—Original Article—

EUS-guided antegrade metal stenting with hepaticoenterostomy using a dedicated plastic stent with a review of the literature (with video)

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ABSTRACT

Background and Objectives: Recently, a novel EUS-guided biliary drainage (EUS-BD) technique consisting of EUS-guided antegrade stenting and EUS-guided hepaticoenterostomy (EUS-AS+HES) using two conventional metal stents (MS) has been reported to decrease adverse events and maintain longer stent patency for malignant biliary obstruction (MBO). However, only a few limited reports have evaluated this technique. Finally, dedicated plastic stents (PSs) have been developed to perform EUS-HES safely. The aim of the present study was to evaluate the outcome in EUS-AS+HES for MBO using the dedicated HES PSs. **Methods:** The results of a total of 23 patients who underwent EUS-AS+HES (18 simultaneous cases and 5 sequential cases) for MBO from October 2014 to July 2017 were retrospectively reviewed. **Results:** Technical and clinical success rates were 100% (23/23). Adverse events were seen in 8.7% (2/23); 2 cases of mild biliary peritonitis, which were successfully managed conservatively. Overall survival was 96 days and the median duration of stent patency, including stent dysfunction, patient death, and last follow-up, was 66.0 days (53 days in simultaneous cases and 78 days in sequential cases). Stent dysfunction was seen in 13.0% (3/23) of patients in 267, 263, and 135 days after the procedure. **Conclusions:** The novel EUS-BD technique, EUS-AS using MS plus HES employing a dedicated PS, was shown to be a feasible procedure for MBO and should yield longer duration of stent patency. Furthermore, sequential antegrade stenting in cases of occluded HES seems to be one other option instead of HES stent exchange. Further large-scale comparison studies with EUS-HES or EUS-AS are required to confirm its clinical efficacy.

Key words: EUS-guided biliary drainage, EUS-guided antegrade stenting, EUS-guided hepaticoenterostomy, malignant biliary obstruction

INTRODUCTION

Transpapillary endoscopic biliary drainage (EBD) is recognized as the gold standard procedure for resolution of malignant biliary obstruction (MBO).[1,2] However, EBD is not always successfully accomplished

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by MBO in cases of inability of selective biliary cannulation such as intradiverticular papilla or inaccessible papilla in which endoscopes cannot reach the ampulla of Vater such as gastric outlet obstruction and cases with surgically altered anatomy, even using balloon enteroscopy-assisted ERCP.[3,4]

Recently, EUS-guided biliary drainage (EUS-BD) has been developed as a novel advanced drainage technique when ERCP has failed in such cases.[5-12] In these EUS-BD techniques, EUS-guided hepaticoenterostomy (EUS-HES), including hepaticogastrostomy or hepaticojejunostomy using a metal stent (MS), has been commonly compared with EUS-guided antegrade stenting (EUS-AS) because of its short procedure time and simple guidewire manipulation across the stricture and papilla. However, bile flow in EUS-HES is not physiological, resulting in short stent patency, in particular, when using nondedicated stents. Thus, we hypothesized that EUS-AS may be an ideal stent placement technique as well as traditional stent placement using ERCP. On the other hand, EUS-AS alone may cause serious bile leak from the puncture site if acute stent dysfunction occurs due to inappropriate stent placement or insufficient stent expansion. Furthermore, re-EUS-BD is required in cases of early or late antegrade stent dysfunction even after full stent expansion. Recently, a novel EUS-BD technique consisting of EUS-HES and EUS-AS using MSs has been reported to decrease adverse events, provide longer stent patency, and simplify re-intervention in patients with distal MBO.[13,14] Furthermore, we have reported the usefulness of a dedicated plastic stent (PS) for HES stents.[15] Here, we evaluate the short- and long-term outcomes of the novel EUS-BD technique, employing EUS-AS using MS plus HES using a dedicated PS for distal MBO [Figure 1].

METHODS

A total of 23 patients (14 men, median age: 69.0 ± 12.2 years, range: 41–91 years) who underwent EUS-AS and EUS-guided HES (EUS-AS+HES) for MBO, excluding hilar bile duct obstruction, from October 2014 to July 2017 at Tokyo Medical University Hospital were retrospectively reviewed.

The EUS-guided antegrade stenting and EUS-guided hepaticoenterostomy procedure

Patients were given antibiotics before the procedure, and the procedure was performed under sedation with flunitrazepam and pentazocine. All procedures were carried out using a linear array echoendoscope (GF-UCT260; Olympus Medical Systems, Tokyo, Japan) connected to an ultrasound processor (EU-ME2; Olympus Medical Systems, Tokyo, Japan).

Simultaneous EUS-guided antegrade stenting and EUS-guided hepaticogastrostomy

First, the accessibility of the intrahepatic bile duct (IHBD) in the left lobe of the liver was carefully scanned from the stomach, and the presence or absence of intervening blood vessels along the puncture route was confirmed using color Doppler imaging. Next, the dilated IHBD was punctured under EUS guidance with a 19G fine-needle aspiration (SonoTip Pro Control; Medi-Globe GmbH, Achenmühle, Germany) [Figure 2a]. After confirming that the bile duct was correctly punctured on cholangiography, an 0.025-inch guidewire (VisiGlide; Olympus, Tokyo, Japan) was inserted into the biliary tract through the needle. In nondilated bile duct dilatation, a 0.018-inch guidewire (Pathfinder; Boston Scientific Japan, Tokyo, Japan) was used after puncture with a 22G needle (Expect; Olympus Medical Systems, Tokyo, Japan). Tract dilation was performed using a tapered catheter (ERCP catheter; MTW Co, Ltd, Düsseldorf, Germany), a dedicated EUS-BD dilator (ES Dilator; Zeon Medical Co, Tokyo, Japan),[16] and/or a 6-Fr thermal dilator (CystGastroset, Endoflex, Voerde, Germany) [Figure 2b]. Thereafter, the guidewire was advanced through the stricture and the papilla of Vater to the duodenum. If necessary, a hydrophilic guidewire (Radifocus, Terumo, Tokyo, Japan) with the ERCP catheter was used for manipulation [Figure 2c]. After confirming the location and the length of the MBO, an uncovered self-expandable MS (SEMS) (10-mm in diameter; Zilver 635; Cook Medical, Bloomington,

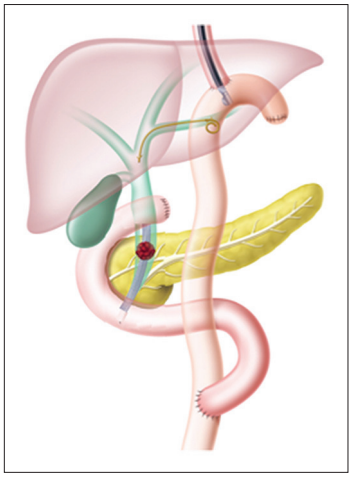

Figure 1. Schema of EUS-guided antegrade stenting using a metal stent plus hepaticoenterostomy using a plastic stent

IN, USA: 10 mm or 8 mm in diameter; X-Suit NIR; Olympus Medical Systems, Tokyo, Japan: 10 mm in diameter; WallFlex; Boston Scientific Japan, Tokyo, Japan) was antegradely placed across the MBO [Figure 2d]. Finally, a dedicated 8-Fr PS (Type IT, Gadelius Medical K. K., Tokyo, Japan)[15] was placed across the HES route [Figure 2e and Video 1].

Sequential EUS-guided antegrade stenting and EUS-guided hepaticoenterostomy have the following primary EUS-guided hepaticoenterostomy

When re-intervention was needed in cases of prior EUS-HES, EUS-AS+HES was sequentially performed after removal of the previously placed HES PS (Type IT, Gadelius Medical K. K) using a therapeutic duodenoscope (TJF-260V, Olympus).

Evaluation

The primary endpoint of this study was the duration of stent patency, including stent dysfunction, patient death, or last follow-up. Secondary endpoints included duration of stent patency in terms of stent dysfunction, technical and clinical successes, overall survival (OS), and procedure-related adverse events. The duration of stent patency was measured from EUS-AS+HES stent deployment until stent dysfunction, patient death, or last follow-up. Stent dysfunction was defined as cholangitis or obstructive jaundice. The duration of stent patency in stent dysfunction was measured from EUS-AS+HES stent deployment to the appearance of stent dysfunction. Technical and clinical successes were defined as successful deployment of the two stents and a 75% reduction in the total bilirubin level or other liver function levels in normal bilirubin level cases before EUS-AS+HES was performed, respectively. OS was measured from the day before EUS-HES in sequential EUS-AS+HES, or simultaneous EUS-AS+HES was done to the time of death or last follow-up. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon's severity grading system.[17] This study was approved by our Institutional Review Board (No. 3974).

Statistical analysis

The results were presented as median values and means (± standard deviations). Duration of stent patency was estimated using the Kaplan–Meier method. SPSS version 13.0 (SPSS, Chicago, IL, USA) statistical software was used to carry out all statistical analyses.

RESULTS

Patient characteristics

The characteristics of the patients are shown in Table 1. The reasons for MBO were as follows: 11 pancreatic cancers, 2 gastric cancers, 2 ampullary cancers, duodenal cancer, bile duct cancer, and 6 metastatic cancers. Among the patients with metastatic cancer, the primary sites were as follows: 3 renal cell cancers, gallbladder cancer, cervical cancer, and bile duct cancer. Reasons for

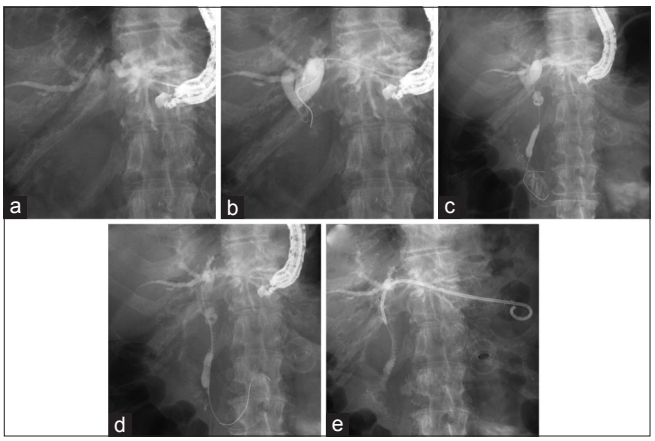

Figure 2. EUS-guided antegrade stenting with hepaticogastrostomy. (a) The intrahepatic bile duct is punctured using a 19G fine-needle aspiration, and contrast medium is injected. (b) After the needle is extracted from the scope with the guidewire kept in the bile duct, the fistula is dilated using a dedicated EUS-biliary drainage dilator. (c) A guidewire is inserted through the malignant biliary obstruction and the Vater's ampulla to the intestinal tract, with corresponding movements of the ERCP catheter. (d) An uncovered self-expandable metal stent is antegradely placed across the malignant biliary obstruction. (e) A dedicated plastic stent is placed across hepaticogastrostomy route through the guidewire

Table 1. Characteristics of all patients

	EUS-AS+HES		
	All	Simultaneous	Sequential
Total number of patients, *n*	23	18	5
Sex, male/female, *n*	14/9	10/8	4/1
Age (median±SD [range], year)	69±12.2 (41-91)	71.5±12.6 (41-91)	62±9.5 (54-80)
Diseases involving biliary strictures, *n*			
Pancreatic cancer	11	8	3
Gastric cancer	2	2	0
Ampullary cancer	2	1	1
Duodenal cancer	1	1	0
Bile duct cancer	1	1	0
Metastasis of other cancer	6	5	1
Reason for EUS-AS+HES, *n*			
Gastric outlet obstruction	13	11	2
Surgical altered anatomy	7	4	3
Failed ERCP	3	3	0

EUS-AS: EUS-guided antegrade stenting, HES: Hepaticoenterostomy, SD: Standard deviation

performing EUS-AS+HES were as follows: 13 gastric outlet obstructions, 7 surgical altered anatomies, and 3 failed ERCPs.

Short-term outcome of EUS-guided antegrade stenting and EUS-guided hepaticoenterostomy

The details of EUS-AS+HES are shown in Table 2. In total, EUS-AS+HES was carried out in all 23 patients including 5 cases of sequential EUS-AS+HES, in which EUS-AS+HES was carried out when primary HES stent dysfunction occurred. Biliary puncture from the stomach was successful in all patients, with a median size of punctured IHBD, 5 mm (range: 3–9 mm), and the accessed biliary branch duct was B2 in 8 patients and B3 in 15 patients. The fistula was dilated using a dedicated EUS-BD dilator in 12 patients, a thermal catheter in 9 patients, and a standard catheter in 2 patients using the guidewire deployed in the bile duct. After tract dilation, the guidewire manipulation through the MBO and the ampulla were successful in all patients, and an uncovered SEMS 10 mm in diameter and 8 mm in diameter was placed across the MBO in 18 patients and 5 patients, respectively. SEMS placed across the papilla was performed in 16 patients. Finally, technical and clinical success rates were both 100% (23/23). EUS-AS+HES-related adverse events are shown in Table 2. There were 2 (8.3%) cases of mild biliary peritonitis only in simultaneous EUS-AS+HES, which were both successfully managed conservatively.

Long-term outcomes of EUS-guided antegrade stenting and EUS-guided hepaticoenterostomy

The long-term outcome is described in Table 2. The OS was 96 days [Figure 3]. Median duration of stent patency including stent dysfunction, patient death, and period to the last follow-up was 66 days in all EUS-AS+HES [Figure 4], 53 days in simultaneous EUS-AS+HES [Figure 5], and 78 days in sequential EUS-AS+HES [Figure 6].

Stent dysfunction was seen in 3 patients in 267, 263, and 135 days after EUS-AS+HES [Figure 7]. Stent dysfunction included stent obstruction in 2 cases and cholangitis with stent obstruction as a result of sludge

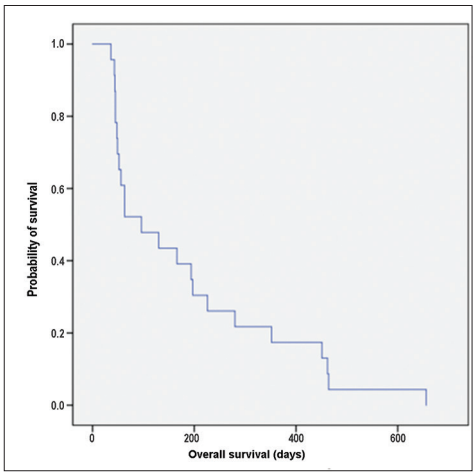

Figure 3. Overall survival. Median overall survival was 96.0 days

Table 2. Details of EUS-antegrade stenting + hepaticoenterostomy

	EUS-AS+HES		
	All	Simultaneous	Sequential
Size of punctured IHBD, mm, median (range)	5 (3-9)	5.5 (5-9)	4 (3-7)
Accessed biliary branch duct (B2/B3), *n*	8/15	6/12	2/3
Fistula dilation device, *n*			
Dedicated EUS-BD dilator	12	11	1
Thermal catheter	9	5	4
Standard catheter	2	2	0
Stent diameter of EUS-AS, *n*			
10 mm	18	15	3
8 mm	5	3	2
EUS-AS across the ampulla, *n*	16	12	4
Technical success, *n* (%)	23/23 (100)	18/18 (100)	5/5 (100)
Clinical success, *n* (%)	23/23 (100)	18/18 (100)	5/5 (100)
Adverse event, *n* (%)	2/23 (8.7)	2/18 (11.1)	0/5 (0)
Biliary peritonitis (grade)	2 (mild)	2 (mild)	0
Overall survival, median (range), days	96 (36-656)	56 (36-656)	280 (63-464)
Duration of stent patency*, median (range), days	66 (36-462)	53 (36-462)	78 (36-134)
Stent dysfunction, *n* (%)	3/23 (13.0)	2/18 (11.1)	1/5 (20.0)

*Stent dysfunction, patient's death, or last follow-up. IHBD: Intrahepatic biliary duct, EUS-AS: EUS-guided antegrade stenting, EUS-BD: EUS-guided biliary drainage, HES: Hepaticoenterostomy

in 1 case. Among them, one case underwent best supportive care because of advanced malignant tumor and poor performance status, without re-intervention. In 2 other patients, re-intervention was carried out by balloon cleaning for the EUS-AS stent and stent exchange for EUS-HES. On the other hand, in cases of prior HES, stent dysfunction was seen in all patients in 168, 85, 77, 53, and 27 days after prior HES. The details of patients and procedure characteristics and outcomes are shown in Table 3.

Cost analysis

Cost analysis for each EUS intervention is demonstrated in Table 4. The total cost of EUS-AS+HES using two MSs is greatest. In contrast, those of EUS-HES using PS are lowest. Those of EUS-AS using MS + HES with PS are intermediate between EUS-AS using MS + HES using MS and EUS-HES using PS and are almost the same as EUS-HES using MS or EUS-AS using MS.

DISCUSSION

It is well known that traditional ERCP, which enables an intraductal approach (duodenum-papilla-bile duct) apart from EUS-BD, the so-called transluminal approach, is still the first-line BD technique, even in high-volume centers of interventional EUS.[18,19]

EUS-guided choledochoduodenostomy (EUS-CDS) and EUS-HES are common EUS-BD techniques, mostly in patients with malignant diseases at the end stage of disease because these techniques are more simple and do not require difficult guidewire manipulation compared with EUS-AS. However, the

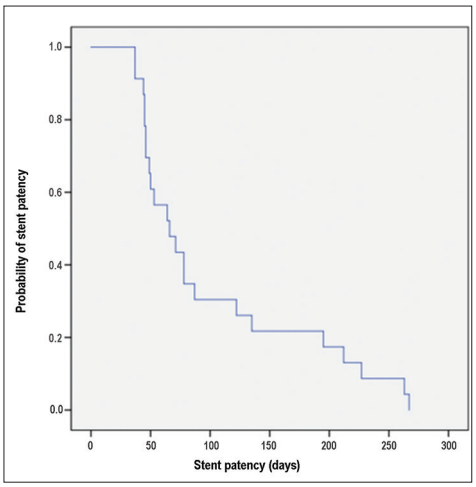

Figure 4. Duration of stent patency including stent dysfunction, patient death, and last follow-up in all EUS-antegrade stenting + hepaticogastrostomy. Median stent patency was 66.0 days

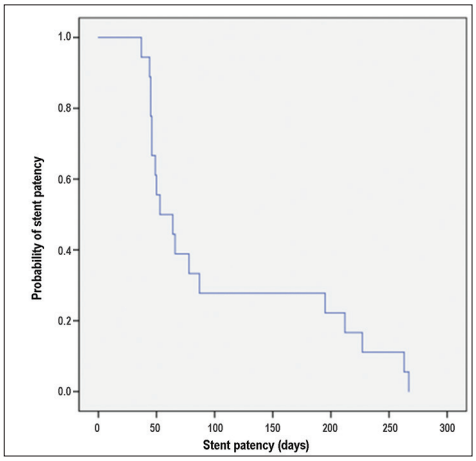

Figure 5. Duration of stent patency including stent dysfunction, patient death, and last follow-up in simultaneous EUS-antegrade stenting + hepaticogastrostomy. Median stent patency was 53.0 days

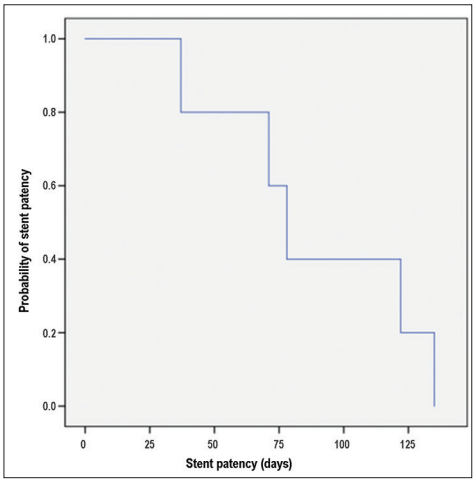

Figure 6. Duration of stent patency including stent dysfunction, patient death, and last follow-up in sequential EUS-antegrade stenting + hepaticogastrostomy. Median stent patency was 78.0 days

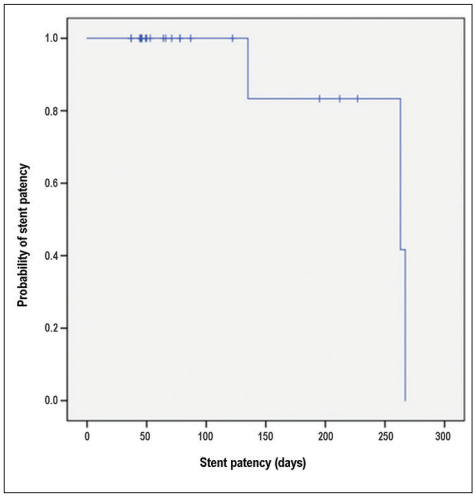

Figure 7. Duration of stent patency in EUS-antegrade stenting + hepaticogastrostomy stent dysfunction. Median stent patency was 263 days

Table 3. Clinical characteristics of EUS-antegrade stenting+hepaticoenterostomy

n	Age/sex	Reason for BO	Reason for procedure	Prior HES (DoST)	Abbd	Fistula dilatation device	AS Stent size	AS across the ampulla	Adverse event	75% RoLF	Stent dysfunction	DoST	Status
1	82/female	AC	SAA	No	B2	T-catheter	10 mm	−	No	Yes	+	267	Death
2	41/female	PC	DO	No	B3	T-catheter	10 mm	Yes	Hyperamylasemia	Yes	−	44	LF
3	78/male	GC	DO	No	B3	T-catheter	8 mm	No	No	Yes	−	37	Death
4	61/male	PC	SAA	No	B2	T-catheter	10 mm	Yes	No	Yes	−	45	Death
5	68/male	PC	DO	No	B3	T-catheter	10 mm	Yes	No	Yes	−	227	Death
6	68/female	PC	FE	No	B3	D-dilator	10 mm	Yes	No	Yes	+	263	Alive
7	81/female	BDC	FE	No	B3	D-dilator	10 mm	Yes	No	Yes	−	87	Death
8	52/male	M	DO	No	B2	D-dilator	8 mm	No	No	Yes	−	50	LF
9	91/male	PC	FE	No	B2	D-dilator	10 mm	Yes	No	Yes	−	195	Death
10	74/male	PC	SAA	No	B3	D-dilator	10 mm	Yes	No	Yes	−	212	Death
11	83/male	DC	DO	No	B3	D-dilator	10 mm	Yes	No	Yes	−	64	Death
12	86/male	GC	DO	No	B3	D-dilator	10 mm	No	No	Yes	−	66	Death
13	64/female	M	DO	No	B2	D-dilator	10 mm	Yes	Biliary peritonitis	Yes	−	46	Death
14	65/female	PC	DO	No	B3	D-dilator	10 mm	Yes	No	Yes	−	46	Surgery
15	76/female	PC	DO	No	B3	D-dilator	8 mm	No	Biliary peritonitis	Yes	−	49	Death
16	61/male	M	SAA	No	B2	S-catheter	10 mm	Yes	No	Yes	−	53	Death
17	86/male	M	DO	No	B3	S-catheter	10 mm	No	No	Yes	−	78	Death
18	69/male	M	DO	No	B3	D-dilator	10 mm	Yes	No	Yes	−	45	Death
19	73/female	AC	DO	Yes (85)	B2	T-catheter	10 mm	Yes	No	Yes	−	71	Death
20	59/male	PC	SAA	Yes (77)	B3	T-catheter	10 mm	Yes	No	Yes	−	78	Death
21	80/male	M	SAA	Yes (168)	B3	T-catheter	10 mm	−	No	Yes	−	122	Death
22	62/female	PC	SAA	Yes (53)	B3	T-catheter	8 mm	Yes	No	Yes	+	135	Death
23	54/male	PC	DO	Yes (27)	B2	D-dilator	8 mm	Yes	No	Yes	−	37	Death

Abbd: Accessed biliary branch duct, AC: Ampullary cancer, AS: Antegrade stenting, BDC: Bile duct cancer, BO: Biliary obstruction, DC: Duodenal cancer, D-dilator: Dedicated EUS-BD dilator, DO: Duodenal obstruction, DoST: Duration of stent patency, FE: Failed ERCP, GC: Gastric cancer, HGS: Hepaticogastrostomy, LF: Last follow-up, M: Metastasis of other cancer, PC: Pancreatic cancer, SAA: Surgical altered anatomy, S-catheter: Standard catheter, T-catheter: Thermal catheter, 75% RoLF: 75% reduction of liver function

Table 4. Cost analyses in EUS-antegrade stenting, EUS-hepaticoenterostomy, and EUS- antegrade stenting+hepaticoenterostomy

	Procedure cost	Device cost	Total costs
EUS-AS (MS) + HES (PS)	$ 2075	$ 1965 + $ 160	$ 4200
EUS-AS (MS) + HES (MS)	$ 2075	$ 1965 + $ 1965	$ 6005
EUS-HES (PS)	$ 2075	$ 160	$ 2235
EUS-HES (MS)	$ 2075	$ 1965	$ 4040
EUS-AS (MS)	$ 2075	$ 1965	$ 4040

EUS-AS: EUS-guided antegrade stenting, EUS-HES: EUS-guided hepaticoenterostomy, MS: Metal stent, PS: Plastic stent

primary indication of EUS-BD is thought to be for "failed ERCP."

On the other hand, retrograde biliary MS placement by ERCP provides long stent patency, often without stent dysfunction, until the patient's death, compared to PSs, although it is much more expensive. In other words, antegrade MS placement by EUS-AS seems to be theoretically better unless EUS-CDS and/or HES shows superiority such as longer stent patency, apart from technical difficulties compared with EUS-AS, which requires skilled guidewire manipulation, which is limited to failed ERCP cases.

In the present study, we demonstrated that EUS-AS using an MS plus HES using a dedicated PS was feasible and could provide a low stent dysfunction rate and anticipate a long stent patency. Moreover, we evaluate EUS-AS+HES because we believe that EUS-AS+HES has three major advantages to EUS-AS alone, as follows: (1) safety using another available drainage route in cases of antegrade stent dysfunction due to acute obstruction and/or tough strictures, (2) easy deployment of the HES stent without any additional needle puncture and guidewire manipulation, and (3) easy re-intervention following stent removal through the HES route in case of antegrade stent dysfunction. In particular, mature HES tract makes it possible to perform simple intervention even in cases of large amounts of ascites at the end stage.

On the other hand, however, there are several disadvantages of EUS-AS+HES compared with EUS-AS alone, as follows: (1) Time-consuming though

it may not be significant (only a few minutes), (2) cost increase, in particular in cases of MS placement for HES, (3) risk of MS migration during and/or after EUS-HES due to the shortening of the MS, even in high-volume centers of interventional EUS,[20] resulting in fatal adverse events,[21] and (4) possible early stent occlusion due to reflux of residue, in particular in case of large bore MSs.

Therefore, we perform dedicated PS, which we reported as a newly designed 8-Fr stent for EUS-HES[15] to overcome those disadvantages, namely cost and stent migration. Although some may think that an 8-Fr diameter is not sufficient for better drainage, the size of the drain in percutaneous transhepatic BD is commonly approximately 8 Fr in diameter. As a result, our previous study demonstrated that the technical and clinical success was 100% and 94.7%, respectively, without any early or late stent migration. The occlusion rate of the present stent was 13.7% during the median follow-up period (5.0 months, range: 0.5–12.5 months). The median duration of stent patency was 4.0 months (range: 0.5–9.0 months).[15] Those data appear to be acceptable for patients with unresectable malignant diseases. Theoretically, a covered MS for EUS-HES has the following potential advantages: (1) it affords better drainage owing to a larger bore stent than a PS; (2) it prevents bile leakage and bile peritonitis; and (3) it prevents bleeding from the tract due to the self-expandable stent. In contrast, current covered MSs may also have several disadvantages as follows: (1) they are more expensive than PSs; (2) popular covered MSs worldwide are all braided-type stents, which show a high shortening rate of more than 40% and have a risk of fatal adverse events such as unexpected stent migration; (3) stent-related occlusion of the left IHBDs is possible; and (4) overdilation of the narrow bile duct is possible. Of these disadvantages, difficulty of stent placement, particularly stent deployment using a braided-type covered MS, is always problematic during EUS-HES. Surprisingly, it has been reported in the literature that there is no obvious difference in the EUS-HES outcome between a PS and a MS.[15] In addition, as for cost analyses, the total cost of EUS-AS using MS + HES using PS is approximately $2000 cheaper than EUS-AS+HES using two MSs, although EUS-hepaticogastrostomy alone using a PS is the cheapest of all procedures [Table 4].

A summary of the medical literature on EUS-AS and EUS-AS+HES using large case series ($n \geq 20$) is shown in Table 5.[22-24] The current data from our unit were superior to data from other literature. Apart from sequential EUS-AS+HES, the success rate (100%) of simultaneous EUS-AS+HES was higher than that in other literature. We assume that the selective hydrophilic guidewire in combination with conventional ERCP catheters and skilled assistants (skilled pancreatobiliary endoscopists) yielded the high success rate of guidewire passage across the stricture and papilla similar to the retrograde fashion of ERCP. Surprisingly, the clinical success rate was also 100% which was the same or better than reported in other literature. In our previous study, since the clinical success rate in EUS-HES alone using a dedicated PS was 94.7%,[15] the present clinical success rate is understandable because of the additional antegrade MS placement. However, the question is why was the clinical success using a dedicated PS for HES better than an MS. We guess that there are the following possible reasons: (1) our antegrade stent was more effective (*i.e.*, it had sufficient expansion and appropriate location of stent placement) compared with

Table 5. Summary of medical literatures of EUS-antegrade stenting and EUS-antegrade stenting + hepaticoenterostomy (*n*≥20)

Authors	Year	Study design	Procedure	*n*	Technical success, *n* (%)	Clinical success, *n* (%)	Adverse event, *n* (%)	OS, days (median)	Stent patency, days (median)	Stent dysfunction, *n* (%)	Time to dysfunction, days
Iwashita *et al.*[22]	2017	P	EUS-AS (MS)*	20	19/20 (95)	19/19 (100)	4/20 (20)	100.5	N/A	3/20 (15)	130,152,160
Ogura *et al.*[23]	2017	P	EUS-AS (MS) + HES (MS)	49	42/49 (85.7)	40/42 (95.2)	5/49 (10.2)	114	114	7/40 (17.5)	320 (mean)
Imai *et al.*[24]	2017	R	EUS-HES (MS)	42	41/42 (97.6)	37/41 (90.2)	11/42 (26.1)	75	68	7/42 (16.7)	N/A
			EUS-AS (MS) + HES (MS)	37	31/38 (83.8)	28/31 (90.3)	4/37 (10.8)	61	63	3/37 (8.1)	N/A
Current study	2018	R	EUS-AS (MS) + HES (PS)	23	23/23[$] (100)	23/23 (100)	2/23 (8.7)	96	66	3/23 (13.0)	135,263,267

*Including 3 cases with simultaneous nasobiliary catheter placement; [$]Simultaneous: 18/18 (100%) and sequential 5/5 (100%). EUS-AS: EUS-guided antegrade stenting, EUS-HES: EUS-guided hepaticoenterostomy, MS: Metal stent, N/A: Not applicable, OS: Overall survival, PS: Plastic stent, P: Prospective study, R: Retrospective study

stents in other institutions and (2) the effectiveness of rescue HES MSs in other institutions was poor due to stent dysfunction caused by kinking of the stent both in the IHBD and stomach, and there was acute stent obstruction due to the IHBD and liver parenchyma in cases of nondilated bile duct, in particular after decompression of the bile duct.

In this current study, we could not perform long-term observation for the stent patency because the duration of stent patency was almost always prescribed by the patient's death. However, EUS-AS+HES has the potential to provide longer stent patency from the results, indicating that the rate of stent dysfunction was low and the time to dysfunction was relatively longer.

Interestingly, the procedure-related adverse event rates in EUS-AS+HES were approximately 10% in each institution, which was better than in EUS-AS (20.0%)[22] or EUS-HES (26.1%)[24] even in the same institution. These data suggest that EUS-AS+HES appears to be able to reduce adverse events in comparison with EUS-AS or HES alone.

Nevertheless, EUS-AS is still technically challenging. Although we know its outcome seems to be better than EUS-HES, conventional EUS-HES alone is acceptable in cases of inability of guidewire passage across the stricture and papilla, in particular by nonexperts of EUS-BD. Then, when HES stent occlusion occurs, ERCP-guided antegrade stenting can be safely performed through the matured tract. Our results demonstrated that sequential antegrade stenting appears to be one option when prior HES stent occlusion occurs, though further cases should be accumulated for evaluation in the future.

The limitations of this study were its retrospective nature, the lack of a control group, and the limitation to a single-center experience.

CONCLUSIONS

The novel EUS-BD technique, EUS-AS using an MS plus HES using a dedicated PS was a feasible procedure for MBO and yielded longer duration of stent patency. Furthermore, sequential antegrade stenting in cases of occluded HES seems to be another option instead of HES stent exchange. Further large-scale comparison studies with EUS-HES, EUS-AS, and EUS-AS+HES are required to confirm its clinical efficacy.

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Conflicts of interest

Takao Itoi is a consultant of Gadelius Medical K. K and no others have any conflict of interest.

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