Postoperative bile leaks: Percutaneous transhepatic treatment by means of retrievable stent

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Authors: S. Choi, D. I. Gwon, G.-Y. Ko, J. H. Kim, H.-K. Yoon, K.-B. Sung; Seoul/KR
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Purpose

Postoperative bile leak is one of the major complications arising after pancreaticoduodenectomy, liver transplantation, hepatic resection, and cholecystectomy.

- Can be managed initially by means of
  - Percutaneous catheter drainage (PCD) or with perioperative placed surgical drains
  - Endoscopic therapy
  - Cannulation of the bile ducts proximal to the leak may be unsuccessful
  - Not feasible when the bile leaks complicate bilioenteric anastomosis or they rise from the cut surface of the liver
  - Early repeat surgery
  - Re-anastomosis or conversion of anastomosis is difficult in some patients

Percutaneous transhepatic biliary drainage (PTBD) is a less-invasive alternative to surgery and is commonly used to treating postoperative bile leaks. In cases of failed endoscopic cannulation and bilioenteric anastomosis, bile flow can easily be diverted away from the defect in the bile duct through the use of PTBD which allows for external biliary drainage, thus leaving the biliary tree under low pressure while the anastomosis heal, and preventing the formation or further accumulation of intra-abdominal biloma or abscesses caused by continued bile leakage. However, PTBD sometimes fails to improve bile leak despite prolonged drainage. In cases of refractory bile leaks despite PTBD, biliary complications and associated infections are the most important causes of prolonged hospital stays for patients undergoing major hepatopancreatic resections, especially those with cancer and/or who have undergone multiple, previous treatments.

The purpose of covered metallic stents to treat bile leaks is complete blockage of the leakage. The use of endoscopic covered metallic stent placement and removal has been described in published reports which have indicated their excellent results. However, the use of percutaneous transhepatic covered metallic stent placement for the management of refractory bile leak is limited because removal of the covered metallic stent is difficult and when permanently placed, the stent has a potential risk of later stent malfunction. To our knowledge, percutaneous treatment using retrievable covered stents has not been rigorously studied as a therapeutic option. Therefore, the purpose of our study is to
investigate the feasibility and efficacy of retrievable covered stent for the management of postoperative bile leaks.

Methods and Materials

[1] Patient Population

- From March 2007 to Feb. 2009
- 11 patients with postoperative bile leaks (M=7, F=4)
- Age from 53 to 71 years (median, 63 years)
- Choledochojejunostomy associated with pylorus-preserving pancreato-duodenectomy (n=8)
- Open cholecystectomy (n=2)
- Left lobectomy (n=1)
- Suspecting bile leaks
- Persistent, bile-colored drainage from the surgical drain (n=8)
- Bile peritonitis or perihepatic biloma detected on CT and/or hepatobiliary scintigraphy (n=3)
- Endoscopic approach
  - Open cholecystectomy (n=2), left lobectomy (n=1): failed to endoscopic stent insertion across the leak
  - The biloma was drained via
  - The surgical drain (n=8) or PCD (n=3)

Figure 1 on page 8 and Figure 2 on page 9 present table 1 which contains the clinical and radiologic characteristics of the 11 patients.

[2] Device
The retrievable covered stent (Song retrievable stent, TaeWoong Medical, Seoul, Korea) (Fig. 3 on page 10).

• Two main components
  - The outer tubular lining: constructed from a polytetrafluoroethylene (PTFE) material
  - The inner supporting stent: woven 16 times from a single thread of 0.1-mm diameter nitinol wire filament in a tubular configuration

• To make the stent removable, two drawstrings made from a nylon monofilament were attached to the upper inner margin of the stent

• A nylon loop, 2-mm in diameter, was hooked inside each bend of the proximal end of the stent and secured with a suture

• Another nylon thread was passed through each of these small nylon loops to form a larger loop that filled the circumference of the inside of the stent. The resulting large loop was tied

• To facilitate stent visibility during the procedure, radiopaque markers were attached at two points 180° apart on the circumference of the stent at both ends and at the center

• In this study, stents 8 to 12-mm in diameter and 40 to 80-mm in length were used.

• The delivery system
  - A standard push-rod assembly consisting of an outer sheath and an inner catheter
  - To improve the accuracy in deployment, radiopaque gold markers were incorporated into the distal end of both the outer sheath and the inner catheter

• Stent removal
  - A 9- or 10-F braided sheath, a dilator (Cook, Bloomington, IN)
  - A retrieval hook wire (TaeWoong Medical) (Fig. 4A on page 11) made of stainless steel wire
  - The end of the retrieval hook wire was constructed in a question-mark configuration in order to hook the drawstring of the stent
  - The distal 20-mm section of the question-mark portion was positioned at an angle of approximately 30° to the axis
• An additional bend was made in this section using pliers so as to prevent the hook from catching the end of the sheath during withdrawal.

[3] Technique

• The treatment protocol was summarized in Figure 5 on page 12.

• Performed under conscious sedation using intravenous pethidine hydrochloride (Demerol, Keukdong Pharmaceuticals, Seoul, Korea) and local anesthesia using intramuscular lidocaine (Jeil Pharmaceuticals, Taegu, Korea).

• Broad-spectrum antibiotics: administered intravenously two hours before the procedures and for at least 48 hours afterwards.

1) The peripheral intrahepatic bile duct was punctured using a 21-gauge Chiba needle (Cook, Bloomington, IN) under fluoroscopic guidance.

2) The needle was then exchanged for a 6-Fr coaxial dilator, and cholangiography was obtained to evaluate the leakage site, the severity of the bile leak, and the combined stricture.

3) The 6-Fr coaxial dilator was removed over a 0.035-inch angled hydrophilic guide wire (Terumo, Tokyo, Japan), and an 8.5-F pigtail catheter (Cook) was then inserted across the bile leak.

** For percutaneous biliary access in patients with a non-dilated bile duct system, our technique is to puncture central bile ducts near the hepatic hilum and to then fill the entire biliary system.

The decision as to whether stenting or only internal/external drainage catheter placement is appropriate in cases of bile leak, depends on factors such as the severity of the bile leak and the presence of a combined stricture. Although there is no standard definition of the severity of bile leak, we classified the severity as major or minor. A bile leak greater than 500 ml/day was defined as a major bile leak, whereas a bile leak less than 500 ml/day was defined as a minor bile leak measured from the surgical drain or the PCD catheter. In cases of major bile leaks or combined strictures, retrievable covered stent placement was planned 2~4 days following PTBD. In cases of minor bile leaks, the initial plan was for internal/external drainage catheter placement only. However, in cases of refractory bile leaks of more than 10 days despite internal/external drainage catheter placement, retrievable covered stent placement was also indicated.
Fig.: The technique used in this study was summerized in this slide.

References: S. Choi; Radiology, Asan Medical Center, Seoul, KOREA, Republic of
Fig.: The process of stent removal summerized in this slide.

References: S. Choi; Radiology, Asan Medical Center, Seoul, KOREA, Republic of

Figure 6 on page 13 shows the process of stent removal by videoclip. It will help you toe understand the process of stent removal more easily.

[4] Study endpoints and definitions

• Major study endpoints included the assessment of technical succes, clinical success, and complications.

• Technical success

• Defined as successful stent placement across the bile leak and stent removal without bile duct injury.

• Clinical success

• Defined as amelioration of any clinical manifestations related to the bile leak.
• Complications: classified as major/minor according to the guidelines of the Society of Interventional Radiology Standards of Practice Committee.

• Major complications: defined as those necessitating major therapy, those necessitating an unplanned increase in the level of care or prolonged hospitalization (>48 hours), and those resulting in permanent adverse sequelae or death.

• Minor complications: defined as those requiring no therapy or nominal therapy including overnight admission for observation only.

• Severe hemobilia: defined as clinically significant bleeding requiring blood transfusion and/or angiographic intervention.

Images for this section:
**Fig. 1:** Table 1: the clinical and radiologic characteristics of 11 patients.

<table>
<thead>
<tr>
<th>No.</th>
<th>Sex</th>
<th>Age</th>
<th>Underlying disease</th>
<th>Surgical procedure</th>
<th>POD (days)</th>
<th>Site of leak</th>
<th>Severity of bile leak</th>
<th>Indications for stent placement</th>
<th>Stent size: diameter (mm) X length (mm)</th>
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<td>Refractory Bl.</td>
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<td>OC</td>
<td>1</td>
<td>Stump(^1)</td>
<td>Major</td>
<td>Major Bl. &amp; stricture</td>
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<td>F</td>
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<td>CJ</td>
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<td>12 X 7</td>
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</tbody>
</table>

\(^1\)Stump means cystic duct stump.

CBD indicates common bile duct; CC, cholangiocarcinoma; PPPD, pylorus-preserving pancreatoduodenectomy; AC, adenocarcinoma; OC, open cholecystectomy; HCC, hepatocellular carcinoma; LL, left lobectomy; RIHD, right intrahepatic bile duct; Bl, ble leak.
**Fig. 2:** Table 1: the clinical and radiologic characteristics of 11 patients.

<table>
<thead>
<tr>
<th>No.</th>
<th>Technical success</th>
<th>Complications</th>
<th>Stent indwelling period (days)</th>
<th>Treatment period* (days)</th>
<th>Clinical success</th>
<th>Follow-up period (days)</th>
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<td>Pseudoaneurysm†</td>
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<tr>
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<td>No</td>
<td>24</td>
<td>43</td>
<td>Yes</td>
<td>184</td>
<td>Healthy</td>
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</tbody>
</table>

*Treatment period means a period between PTBD catheter insertion and removal.
†A pseudoaneurysm of right posterior inferior hepatic artery was successfully treated by means of selective embolization.
Fig. 3: Retrievable covered stent used in the study. A, Lateral view of the retrievable covered stent. The PTFE material completely covers the inner nitinol stent so that none of the stent metal is exposed to the bile duct mucosa. B, “End on” view of the retrievable covered stent. To make the stent removable, two drawstrings (arrow heads) and ten nylon loops (arrows) were attached to the upper inner stent margin.
Fig. 4: A, Retrieval hook wire: constructed in a question-mark configuration in order to hook the drawstring of the stent. B, Traction on any one drawstring caused the end of the stent to pull together and collapse into a funnel configuration.
Fig. 5: The treatment protocol used in this study was summarized in Fig 5.
Fig. 6: This videoclip shows the process of stent removal. At first, a safety wire was placed into the common bile duct and a 9-F sheath with a dilator was passed over the guide wire into the proximal stent lumen. After the dilator was removed from the sheath, a retrievable hook wire was introduced into the sheath to remove the stent, and the hook was pulled out of the stent so that the hook caught the drawstring. Traction on any one drawstring caused the end of the stent to pull together and collapse into a funnel configuration. When this occurred, the retrieval hook wire was withdrawn through the sheath to collapse the stent. At last, the sheath, stent, and retrievable hook wire were pulled out of the biliary duct through the percutaneous tract.
Results

<RESULTS>

[1] Percutaneous Approach and Patient Characteristics

• Major bile leaks: 7 patients (63.6%)

• Minor bile leaks: 4 patients (36.4%)

• The mean interval between surgery and PTBD: 6 ± 4 days (range, 1~13 days)

• Percutaneous transhepatic access to a peripheral intrahepatic bile duct was successfully achieved in all patients

• Pre-PTBD CT revealed dilated intrahepatic bile duct in only two patients (18.2%)

• A right approach was used in all patients

A right approach was used in all patients. Bile leaks were detected at the biliary-enteric anastomosis in eight patients (72.7%), at the cystic duct stump in two patients (18.2%), and in the right intrahepatic bile duct in one patient (9.1%) (Fig. 1 on page 20). In five patients (45.5%), anastomotic (n = 2) or non-anastomotic (n = 3) strictures were combined with bile leaks.

[2] Retrievable Covered Stent Placement and Removal

• Retrievable covered stent placement

• Performed 2~4 days after PTBD in nine patients with major or minor bile leak with combined stricture

• Performed 12 and 15 days after PTBD in two patients with refractory bile leak despite internal/external drainage, respectively

• Stent deployment

• Technically successful in all patients, and correct positioning was verified after each placement

• Stent sizes: 8-mm X 5-cm (n=2), 10-mm X 6-cm (n=1), 12-mm X 4-cm (n=1), 12-mm X 5-cm (n=2), 12-mm X 6-cm (n=1), and 12-mm X 7-cm (n=4)
Bile drainage via surgical drains or PCD dramatically decreased soon after stent insertion, and drains were withdrawn within nine days following stent insertion. In five patients (patients 3~5, 7 and 8), a transient, mild serum bilirubin increase (< 3mg/dL) was observed caused by blockage of opposite or ipsilateral intrahepatic bile ducts by the stents, however, it was normalized within four days after stent insertion in these patients. Also in these patients, post-stenting follow-up CT (n = 3) and hepatobiliary scintigraphy (n = 2) showed mild dilation of the blocked intrahepatic bile ducts or mildly decreased radioactive flow of the blocked intrahepatic bile ducts, however, no patients had symptoms or signs of cholangitis during the follow-up period.

• Stent removal
  • Successfully achieved in all patients at a mean of 31 days (range, 14~64 days) after stent insertion using the standard stent removal technique described in the Methods Sections
  • All removed stents revealed intact PTFE coverings with clean stent lumens as well as intact drawstrings and nylon loops (Fig. 2 on page 21).
  • In three patients, only minimal tissue proliferation around the margin of the stents was seen after stent removal.

• Cholangiography performed immediately following stent removal revealed the disappearance of bile leaks without residual strictures.

• In all patients, PTBD catheters were withdrawn at a mean PTBD catheter indwelling period of 41 days (range, 20~80 days), and clinical success was achieved in all patients (Fig. 3 on page 22 and Fig. 4 on page 24).

• During the mean follow-up period of 335 days (range 184~699 days), all patients remained healthy.

[3] Complications

A major complication subsequent to PTBD occurred in one patient (9.1%) (patient 6). The patient had severe hemobilia secondary to a pseudoaneurysm of a right intrahepatic artery that was successfully treated by means of selective transarterial embolization. There were no complications directly related to stent placement or removal. There were also no minor complications.

Stent migration was observed in one patient (9.1%) (patient 2) on follow-up cholangiography obtained 31 days following stent insertion. However, this stent was successfully removed without any complications, and follow-up cholangiography
obtained three days following stent removal showed the bile leak to be completely healed (Fig. 5 on page 25).

<DISCUSSION>

To date, a variety of covering materials, such as polyurethane, silicon, and PTFE, have been manufactured and tested. Several studies have compared covered, i.e. silicone-covered or polyurethane-covered and uncovered stents, although the data regarding the efficacy and the safety of these covered stents are controversial. Previous investigators have reported tears in the polyurethane and silicon covering membrane during or after stent placement, and which resulted in tumor ingrowth. Moreover, the polyurethane and silicon covering membrane may be degraded by bile, pancreatic juice or gastric juice. However, PTFE covering membrane is more resistant to chemicals, i.e. acids and alkalis and to bacterial growth, both of which reduces the risk of bile incrustation. In the previous studies, the use of PTFE-covered metallic stent has proved feasible in the treatment of malignant biliary disease.

[1] PTFE-covered retrievable stent

• The retrievability of PTFE-covered retrievable stents

• Serves as an effective barrier to bile leakage and as a relatively friction-free surface.

• Particularly suitable for potential removal without becoming incorporated into the bile duct wall.

** Petersen et al: reported the PTFE covering of the stent appears to prevent early tissue proliferation and incorporation of the stent into the bile duct epithelium.

• As nitinol stents are able to recompress to a small volume, this should facilitate their removal through a relatively narrow channel without requiring increasing the size of the tract.

** A few investigators have reported that a PTFE-covered retrievable stent is feasible and safe for treating benign or malignant biliary strictures.

• The placement and removal of a retrievable covered stent

• Technically successful in all patients

• No device malfunction, such as rupture or tear of the PTFE membrane occurred.

• A 100% clinical success rate
• This clinical success rate was similar or superior to previously reported data regarding PTBD catheter treatment only.

• The treatment period: 20~80 days (mean, 41 days) in the current study

• Similar or less than the treatment period of mean 27~78 days reported in other studies.

• Five patients (45.5%) with bile leaks associated with combined strictures also treated well following stent removal

• Restriction did not occur during the mean follow-up period of 335 days (range 184~699 days).

• The additional balloon dilation with/without metallic stent placement in the combined stricture, was also effective in patients treated by PTBD alone.

• Usually requires an additional treatment period.

• Anastomatic rupture after balloon dilation sometimes occurred.

• Secondary stricture at the previous leakage site

• Not a rare complication after successful initial treatment.

• May be caused by peribiliary fibrosis which can be induced by local inflammation resulting from bile leakage.

• Most of these strictures can be treated easily and successfully through the percutaneous route before withdrawal of the drainage catheter.

• The treatment period can also be long and repeated PTBD, if the drainage catheter was withdrawn, can be required for secondary interventions such as balloon dilation or stenting.

• In the current study, we did not observe any secondary stricture at the leak site after removal of the stent and before withdrawal of the drainage catheter.

• During the mean follow-up period of 335 days, no patient had symptoms or signs of biliary obstruction.

• The major limitation of this treatment

• Percutaneous transhepatic access to a peripheral bile duct is frequently difficult in patients with postoperative bile leaks as they usually have non-dilated intrahepatic bile ducts.
• In the current study, we could access peripheral bile ducts in all patients using fluoroscopy guidance although nine patients (81.8%) had non-dilated ducts and place a retrievable covered stent via the peripheral bile ducts.

• Previous studies have shown that PTBD can be used in patients with non-dilated bile ducts with a similar rate of complications as in patients with bile duct dilatation.

• Vascular complications after PTBD have been reported in a total of 7~19% of patients and usually consist of transient hemobilia.

• Arterial injury is relatively rare, with a frequency of 2%.

• Although we experienced one patient (9.1%) with severe hemobilia associated with PTBD, this patient was effectively managed by means of selective arterial embolization without sequelae.

** We assume that percutaneous transhepatic management is challenging for the treatment of postoperative bile leaks even when the intrahepatic bile ducts are not sufficiently dilated.

[2] Limitations

1) A chance of branching duct occlusion caused by the stent.

• In the current study, elevation of serum bilirubin was observed in five patients (45.5%) following stent placement and was caused by opposite or ipsilateral intrahepatic bile duct occlusion caused by the stent.

• The elevation had normalized within four days after stent placement and without evidence of cholangitis although follow-up CT or hepatobiliary scintigraphy revealed mild dilation or decreased radioactive flow of the blocked bile ducts.

• Therefore, we suggest that blockage of intrahepatic bile ducts caused by a retrievable covered stent may not induce major complications although close follow-up is necessary in such cases.

2) Stent migration

• Observed in one patient (9.1%) at the time of stent removal although a pigtail-shaped drainage catheter tip was positioned just beneath the distal margin of the stent in order to prevent distal migration.
• To prevent stent migration, Wang et al used a covered stent with anchoring fins (Viabil, Conmed, Utica, NY) and found mucosal ulceration of the bile duct in four of six patients following stent removal; may have been related to the anchoring fins of the stents.

• Therefore, further investigations for reducing stent migration will be necessary.

3) The optimal duration of stent placement is still undermined.

• Stent indwelling periods have ranged from 12 to 14.7 weeks for treating bile leaks using endoscopy-guided covered metallic stent placement.

• Wang et al.: suggested that more than a six week stent indwelling period might be appropriate when dealing with complex leaks or in patients with multiple comorbidities.

• Gwon et al.: suggested that the optimal time for stent removal for treatment of benign biliary strictures might be six weeks not only because good stent patency without the development of significant narrowing of the stent was commonly seen within that period, but also because PTFE damage was not a common occurrence during that period.

• In the current study, we used 2~4 weeks for the stent indwelling period in patients with only major bile leaks or refractory bile leaks.

• For treatment of any bile leaks with combined stricture, we used 4~8 weeks for the stent indwelling periods, and thus obtained successful outcomes.

Images for this section:
Fig. 1: Bile leaks were detected at the bilioenteric anastomosis in eight patients (72.7%), at the cystic duct stump in two patients (18.2%), and in the right intrahepatic bile duct in one patient (9.1%).
Fig. 2: A removed stent from patient 1. A, lateral view of the removed stent shows the intact PTFE membrane. Note that the retrieval hook wire (arrow head) catches the drawstring of the stent (arrow). B - C, "End on" view of the proximal(B) and distal(C) stent shows no granulation tissue in or around the removed stent.
**Fig. 3:** A 64-year-old man with a bile leak and occlusion at the anastomosis following PPPD (patient 3). A, A 90-minute delayed hepatobiliary scintigraphy image shows anastomotic occlusion (arrow) and bile leak via two surgical drains (arrow heads). B, PTBD was performed through a segment 6 duct three days after hepatobiliary scintigraphy. A cholangiogram obtained immediately after PTBD, shows the bile leak (white arrow heads) and anastomotic occlusion (black arrow). C, Follow-up cholangiography performed six days after PTBD, shows persistent contrast leakage at the anastomosis and the anastomotic stricture (not shown). A 12-mm-diameter and 5-cm-long retrievable covered stent (white arrow heads) was inserted across the stent for follow-up cholangiography and stent removal. To prevent distal stent migration, the pigtail-shaped drainage catheter tip was placed just beneath the distal stent margin (black arrow). Bile drainage via the surgical drains decreased dramatically soon after the stent insertion, and the drains were withdrawn five days following the stent insertion. D, A 90-minute, delayed image of follow-up hepatobiliary scintigraphy obtained seven days following stent insertion shows good bilioenteric radioactive transit without bile leak. E. After the retrieval hook catches onto one drawstring, traction on the drawstring causes the end of the stent to pull together. The stent then partially collapses into the 9-F sheath (arrow heads). The retrieval hook, the stent, and the 9-F sheath could then be successfully removed through the percutaneous tract. Follow-up cholangiography
performed immediately following stent removal shows the patent anastomosis without bile leak (not shown). A 10-F pigtail catheter was inserted into the intrahepatic bile duct for follow-up cholangiography. F. Two days following stent insertion, follow-up cholangiography showed the anastomosis to be patent and without contrast leakage. The drainage catheter was removed immediately following the follow-up cholangiography. The patient remained healthy and without a recurrent bile leak or anastomotic stricture for 403 days following the PTBD catheter removal.

**Fig. 4:** A 71-year-old man with a bile leak and intrahepatic bile duct stricture at the resection site following left lobectomy (patient 8). A, A CT image shows intrahepatic biloma at the resection site (white asterisk). B. A cholangiogram obtained immediately after percutaneous puncture of a segment 6 duct, shows a large amount of contrast leakage (white asterisk) as well as combined stricture (black arrow) at the resection site. C. A follow-up cholangiogram obtained six days after PTBD, shows persistent contrast leakage at the anastomosis and anastomotic stricture (not shown). An 8-mm-diameter and 5-cm-long retrievable covered stent was inserted across the bile leak (white asterisk), after which an 8.5-F pigtail catheter was inserted across the stent. D. The surgical drains were withdrawn nine days following stent insertion. A follow-up CT image obtained 21 days following stent insertion, shows the stent (black arrow) to be well-positioned and
no further biloma formation around the resection site. E. The stent was removed 35 days following insertion. A follow-up cholangiogram obtained six days following stent removal, shows the right intrahepatic bile duct (white arrow) to be patent and without contrast leakage. The drainage catheter was removed immediately following the follow-up cholangiography. The patient remained healthy, and without recurrent bile leak or stricture for 214 days following the PTBD catheter removal.

**Fig. 5:** A 64-year-old man with an anastomotic bile leak following PPPD (patient 2). A. A cholangiogram obtained immediately following the retrievable covered stent insertion, shows the stent (black arrow heads) to be well-positioned across the anastomosis. Note both intraperitoneal contrast leak (white asterisk) and contrast leakage through the surgical drain (white arrow). B. A follow-up cholangiogram shows distal migration of the stent into the jejunal loop (black arrow heads), but no evidence of contrast leakage from the anastomosis is noted. The stent was then successfully removed through the percutaneous tract. The patient remained healthy, and without recurrent bile leak or stricture for 636 days following the PTBD catheter removal.
Conclusion

In conclusion, placement and removal of a retrievable covered stent for treatment of postoperative bile leak and combined stricture, as described in the current study, is feasible and represents a major advance in the percutaneous management of postoperative bile leaks, regardless of the site of origin and the type of leak. Although the number of patients included in the current study is too small to allow general conclusions regarding its clinical efficacy, the use of a retrievable covered stent, performed under local anesthesia, seems to be effective for treating postoperative bile leaks as well as combined strictures, especially those that are not able to be controlled with PTBD alone, and it can also be a low-risk option in order to avoid unnecessary surgery.

References


**Personal Information**

Sanghyun Choi MD.

Department of Radiology, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea.

E-mail: samulboy@empal.com