

Experience in endoscopic retrograde cholangiopancreatography management of postcholecystectomy biliary leak in a Colombian referral hospital

Andrés Delgado-Villarreal,^{1*} Raúl Cañadas-Garrido,² Cristiam Pulgarín,¹ Óscar Muñoz-Velandia.³

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Citation:

Delgado-Villarreal A, Cañadas-Garrido R, Pulgarín C, Muñoz-Velandia O. Experience in endoscopic retrograde cholangiopancreatography management of postcholecystectomy biliary leak in a Colombian referral hospital. *Revista Colomb. Gastroenterol.* 2022;37(4):383-389. <https://doi.org/10.22516/25007440.905>

¹ Internist, Gastroenterology and Digestive endoscopy fellow, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio. Bogotá, Colombia.

² Internist, Specialist in Gastroenterology and Digestive endoscopy. Professor, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio. Bogotá, Colombia.

³ Internist, PhD in Clinical Epidemiology, Professor, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio. Bogotá, Colombia.

*Correspondence: Andrés Delgado-Villarreal.
afernando.delgado@javeriana.edu.co

Received: 20/04/2022

Accepted: 06/09/2022



Abstract

Introduction: Postcholecystectomy biliary leak is rare. Management is mainly endoscopic, but in the literature, there is no consensus on the first-line technique between sphincterotomy, biliary stent, or combination. **Materials and methods:** A case series study was conducted that included all ERCP performed at the San Ignacio University Hospital in Bogotá, Colombia, between January 2010 and March 2021 due to biliary leak after cholecystectomy. Demographic characteristics, clinical manifestations, resolution, adverse events, and hospital length stay were recorded according to the endoscopic technique. **Results:** 24 patients with postcholecystectomy biliary leak managed with ERCP were included. The median age was 59 years (interquartile range [IQR]: 53.5-67). In 75% the surgery was laparoscopic. The most frequent clinical manifestation was increased biliary drainage > 150 mL/24 hours (50%), followed by abdominal pain (39%). The main fistula's location was the cystic duct in 40%. Management with sphincterotomy was 25%, with a biliary stent, 8.4%, and combined, 66%; leak resolution occurred in 100%, 50%, and 87%, respectively, with a shorter hospital length stay in the combined management of 3.5 days compared to four days in sphincterotomy. Only one adverse bleeding event occurred in the sphincterotomy group. **Conclusion:** Sphincterotomy and combined therapy are options with reasonable resolution rates and low hospital length stay for managing postcholecystectomy biliary leak. Prospective, randomized, and multicenter trials will be required to define the best technique.

Keywords

Cholecystectomy, biliary leak, sphincterotomy, biliary stent, ERCP.

INTRODUCTION

Lithiasis of the gallbladder is a frequent reason for emergency and outpatient consultation⁽¹⁻³⁾. It is managed by cholecystectomy^(4, 5), which in recent decades has been mainly laparoscopic⁽⁶⁾. Among its complications are biliary fistulas, which occur in 1% of surgeries and whose risk factors include difficulty in the dissection and viewing of the bile duct due to inflammation⁽⁷⁻⁹⁾, obesity, and anatomical variants⁽¹⁰⁻¹²⁾. Bile leaks may be due to direct injury during surgery, which frequently goes unnoticed^(11, 13). However,

they may also occur due to bile duct stones that increase pressure in the duct or detach the clips⁽¹⁴⁾. The patient exhibits complications in the postoperative period, such as abdominal pain, collections, or biliary peritonitis^(14, 15).

When there is no complete section of the biliary tree, the management of choice should be endoscopic retrograde cholangiopancreatography (ERCP), but the endoscopic method of choice needs to be clarified. Some studies show that papillotomy alone is better, while others suggest the insertion of plastic biliary stents or combined therapy⁽¹⁶⁻¹⁹⁾; this is why international scientific societies diverge in their

recommendations. On the one hand, the American Society for Gastrointestinal Endoscopy (ASGE) recommends sphincterotomy alone or placement of a biliary stent or nasobiliary drainage with or without sphincterotomy to decrease the pressure gradient between the bile duct and the duodenum⁽²⁰⁾. On the other hand, the European Society of Gastrointestinal Endoscopy (ESGE) recommends only the placement of biliary stents without sphincterotomy, except in older adults, for whom it recommends sphincterotomy only to avoid another ERCP⁽²¹⁾.

Given the contradictory recommendations on first-line endoscopic therapy, we decided to conduct a retrospective study to describe the experience in managing post-cholecystectomy biliary fistulas in a high-complexity care center and hypothesize about the technique with better clinical resolution and fewer complications to be evaluated in subsequent prospective studies.

MATERIALS AND METHODS

A descriptive observational case series study was carried out. From the medical record system of the San Ignacio University Hospital in Bogotá, Colombia, a tertiary care hospital, we identified the procedures performed under CUPS ERCP codes (511000, 518902, 512301, and 518801) between January 2010 and March 2021, both outpatient and inpatient. Medical records were reviewed, selecting patients whose indication for the procedure was suspected post-cholecystectomy biliary fistula. Patients under 18 years of age who received percutaneous or surgical management of the bile duct before ERCP were excluded. The identity of the patients was not referenced in the data analysis or the results reports. The institutional ethics committee approved the study.

The characteristics of patients and the procedures performed were collected from the information systematically documented in the medical record. The findings determined the presence of biliary fistula and its Strasberg-Bismuth classification during cholecystectomy surgery, reoperation, or ERCP. A high-grade biliary fistula was that viewed before the contrasting agent reached the intrahepatic bile duct, and low-grade was when the contrasting agent occupied the intrahepatic bile duct before viewing the leak^(22, 23). According to the specialist's criteria, the patients underwent sphincterotomy alone, a plastic biliary stent (7 Fr or 10 Fr), or combined therapy. The time from cholecystectomy to complication management by ERCP was recorded. Resolution of the biliary fistula was considered if any of the following five conditions were met: improvement of abdominal pain at 24 hours; resolved extravasation of contrast medium during ERCP; decreased abdominal drainage output < 150 mL for up to 72 hours; resolution of the

abdominal collection in the imaging control by ultrasound, MRI, or tomography at seven days; or absence of fever, abdominal pain, jaundice, peritonitis, or abdominal collection seven days after drainage removal. The resolution time of the biliary fistula and the need for a new endoscopic, surgical, or percutaneous intervention were measured.

As patient safety measures, we established by the medical record if there was bleeding (melena, hematemesis, or drop in hemoglobin > 2 g/dL until day 7 of endoscopic therapy), acute pancreatitis (new or increased abdominal pain plus elevation of amylase > 3 times the upper limit of normal at 24 hours that would have required hospitalization > 2 days), cholangitis (fever > 38 °C *de novo* and cholestasis with increased bilirubin > 2 mg/dL up to 7 days), perforation (gas or contrast medium outside the digestive tract up to 7 days later), and mortality (death from any cause during hospitalization) after ERCP. The hospital stay after endoscopic therapy was measured.

Statistical analysis

Quantitative continuous data are expressed as means and standard deviation (SD) in the case of normal distribution (Shapiro-Wilk test) or as median and interquartile range (IQR) if this assumption was not met. Qualitative data are presented as absolute frequencies and percentages; no statistical tests were performed to compare these proportions, given the study design. We conducted the analysis using the statistical program Stata 16.

RESULTS

In the 11 years of observation, 2,436 ERCP procedures were performed, for which the indication was biliary fistula in 39 patients. Fifteen procedures were excluded: biliary fistula was ruled out in ten, three had failed cannulation, one received percutaneous management, and in another, the biliary fistula was secondary to a gunshot wound, leaving 24 patients for analysis.

The median age was 59; the youngest patient was 32, and the oldest was 76. Also, 54.2% were men. The type of cholecystectomy was primarily laparoscopic (87.5%). However, in three patients, it was necessary to convert it to open surgery due to inflammation secondary to a pyocolocyst, which prevented an adequate anatomical view of the bile duct (**Table 1**).

The most frequent clinical manifestation was increased bile production (greater than 150 mL in 24 hours) through the abdominal drainage lodged in the liver bed, which occurred in 12 patients, followed by 11 patients with increased abdominal pain after cholecystectomy. Abdominal collection > 3 cm documented by ultrasound, tomography, or

MRI (29.1%) and biliary peritonitis (12.5%) were associated with late management with ERCP of the bile leak (16 and 5 days on average, respectively) versus three days in patients without either of these two manifestations (**Table 2**). The intraoperative finding of bile leak during cholecystectomy occurred in one-third of the patients. No patient had a fever as a manifestation of the fistula.

Table 1. Sociodemographic and clinical characteristics of the included patients

Characteristic	Value
Age in years, median (IQR)	59.5 (53.5-67)
Male sex, n (%)	13 (54.2%)
Type of cholecystectomy, n (%)	
- Open	3 (12.5%)
- Laparoscopic	18 (75%)
- Converted laparoscopic	3 (12.5%)
Mean blood pressure in mm Hg, mean ($\pm$ SD)	84 ($\pm$ 14)
Heart rate per minute, median (IQR)	79 (71-90)
Temperature > 38.3 °C, n (%)	0 (0%)
Hemogram, median (IQR)	
- Leukocytes	8400 (6300-12230)
- Hemoglobin, g/dL	12.2 (10.45-15.15)
- Platelets by thousands	306 (217-386)
Total bilirubin in mg/dL, median (IQR)	2 (0.6-4.9)
Alkaline phosphatase in IU/L, median (IQR)	176 (96-267)
Glutamic-oxaloacetic transaminase in IU/L, median (IQR)	52 (47-67)
Glutamic-pyruvic transaminase in IU/L, median (IQR)	88 (44-111)
Charlson comorbidity index > 2 points, n (%)	15 (62.5%)

SD: standard deviation; dL: deciliter; g/dL: grams per deciliter; IQR: interquartile range; IU: international units. Source: The authors.

Regarding complete blood count, only four patients had leukocytes greater than 12,000 cells/mm³, bilirubin was greater than 3 mg/dL in 20.8%, and alkaline phosphatase had a median of 1.46 times the upper limit of normal. Still, there was no significant increase in transaminases (**Table 1**). Most patients with biliary fistula had comorbidities, with a Charlson index greater than 3 in 37%.

The biliary fistula was diagnosed during ERCP in 96% of the patients; only one was diagnosed by magnetic resonance cholangiopancreatography (MRCP) before endoscopic intervention. The most frequent location of the fistula was the cystic duct (40%), followed by the duct of

Luschka (27%) and common hepatic duct (13%), which in the Strasberg-Bismuth classification represents 68% of type A and 22% of type D; in two patients the anatomical site of the leak could not be identified. Low-grade biliary fistulas predominated in 73%.

Table 2. Clinical manifestation upon diagnosis

Clinical manifestation	Value
Increased abdominal pain, n (%)	11 (39.2%)
Abdominal collection > 3 cm, n (%)	7 (29.1%)
Biliary peritonitis, n (%)	3 (12.5%)
Biliary drainage by abdominal catheter in mL/24 hours, n (%)	
- < 150 mL/24 hours	8 (40%)
- 151-300 mL/24 hours	6 (30%)
- > 300 mL/24 hours	6 (30%)
Biliary fistula viewed during cholecystectomy, n (%)	8 (33.3%)
Residual choledocholithiasis	0 (0%)

mL: milliliters. Source: The authors.

Endoscopic management with papillotomy was performed in 25%, plastic biliary stents in 8.4%, and combined endoscopic therapy in 66%. Most patients' time from cholecystectomy to ERCP was longer than three days. The fistula was resolved in all patients with papillotomy, one of the two patients with a plastic biliary stent, and 87.5% of patients with combination therapy (**Table 3**). The patients with no resolution had high-grade fistulas, one with a Strasberg-Bismuth E2 lesion managed with hepaticojejunostomy and the other two with type D, one of whom underwent a new ERCP at week 6 with the placement of a fully covered metal biliary stent and resolved the fistula after three weeks. Patients treated early before 72 hours had a 100% resolution of the fistula compared to late patients (82%), and the mean hospital stay was shorter, with a median of three days versus four days.

Resolution time in 80% was less than three days; when differentiating by type of endoscopic therapy, papillotomy alone and combined had the same resolution time, with a median of 1.5 days (**Table 3**). In management with biliary stent alone, the only patient who improved did so after five days.

As adverse events after ERCP, there were no episodes of acute pancreatitis, perforations, cholangitis, or deaths. There was only one case of bleeding in a patient in the papillotomy group, which was resolved by endoscopic management with adrenaline.

Hospital stay independent of ERCP therapy had a median of four days (IQR: 2.25-9.75); in other words, 25% had a

post-ERCP hospitalization of fewer than three days, 50% between 3-7 days, and 25% greater than seven days. When evaluating by type of endoscopic management, the shortest duration of hospitalization was with combined therapy, with a median of 3.5 days (IQR: 2-9.75), followed by papillotomy with an average of four days (2.75-8.5). The two cases of plastic biliary stent had a hospital stay of six and 89 days. Patients managed before 72 hours had a median length of stay of three days, compared with four days for patients treated after 72 hours.

Table 3. Outcomes of endoscopic management in post-cholecystectomy biliary fistulas

Outcomes	Value
Endoscopic technique, n (%)	
- Papillotomy	6 (25%)
- Plastic stent insertion	2 (8.4%)
- Combined	16 (66.6%)
Time to perform ERCP, n (%)	
- < 1 day	5 (20.8%)
- 1-2 days	2 (8.3%)
- > 3 days	17 (70.8%)
Fistula resolution, n (%)	
- Papillotomy	6/6 (100%)
- Plastic stent insertion	1/2 (50%)
- Combined	14/16 (87.5%)
Fistula resolution time in days, n (%)	
- < 3 days	17 (80.9%)
- 4-7 days	4 (19%)

ERCP: endoscopic retrograde cholangiopancreatography. Source: The authors.

DISCUSSION

The present study describes the experience in endoscopic management of post-cholecystectomy biliary fistulas at a Colombian referral hospital. Our results show that the primary method of endoscopic therapy was papillotomy plus plastic biliary stenting, followed by papillotomy alone and biliary stenting alone, which was little used. The resolution was achieved in 100% of patients with papillotomy vs. 87% in combined therapy and 50% in the plastic biliary stent alone.

The compromise between men and women was similar; fistulas predominated between the sixth and seventh decades of life, which is consistent with the age of manifestation of cholelithiasis^(24, 25). Laparoscopic cholecystectomy was the method of choice for managing gallbladder disease in

87%, which for several decades has shown a shorter hospital stay and morbidity⁽⁶⁾.

The main clinical manifestations were increased bile production through abdominal drainage and increased abdominal pain, which was associated with early management (median of three days). On the contrary, abdominal sepsis with collections and biliary peritonitis were less frequent (29% and 12%) and late. These findings are similar to other studies, such as Pandit et al., who found sepsis of abdominal origin in 35% of patients⁽²⁶⁾, which could suggest that timely diagnosis and management reduce complications. In our series of cases, the finding of biliary fistula during surgery was 33%, which is higher than that of other publications, with reports between 8% and 22%^(26, 27), allowing for earlier endoscopic management in our study. Using imaging, such as ultrasound and tomography, was helpful in diagnosing abdominal collections. At the same time, MRCP was performed only in three patients and was diagnostic in one case, which contrasts with other studies in which its use was more significant⁽²⁸⁾.

In our study, the most frequent location of the biliary fistula was in the cystic duct (40%), the proportion of which was lower than in other studies: Rainio⁽²⁷⁾ reported this location in 64% and Haidar⁽²⁹⁾ in 79%. It was impossible to identify the fistula's origin in only 8% of our patients. High- or low-grade fistulas are not described in all studies⁽¹⁴⁾, which is our strength, and we found that all patients who failed endoscopic therapy had high-grade fistulas. Sandha et al. noted that this fistula has better resolution with combined therapy⁽¹⁶⁾.

As described, we had an overall resolution of biliary fistulas of 87.5%, with a time longer than three days from surgery to ERCP in most patients. This was called *expectant management* in the study by Abbas et al.⁽¹⁹⁾, the most extensive retrospective study to date, with 1,028 patients, in which no differences in adverse events were found. However, we must analyze it carefully since they were variables requiring invasive hemodynamic, respiratory, or renal support that we did not assess in our study. We highlight that the three patients who failed had a prolonged average of 24 days from cholecystectomy to ERCP, which leaves the door open to research on the time to perform the ERCP.

It should be noted that, in our study, papillotomy plus plastic stent insertion had lower fistula healing rates than plastic stent insertion alone. This finding is different from the study by Mavrogiannis⁽³⁰⁾, in which no differences were found in healing rates, but more patients were assigned to these groups. The hospital stay of all ERCPs was shorter than that reported by Abbas⁽¹⁹⁾, with a median of 11 days versus four days, and similar to Rainio's⁽²⁷⁾ and Chandra's⁽³¹⁾

results. Hospital stay was slightly shorter in patients who underwent ERCP before 72 hours and those who received combined therapy or papillotomy (3.5 versus four days). Adverse events in the study were low: only 4% had post-papillotomy bleeding, which was managed endoscopically. There was no mortality in our case series.

Our study has limitations, considering that a series of cases only allows for formulating hypotheses on the technique of choice for managing biliary fistulas. Our sample size is relatively small; specifically, the number of patients managed exclusively with plastic stent insertion is minimal, which does not adequately evaluate this management technique. The low prevalence of biliary fistulas prevents the collection of large case series; however, this is the most extensive series reported in Colombia. Prospective, randomized, multicenter studies will be required to define the techniques with the best rates of clinical resolution and adverse events.

CONCLUSIONS

This retrospective study found that early diagnosis of biliary fistulas is related to less development of collections, biliary peritonitis, and hospital stay. ERCP plays an essential role in diagnosing and managing post-cholecystectomy biliary fistulas, with good results in terms of resolution with sphincterotomy techniques alone or combined with plastic biliary stent and a low risk of adverse events. Although our study design does not allow direct comparison between methods, our data suggest that stent-only management may need to be improved. Randomized trials and meta-analyses will be required to compare the different management techniques directly.

Conflicts of interest

We declare no conflicts of interest.

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