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## EUS-guided hepaticogastrostomy with a fully covered metal stent as the biliary diversion technique for an occluded biliary metal stent after a failed ERCP (with videos)

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**Background:** Percutaneous transhepatic biliary drainage (PTBD) may be the last resort for an occluded biliary metal stent when the ERCP was unsuccessful.

**Objective:** Because an EUS-guided biliary drainage has been proposed as an effective alternative for PTBD after a failed ERCP, we conducted this study to determine the feasibility and usefulness of an EUS-guided hepaticogastrostomy (EUS-HG) with a fully covered self-expandable metal stent (FCSEMS) for an occluded biliary metal stent after a failed ERCP.

**Design:** A case study.

**Setting:** A tertiary referral center.

**Patients and Interventions:** Five patients who had an occluded biliary metal stent inserted after a hilar bilateral metal stent or a combined duodenal and biliary metal stent insertion and for whom reinterventional ERCP was unsuccessful underwent an EUS-HG with an FCSEMS for alternative PTBD.

**Main Outcome Measurements:** Technical and functional success, procedural complications, reinterventional rate after EUS-HG with an FCSEMS, and short-term stent patency.

**Results:** In all 5 patients, an EUS-HG with an FCSEMS was technically successful. No procedural complications, such as bile peritonitis, cholangitis, and pneumoperitoneum, were observed. Functional success was also 100% (5/5). During the follow-up period (median 152 days, range 64-184 days), no late complications, such as stent migration and occlusion, were observed. Thus, no biliary reintervention was performed during the follow-up period.

**Limitations:** A small series of patients without a control group.

**Conclusions:** The EUS-HG with an FCSEMS may be feasible, effective, and an alternative PTBD for an occluded biliary metal stent after a failed ERCP.

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Occlusion of self-expandable metal stents SEMSs placed to palliate malignant biliary obstruction is not uncommon.<sup>1-5</sup> In this situation, mechanical cleansing with an extraction balloon, additional plastic, or an SEMS via a transpapillary approach may be a suitable treatment for SEMS occlusion.<sup>3-5</sup> However, this reinterventional ERCP for an occluded metal stent may be unsuccessful in patients with accompanying duodenal obstruction,

*Abbreviations:* EUS-BD, EUS-guided biliary drainage; EUS-HG, EUS-guided hepaticogastrostomy; FCSEMS, fully covered self-expandable metal stent; PTBD, percutaneous transhepatic biliary drainage; SEMS, self-expandable metal stent.

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high-grade hilar stricture, or wire mesh of the hilar bilateral metal stent unable to be crossed by a guidewire.<sup>6-8</sup> In such circumstances, percutaneous transhepatic biliary drainage (PTBD) may be an effective alternative. However, PTBD has a relatively high rate of complications and is frequently associated with patient discomfort related to external drainage.<sup>7</sup> EUS-guided biliary drainage (EUS-BD) has therefore been introduced as an alternative to PTBD in cases of biliary obstruction when the ERCP is unsuccessful.<sup>9-19</sup> Recently, to reduce the EUS-BD-associated procedural complications, such as bile peritonitis and cholangitis, an EUS-BD with a fully covered self-expandable metal stent (FCSEMS) was introduced in cases of malignant biliary obstruction after a failed ERCP.<sup>20</sup> This pilot study was conducted to determine the proof of concept for feasibility and usefulness of EUS-guided hepaticogastrostomy (EUS-HG) with an FCSEMS as the biliary diversion technique for an occluded biliary metal stent after

the placement of a hilar bilateral metal stent or combined duodenal and biliary stent in patients with malignant biliary obstruction for whom reinterventional ERCP was unsuccessful and PTBD was indicated.

## PATIENTS AND METHODS

### Study population

This study was approved by the Institutional Review Board at the University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea. All patients provided written informed consent for participation in this study. A total of 3600 ERCPs are performed in this 2600-bed tertiary referral hospital annually. From October 2008 to March 2009, 28 consecutive patients with a malignant biliary obstruction were admitted for occluded metal stents. Sixteen (57%) of 28 patients had an occluded hilar metal stent. The remaining 12 (43%) patients had an occluded distal biliary metal stent. Twenty (71%) of 28 patients had successful reintervention with ERCP. Eight patients (6 with an occluded hilar metal stent and 2 with an occluded distal biliary metal stent) required PTBD for reintervention during the study period; however, 5 patients refused to undergo PTBD. Therefore, PTBD was performed in only 3 patients. Thus, 5 (18%) of the 28 patients were enrolled in this study. Study eligibility was determined as follows: (1) reinterventional ERCP for an occluded biliary metal stent was unsuccessful because of persistent duodenal narrowing despite the placement of a duodenal stent ( $n = 2$ ) or the patient had a high-grade left-sided hilar stricture from segmental tumor progression and the wire mesh of the hilar bilateral metal stent was unable to be crossed by a guidewire ( $n = 3$ ) and (2) refusal to undergo PTBD ( $n = 5$ ). Reinterventional ERCP was performed by 4 experienced pancreatobiliary endoscopists (M.H.K., S.K.L., D.W.S., and D.H.P.). Each endoscopist performs 850 to 1200 ERCPs annually. EUS-BD was performed by 1 experienced endoscopist (D.H.P.) who performs more than 350 EUS procedures and 1100 ERCPs for pancreaticobiliary diseases annually. Two hundred EUS-guided drainage procedures or FNA, including 14 cases of EUS-BD, were performed by this endosonographer to achieve procedural expertise before the start of this study. In this study, stent occlusion was classified as predominantly tumor ingrowth (seen on fluoroscopy as a narrowing within the stent), tumor overgrowth (seen radiographically or endoscopically as a new narrowing at the proximal or distal margin of the stent), or sludge/debris (demonstrated as echoendoscopic findings or multiple radiographic filling defects that disappeared after extraction with a biliary balloon along with endoscopic visualization of the extracted sludge).<sup>3</sup>

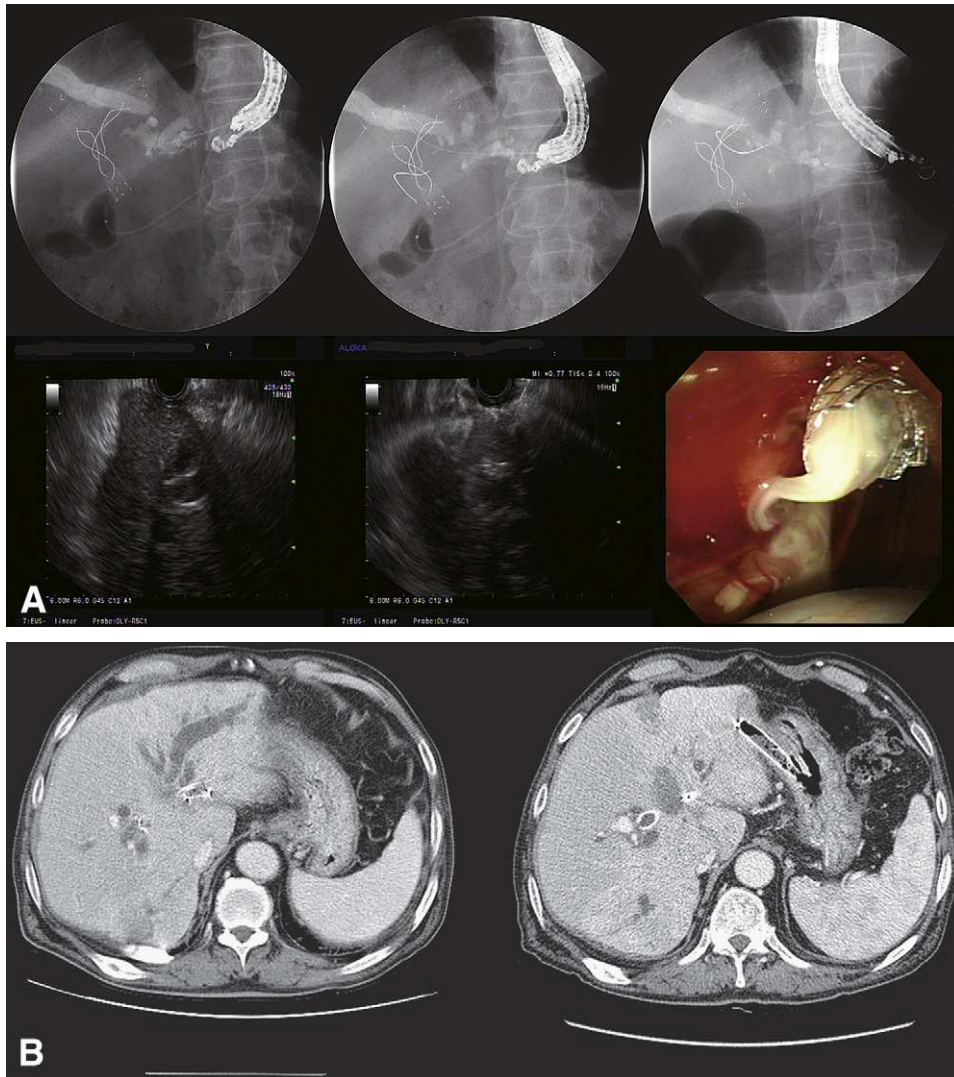
### Techniques

Antibiotics were permitted in all cases for 3 to 5 days before and after the intervention. The ERCP was initially

attempted in each patient by using a therapeutic duodenoscope (TJF-240; Olympus Optical Co, Tokyo, Japan). When the ERCP was unsuccessful, an EUS was performed by using a GF-UCT 240 linear-array echoendoscope (Olympus Corp, Tokyo, Japan) in a second session (same or next day). An EUS-guided choledochoduodenostomy was not considered because of the position of the occluded biliary metal stent. Therefore, the patients underwent an EUS-HG as the diversion technique. During the intrahepatic (transgastric-transhepatic) approach, the echoendoscope was placed in the cardia or the lesser curvature of the stomach and was oriented to view the intrahepatic system. For patients with a hilar metal stent, the dilated segment 3 was determined as the puncture site rather than segment 2 of the occluded metal stent because guidewire coiling and placement of an FCSEMS was considered to be easier in the dilated segment 3 (Fig. 1A). Color Doppler US was used to identify regional vasculature. A bile duct puncture was performed with a 19-gauge needle (EUSN-19-T; Cook Endoscopy, Winston-Salem, NC). To confirm successful biliary access, contrast medium was injected under fluoroscopy to demonstrate biliary opacification. A 0.035-inch guidewire was introduced through the EUS needle and advanced in an antegrade fashion (Fig. 1). Afterward, 6F and 7F tapered, biliary, dilator catheters (catheter tip, 4F; Cook Endoscopy) were inserted and removed, in that order, over the guidewire to dilate the tract. If there was resistance when advancing the 6F bougie catheter, a triple-lumen needle-knife (Microtome; Boston Scientific, Natick, Mass) with a 7F shaft diameter was inserted over the guidewire to dilate the tract. For this, the tip of a needle with a pure current was gently inserted over the guidewire to the biliary system. The needle was then withdrawn, and the needle-knife was pushed in to dilate the tract. A commercially available, fully silicon-covered metal stent with an 8F deployment system and an olive tip (BONASTENT, a nitinol stent with a 10-mm diameter and 6-cm length; Standard Sci Tech Inc, Seoul, South Korea) was placed under echoendoscopic and fluoroscopic view. This stent with both ends flared was designed to prevent distal or proximal migration.

### Definition of events

Technical success was defined as the passage of the metal stent across the stomach or duodenum, along with the flow of contrast medium and/or bile through the stent. Functional success was defined as a decrease in bilirubin to less than 75% of the pretreatment value within the first month. An early complication was defined as any stent-related complication within 30 days, including complications of bile leakage, pneumoperitoneum, bleeding, and stent migration. A late complication was defined as any stent-related complication, such as stent migration and stent occlusion, occurring 30 days after stent placement. Biliary reintervention was defined as any type of endoscopic, percutaneous, or surgical procedure that was



**Figure 1.** Case 2. **A**, EUS-HG. In the intrahepatic approach, the linear array echoendoscope was placed in the lesser curvature of the stomach and oriented to view the left intrahepatic system. The missing bile duct segment 3 and tumor overgrowth were noted by ERCP and the echoendoscope. The bile duct (segment 3) puncture was performed with a 19-gauge needle. To confirm successful biliary access, contrast medium was injected under fluoroscopy to demonstrate biliary opacification. A 0.035-inch guidewire was introduced through the EUS needle and advanced in an antegrade fashion. A fully covered metal stent was placed under echoendoscopic and fluoroscopic view. After stent placement, pus was drained from the fistula site. **B**, The initial CT scan showed focal B3 (bile duct segment 3) ductal dilation despite placement of a bilateral metal stent. A follow-up CT scan showed the decompression of the B3 ductal dilation with the previously inserted FCSEMS via the hepaticogastrostomy site.

required to improve biliary drainage after the placement of the stent. Stent occlusion was defined as the recurrence of jaundice and cholestasis and/or evidence of a dilated biliary system on US or CT with a direct view of the upper endoscope, which in all cases would require biliary intervention. Procedure time was defined as the time between the puncture of the biliary tract with a 19-gauge needle and the placement of an FCSEMS.

### Follow-up

The cutoff date for data analysis was April 2009. Biochemical parameters and simple abdominal films were assessed after 2 days, 1 week, and 1 month after stent

placement and every month thereafter. Patient follow-up was based on outpatient examination findings. Imaging (US or CT and simple abdominal films) was routinely performed every 3 months. Follow-up data were collected prospectively.

### Observations

Patient characteristics, EUS-HG findings, and follow-up results are presented in Table 1. In 3 patients with a hilar bilateral metal stent, the main left duct dilation caused by segmental tumor progression was shown to be aggravated on the CT scan. These patients had cholangitis. During ERCP, tumor ingrowth of the left main duct and the

**TABLE 1. Patient characteristics and results of EUS-guided biliary drainage with a fully covered metal stent for an occluded biliary metal stent**

Patient no.	Age/sex	Diagnosis	Days to reintervention	Initial metal stent	Cause of occluded stent/ location of occluded site/ symptom/reason for failed ERCP	Complications	Reinterventions	Duration of secondary stent placement (days)/ follow-up periods (days)	Status
1	65/F	Klatskin tumor (II*)	151	Bilateral hilar metal stent (side by side)	Tumor ingrowth/left main duct/ cholangitis/ not accessible	None	None	183/183	Alive
2	66/ M	Klatskin tumor (IV*)	93	Bilateral hilar metal stent (stent-in-stent)	Tumor ingrowth/left main duct/ cholangitis/ not accessible	None	None	152/152	Alive
3	77/ M	Klatskin tumor (IIIb*)	214	Bilateral hilar metal stent (side-by-side)	Tumor overgrowth/†B3/ cholangitis/ not accessible	None	None	91/91	Alive
4	72/ M	Distal CBD cancer	124	Covered biliary metal stent	Tumor overgrowth of distal end of stent/ jaundice/because the duodenal stenosis	None	None	184/184	Alive
5	54/F	Pancreatic head cancer	243	Covered biliary metal stent	Tumor overgrowth and proximal stent migration/jaundice/ because of the duodenal stenosis	None	None	64/64	Alive

\*Bismuth type.

†Bile duct segment.

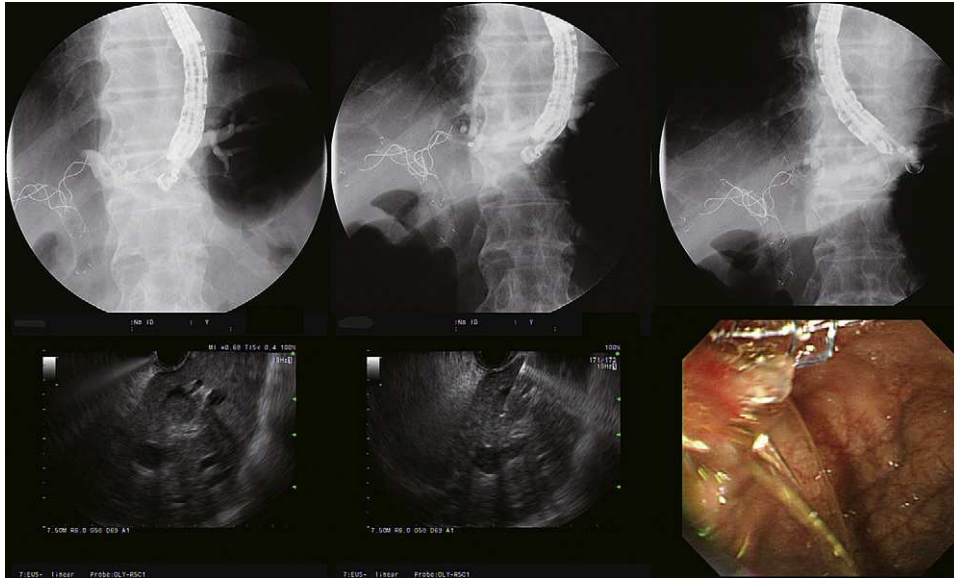
missing duct of segments 2 and 3 were noted in 2 of these 3 patients. Tumor overgrowth and the missing duct of segment 3 were observed in the last of these 3 patients. Based on the CT and endoscopic retrograde cholangiographic findings, a stent in the right main duct was intact in these patients. Selective guidewire cannulation to the occluded segments 2 and 3 was unsuccessful because of the high-grade stricture and wire mesh of the stent. Therefore, intrahepatic EUS-BD was performed (Figs. 1 and 2; Video 1, available online at [www.giejournal.org](http://www.giejournal.org)). In 2 patients with a duodenal stent and a biliary metal stent, tumor overgrowth and/or biliary stent proximal migration resulting in bile duct dilation were noted. These patients had obstructive jaundice. Although the duodenal stent was relatively intact, the ERCP was unsuccessful because of duodenal stenosis by the tumor ingrowth of the duodenal stent. Intrahepatic EUS-HG was therefore performed for the decompression of the bile duct (Figs. 3 and 4; Video 2, available online at [www.giejournal.org](http://www.giejournal.org)).

In all 5 patients, an EUS-HG with an FCSEMS was technically successful. The median diameter of the left intrahepatic bile duct as determined by EUS was 8.3 mm (range

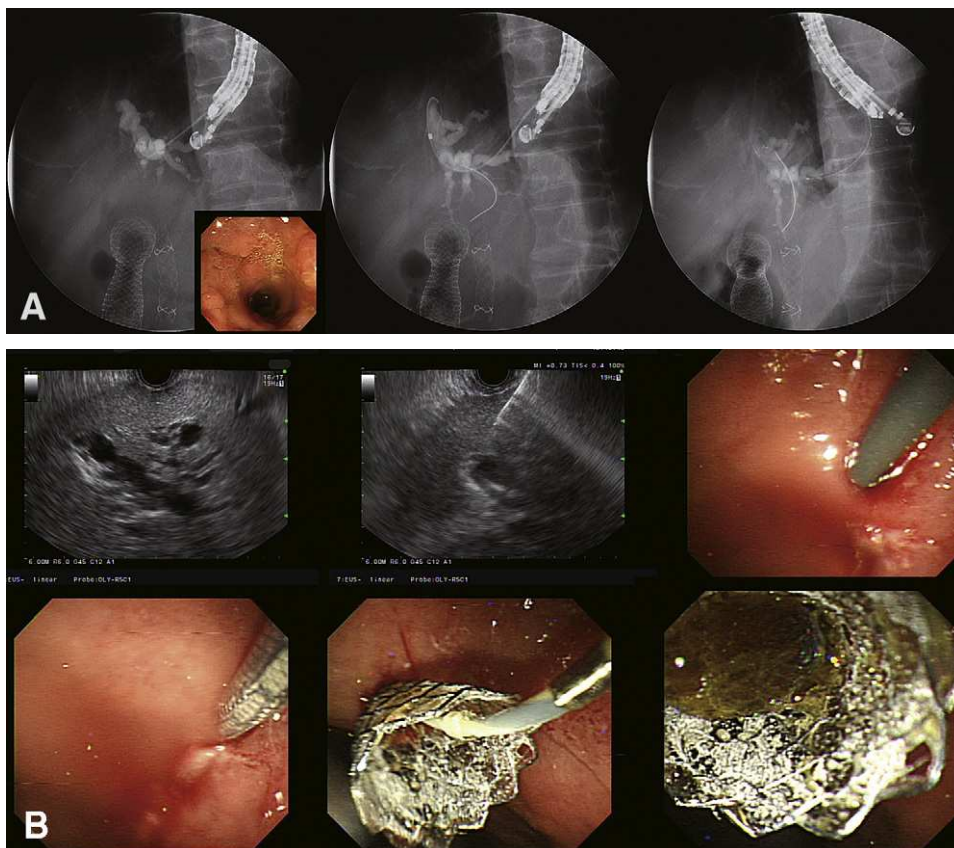
5.3-9.4 mm). During the EUS-HG, no wire passage for rendezvous was attempted in any patient. For fistula dilation, a needle-knife application was performed for 1 patient. A bougie dilator without the need of a needle-knife was performed for the other 4 patients. After an EUS-HG with an FCSEMS, pus or turbid bile was drained from the drain site in all patients (Fig. 1A). The median procedure time was 30 minutes (range 25-40 minutes). No procedural complications, such as bile peritonitis, cholangitis occluding tertiary or small intrahepatic branches with a covered metal stent, and perforation, were observed. Functional success was 100% (5/5). During the follow-up period (median 152 days; range 64-184 days), no late complications, such as stent migration and occlusion, were observed. Thus, no biliary reintervention was performed during follow-up.

## DISCUSSION

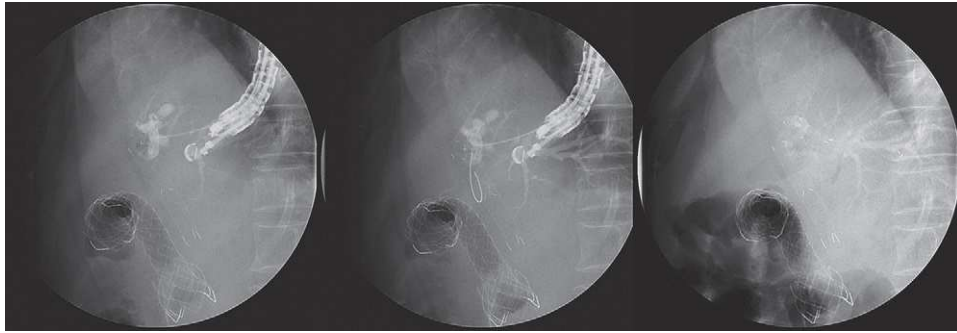
A significant number of SEMS placed to palliate malignant biliary obstructions will become occluded.<sup>3,5</sup> To



**Figure 2.** Case 3. Tumor overgrowth and echogenic debris on the B3 segment were noted on EUS-guided cholangiography and the EUS findings. An EUS-HG with the placement of an FCSEMS was performed via the B3 duct.



**Figure 3.** Case 4. **A**, ERCP failed because of duodenal narrowing despite placement of a duodenal stent (inset). The previously inserted duodenal and biliary stents were observed. **B**, The EUS-HG was performed via the B3 segment.



**Figure 4.** Case 5. ERCP failed because of duodenal narrowing despite placement of a duodenal stent. An EUS-HG was performed via the B3 segment.

**TABLE 2. Summary of published studies and current study on EUS-guided hepaticogastrostomy with an intrahepatic biliary stent**

Study	No. of EUS-BD–intrahepatic biliary stents	% Technical success	% Clinical success	Initial intrahepatic biliary stent (no. cases)	Procedure-related complications (no. cases)
Burmester et al, <sup>10</sup> 2003	1	100	100	Plastic (1)	None
Giovannini et al, <sup>18</sup> 2003	1	100	100	Plastic (1)	None
Kahaleh et al, <sup>12</sup> 2006	2	100	100	Plastic (2)	None
Artifon et al, <sup>17</sup> 2007	1	100	100	Partially covered metal stent (1)	None
Bories et al, <sup>9</sup> 2007	11	91	100	Plastic (7), partially covered metal stent (3)	Plastic stents: transient ileus (1) and early stent clogging (1); partially covered metal stent: biloma (1) and cholangitis (1)
Will et al, <sup>19</sup> 2007	4	100	75	Partially covered metal stent (2), uncovered metal stent (2)	Partially covered metal stent: cholangitis (1)
Park et al, <sup>20</sup> 2009	9	100	100	Fully covered metal stent (9)	Self-limited pneumoperitoneum (2)
Current study	5	100	100	Fully covered metal stent (5)	None

Modified from Savides et al.<sup>21</sup>

manage occluded biliary metal stents, endoscopic insertion of a second plastic stent or an SEMS may be suitable management.<sup>3,5</sup> Although the technical success rate of repeated ERCPs for an occluded biliary metal stent may be higher in previous retrospective studies of distal biliary malignant obstruction,<sup>3-5</sup> repeat transpapillary stent placement may be unsuccessful for an occluded biliary metal stent after the placement of a hilar bilateral metal stent (side-by-side or stent-in-stent placement) or combined duodenal and biliary metal stent placement.<sup>6,7</sup> In such circumstances, PTBD with stenting may be an alternative management option. However, PTBD with stenting has a complication rate of 10% to 30%, with the possible development of cholangitis, bile leak, fistula formation, peritonitis, emphysema, and stent occlusion.<sup>7,21</sup> EUS-BD was therefore introduced as an alternative for the management of PTBD. However, technical issues relating to reducing

the risk of bile leaks with EUS-BD require further evaluation.<sup>21,22</sup> Our recent previous study<sup>20</sup> suggested that EUS-BD with an FCSEMS might be feasible and useful as an alternative to PTBD in the case of failed ERCP because no bile leak or cholangitis was observed. In this study, EUS-BD with an FCSEMS may therefore be considered as the possible indication for the management of an occluded biliary metal stent after a failed ERCP. Although an EUS-guided choledochoduodenostomy may be an alternative to PTBD after failed ERCP,<sup>23</sup> this approach may be impossible in patients with an occluded biliary metal stent at the common bile duct.

There is a major concern about the generalization of this diversion technique for an occluded biliary metal stent in other institutions where endoscopists may have varying levels of experience and familiarity with EUS-HG. Based on previous literature and the current study, the

overall technical and clinical success and complication rates of EUS-HG with a biliary stent were 90% to 100%, 75% to 100%, and 21%, respectively (Table 2).<sup>21</sup> Therefore, this procedure should ideally be undertaken only at tertiary centers by an expert endoscopist. Because reinterventional ERCP for an occluded biliary metal stent may be feasible and effective in most patients with distal biliary obstruction,<sup>3-5</sup> EUS-HG with an FCSEMS may only be recommended for an occluded distal biliary metal stent that is not accessible by conventional technique (eg, accompanying duodenal obstruction or stenosis).

In conclusion, our very preliminary data on the procedures performed by a single expert endoscopist, which highlight the difficulty of dealing with an occluded biliary metal stent after placement of a hilar bilateral metal stent or combined duodenal and biliary stent, suggest that an EUS-HG with an FCSEMS may be a feasible and relatively safe alternative to PTBD as the biliary diversion technique in select patients after a failed ERCP.

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