer risks of bleeding and perforation. However, biliary stent placement necessitates a second endoscopic procedure for stent removal. It has been recommended that repeat ERCP be performed 4–6 weeks or later when clinical

[1]Division of Gastroenterology and Hepatology, Mayo Clinic Rochester, Rochester, Minnesota, USA. **Correspondence:** Todd H. Baron, MD, FASGE, Mayo Clinic Rochester, 200 First Street SW, Rochester, Minnesota 55905, USA. E-mail: Baron.todd@mayo.edu
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improvement is achieved and to definitively document leak closure (19,20). This is the typical strategy at our institution. Our hypothesis was that most uncomplicated bile leaks are closed in 4–6 weeks and repeat cholangiography is unnecessary. In this retrospective study, we sought to determine whether repeat cholangiography is required at the time of stent removal in patients who have clinically resolved their leak.

METHODS

Patients

Potential subjects for this retrospective case series were identified from an endoscopy database. This database is an electronic record of all endoscopies performed at Mayo Clinic, Rochester, MN since 1995. The database was queried to obtain a list of all adult (>18-years old) patients who had undergone an ERCP with bile leak listed as a preprocedure indication or postprocedure diagnosis with placement of a biliary stent during the procedure from 1 January 1996 to 31 October 2008. Only patients who had a postcholecystectomy bile leak definitively demonstrated on ERCP and had authorization to be included in research studies documented in the charts were further studied. Exclusion criteria included bile leaks secondary to liver lacerations or resection, trauma, or any procedure other than cholecystectomy. Patients who underwent biliary stent placement for postcholecystectomy bile leak but died of unrelated causes before an assessment for bile leak closure could be obtained were also excluded. This study was approved by the Institutional Review Board of the Mayo Clinic, Rochester, MN on 4 November 2008.

Data abstraction

Medical records were reviewed by the primary investigator (N.C.P.). Standardized data for each patient were collected. These data included baseline demographics, including age, sex, and comorbidities. Cholecystectomy details recorded included type of surgery performed (open, laparoscopic, or laparoscopic to open conversion), whether the surgery was complicated or not, number of operative drains placed, how the bile leak was diagnosed, and interval between surgery and initial ERCP. Procedural details for the ERCP with stent placement included whether the patient had prior biliary sphincterotomy or whether biliary sphincterotomy was performed during ERCP and stent placement, site of biliary leak, and number and size of biliary stents placed. Details for the follow-up ERCP included interval between the two procedures, whether the leak had resolved by the time of repeat procedure and stent removal, presence of choledocholithiasis or stricture, and any ERCP-related complications.

Definitions

Age was defined as the age at the time of initial ERCP. Comorbidities were defined by the Charlson Score, a validated scale that combines age and medical comorbidities (21). Cholecystectomy was considered complicated if a laparoscopic procedure was converted to open or if the procedure was described as complicated by the attending surgeon in the operative note. Bile duct injuries were classified into four types as defined earlier: (22) type A—leak from the cystic duct stump or cholecysto-hepatic duct of Luschka; type B—leak from the common bile duct or common hepatic duct with or without a concomitant bile duct stricture; type C—a bile duct stricture without any leak; type D—complete transection of the bile duct. For the purposes of this study, simple bile leaks were defined as type A leaks, and complex bile leaks defined as type B, C, or D. Complications of repeat ERCP included cholangitis, pancreatitis, or postsphincterotomy bleeding with or without hospitalization within 30 days of the procedure. Date of resolution of leak was defined as either the date of the first repeat ERCP that demonstrated no persistent leak or the date of removal of any radiologically placed percutaneous drain, whichever came first.

Statistical analysis

Descriptive statistics were used in this retrospective case series to describe characteristics of the patients, procedures, and outcomes. Continuous variables are expressed as means with standard deviations for parametric values and medians with interquartile ranges for nonparametric values. Dichotomous or categorical variables are described as number and percentage with each characteristic. Median time to bile leak closure with 95% confidence intervals was estimated using a Kaplan–Meier survival curve.

RESULTS

A total of 89 patients underwent ERCP with biliary stent placement for postcholecystectomy bile leak at the Mayo Clinic between 1 January 1996 and 31 October 2008. At our institution, standard practice for management of postcholecystectomy bile leaks is biliary stent placement with or without biliary sphincterotomy, and therefore data on patients treated with sphincterotomy alone are not available. Two (2.2%) patients were lost to follow-up. Seven (7.9%) patients died with the stent in place without a repeat ERCP or other method of determining leak closure. These deaths occurred from day 1 to 3 years after stent placement, and none of the deaths were definitely related to complications of the bile leak or ERCP. Cardiac arrest was the cause of death for the patient who died one day after stent placement. This patient was 78-years old and had multiple comorbidities including congestive heart failure, atrial fibrillation, and chronic renal insufficiency and in the absence of a postmortem examination the exact cause of death remains unknown. Three (3.4%) patients did not undergo repeat endoscopic procedures as a stent was not present on scout radiographs obtained just before ERCP and there was clinical resolution of the leak at 4 weeks from the initial ERCP. Thirteen (14.6%) patients underwent a follow-up Esophagogastroduodenoscopy (EGD) with stent removal instead of repeat ERCP. The remaining 64 (71.9%) underwent follow-up ERCP to evaluate for resolution of bile leak (**Figure 1**). The baseline characteristics of these 64 patients are summarized in **Table 1**.

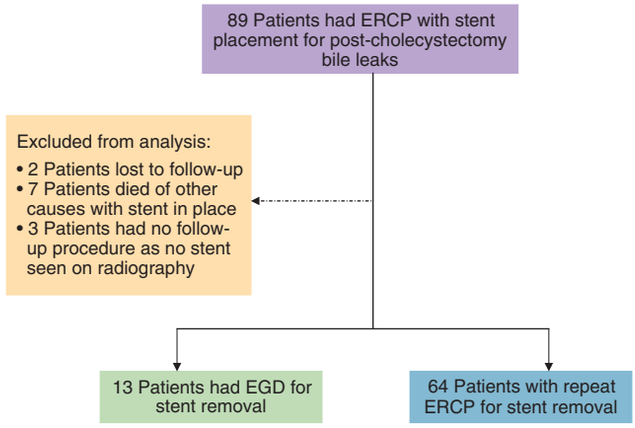

Figure 1. Schematic of subjects included in the study.

The median time from cholecystectomy to first ERCP was 6 days (interquartile range (IQR) 3–10), although 9 (14%) patients underwent ERCP more than 2 weeks after surgery. Four patients had a common bile duct stricture noted at the first ERCP and common bile duct stones were removed in two additional patients. Sphincterotomies were performed in 37 (58%) of procedures, whereas 4 patients had had a prior sphincterotomy. All patients underwent primary biliary stent placement. Only 1 patient had a metal stent placed for a large leak. The remaining 63 patients had plastic stents, including fifty five 10 Fr (French) (87%), five 7 Fr (8%), and on each of 8.5 Fr, 11 Fr and 11.5 Fr stents. The proximal end of the biliary stent was located above the common hepatic duct in 9 (14%) patients. A second plastic biliary stent was placed in 8 (12.5%) patients based on the endoscopist's discretion. Additional percutaneous drains were placed by interventional radiology into bilomas in 19 (30%) patients. No patients required surgery after stent placement.

The median time from first ERCP with biliary stent placement to repeat ERCP was 36 days (IQR 26–48). In 57 (89%) patients the bile leak was demonstrated to have resolved on the repeat ERCP. Of the 7 (11%) patients who did not have resolution of the bile leak at first repeat ERCP, 6 (86%) underwent their first repeat ERCP within 2 to 14 days after biliary stent placement, 4 of whom had resolution of their leak demonstrated by day 39. A potential reason for early repeat ERCP before the recommended 6 week interval is that our institution has an open access endoscopy unit and these ERCPs were ordered by the patients' primary provider and not the endoscopist performing the initial ERCP. The remaining three (4.7%) patients had more complicated clinical courses. One patient had a common hepatic duct leak and required placement of an additional two biliary stents at the second ERCP. The leak resolved at day 62. One patient presented initially with multiple intraabdominal abscesses, requiring multiple percutaneous drains, and resolved his leak by day 108. The final patient had a very large common hepatic duct leak and underwent metal stent placement at the repeat ERCP, and eventually resolved his leak by day 171 after first biliary stent placement.

Table 1. Baseline characteristics of 64 consecutive patients who underwent repeat ERCP after endoscopic placement of a biliary stent for postcholecystectomy bile leaks

Characteristic	*n*=64 subjects
Age in years, mean (s.d.)	54 (20)
Female sex	41 (64%)
Charlson score, median (IQR)	1 (0–3)
Cholecystectomy details	
Open	14 (22%)
Laparoscopic	38 (59%)
Laparoscopic to open conversion	12 (19%)
Complicated	24 (38%)
Number of operative drains	
0	25 (39%)
1	32 (50%)
>1	1 (1.6%)
Bile leak characteristics	
Simple	46 (72%)
Complex	18 (28%)
Method of diagnosis	
Computed tomography	27 (42%)
Surgical drain	22 (34%)
Presence of ascites	1 (1.6%)
HIDA	5 (8%)
Elevated liver enzymes	2 (3%)
Intraoperative injury	1 (1.6%)
MRI	1 (1.6%)
Clinical diagnosis	5 (8%)

ERCP, endoscopic retrograde cholangiopancreatography; HIDA, hepatobiliary iminodiacetic acid scan; IQR, interquartile range; MRI, magnetic resonance imaging.

There were no adverse events, including bleeding, pancreatitis, or cholangitis, related to the repeat ERCP. None of the patients had strictures noted at the second ERCP including the ones in whom a stricture was identified initially. All biliary stents were removed in 58 (91%) of patients at the repeat ERCP, and only 4 (6%) patients had evidence of choledocholithiasis. Of these four patients who had bile duct stones noted during repeat ERCP, which were not identified on the initial ERCP, two already had biliary sphincterotomy performed at their initial ERCP. The first of these patients had multiple stones identified during the first ERCP and the endoscopist was not confident that complete stone clearance was achieved. The second patient formed sludge around the biliary stent and we speculate that it would have spontaneously passed through the sphincterotomy had the stent been removed using EGD. The third patient was lost to follow-up after initial ERCP and the stent remained in

place. Fourteen months later, he presented with cholangitis, and ERCP showed development of concretion around the stent necessitating biliary sphincterotomy. This would have been avoided if the stent had been removed in a timely fashion. The fourth patient had not had a sphincterotomy at the first ERCP and at the second ERCP the diameter of the common bile duct had markedly increased. A sphincterotomy was performed with removal of a small stone. Therefore, of the 64 patients analyzed, repeat ERCP changed the management strategy in only this one patient.

Of the patients that had a follow-up EGD with stent removal, the median time between ERCP and EGD was 29 days (IQR 23–38). All of these patients had simple leaks. The decision to perform an EGD instead of an ERCP was at the discretion of the endoscopist. After a median follow-up of 38 months (IQR 21–45) these patients remained without biliary symptoms.

The median interval from endoscopic placement of biliary stent to demonstration of resolution of bile leak was 33 days (IQR 22–44) (**Figure 2**). The probability of demonstration of resolution of the bile leak within 6 weeks tended to increase with time regardless of whether the leak was simple or complex (**Table 2**).

DISCUSSION

Biliary leak is a complication that occurs in 1–2% of cholecystectomies. However, as there are more than 750,000 cholecystectomies performed a year (23), this is a commonly seen problem and one that gastroenterologists are almost always able to manage with ERCP. A recent study showed a static incidence of bile duct injuries seen in all ERCPs performed at a tertiary referral center over a 10-year period (10). Bile leak can be managed by various therapeutic techniques, all of which are aimed toward decreasing the transpapillary pressure, thereby allowing bile to flow through the path of least resistance and allow the leak to close. Recent data suggest that placement of a biliary stent is more efficacious and has a lower complication rate than biliary sphincterotomy (18,24). However, biliary stents need to be endoscopically removed after clinical resolution of the leak.

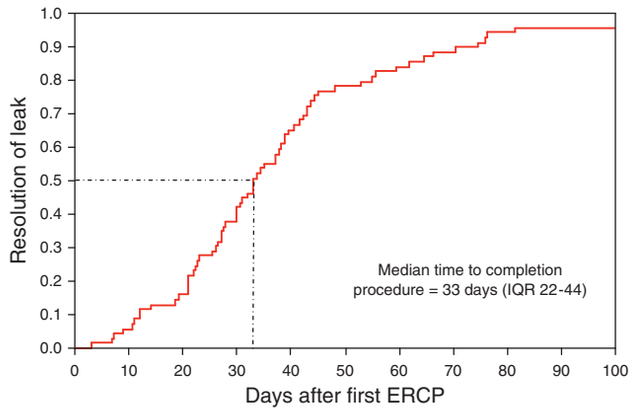

Figure 2. Kaplan–Meier graph showing probability of resolution of bile leak after ERCP with biliary stent placement for postcholecystectomy bile leak. ERCP, endoscopic retrograde cholangiopancreatography; IQR, interquartile range.

The exact timing of resolution of bile leaks is hard to determine. In earlier studies (16), doubling in the output from the endoscopically placed nasobiliary tubes coincided with closure of the bile leak and this occurred within 5 days. When endoscopic biliary stents are placed, the precise time when the leak closes cannot be determined. Hence, clinical parameters are used to determine when the leak has closed and removal of the stent is safe. These include improvement in the presenting symptoms and/or signs of the bile leak, including abdominal pain, elevated bilirubin, and liver enzymes. If an external drain is placed at the time of surgery or a percutaneous drain placed into a biloma, cessation of drain output indicates healing of the leak. Previous literature has suggested that these biliary stents can usually be removed anywhere from 4 (7,25) to 12 (19,26,27) weeks after initial placement.

In the published literature, there is no uniform recommendation regarding the need for cholangiography at the time of stent removal. In some studies, a repeat ERCP is performed at the time of stent removal with documentation of leak closure by a cholangiography. In other studies an EGD is performed to remove the stents. However, there are no published data supporting the need or lack thereof for ERCP or EGD. Thus, we decided to perform this retrospective study of our practice to determine the need for repeat ERCP.

We achieved closure of bile leaks in all patients. However, the number of patients managed non-endoscopically, i.e., by surgical or percutaneous drainage alone, and their outcomes at our institution were not investigated. Repeat ERCP did not show any biliary strictures but did show stones or sludge in four patients. However, as mentioned in the results section, two of these patients had sphincterotomy performed at the first ERCP and in our opinion, would likely have passed these small stones and

Table 2. Number of simple and complex bile leaks that either closed or required re-intervention at completion procedure up to 6 weeks

Time to intended completion procedure	<2 Weeks		2–4 Weeks		4–6 Weeks	
	No intervention	Re-intervention	No intervention	Re-intervention	No intervention	Re-intervention
Simple	5	1	12	1	15	1
Complex	3	0	2	1	5	0
Total	8	1	14	2	20	1

sludge without repeat cholangiogram and balloon sweeping. The third patient inexplicably developed a marked increase in common bile duct diameter despite the indwelling stent and ERCP with sphincterotomy was performed. The fourth patient was lost to follow-up and presented with cholangitis 14 months later, which necessitated a repeat ERCP. Thus, repeat ERCP changed the management in only 1 of the 64 patients. Our data suggest that EGD is appropriate for biliary stent removal if the patient is clinically well with resolution of drainage output and/or removal of drains and the stent has been in place for at least 4 weeks.

The optimal timing and method of biliary stent removal is unknown because the actual timing of leak closure is difficult to determine. It is generally accepted that the biliary stent should be removed 4–6 weeks after initial ERCP if the patient is clinically well. If there is clinical evidence of an ongoing leak at that time, then repeat ERCP with stent upsizing (size and/or number) should be performed. In our study, 57 patients had repeat ERCP with stent removal at a median time of 36 days. Six patients had a repeat ERCP at less than 14 days for clinical deterioration. In these six patients, the leaks had not yet closed as confirmed by cholangiography. Of these patients, 4 had resolved their leak by day 39. We feel that these four patients do not show failure of closure at their first ERCP, but instead represent cases where ERCP was repeated too early in their clinical course, especially as a stent of the same size was simply replaced in all four cases. The remaining three patients had complicated clinical courses and do not represent the majority of postcholecystectomy leaks. Our follow-up data on the 13 patients who underwent EGD without formal cholangiography for stent removal support this practice in patients who have clinically resolved their leak as determined by absence of external drain output and/or removal of external drains.

In the state of Minnesota, per the Ambulatory Payment Classification, the Medicare reimbursement for an ERCP with removal of biliary stent (coded as 43269) is $1,434.89 with patient co-pay of $358.73, totalling $1,793.63. Medicare reimbursement for an EGD with stent removal (coded as 43247) it is $226.19 with co-pay of $75.74 totalling $301.93. This is a considerable cost difference to the healthcare system and patients and the implications of performing an EGD rather than ERCP are immense given the number of bile leaks in the United States. About 500,000 cholecystectomies are performed a year in the United States (23); 80% (roughly 400,000) are done laparoscopically and 20% (roughly 100,000) are done through the open approach. The known incidence of bile duct injury with laparoscopic cholecystectomy is 0.5% (28) whereas it is 0.2% (29) with the open approach. This would give us an approximate occurrence of 2,200 bile duct injuries a year. Conservatively, if we assume at least 50% of these injuries are bile leaks, we would expect roughly 1,000 bile leaks a year. These leaks are almost always treated endoscopically with ERCP, and we assume conservatively at least 50% of these patients are treated with placement of a biliary stent. Of these 500 patients, 80% (400) will undergo repeat ERCP for stent removal. Medicare charges vary slightly between different states in the United States, but we can assume a difference of $1,500 between an ERCP and EGD described above. If these 400 patients were to undergo an EGD instead of an ERCP, this would result in a savings of $500,000 a year. The actual numbers of bile leaks treated with biliary stent placement are likely to be higher and the cost savings greater when private payer costs are taken into account. It must be noted that these calculations are based on the cost of ERCP in the United States. In other parts of the world where ERCP is not as expensive, these cost savings may not be the same, but savings in physician time and patient risk would likely remain.

A limitation of our study is its retrospective nature. In addition, we were unable to describe the outcome of all patients who developed biliary leaks post cholecystectomy. However, this was not the focus of our study. The number of cholecystectomies performed during this time period is unknown as some of these patients had their surgeries performed at our center but others were referred after surgery performed elsewhere.

In conclusion, in our experience, a repeat ERCP to remove a biliary stent placed to treat a postcholecystectomy bile leak did not add to the management of patients who were doing well clinically. It is our opinion that in these patients, an EGD with stent removal is sufficient and likely a cost-effective alternative. The potential cost effectiveness of this approach would have to be confirmed in a large prospective study.

CONFLICT OF INTEREST

Guarantor of the article: Todd H. Baron, MD, FASGE.
Specific author contributions: Nayantara Coelho-Prabhu: study plan, data collection, author on manuscript.
Todd H. Baron: study plan, supervising author on manuscript.
Both have approved the final draft.
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Potential conflicts of interest: None.

Study Highlights

WHAT IS CURRENT KNOWLEDGE

- ✓ Bile leaks are a common complication after cholecystectomy.
- ✓ They are treated most commonly with an endoscopic retrograde cholangiopancreatography (ERCP) with biliary stenting.
- ✓ Repeat ERCP is performed at 4–6 weeks to document closure of the leak with subsequent stent removal.

WHAT IS NEW HERE

- ✓ Repeat ERCP does not change the management in an uncomplicated postcholecystectomy bile leak.
- ✓ Esophagogastroduodenoscopy with stent removal is effective if performed at 4–6 weeks after stent placement if the patient is clinically well.
- ✓ This results in significant savings in time, cost, and equipment.

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