



Selective Trans-Catheter Coil Embolization of Cystic Duct Stump in Post-Cholecystectomy Bile Leak

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Abstract

Background Percutaneous drainage is a first-line treatment for bilomas developed post-cholecystectomy in the setting of bile leak from the cystic duct stump. Percutaneous drainage is usually followed by surgical or endoscopic treatment to address the leak.

Aims This study aimed to evaluate outcome of selective coil embolization of the cystic duct stump via the percutaneously placed drainage catheters in patients with post-cholecystectomy bile leak.

Methods Seven patients with persistent bile leak after laparoscopic cholecystectomy who underwent percutaneous catheter placement for biloma/abscess formation in the region of the gallbladder fossa were followed. These patients underwent selective trans-catheter cystic duct stump coil embolization from Feb 2013 to Feb 2019. Procedural management, complications, and success rates were analyzed.

Results All patients underwent placement of a percutaneous catheter for drainage of biloma formation in the gallbladder fossa post-cholecystectomy. Selective coil embolization of the cystic duct was performed through the existing percutaneous tract on average 3.5 weeks after percutaneous catheter placement, resulting in resolution of the biloma. All bile leaks were immediately closed. None of the patients showed recurrent bile leak or further clinical symptoms. Coil migration to the common bile duct was diagnosed in a single case, after 2.5 years, with no bile leak reported.

Conclusions Selective trans-catheter coil embolization of the cystic stump is a feasible and safe procedure, which successfully seals leaking cystic duct stumps and can circumvent the need for repeat surgical or endoscopic intervention in selected patient populations.

Keywords Cholecystectomy · Bile leak · Cystic duct · Stump · Coil · Embolization

Introduction

Cholecystectomy has become one of the most commonly performed surgical procedures worldwide [1], with approximately 750,000 cholecystectomies performed annually in the USA. Although it is overall a fairly benign and well-tolerated procedure, it can be associated with risks and complications [2]. Among these, post-surgical bile leak is a relatively uncommon but serious complication, occurring in 0.5–3% of all cases [3]. When a bile leak occurs, it may arise from

the cystic duct stump, ducts of Luschka, or injury from the biliary tree [4].

The clinical manifestations of bile leak and biloma are non-specific and may include persistent abdominal tenderness, generalized malaise, and anorexia [5, 6]. Majority of these patients present within the first week, but symptoms can manifest up to 30 days after surgery [7]. The initial diagnostic work up typically includes right upper quadrant ultrasound, CT scan of the abdomen with IV contrast, and/or confirmatory HIDA scan [6].

Image-guided biloma/gallbladder fossa drain placement is the first therapeutic step, which also confirms the diagnosis [5]. Majority of post-cholecystectomy leak cases spontaneously resolve [8]. In cases where there is no spontaneous resolution, endoscopic approaches including sphincterotomy, transhepatic biliary drainage catheter placement, and

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bile duct stenting have been recommended as the first-line treatment [9, 10]. Alternatively, reoperation with ligation or reclipping of cystic duct stump is suggested in the surgical guidelines [11]. Cases of successful percutaneous cystic duct embolization with a variety of embolic materials have been reported during recent years [12, 13]. Since most patients with bile leaks receive a gallbladder fossa drainage catheter as a part of the initial treatment plan [5], the created tract could easily be accessed for first-line intervention in patients whom the cystic duct remnant can be visualized under fluoroscopy.

In this study, we aim to evaluate safety and feasibility of cholecystectomy stump catheterization and coil embolization in patients with persistent bile leak, possibly eliminating the need for repeat surgery or endoscopic intervention.

Methods

Study Design

This was a retrospective analysis of seven cases from three centers affiliated with Yale Medicine from Feb 2013 to February 2019. This study was HIPAA compliant retrospective data review, and obtaining consent form is waived by the IRB committee of the Yale University School of Medicine (IRB ID: 2000023935).

Studied Population

All patients were referred to our department for percutaneous biloma drainage by the surgical team after the diagnosis of post-cholecystectomy bile leak. All subsequent procedures were performed after careful deliberation with the referring surgeon. Candidates for coil embolization of the cholecystectomy stump had to meet the following criteria before being considered for the procedure:

1. Post-cholecystectomy status
2. Confirmed bile leak on HIDA scan, CT scan, or aspiration
3. Placement of drainage catheter in gallbladder fossa for biloma
4. Persistent bile leak from stump after 2 weeks, evidenced by > 10 cc bile drainage per day through gallbladder fossa drainage catheter
5. Patient opted to undergo coiling
6. Surgeon's agreement/multidisciplinary approach decision.
7. Patient not an ERCP candidate due to unfavorable anatomy, such as history of Roux-en-Y gastric bypass

8. Failed ERCP attempt in the setting of esophageal stricture, duodenal diverticulum, or failed cannulation of ampulla of Vater
9. Patient unable to tolerate endoscopy under anesthesia due to clinical comorbidities.
10. Patient with successful ERCP, who still has persistent bile leak through cystic duct stump.

Persistent leakage was defined as greater than 10 cc of bile drainage per day after 2 weeks of biloma/biliary fossa drainage catheter placement, or patency of the cystic duct stump on cholangiogram through the indwelling percutaneous transhepatic internal–external biliary drainage catheter (PTBD).

Imaging

Imaging is vital for establishing the diagnosis of cystic duct injury, delineating the extent of injury, and planning for an appropriate intervention and approach. Imaging modalities include cholescintigraphy, computed tomography (CT), ultrasonography (US), magnetic resonance cholangiopancreatography (MRCP), endoscopic retrograde cholangiopancreatography (ERCP), percutaneous transhepatic cholangiography (PTC), and fluoroscopy with injection of a contrast medium via a surgically or percutaneously placed catheter. Because each option has different advantages and limitations, many patients undergo several imaging studies for diagnostic evaluation.

Right upper quadrant ultrasound and CT scan of abdomen and pelvis with intravenous contrast were obtained as initial work up to depict fluid collections, biliary duct dilatation, and possible associated vascular injuries in all patients. Four out of six patients had confirmatory HIDA scan to establish the diagnosis of bile leak.

Fluoroscopy performed during the injection of a contrast medium via an existing percutaneously placed biloma/gallbladder fossa drainage catheter sought to opacify the bile ducts and identify the potential leak. However, this technique should not be used in patients who show signs of infection, and it is most likely to be successful in collections that are small or that have undergone sufficient drainage to allow the biloma cavity to collapse around the catheter [14] and for any superimposed infection to clear. If the patients had dilated biliary system or any concern for distal obstruction, a percutaneous transhepatic biliary drainage catheter placement and transhepatic cholangiograms were performed to evaluate potential proximal bile duct injuries including common duct ligation or transection, possible injury to an aberrant right hepatic bile duct, and control bile leakage in the event of an injury.

Coil Embolization Technique

All patients underwent placement of gallbladder fossa drainage catheter after diagnosis of bile leak. Figure 1 demonstrates step by step coil embolization of the cystic duct stump. First, a scout image was obtained to confirm the position of the drainage catheter in the gallbladder fossa. Contrast was subsequently injected through the drainage catheter to delineate the biloma and communication with the cystic duct. The drain was then trimmed at the hub, and the retention suture was removed after administration of local anesthesia with 1% lidocaine. The catheter was then unformed and removed over a 0.035 inch super-stiff Amplatz wire (Boston Scientific, Marlborough, MA). A Brite Tip sheath (6 or 8 Fr, Cordis, Miami Lakes, FL) was placed into the cavity over the wire followed by a Kumpe catheter (4 or 5 Fr Angiodynamics, Latham, NY) or Glidcath (4 or 5 Fr Terumo, Somerset, NJ), and subsequently, the Amplatz wire was exchanged for an angled 0.035 or 0.018 inch HiWire hydrophilic wire guide (Cook, Bloomington, IN). Subsequently, the cystic duct and then common bile duct were selected retrograde with the Glidewire followed by a Kumpe of Glidcath catheter. The Glidewire was removed, and contrast was injected to confirm placement of the catheter within the cystic duct. Then, coil embolization of the distal cystic duct and

stump was performed with appropriately sized coils from the cystic duct insertion into the common bile duct and back to the stump, always crossing the area of previous clip with a portion of the coil. The catheter was then withdrawn slightly into the gallbladder fossa, and contrast was injected to confirm occlusion of the stump. The Amplatz wire was then introduced through the catheter, and the catheter is exchanged for a new pigtail catheter, with its distal tip formed in the targeted pocket. The wire was removed, and the pigtail was locked. Brief contrast injection was then performed to confirm catheter placement.

Statistical Analysis

Statistical analysis and data management were performed using SPSS statistical software version 22.0 (IBM Co., Armonk, NY). Mean \pm standard deviation (SD) was used to present quantitative data, and number (%) was used to show qualitative data. Pearson's Chi-square test was used to determine patients' baseline characteristics and clinical variables to determine predictors of adverse outcomes. Complication/recurrent-free survival was calculated based on the time of intervention to date of a recurrence or complication. *P* value less than 0.05 was considered significant.

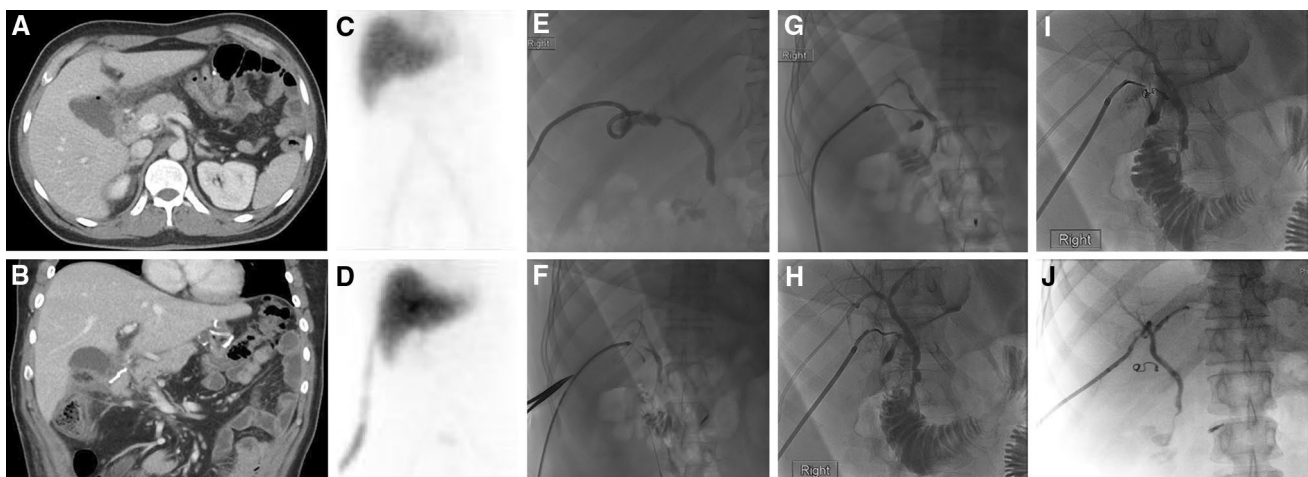


Fig. 1 Coil embolization of the cholecystectomy stump. **a, b** The patient presented with abdominal pain 7 days after undergoing cholecystectomy. Axial and coronal CT images through the abdomen and pelvis with IV contrast showed a fluid collection in the gallbladder fossa. **c, d** 0 and 60 min after injection of radiotracer on follow-up HIDA scan confirmed bile leak. **e** The patient had a gallbladder fossa and an internal–external biliary drainage catheters placement 5 days after presentation and 12 days after cholecystectomy, once the patient was diagnosed with bile leak. However, contrast injection through the gallbladder fossa drain 16 days after cholecystostomy demonstrated a small persistent fluid collection with communication to the cystic

duct, compatible with cystic duct bile leak. **f** A 0.035 inch Amplatz wire was advanced through this drainage catheter and the catheter exchanged for an 8-French 23 cm sheath. **g** Through the sheath, a 5-French Kumpe catheter and 0.035 inch Glidewire were advanced into the cystic duct and common bile duct. **h** The Kumpe catheter was positioned in the cystic duct, and **i** a 4-mm-interlock embolization coil was deployed in the cystic duct and extended to the stump and then finished/anchored in the gallbladder fossa. **j** The Kumpe catheter was retracted to the gallbladder fossa, and contrast injection in the gallbladder fossa did not show significant opacification of the cystic duct

Results

Demographic Characteristic

Demographic and clinical characteristics of the patients are demonstrated on the Table 1. The mean age of the patients was 58.0 ± 11.3 years, ranging from 44 to 76 years. Only two of the patients, 28.6%, were female, and the rest, 71.4%, were male.

Interval time from cholecystectomy to presentation with bile leak was 8.8 ± 4.1 (3–14) days. Interval time to placement of a gallbladder fossa drainage catheter was 14.00 ± 9.2 (4–28) days. Interval time from placement of a drainage catheter until coil embolization was 23.7 ± 6.3 (15–33) days.

All procedures were done in the outpatient setting. Four procedures were completed under moderate sedation, while two were performed only using Fentanyl. None of the procedures took more than 30 min. The mean follow-up interval was 27.4 ± 28.8 (1–78) months.

Outcome

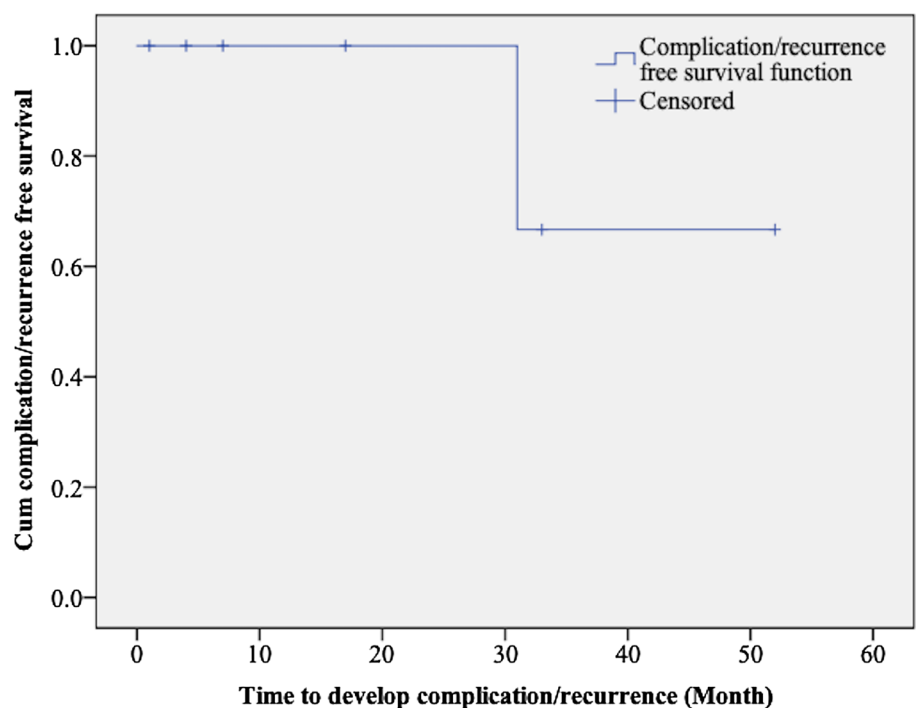
Gallbladder fossa drainage catheter was removed 10.9 ± 11.6 (1–34) days after coil embolization of the cholecystectomy stump in all cases. However, the interval of internal–external biliary catheter removal in patients with this catheter varied based on the performing physician.

There was no immediate or early complication after coil embolization of the cholecystectomy stump. The complication/recurrent-free survival is shown in Fig. 2. Only a

Table 1 Demographic and clinical characteristics of the patients who underwent coil embolization of the cholecystectomy stump

Patient	Age	Gender	Interval from surgery to symptomatic (day)	Interval from surgery to biliary drain placement (day)	Interval from drain placement to coil embolization (day)	Interval from coil embolization to biliary drain removal (day)	Complications
1	60	Female	5	6	20	34	Migrated coil
2	52	Male	11	30	19	1	None
3	44	Male	7	12	16	6	None
4	67	Male	9	7	30	2	None
5	76	Male	14	4	24	18	None
6	61	Male	3	23	33	7	None
7	47	Female	13	18	25	8	None

Fig. 2 Complication/recurrence-free survival. Between 1 and 78 months of follow-up, only a single presented with late complication of coil migration 31 months after coil embolization of the cholecystectomy stump



single patient experienced delayed complication after coil embolization of the cholecystectomy stump. Migration of the coil was noted on follow-up evaluation of the patient 31 months later (Fig. 3) when the patient presented with abdominal pain, nausea, and jaundice. This was believed to be related to the anterograde coiling technique, accessing the cystic duct through the common bile duct. To treat this complication, a 65 cm 5-French Berenstein catheter was then advanced to the duodenum. During these exchanges, it became evident that at least one end of the coil was free and encrusted coil was free floating within the common bile duct. A 20-mm gooseneck snare was then used to capture the loose end of the coil. The coil was then extracted through the sheath. Follow-up cholangiogram demonstrated a few small mobile filling defects in the common bile duct, presumably representing pieces of tissue that had broken loose from the stone. Subsequently, balloon dilation of the patient's biliary sphincter was performed, which was followed by anterograde balloon sweeps to push the fragments forward into the small bowel. At the end, a new 12-French internal/external biliary drain was advanced into the biliary tree, and the distal pigtail was formed in the duodenum. The patient returned 2 weeks later, and the catheter was removed after successful caping trial.

Discussion

Our findings demonstrate coil embolization of the cystic duct stump to control post-cholecystectomy bile leak to be safe, feasible, and effective. This brief procedure can be done in the outpatient setting with minimal sedation in patients with gallbladder fossa drainage catheter who are not an ERCP candidate or had failed ERCP attempts.

Although a rare complication, postoperative biliary leak is a potentially serious complication following cholecystectomy. Post-cholecystectomy biliary leakage risk is increased in patients who undergo urgent cholecystectomy, and is usually secondary to inflammation, and adherent anatomical structures rendering surgery more difficult as anatomical planes and aberrant anatomy are not readily discernible [15, 16].

Less invasive methods, including percutaneous transhepatic biliary drainage catheter placement or percutaneous drainage of bilomas have been proven as successful treatment options [17, 18]. However, successful percutaneous management of bile leaks may require treatment courses that could last between 6 and 12 weeks [17, 19].

Given the nature of these patients, endoscopic interventions have replaced surgery as first-line treatment of post-biliary duct injury/leak, avoiding reoperation in patients who were already difficult surgical candidates [16, 20].

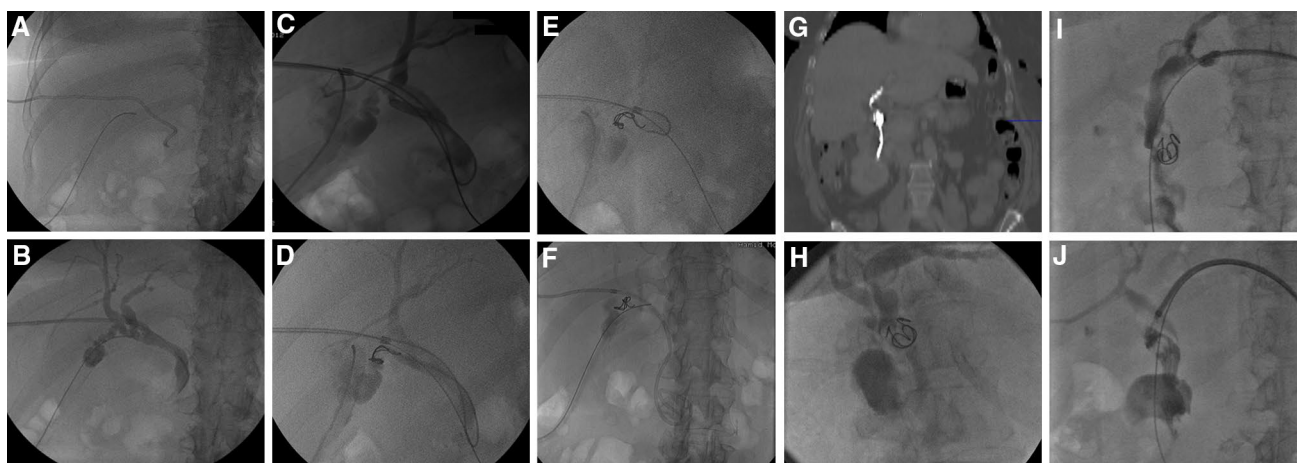


Fig. 3 Coil embolization of the cholecystectomy stump with delayed complication of coil migration. **a** The patient underwent placement of a gallbladder fossa drainage catheter and an internal–external biliary drainage catheter 6 days after presentation with bile leak. **b** The internal–external biliary drainage catheter was exchanged for an 8-French 23 cm sheath, and a 5-French Kumpe catheter and 0.035 in. Glidewire was advanced anterogradely into the biliary tree, common bile duct and then into the cystic duct through the sheath, unlike the defined protocol where the cystic duct is supposed to be retrogradely accessed through the biloma or gallbladder fossa drainage tract. **c** The Kumpe catheter was advanced into the duodenum,

and advanced back into the common bile duct, and cystic duct. **d** Contrast injection confirmed placement of the Kumpe catheter within the cystic duct. **e** Coil embolization of the duct was performed with two 14-4 Nester coils and three 4/3 Tornado coils. **f** A new internal–external biliary drainage catheter was placed via same access. **g** 30 months later, the patient presented with jaundice. Coronal view of the CT scan showed distended intrahepatic bile ducts and dilated proximal common bile duct secondary to migrated cystic duct coil, which was confirmed on a cholangiogram (**h**). **i** The left hepatic duct was accessed, and the coil was eventually retrieved (**j**)

Traditionally, ERCP with sphincterotomy with or without plastic or self-degradable stents is done to decompress the trans-papillary pressure gradient, thus facilitating unimpeded bile flow to promote the spontaneous closure of the leak. Placement of a nasobiliary drain also allows healing by bile diversion, or placement of a fully covered self-expanding metal stent covers the cystic duct origin [10]. Endoscopic management success rates are reported between 82 and 100% [21]. However, endoscopy fails under certain conditions including ongoing severe acute necrotizing pancreatitis with deformity of the duodenum, hepaticojejunostomy, and Roux-en-Y reconstruction, or bile leaks at the cut surface of the liver [12]. In these situations, percutaneous transhepatic biliary drainage catheter placement still represents the approach of choice and provides a considerable reduction in repeated laparotomies. Additionally, it is important to note, however, that ERCP with sphincterotomy and stent placement is not without its own complications including post-ERCP pancreatitis, hemorrhage post-sphincterotomy, need for repeat ERCP, and anesthesia risk [20]. It is our contention that percutaneous biloma/gallbladder drainage catheter placement with follow-up coil embolization of the cholecystectomy stump is a viable less invasive alternative method in comparison with repeat surgery, ERCP, or even percutaneous transhepatic biliary drainage catheter placement.

Percutaneous management of postoperative bile leaks with an ethylene-vinyl alcohol copolymer (Onyx) is a technically feasible alternative treatment option, if percutaneous or endoscopic approaches fail and redo-surgery is deemed harmful or difficult [12]. Previous methods of percutaneous embolization of bile leakage with permanent liquid agents are limited due to poor control during the application process in the absence of blood flow. This may cause irreparable damage to the bile system [12]. Modified techniques, however, dictate using high concentrations of EVOH (8% EVOH; Onyx 34), along with a coil basket to prevent dislocation of non-polymerized Onyx, allowing a slow rinse of the biliary leak site after Onyx application with saline to help accelerate the polymerization. This technique could be considered to optimize Onyx embolization of the cystic duct, bypassing previous complications [12, 22].

Successful percutaneous use of NBCA to occlude biliary leak has been successfully performed [23]. NBCA is a low viscosity tissue glue monomer that polymerizes and becomes solid in contact with body fluids at neutral pH. Because of persistent bile leak from cystic duct stump, a combination of coils and NBCA is favored over NBCA or coils alone [24, 25]. With this method, the coils act as a scaffold for the glue. However, coil migration and subsequent cholangitis have been reported [25], as have been reported for coil embolization [26] and noted in our study.

Once minimally invasive endoscopic or radiological techniques fail, surgical options are required and include liver

resection, bile duct reconstruction or bilioenteric anastomosis [27]. However, surgical re-exploration is often complicated due to the presence of adhesions and altered anatomy [28].

The advantages of percutaneous biloma/gallbladder fossa drainage catheter placement with follow-up coil embolization of cystic duct stump are largely self-evident. A minimally invasive retrograde approach through an already present biloma/gallbladder fossa drainage catheter tract is appealing for both the physician and the patient. No new entry site is needed, thus minimizing pain, infection, bleeding, anesthesia, and damage of surrounding structures. Risks of this minimally invasive procedure include bleeding, non-target organ damage, and infection. Therefore, this procedure is recommended in patients who already have a biloma/gallbladder fossa drainage catheter in place, or patients who are not suitable for endoscopy and ERCP. Additional potential draw back of this procedure is the prolonged time period of drainage catheter in place in contrast to endoscopic methods such as ERCP. Finally, concurrent placement of PTBD with biloma/gallbladder fossa drainage catheter could be a technically challenging procedure in patients without intrahepatic biliary ductal dilatation.

To our knowledge, this is the first multi-patient study investigating the safety, feasibility, and efficacy of coil embolization in patients with biliary leakage occurring post-cholecystectomy. Our results clearly demonstrate the safety and efficacy of coil embolization therapy in the treatment of patients with biliary leakage. Although our group of patients was small, bile leak closure was achieved in all patients. No immediate or early complication is seen. The only delayed complication was coil migration, which was attributed to procedure technique where coiling was conducted from the gallbladder fossa to the cystic duct rather than a cystic duct to gallbladder fossa approach.

While the current study is limited by a very small population and lack of comparison with other modalities/techniques, large scale future studies in collaboration with surgeons and gastrointestinal specialists are needed to precisely compare this approach to the other techniques. Direction of further studies should focus on determining the waiting time until coiling, time interval until capping trial, and time of PTBD removal.

In conclusion, cystic duct stump coil embolization is a minimally invasive, safe, and cost-effective procedure which can successfully seal leaking cystic duct stumps on outpatient basis in under 30 min in patients with biloma/gallbladder fossa drainage catheter and in whom ERCP is contraindicated.

Author's contribution NN assisted two clinical cases and involved in data collection, analysis, drafting the manuscript, and revision of the

manuscript. HJ helped in collecting the data, writing the discussion section and editing/revising the manuscript. MA done two clinical cases. IL involved in one clinical case and revising the manuscript. HM done one clinical case. RRA involved in one clinical case. JSP involved in conceptualized, supervision, and revision of the manuscript. JCPL done two clinical cases, involved in conceptualization, supervision, methodology, and revision of the manuscript.

Compliance with ethical standards

Conflicts of interest The authors declare no conflicts of interest.

Ethical approval This was a retrospective study with IRB approval from Yale University School of Medicine (IRB ID: 2000023935).

Informed consent Obtaining informed consent form was waived.

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