



## Bile duct/Gallbladder

## Primary endotherapy for Strasberg type C bile leaks

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## ABSTRACT

**Background:** Endotherapy is considered by some as the treatment of choice for most external biliary fistulas after laparoscopic cholecystectomy except for those originating from isolated/disconnected ducts, as in Strasberg type C lesions. Endoscopic intervention is not generally considered among treatment options because the isolated duct cannot be opacified during cholangiography and is inaccessible with the usual endoscopic methods.

**Methods:** Our interventional endotherapy for this type of complication consists of cannulating the isolated duct by passing a guidewire out of the cystic duct or the disruption of the common bile duct into the pathway of the biliary fistula. The key element of this endoscopic treatment is to restore the continuity of the biliary tree. Our case series (from March 2012 to September 2017) consists of 19 patients (9 males, 10 females) with Strasberg type C bile leaks. The access to the transected biliary duct was obtained by purposeful puncture of the cystic duct stump into the peritoneal cavity and then intubation of the biliary duct by a 0.035 hydrophilic guidewire. In 17 cases, we performed direct cannulation of the isolated transected duct. In 2 cases, we performed an endoscopic “step-up approach” (a 2-session variant of the technique).

**Results:** Technical and clinical success rates were both 100%. Drainage from the abdominal drain stopped in a mean of 1.2 days. There was 1 recurrence after 4 weeks (attributable to displacement of the metal stent), but we were able to retreat the patient endoscopically. Our technique is minimally invasive but very effective in healing the fistulas. Operative repair, in contrast, is a major operation with increased morbidity, prolonged hospital stay, and is more costly. Moreover, on the basis of the available literature, endotherapy passing through the abdominal cavity became safe in expert centers.

**Conclusion:** The described endoscopic treatment is innovative, safe, and effective and is applicable in tertiary-level centers but requires considerable interventional endoscopic expertise. This minimally invasive procedure can increase the rate of fistula healing and decreases the need for more aggressive and risky operative procedures.

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## Introduction

Cholecystectomy is one of the most common operations worldwide.<sup>1</sup> Postoperative adverse events are also common and include, among others, bile leakage from hepatic ducts separated from the biliary tree (Strasberg type C).<sup>2</sup> In these cases, operative reintervention is associated with high morbidity and often technical difficulty, especially when performed late, because of intra-peritoneal infected fluid collections, often involving the transected ducts.<sup>2,3</sup> Endoscopic treatment is generally not considered, because

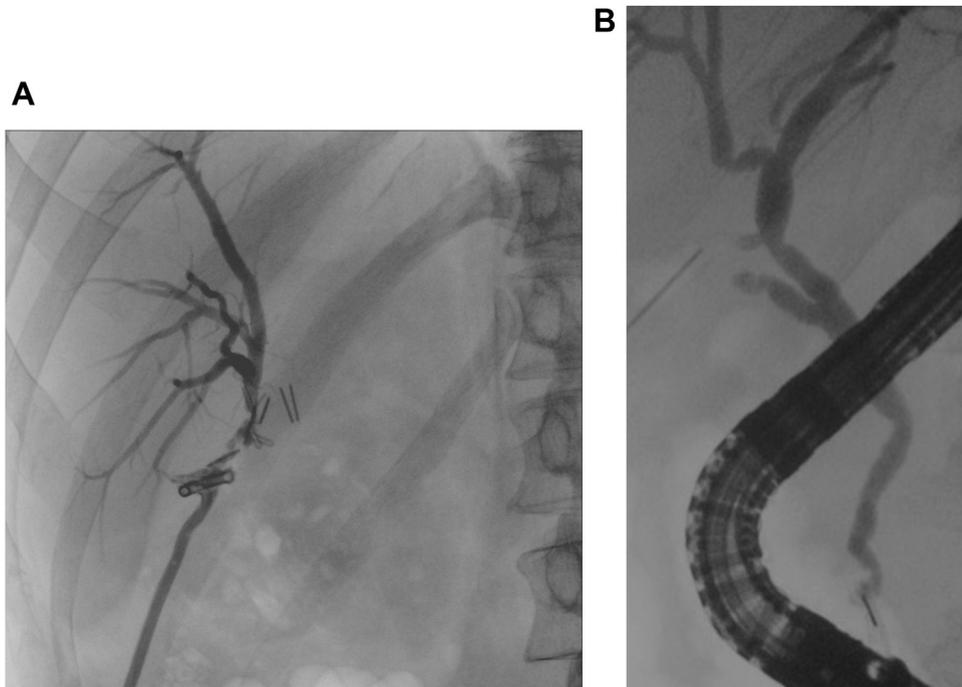
the isolated duct cannot be opacified<sup>2,3</sup>; however, we have described an applicable primary endotherapy in similar complications after hepatic resection.<sup>4</sup> We report a series of Strasberg type C bile leaks after cholecystectomy that were treated endoscopically by our service.

## Materials and Methods

From March 2012 to November 2017, a total of 19 consecutive patients affected by Strasberg type C bile leak were retrieved retrospectively from our prospectively collected institutional database. Only patients with a Strasberg type C leak, defined as postcholecystectomy biliary leakage from an isolated duct, were included in this case series. The diagnosis of Strasberg type C leak was based on postoperative magnetic resonance

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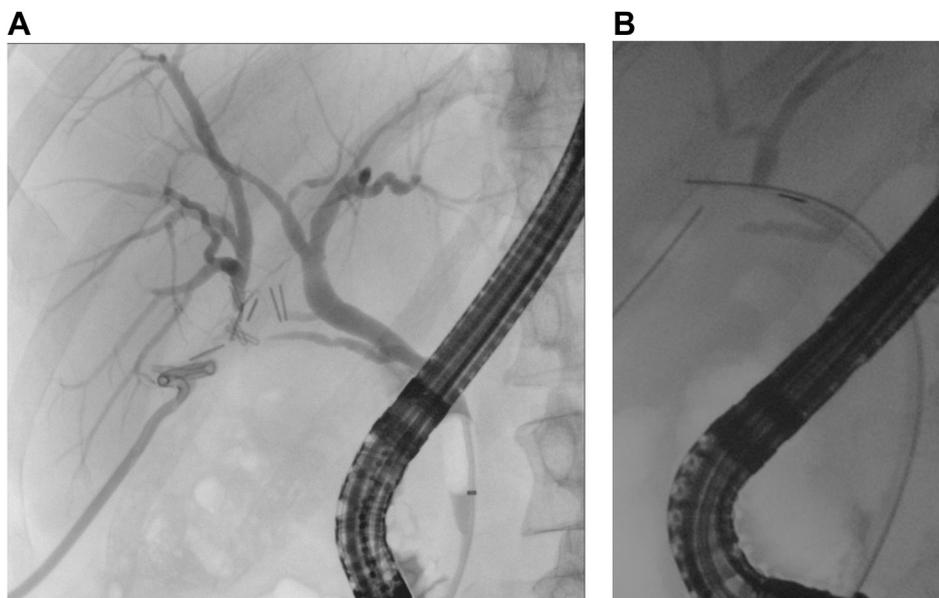


**Fig 1.** (A) A transected bile duct was opacified during the injection of contrast agent through the percutaneous drain. (B) A distal transected bile duct was opacified at the cholangiography. The diagnosis of a Strasberg type C bile leak was then made.

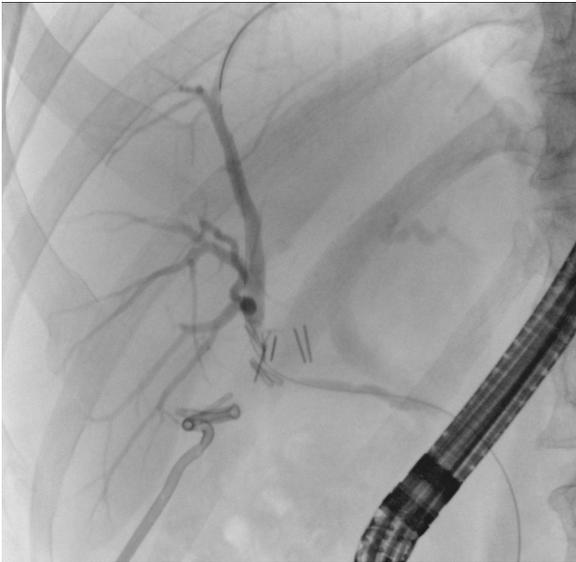
cholangiopancreatography (MRCP) and confirmed during endoscopic retrograde cholangiography (ERC) associated with contrast injection from the operative or percutaneous drain (Fig 1). All patients had an abdominal drainage tube placed during operation or by interventional radiologists. In 5 patients, we could visualize the transected ducts from direct injection of contrast agent through these drains. The study was approved by our institutional review board (Niguarda-Ca' Granda Hospital, Milan, Italy), and informed written consent was obtained from patients before all procedures described.

We proposed a similar endoscopic approach to that in the treatment of bile leaks from isolated ducts after hepatectomies.<sup>4</sup>

After a performing endoscopic biliary sphincterotomy on patients, we restored the continuity of the biliary tree, using a biliary stent to reconnect the transected duct to the common bile duct. The access to the cut duct was achieved by accessing the subhepatic peritoneal cavity, performed either by perforating the cystic stump, using a hydrophilic angled 0.035 guidewire (DWG, Cook Medical, Bloomington, IN) or by passing a guidewire out of a preexistent, iatrogenic common bile duct disruption that had occurred during the cholecystectomy (Fig 2). The guidewire was used to “find” and intubate the proximal (hepatic) opening of the transected duct (Fig 3). A mechanical or pneumatic dilation was performed, before stenting, using a 4-mm balloon, (Hurricane, Boston Scientific Corp,



**Fig 2.** (A) At the time of endoscopic retrograde cholangiography, the cystic duct stump and the hepatic end of the transected stump of the isolated duct were identified. (B) The guidewire was pushed into the peritoneal cavity through the cystic stump.

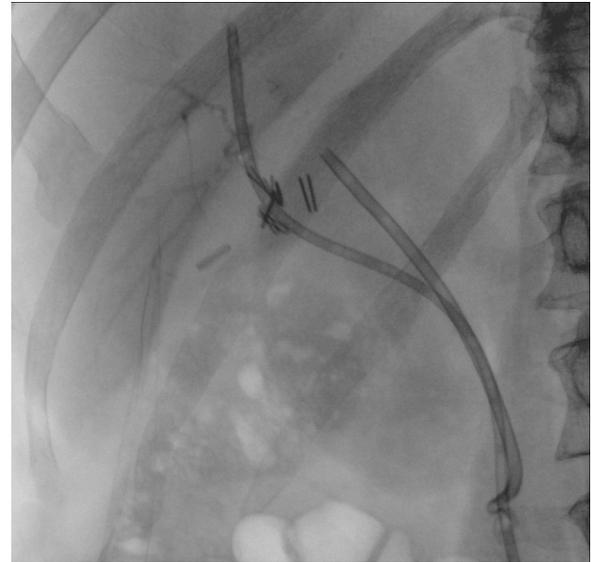


**Fig 3.** The isolated duct was cannulated by perforating the cystic stump in the middle of the surgical clips with the guidewire.

Gladstone, NJ) a 7/8, 5 Fr Soehendra boogie (SSDC-7/8,5 Cook Medical) or a 6-Fr cystostome (CST-6, G-Flex; Fig 4). Thereafter, an 8.5- to 10-Fr, 9- to 12- cm plastic stent (Cook Medical) or a 6-mm, fully covered self-expandable metal stent (fc-SEMS, Wallflex, Boston Scientific Corp) was used to restore the continuity of the biliary tree (Fig 5). If a single-step, direct cannulation of the cut bile duct failed, a “step-up approach” was used. This approach involved at a first endoscopic retrograde cholangiopancreatography (ERCP) session, the placement of an fc-SEMS with the proximal end in the subhepatic, intra-abdominal space as near as possible to the transected duct and the distal end in the duodenum via a transpapillary track. During a second ERCP session, 4 to 6 weeks later, we were able to stent the transected duct directly after searching the pathway with a hydrophilic 0.035-angled guidewire, thereby restoring continuity of the biliary tree as in the single step approach. A plastic or fc-SEMS was placed in the common bile duct



**Fig 4.** The pathway to the transected duct was dilated using a 4-mm pneumatic balloon.



**Fig 5.** An 8.5-Fr, 15-cm plastic stent was placed to connect the isolated duct and the biliary tree via the cystic duct stump. A transpapillary 8.5-Fr, 9-cm plastic endobiliary stent was also placed to keep the common bile duct patent.

in all the cases. The biliary stent was removed after a mean time of 6 months. An MRCP or an abdominal computed tomography (CT) was performed 6 months after removal of the stent.

## Results

During the study period, 19 patients (10 females, 9 males; mean  $\pm$  SD age:  $55 \pm 6$  years) were referred to our unit because of a refractory, postoperative bile leak after cholecystectomy (18 laparoscopic, 1 open). All patients had a surgical drain placed (in 3 cases placed after a second-look laparotomy). The mean fistula output was 260 ml per day (range: 190–340 ml). The patients were referred to our endoscopy center at a mean postoperative time of 6.5 days (range: 4–10). Although all patients had undergone an MRCP, the diagnosis of the type of leak was made during the ERCP. A diagnostic cholangiography both transpapillary and through the abdominal or percutaneous drains, were performed first during ERCP to verify the integrity of the biliary tree and localize the site of the leak. Moreover, opacification of the injured bile duct from the abdominal drain helps to direct the guidewire into the proximal (hepatic) end of the isolated transected duct (Strasberg type C biliary leaks). In 11 cases, the posterior right hepatic duct was transected. In 8 cases, the bile leak came from a segmental, transected bile duct (in 4 cases from S7, in 3 from S8, and in 1 case from S6). Technical and clinical success rates were both 100%. We performed a biliary sphincterotomy in 6 patients and resphincterotomy in 7. Access to the transected biliary radicle was obtained by purposeful puncture of the cystic duct stump into the peritoneal cavity and then cannulation of the biliary duct using a 0.035 hydrophilic guidewire (DWG, Cook Medical) in 16 cases and from an iatrogenic intraoperative disruption of the common bile duct (concomitant to the Strasberg type C lesion) in 3 cases. In 17 cases, we cannulated the isolated transected duct directly (in 2 patients, with the help of a percutaneous biliary drain). In the remaining 2 cases, we performed an endoscopic “step-up approach.” Before stenting of the transected bile duct, we dilated the pathway using a 4-mm dilation balloon (Hurricane, Boston Scientific Corp) in 12 cases, a 7/8.5-Fr Soehendra boogie (SSDC-7/8,5 Cook Medical) in 4, a 6-Fr cystostome (CST-6, G-Flex) in 2, and a 10-Fr Soehendra stent

extractor (SSR-10 Cook Medical) in 1. We placed a 10-Fr plastic stent into the transected bile duct in 9 cases and a 6-mm, 6-cm fc-SEMS in 10. Moreover, to drain the biliary tree, we placed an additional transpapillary, 10-Fr plastic stent in 13 patients and a 8-mm 8-cm fc-SEMS in 6 patients.

The outflow from the abdominal drains topped in 24 h in 10 cases, by 48 h in 5 cases, and by 72 h in the other 4 cases. When the fistula output stopped, the abdominal drainage tube was removed after confirmation of the absence of any intra-abdominal fluid collection by abdominal ultrasonography or CT. A total of 5 patients developed postprocedural fever attributable to transient bacteremia.

All patients were discharged within 1 week (range: 3–7 days). Mean follow-up has been 13 months (range: 6–18 months). There was one biliary fistula recurrence after 4 weeks (attributable to displacement of the fc-SEMS), but we were able to retreat the patient endoscopically by a second biliary stenting. There appeared to be no difference in effectiveness nor in the rate of displacement between plastic and fc-SEM stents. All patients underwent MRCP or CT 6 months after the removal of their stent. We found a variable degree of atrophy of the hepatic segments drained by the transected hepatic duct in these cases; however, there were no signs of parenchymal infection nor recurrence/persistence of a collection of intraperitoneal fluid.

## Discussion

Postcholecystectomy bile leak is not an uncommon adverse event and can occur in as many as 1% of the patients undergoing cholecystectomy.<sup>1,2</sup> Leaks are classified according to volume and location (low-output or high-output fistulae).<sup>5</sup> There are numerous anatomic classifications of postoperative bile leaks/injuries. The Strasberg classification is a general and detailed classification of bile duct injuries during laparoscopic cholecystectomy.<sup>2</sup>

To promote the healing of a biliary fistula, restoration of the continuity of the biliary tree should be obtained. This goal can be achieved by accessing the disconnected bile duct through the peritoneal cavity and connecting this pathway to the cystic duct of the extrahepatic bile duct. In our retrospective study of patients with a Strasberg type C bile leak, we were able to obtain a 100% treatment success by this innovative, interventional, primary endotherapy.

Generally, in the available literature, Strasberg type C bile leaks are managed by reoperative surgery. Operative repair, however, is a major operation with increased morbidity, prolonged hospital stay, and is more costly.<sup>3</sup> The present method is based on published experience of our unit in the endoscopic, transperitoneal management of other types of postoperative biliary fistulas.<sup>4,6</sup> Our ability to access the transected duct via an ERCP approach can be explained in the following points:

- The bile from the site of the biliary injury comes out through the surgical or percutaneous drain and thereby following a constant route;
- The inflammatory peritoneal reaction leads to an inflammatory, fibrous-lined pathway (the biliary fistula);
- Entering the peritoneal cavity with a fully coated, hydrophilic guidewire and then using delicate, image-guided maneuvers without undue trauma to cannulate directly the transected, isolated duct; and

- If necessary, using a 2-stage, “step-up approach” according to the same principles of the endoscopic treatment for an isolated duct after hepatic resections,<sup>4</sup> with placement of an fc-SEMS with the proximal (intra-peritoneal) end as near as possible to the site of the isolated transected bile duct to drain the bile into the duodenum.

The main principle of this “step-up approach” is the gradual creation of an internal, controlled biliary fistula that would facilitate the cannulation of the disconnected duct during the second step. In this set, 2 sessions (the second scheduled 4–6 weeks after the first) are needed to obtain the result; however, if direct cannulation was successful at the first session, no other therapeutic session is required.

Our technique is minimally invasive, but very effective in healing this type of fistula. The technique is a complex endoscopic intervention and requires appropriate skills and materials. Currently, endoscopic intervention is breaking taboos. Controlled, purposeful perforation into the peritoneum in specific and controlled situations is no longer considered an abdominal catastrophe. The gained experience with transmural EUS-guided drainage of biliary tree and fluid collections was a major paradigm shift.<sup>7</sup> Likewise, our method uses an endoscopic approach to access areas outside the biliary lumen to restore and treat inaccessible biliary leaks.

After removal of the biliary stent that creates a controlled “fistula,” the natural history of this complication is a slow closure of the tract of the fistula associated with a gradual, asymptomatic atrophy of the involved hepatic parenchyma. The constant flow of bile through the new pathway avoids infection of the isolated hepatic parenchyma. Indeed, in our experience, we did not observe any late cholangitis.

In conclusion, the described endoscopic treatment is innovative, safe, and effective. It is applicable in tertiary-level endoscopic centers but requires considerable expertise. This minimally invasive procedure can increase the rate of fistula healing and will eventually decrease the need for more aggressive and risky operative procedures.

## Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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