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BRIEF ARTICLE

Endoscopic ultrasound-guided biliary drainage with placement of a fully covered metal stent for malignant biliary obstruction

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Abstract

AIM: To determine the utility of endoscopic ultrasound-guided biliary drainage (EUS-BD) with a fully covered self-expandable metal stent for managing malignant biliary stricture.

METHODS: We collected data from 13 patients who presented with malignant biliary obstruction and underwent EUS-BD with a nitinol fully covered self-expandable metal stent when endoscopic retrograde cholangiopancreatography (ERCP) fails. EUS-guided choledochoduodenostomy (EUS-CD) and EUS-guided hepaticogastrostomy (EUS-HG) was performed in 9 patients and 4 patients, respectively.

RESULTS: The technical and functional success rate was 92.3% (12/13) and 91.7% (11/12), respectively. Using an intrahepatic approach (EUS-HG, $n = 4$), there was mild peritonitis ($n = 1$) and migration of the metal stent to the stomach ($n = 1$). With an extrahepatic approach (EUS-CD, $n = 10$), there was pneumoperitoneum ($n = 2$), migration ($n = 2$), and mild peritonitis ($n = 1$). All patients were managed conservatively with antibiotics. During follow-up (range, 1-12 mo), there was re-intervention (4/13 cases, 30.7%) necessitated by stent migration ($n = 2$) and stent occlusion ($n = 2$).

CONCLUSION: EUS-BD with a nitinol fully covered self-expandable metal stent may be a feasible and effective treatment option in patients with malignant biliary obstruction when ERCP fails.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP)

is a well-established technique for providing biliary decompression in patients with bile duct obstruction. The success rate for effective biliary decompression with ERCP ranges from 90% to 95%[1]. However, there are patients in whom ERCP fails because of unsuccessful biliary cannulation, or inaccessible papilla due to duodenal stenosis caused by tumor invasion. In these cases, percutaneous biliary drainage (PTBD) is required. However, PTBD can lead to significant complications, including biliary peritonitis, hemobilia, pneumothorax, hematoma, liver abscesses, and patient discomfort related to the catheter[2].

Therefore, endoscopic ultrasound-guided biliary drainage (EUS-BD) using plastic stents has been introduced as an alternative to PTBD in cases of biliary obstruction when ERCP fails[3-6]. However, plastic stent malfunction due to stent clogging after EUS-BD is not uncommon[3,7,8]. Fully covered self-expandable metal stent (FCSEMS) with a large bore diameter may have advantages over plastic stents. Recently, EUS-BD with a FCSEMS was introduced in a few cases of malignant biliary obstruction after a failed ERCP[9]. The current study was conducted to determine the feasibility, outcomes, and risks of EUS-guided hepaticogastrostomy (EUS-HG) and EUS-guided choledochoduodenostomy (EUS-CD) with an FCSEMS as a biliary diversion technique in patients with malignant biliary obstruction for whom interventional ERCP was unsuccessful.

MATERIALS AND METHODS

Study population
We collected data on all patients who presented with obstructive jaundice and who underwent EUS-BD after a failed ERCP during a 20-mo period from February 2009 to September 2010. Failed ERCP was defined as the inability to relieve jaundice or failed biliary cannulation. A total of 2209 ERCPs at Wonkwang University Hospital (*n* = 780) and Jeonbuk National University Hospital (*n* = 1429) were performed during the study period, and 366 required biliary decompression. Of the 22 (6%) patients who underwent alternative methods for biliary decompression as a result of failed ERCP, 13 had EUS-BD. Study eligibility was determined as follows: (1) Initial biliary cannulation or bile duct decompression by ERCP failed because of accompanying duodenal obstruction, periampullary tumor infiltration, and difficult cannulation (*n* = 11); (2) A high-grade left-sided hilar stricture as a result of segmental tumor progression with an occluded biliary metal stent was unable to be crossed by a guidewire (*n* = 2); (3) The patient refused PTBD (*n* = 13).

ERCP was performed by 3 experienced endoscopists (Kim TH, Kim SH and Lee SO). Each endoscopist performs 400 to 450 ERCPs annually. EUS-BD was performed by 2 experienced endoscopists (Kim TH and Kim SH) who perform more than 250 EUS procedures for pancreaticobiliary diseases annually.

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)[10]. The Institutional Review Boards at Wonkwang University Hospital and Jeonbuk National University Hospital, South Korea approved this study. All patients provided written informed consent for participation in this study.

Techniques
Antibiotics were permitted in all cases for 3 d to 5 d before and after the intervention. 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 using a GF-UCT 240 linear-array echoendoscope (Olympus Corp., Tokyo, Japan) in a second session (on the same or next day). These patients underwent an EUS-HG or EUS-CD. Using the transgastric approach, the echoendoscope was placed in the cardia or the lesser curvature of the stomach to view the dilated segment 3 of the liver (Figure 1). Using the transduodenal approach, the echoendoscope was placed in the duodenal bulb to image the extrahepatic bile duct (Figure 2). Color Doppler ultrasonography was used to identify the regional vasculature, and a bile duct puncture was performed with a 19-gauge needle (EUSN-19-T; Cook Endoscopy, Winston-Salem, NC, United States). 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 or retrograde fashion. Afterwards, 6F and 7F tapered, biliary, bougie catheters (catheter tip, 4F; Cook Endoscopy) were inserted and removed, over the guidewire to dilate the tract. If there was resistance when advancing the 6F bougie catheter, a needle-knife (Microtome; Boston Scientific, Natick, MA, United States) with a 7F shaft diameter or tapered MTW catheter (WTW, Endoscopie, Wesel, Germany) was inserted over the guidewire to dilate the tract. To accomplish this, the tip of a needle-knife (Microtome) with a pure current was gently inserted over the guidewire into 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.

Definition of events
Technical success was defined as the deployment 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 reduction in bilirubin to less than 50% of the pretreatment value
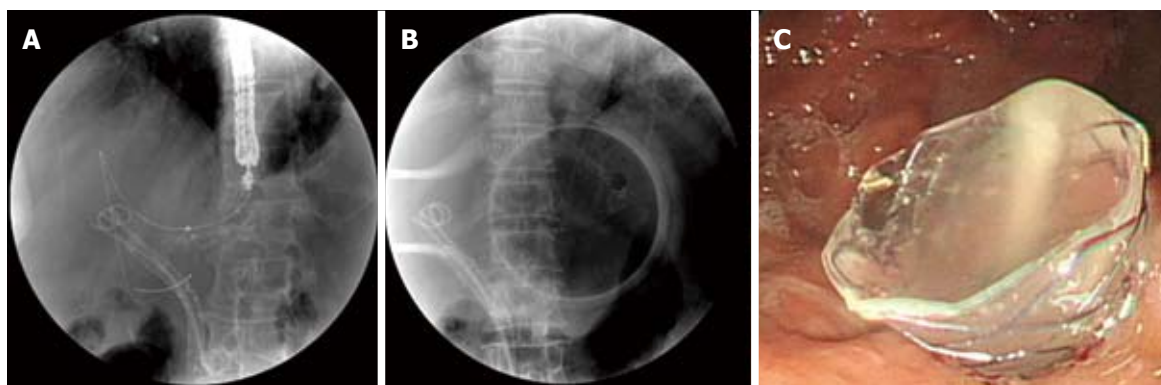
Figure 1 Endoscopic ultrasound-guided hepaticogastrostomy. A: In the intrahepatic approach, the linear array echoendoscope was placed in the lesser curvature of the stomach for viewing the left intrahepatic system. A 0.035-inch guidewire was introduced through the endoscopic ultrasonography-needle and advanced in an antegrade manner; B and C: A fully covered metal stent was placed under echoendoscopic and fluoroscopic view.
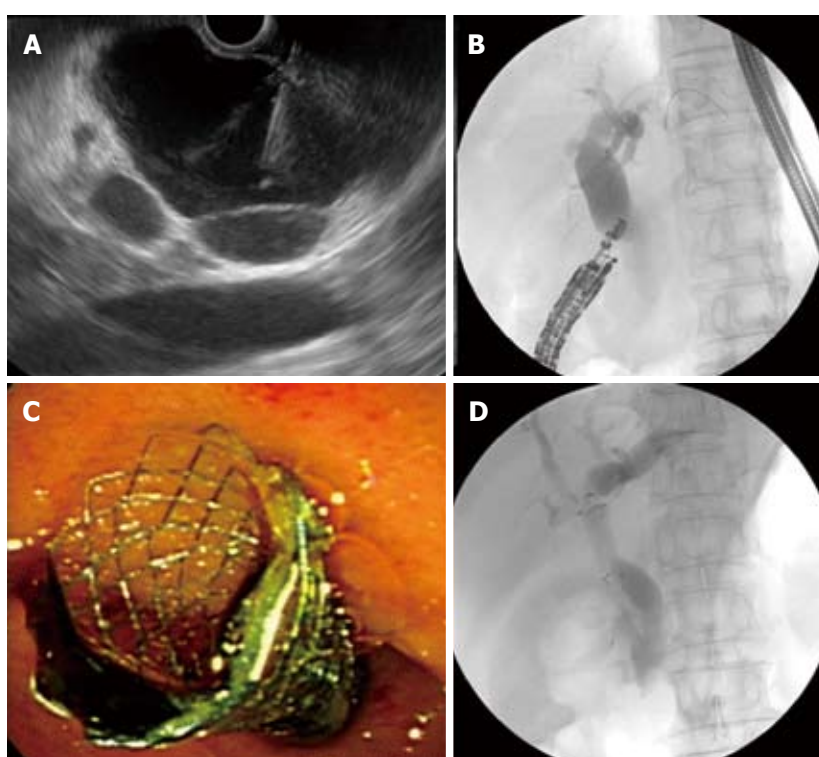

Figure 2 Endoscopic ultrasound-guided choledochoduodenostomy. A: The extrahepatic approach was carried out using an echoendoscope in the duodenal bulb, permitting imaging of the choledochus. Bile duct puncture was carried out with a 19-gauge needle; B: A 0.035-inch guidewire was introduced through the endoscopic ultrasonography-needle and advanced in a retrograde fashion; C and D: A fully covered metal stent was placed under echoendoscopic and fluoroscopic view.

within 2 wk[11]. An early complication was defined as any stent-related complication within 30 d, 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 d after stent placement. Biliary reintervention was defined as any type of endoscopic, percutaneous, or surgical procedure that was required to improve biliary drainage after placement of the stent. Stent occlusion was defined as the recurrence of jaundice and cholestasis and/or evidence of a dilated biliary system on ultrasound (US) or computed tomography (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 puncture of the biliary tract with a 19-gauge needle and placement

of an FCSEMS.

Follow-up
Follow-up continued from stent insertion until the death of the patient or to the end of the study. Biochemical parameters and simple abdominal films were assessed at 2 d, 1 wk and 1 mo after stent placement and every 2 mo thereafter. Patient follow-up was based on outpatient examination findings. Imaging (US or CT and simple abdominal films) was routinely checked every 3 mo.

Statistical analysis
Procedure time (intrahepatic and extrahepatic approaches) and liver function test before and after the EUS-BD using a metal stent were compared using a 2-sample Wilcoxon signed-rank test. Statistical analysis was carried out using

Table 1 Patients' clinical characteristics and results of endoscopic ultrasound-guided biliary drainage (*n* = 13)

No. of patient	Age/sex	Diagnosis	Reason for failed ERCP	Biliary drainage route	Device for puncture/ dilatation	Diameter length of stent (mm/cm)	Technical success	Functional success	Complication	Reintervention	Duration (mo) of 1st stent placement	Status
1	60/M	CBD cancer	Duodenal stenosis due to duodenal ulcer	Transduodenal	19G FN/cystostome	10/6	Success	Success	No	No	Whipple's operation	Alive
2	83/F	CBD cancer	Failed to access the bile duct	Transduodenal	19G FN/cystostome	10/6	Success	Success	Obstruction	Stent reinsertion	6	Dead
3	76/F	CBD cancer	Failed to access the bile duct	Transduodenal	19G FN/cystostome	10/4	Success	Success	Migration	Stent reinsertion	2	Dead
4	68/F	CBD cancer	Duodenal obstruction due to mass	Transduodenal	19G FN/cystostome	10/6	Success	Success	No	No	7	Alive
5	66/M	Pancreatic cancer	Periampullary tumor infiltration	Transduodenal	19G FN/tapered ERCP cannula and cystostome	10/4	Success	Success	Pneumoperitoneum/peritonitis	No	3	Dead
6	68/M	Pancreatic cancer	Periampullary tumor infiltration	Transduodenal	19G FN/bougie dilatator	10/6	Success	Success	No	No	1	Dead
7	67/F	Pancreatic cancer	Periampullary tumor infiltration	Transduodenal	19G FN/NK and bougie dilatator	10/6	Success	Success	No	No	3	Alive
8	59/M	Pancreatic cancer	Periampullary tumor infiltration	Transduodenal	19G FN/tapered ERCP cannula and cystostome	10/6	Success	Success	No	No	4	Alive
9	80/M	Pancreatic cancer	Periampullary tumor infiltration	Transduodenal	19G FN/tapered ERCP cannula and cystostome	10/6	Success	Success	No	No	3	Alive
10	81/M	Klatskin's tumor	Stricture could not be crossed (hilar)	Transgastric	19G FN/cystostome	10/6	Success	Fail	Migration/pneumo-peritoneum/peritonitis	PTBD	5	Dead
11	55/M	Intrahepatic cholangiocarcinoma	Stricture could not be crossed (hilar)	Transgastric	19G FN/cystostome	10/6	Success	Success	No	No	3	Dead
12	62/M	Pancreatic cancer	Stricture could not be crossed (distal CBD)	Transgastric	19G FN	10/6	Failed					Dead
13	70/M	CBD cancer	Stricture could not be crossed (distal CBD)	Transgastric	19G FN/bougie dilatator	10/6	Success	Success	Migration	Stent reinsertion	2	Alive

F: Female; M: Male; CBD: Common bile duct; G: Gauge; NK: Needel knife; FN: Fine needle; PTBD: Percutaneous biliary drainage; ERCP: Endoscopic retrograde cholangiopancreatography.

SPSS 12.0 (SPSS, Chicago, IL, United States), and a 2-tailed *P* value of < 0.05 was considered statistically significant. Findings are expressed as the median and range.

RESULTS

Patient characteristics, procedural data, and follow-up results are presented in Table 1. A total of 13 patients (9 men and 4 women) with malignant biliary obstruction underwent EUS-BD with a fully covered metal stent after a failed ERCP. The etiology of biliary obstruction was pancreatic cancer in 5 patients, distal common bile duct cancer in 6 patients, Klatskin's tumor in 1 patient, and peripheral cholangiocarcinoma in 1 patient.

Reasons for failed ERCP were duodenal stenosis due to a previous duodenal ulcer (*n* = 1), tumor obstruction of the duodenum (*n* = 1), periampullary tumor infiltration (*n* = 5),

Table 2 Summary of published studies and current study on endoscopic ultrasound-guided biliary drainage with metal stent

Study	No. of EUS-BD-metal biliary stents	Technical success %	Clinical success %	Type of metal stent	Procedure-related complications (No. cases)
Will *et al*[6]	6	100	83.3	Partially covered (3), uncovered (3)	Cholangitis (1)
Artifon *et al*[27]	1	100	100	Partially covered	None
Bories *et al*[3]	11	91	100	Partially covered metal stent (3)	Biloma (1), cholangitis (1)
Park *et al*[9]	9	100	100	Fully covered	Pneumoperitoneum (2)
Park *et al*[28]	5	100	100	Fully covered	None
Siddiqui *et al*[29]	8	100	100	Fully covered	Duodenal perforation (1)
This study	13	92.3	91.7	Fully covered	Mild peritonitis (2)

EUS-BD: Endoscopic ultrasound-guided biliary drainage.

failure to access the common bile duct (*n* = 2), high-grade stricture of the distal common bile duct with an occluded biliary plastic stent (*n* = 2), and high-grade left-sided hilar stricture from segmental tumor progression with an occluded biliary metal stent (*n* = 2). Patients with obstruction of the duodenum received a concomitant duodenal stent at time of the procedure.

Technical and functional success

Technical success was 92.3% (12/13); there was 1 failure of guidewire insertion after puncture through the transgastric approach, because the diameter of intrahepatic bile duct was so small and had sharp angulation. During EUS-BD, no wire passage for rendezvous was attempted in any of the patients. For biliary access, a cystostome only was used in 6 of the 12 patients (4 extrahepatic approach and 2 intrahepatic approach), a tapered MTW catheter and a cystostome together were used 3 of 12 patients, and just bougie dilatators were used in 3 patients, respectively. Median procedure time was 19.5 min (range, 14-35 min). Nine patients were treated using an extrahepatic approach (all transduodenal). Four patients were treated using an intrahepatic approach (all transgastric). The median diameter of the left intrahepatic bile duct as determined by EUS was 7.3 mm (range, 5.3-9.4 mm).

Functional success was 91.7% (11/12). After the placement of a EUS-BD, the median bilirubin level decreased significantly from 11.6 mg/dL to 1.7 mg/dL (*P* = 0.001). The median alkaline phosphatase level also decreased significantly from 1629.0 IU/L to 113.0 IU/L (*P* = 0.001). Migration of a metal stent to stomach occurred in 1 patient treated with the transgastric approach.

Early complications after endoscopic ultrasound-guided biliary drainage

With the intrahepatic approach (*n* = 4), there was stent migration to the stomach with mild peritonitis (*n* = 1). With the extrahepatic approach (*n* = 9), there was pneumoperitoneum with mild peritonitis (*n* = 1). All patients with peritonitis were managed conservatively with antibiotics. Bleeding and cholangitis were not observed in any of the enrolled patients after the procedure. In addition, there was no significant pain after the procedure. Two patients with duodenal obstruction also received duodenal metal stents.

Follow-up

One patient with distal common bile duct (CBD) cancer

underwent curative resection (Whipple's operation), and this procedure did not disturb the operative procedure. None of the patients, except the patients that underwent the operation, were lost during the follow-up period (median, 5 mo; range, 1-12 mo). With regard to re-intervention, there was re-intervention in 4 of the 13 cases (30.7%), which was necessitated by stent migration (*n* = 3) and stent occlusion (*n* = 1). Stent migration occurred 2 d later (EUS-HG) and 2 mo later (EUS-CD and EUS-HG), respectively. In the patients with stent migration, the stents passed spontaneously without lodgment in the bowel. A second FCSEMS was placed through the previous choledochoduodenostomy site in 1 patient. In 2 patients with stent migration, PTBD was inserted into the obstructed left hepatic duct due to his severe general weakness. In 1 patient with stent occlusion by tumor ingrowth into the metal stent (choledochoduodenostomy), an additional FCSEMS was placed through the previous choledochoduodenostomy site.

DISCUSSION

EUS-BD may be an alternative method in some patients when endoscopic biliary drainage is unsuccessful because of failed biliary cannulation or tumor infiltration, which limits the endoscopic approach to the major papilla. At present, there are 2 approaches for EUS-BD, the transgastric route and the transduodenal route. A plastic or metal stent can be placed by this method. However, most papers reported EUS-BD with a plastic stent[4,5,7,8,12-14]. We thought that FCMEMS with a large bore diameter may have advantages over the plastic stent. There are a few papers describing EUS-BD with a metal stent[6,9,15] (Table 2), however, there are no reports regarding preoperative drainage of biliary obstruction by EUS-BD. The current study demonstrated that transduodenal EUS-BD using a nitinol FCSEMS may be safe and feasible after a failed ERCP. The reasons for failed ERCP were duodenal stenosis by a duodenal ulcer, periampullary tumor invasion, and difficult biliary cannulation. In one patient with distal CBD cancer who had duodenal stenosis due to a previous duodenal ulcer, initially EUS-BD was performed to resolve cholangitis and bile drainage, and Whipple's operation was performed. But EUS-guided metal insertion in this patient did not disturb the operation procedure.

A significant number of self-expandable metal stent

(SEMS) and plastic stents placed to palliate malignant obstructions will be occluded. Repeat transpapillary stent placement may be unsuccessful for an occluded biliary metal or plastic stent after the placement of a hilar metal stent or combined duodenal and biliary metal stent placement. In such circumstances, PTBD may be uncomfortable for patients and has a 10%-30% complication rate, with complications such as cholangitis, bile leak, peritonitis, and stent occlusion[16]. EUS-HG with a FCSEMS may be recommended in such circumstances. In our 2 patients with a hilar metal stent, dilation of the left main duct caused by segmental tumor progression was shown to be aggravated. In another 2 patients with periampullary cancer drained by a pigtail plastic stent, this stent was occluded by tumor ingrowth and bile plug. Because these patients had jaundice and cholangitis, EUS-HG with a FCSEMS was performed. Some experts have recommended the intrahepatic approach because it seems to be safer[7,15]. In the intrahepatic approach, one-step placement of a partially covered wall stent may have been limited in earlier studies because there was 1 bile peritonitis and 1 cholangitis. However, we found the transduodenal or extrahepatic approach to be safer and more effective and it is probably less technically difficult compared with the intrahepatic approach. The advantage is that the duodenum is very close to the extrahepatic bile duct and the duodenal wall is thin without major vascular structures.

There were complications with EUS-BD, including stent migration, pneumoperito-neum, and cholangitis[17,18]. In this study, during follow-up (median, 3 mo), there was re-intervention (4/12, 33.3%) necessitated by stent migration ($n = 3$) and stent occlusion ($n = 1$). The 3 stent migrations occurred 2 d later (EUS-HG), 2 mo later (EUS-CD), and 2 mo later (EUS-CD). The stent migration rate (3/12, 25.0%) was higher than that reported (7%) in another paper[9]. Although a flare at both ends and minimal shortening of this newly designed nitinol stent may contribute to the prevention of stent migration[19], a slippery covered metal stent with low axial force may lead to migration. In addition, marked CBD dilatation may have affected FCSEMS floating resulting in the minimization of the anchoring effect of the proximal flared end of the FCSEMS.

Studies with uncovered SEMS reported stent occlusion rates ranging between 18% and 46%[20,21] with the main cause of obstruction being tumor ingrowth. Although partially or fully covered SEMS were designed to prevent this complication, these stents can not completely protect tumor ingrowth in the biliary metal stent[22]. Occasional authors have reported no tumor ingrowth with covered SEMSs. However, these series often include few patients and frequently have a relatively high prevalence of tumor overgrowth or sludge formation as a cause of stent failure[23-25]. Our study shows tumor overgrowth was observed in one case with distal CBD cancer.

During the EUS-BD procedure, the leakage of bile into the peritoneum with peritonitis can occur because the gap between the stent and the fistula is likely to occur. The shortening of metal stent can lead to failure of correct stent placement, and stent migration and dislocation after placement. Experience with partially coverd SEMS is limited and associated with a higher complication rates due to stent shortening[3,6]. To prevent bile leakage, we placed a FCSEMS that is made of nitinol. This stent, with both ends flared, was designed to prevent distal or proximal migration. The nitinol stent has less shortening compared with a partially covered Wall stent, and a fully covered metal stent may prevent bile leakage[19]. Therefore, due to the characteristics of this stent, it may prevent bile peritonitis. Because the diameter of the working channel of the linear array echoendoscope is only 3.7 mm, it is possible to quickly perform one-step placement of FCSEMS with an 8F-diameter delivery device. In this study, although bile leakage occurred during the procedure, all patients had only mild peritonitis and were treated with conservative management, such as antibiotics and nothing by mouth.

If the gap between the bile duct and the GI tract grows farther after EUS guided biliary drainage with stent, early migration of stent into the abdominal cavity may occur, particularly in the case of a transgastric approach. A fatal complication due to sepsis after development of large fistula related to stent migration into the abdominal cavity has recently been reported[26]. However, bile leakage *via* the relatively large fistula can make bile peritonitis and the bile duct collapse. Therefore, it may be difficult or impossible to carry out EUS-BD in these patients. In such a case, PTBD or emergency surgery must also be considered. To prevent severe complications, an endoscopist must have considerable knowledge about periduodenal and hepatobiliary anatomy in linear array EUS. Also, the procedure must be performed quickly and efficiently with appropriately sized stents. When selecting a stent, stent structure, axial force and shortening of stent should be considered.

In conclusion, EUS-guided transgastric or transduodenal biliary drainage with one-step placement of an FCSEMS may be a promising alternative method to PTBD. It may be a reasonable, feasible, and promising minimally invasive endoscopic approach in selected patients as indicated as above. However, several complications can occur, and special attention of the potential complications such as peritonitis and migration are needed. Therefore, additional experience and the development of new comfortable accessories for this procedure are needed. Also, a large case series and prospective trials are needed to further assess this technique.

COMMENTS

Background
For palliation of patients with malignant biliary obstruction, percutaneous biliary drainage (PTBD) is a classic method in some patients when endoscopic biliary drainage is unsuccessful because of failed biliary cannulation or tumor infiltration, which limits the endoscopic approach to the major papilla. Recently endoscopic ultrasonography-guided biliary drainage (EUS-BD) with plastic stent or uncovered self-expandable metal stent (SEMS) has been introduced as an alternative to PTBD in these cases of biliary obstruction.

Research frontiers
The authors thought that a nitinol fully covered SEMS (FCSEMS) with a large bore diameter may have advantages over the plastic stent and other types of metal stent.

Innovations and breakthroughs
Technical and functional success with FCSEMS for palliation of patients with malignant biliary obstruction was respectively 92.3% (12/13) and 91.7% (11/12). Although there was early mild complication such as one case of immediate

stent migration and 2 cases of bile peritonitis, all complications improved with conservative treatment.

Applications
EUS-guided transgastric or transduodenal biliary drainage with one-step placement of a nitinol FCSEMS may be a promising alternative method to PTBD. Additional experience and the development of new comfortable accessories for this procedure are needed. Also, a large case series and prospective trials are needed to further assess this technique.

Terminology
There are 2 approaches for EUS-BD, the transgastric route and the transduodenal route. EUS-guided hepaticogastrostomy was performed through the transgastric route, and EUS-guided choledochoduodenostomy through the transduodenal route.

Peer review
The authors reported high success rate with this challenging procedure. They clearly demonstrated that extrahepatic approach is easier and safer than intrahepatic approach, Although technical expertise is important, the authors demonstrated more than 90% technical success with low major complication rates. This paper motivates talented endoscopists to solve biliary obstruction *via* EUS guided technics.

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