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Introduction of endoscopic ultrasound-guided hepaticoenterostomy – experience from a general hospital in Japan

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ABSTRACT

Background and study aims Endoscopic ultrasound-guided biliary drainage (EUS-BD) is a widely used alternative to endoscopic retrograde cholangiopancreatography (ERCP) when ERCP is unsuccessful or there are contraindications such as duodenal stenosis or postsurgical intestinal reconstruction. Therefore, we retrospectively investigated the therapeutic outcomes of EUS-BD in a medium-sized hospital.

Patients and methods We included 31 consecutive patients who underwent EUS-BD at the Kitasato University Medical Center between April 2018 and October 2021. Patient characteristics, technical and clinical success rates, stent patency, adverse events (AEs), and procedure time were analyzed.

Results Of the 31 patients included in this study, one underwent endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS) and 30 underwent endoscopic ultrasound-guided hepaticoenterostomy (EUS-HES). The technical success rates were 100% for EUS-CDS and 96.8% for EUS-HES because EUS-HES was unsuccessful in one patient who then underwent EUS-CDS as an alternative treatment. The clinical success rates were 100% for EUS-CDS and 96.7% for EUS-HES. The median follow-up period was 84 days (range: 14–483 days). Zero and 5 (16.6%) patients who underwent EUS-CDS and EUS, respectively had stent dysfunction. The median stent patency (stent dysfunction and death) for EUS-HES was 124 days. AEs were observed in only two patients (6.7%) who underwent EUS-HES.

Conclusions EUS-BD is now more widely used than before, and advances in the devices used have enabled the procedure to be performed more safely. Our results suggest that this introduction in medium-sized hospitals can be conducted safely.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard method for treating malignant biliary obstruction (MBO) [1–3]. However, it may be unsuccessful in cases in which it is impossible to reach the duodenal papilla (because of duodenal stenosis or postsurgical intestinal reconstruction) or cannulation of the bile duct is impossible. In such cases, endoscopic ultrasound-guided biliary drainage (EUS-BD), which is widely used as an alternative to ERCP, is used [4–9].

EUS-BD encompasses procedures such as EUS-guided hepaticoenterostomy (EUS-HES), including EUS-guided hepaticogastrostomy (EUS-HGS), EUS-guided hepaticojejunostomy (EUS-HJS), EUS-guided choledochoduodenostomy (EUS-CDS), and EUS-guided antegrade stenting (EUS-AS).

Percutaneous transhepatic biliary drainage (PTBD) was formerly performed for biliary drainage when ERCP was unsuccessful, but comparative trials of EUS-BD and PTBD have shown that EUS-BD is safer [10–11], and the use of EUS-BD is expected to increase in the future.

Although the published therapeutic outcomes of EUS-BD are favorable [4–9], they are limited to procedures conducted in high-volume centers, and their outcomes in general hospitals are unknown. In 2012, Vila et al. published a study on the outcomes of the introduction of EUS-BD in which they reported that in hospitals with an experience rate of < 20 procedures, the technical success rate was 67.2 % and the rate of complications was 23.2 % [12] suggesting that caution is required during the introductory phase of EUS-BD.

However, with the expanding use of EUS-BD procedures, various guidance has now been published [13, 14] and coupled with advances in the devices used, these procedures are now more standardized than previously reported. Thus, the introduction of these procedures may be carried out with greater safety; however, the outcomes of this introductory phase are unknown. Therefore, we retrospectively investigated the therapeutic outcomes of the introduction of EUS-BD in a medium-sized hospital.

Patients and methods

Patients

We studied consecutively 31 patients that underwent EUS-BD at the Kitasato University Medical Center between April 2018 and October 2021. We retrospectively investigated the patients' characteristics, technical and clinical success rates, stent patency, adverse events (AEs), and procedure time. This study was approved by the institutional review board (IRB) of our hospital (IRB approval number: 2021026).

Hospital

Our hospital is a branch of Kitasato University Hospital, it has approximately 400 hospital beds and around 250 cases of ERCP per year, and it is a medium-scale hospital rather than a high-volume center. The surgeons and radiologists are full-time, and it is an environment where emergency surgery or interventional radiology treatment can be conducted in the event of problems such as perforation or bleeding.

The present procedure was conducted by two endoscopists. One of them (M.K.) conducted two cases, the individual is an advisory doctor for ERCP and EUS, with experience with over 10,000 cases of both ERCP and EUS, and experience with over 50 cases of EUS-BD. The other individual (T.K.) conducted the remaining 29 cases, this individual is also an ERCP and EUS specialist whose experience is over 1000 cases for ERCP, over 1000 cases for EUS, over 300 cases for EUS-FNA, and around 20 cases in a high-volume center at another hospital for EUS-BD.

Definition

Technical success was defined as successful stent placement within the bile duct, targeted from the gastrointestinal tract (stomach, duodenum, or jejunum). Clinical success was defined as the normalization or a ≥ 50 % improvement of the total bilirubin level within 2 weeks.

The bile duct diameter was measured using endoscopic ultrasound during the procedure, and the procedure time was defined as the time from endoscope insertion to withdrawal. Stent dysfunction was defined as the recurrence of jaundice or development of cholangitis due to stent occlusion or migration. The duration of stent patency was defined as the time from insertion to the occurrence of stent dysfunction or death.

AE severity was classified according to the lexicon of the American Society of Gastrointestinal Endoscopy (ASGE) [15].

EUS-BD methods

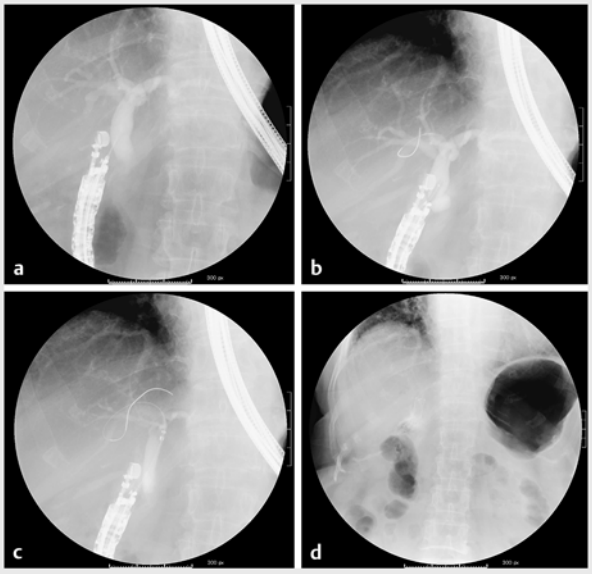
Endoscope and monitoring device: A linear endoscopic ultrasound system (UCT260; Olympus Medical Systems, Tokyo, Japan) and a ME-2 monitoring device (Olympus Medical Systems, Tokyo, Japan) were used.

EUS-CDS methods

The distal bile duct was visualized from a distant position from the duodenal bulb. After confirming that there were no intervening blood vessels, the bile duct was punctured using a 19G FNA needle (EZ Shot 3; Olympus, Tokyo, Japan). The bile was aspirated, and when this was confirmed, contrast enhancement was conducted to visualize the bile duct, after which a 0.025-inch guidewire (GW) (Visiglide2: Olympus, Tokyo, Japan) was placed in the intrahepatic bile duct. The fistula was dilated with a balloon dilator (REN; Kaneka, Osaka, Japan, diameter 4mm) and a fully covered self-expandable metal stent (SEMS, diameter 10 mm; length 6 cm) was placed (▶ **Fig. 1**).

EUS-HES method

The left hepatic lobe was visualized from the stomach or jejunum and intrahepatic bile duct (the bile duct of segment 2 (B2) and the bile duct of segment 3 (B3)) of the hepatic left lobe was identified. The puncture was attempted from B3; however, puncturing from B2 can be considered if it can be differentiated from a transesophageal puncture. A 19G FNA needle was used to conduct the puncture unless the diameter of the bile duct was narrow, in which case a 22G needle was used. After the puncture, the bile was aspirated and confirmed through contrast enhancement to visualize the bile duct. A 0.025-inch guidewire (GW) (Visiglide2: Olympus, Tokyo, Japan) was then placed in the intrahepatic bile duct. The fistula was dilated using either a 7F mechanical dilator (ES Dilator; Zeon Medical Co., Tokyo, Japan) or a small-diameter balloon dilator (REN; Kaneka, Osaka, Japan, diameter 4 mm). A stent was then placed to connect the bile duct to the stomach. The stent used was either a plastic stent (PS) (Type IT stent, Gadelius Medical, Tokyo, Japan 7F, 14 cm) or a partially covered SEMS (pcSEMS) with the last 1 cm uncovered (NiTi-S S-Type Stent or NiTi-S



▶ **Fig. 1** EUS-guided choledochoduodenostomy for pancreatic cancer with malignant biliary obstruction. **a** The distal bile duct was punctured with a 19G needle. **b** The bile duct was contrast-enhanced, a GW was placed, and the fistula was dilated with a balloon. **c** The stent delivery system was inserted into the bile duct and fixed. **d** The stent was deployed for successful placement.

S-Type Stent Spring Stopper; Taewoong Medical Co. Ltd., Gimpo, Korea, diameter 8 mm; length 10 cm or 12 cm) (▶ **Fig. 2**).

In some patients, AS was performed during EUS-HES. When AS was performed after GW placement, an ERCP contrast catheter was used to break through the stenosis and place the GW. When fistula dilation was not performed, a small-diameter uncovered SEMS (either Zilber 635; Cook Japan Co., Tokyo, Japan or YABUSAME: Kaneka, Osaka, Japan, diameter 8 mm; length 4 cm, 6 cm, 8 cm) was placed in the stenosis above or across the papilla depending on the location of the stenosis. After the AS was completed, a PS was placed via the HES route to complete the procedure (▶ **Fig. 2**).

Treatment before and after EUS-BD

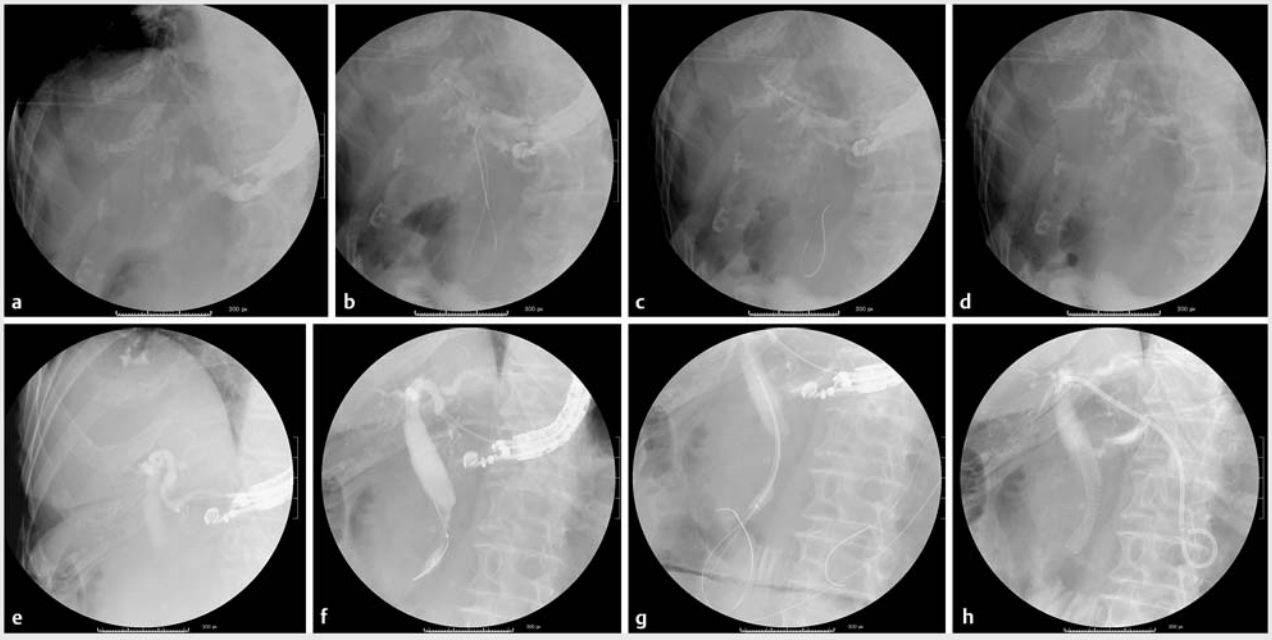
After performing the EUS-BD, a second- or third-generation cephem antibiotic was administered intravenously for prophylaxis on the day before the procedure, the day of the procedure, and twice daily after the procedure for two days. In patients with concomitant cholangitis, the duration of antibiotic administration was extended as required depending on the infection. Computed tomography was performed the day after the procedure to check for AEs.

Statistical analysis

In this study, continuous variables were expressed as a median. Stent patency was estimated using the Kaplan-Meier method. SPSS Version 17.0 for Windows was used for statistical analysis.

Results

The characteristics of the 31 patients included in this study are shown in ▶ **Table 1**. EUC-CDS was performed in one patient and EUS-HES in 30 patients. The mean age was 73 years (range, 50–

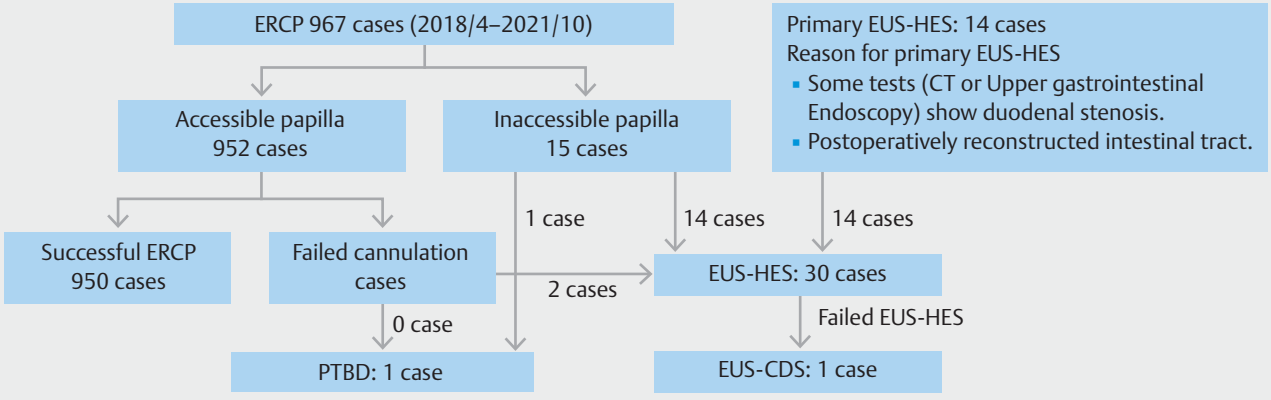


▶ **Fig. 2** **a–h** EUS-guided hepaticoenterostomy for pancreatic cancer with malignant biliary obstruction, and **e–h** EUS-guided hepaticoenterostomy with antegrade stenting for gastric cancer with malignant biliary obstruction.

▶ **Table 1** Baseline characteristics of the 30 patients who underwent EUS-guided biliary drainage.

	EUS-CDS (n = 1)	EUS-HGS (n = 30)	EUS-BD (n = 31)
Age (median, range)	83	73 (50–94)	73 (50–94)
Sex (male/female)	0/1	16/14	16/15
Disease(n)			
▪ Malignant	**1**	**24**	**25**
▪ Pancreatic cancer	1	16	17
▪ Biliary tract cancer		5	5
▪ Gastric cancer		2	2
▪ Benign		**6**	**6**
▪ Bile duct stone		4	4
▪ Chronic pancreatitis		2	2
Indication for EUS-BD			
▪ Duodenal stenosis	1 (100 %) failed EUS-HGS	19 (63.3 %)	20 (64.5 %)
▪ Postoperative intestinal reconstruction	0	9 (30.0 %)	9 (29.0 %)
▪ Failed ERCP	0	2 (6.7 %)	2(6.5 %)
Total bilirubin level (median, range mg/dL)	4.9	4.3 (0.6–24.4)	4.4 (0.6–24.4)

EUS-CDS, endoscopic ultrasound-guided choledochoduodenostomy; EUS-HGS, endoscopic ultrasound-guided hepaticoenterostomy; EUS-BD, endoscopic ultrasound-guided biliary drainage; ERCP, endoscopic retrograde cholangiopancreatography.



▶ **Fig. 3** This figure shows the number of ERCP cases during the study period and the reason for the indication of EUS-BD for the indication of EUS-BD in this study.

94 years). Among the 31 patients, 16 were men and 15 women (including the patients who underwent EUS-CDS).

The most common underlying disease was pancreatic cancer in 17 patients (54.8 %, including patients who underwent EUS-CDS). Five patients (16.1 %) had biliary tract cancer and two (6.5 %) had gastric cancer. Furthermore, 25 (80.6 %) and six patients (19.4 %) had malignant and benign conditions respectively. Nine patients (29.0 %) underwent surgical intestinal reconstruction, excluding Billroth-I reconstruction. The median total bilirubin level before the procedure was 4.4 mg/dL (0.6–24.4 mg/dL).

▶ **Fig. 3** shows the indications for EUS-HES during the study period. Of the 30 patients who underwent EUS-HES, 14 patients underwent primary EUS-HES and 16 patients underwent prior ERCP. During the study period, a total of 967 ERCPs were performed. Fourteen patients underwent EUS-HES because the duodenal papillae could not be reached due to duodenal stenosis, and two patients underwent EUS-HES because cannulation of the bile duct could not be achieved. The reason for primary

▶ **Table 2** Clinical outcomes of EUS-guided biliary drainage.

	EUS-CDS (n = 1)	EUS-HGS (n = 30)	EUS-BD (n = 31)
Technical success (%, n)	100 %	96.8 % (30/31)	100 %
Clinical success (%, n)	100 %	96.7 % (29/30)	96.8 % (30/31)
Type of stent (SEMS/PS/PS + AS)	1/0/0	9/15/6	10/15/6
Adverse events (Grade, n)	0	2	2
▪ Biliary peritonitis	0	1 (mild)	1 (mild)
▪ Pneumoperitoneum	0	1 (mild)	1 (mild)
▪ Stent migration	0	0	0
▪ Other	0	0	0
Stent dysfunction rate (%, n)	0 %	16.6 % (5/30)	16.1 % (5/31)

EUS, endoscopic ultrasound; EUS-CDS, endoscopic ultrasound-guided choledochoduodenostomy; EUS-HGS, endoscopic ultrasound-guided hepaticoenterostomy; EUS-BD, endoscopic ultrasound-guided biliary drainage; SEMS, self-expanding metal stent; PS, plastic stent; AS, antegrade stenting.

EUS-HES was duodenal stenosis or postoperative reconstructed intestinal tract.

▶ **Table 2** shows the therapeutic outcomes of EUS-BD. The technical success rates were 100 % for EUS-CDS and 96.8 % for EUS-HES because EUS-HES was unsuccessful in one patient who then underwent EUS-CDS as an alternative procedure on-the-spot. The clinical success rates were 100 % for EUS-CDS and 96.7 % for EUS-HGS. The stents inserted were fully covered SEMS in the patients who underwent EUS-CDS, SEMS in nine patients, PS in 15 patients, and PS + AS (SEMS) in six of the patients who underwent EUS-HES.

▶ **Table 3** shows the technical features of EUS-HES. The bile duct was punctured at B2 in three patients (10 %) and B3 in 27 (90 %) patients. The median bile duct diameter was 2.8 mm (range: 1.2–8.4 mm). A 19G needle was used in 26 patients (86.7 %) and a 22G needle in four patients (13.3 %). The double-GW technique was used in nine patients (30 %), mainly those in whom a 22G needle was used. The puncture sites were as follows: transgastric, 25 cases; and transjejunum, five cases.

The median follow-up period was 84 days (range: 14–483 days). Stent dysfunction did not occur in patients who underwent EUS-CDS but was observed in 16.6 % (5/30) of the patients who underwent EUS-HES. The median stent patency duration for patients who underwent EUS-HES was 124 days (▶ **Fig. 4**).

AEs were observed in only two (6.7 %) patients who underwent EUS-HES. In both cases, the symptoms were mild and improved with conservative treatment.

▶ **Table 3** Technical features of EUS-guided hepaticoenterostomy.

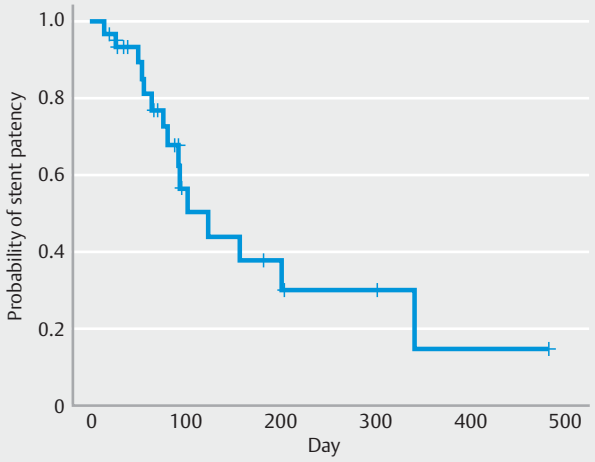
Technical success (%)	**96.8 % (30/31)**
Clinical success (%)	96.7 % (29/30)
Procedure time (median, range min)	14.5 min (8–62)
EUS-HES/EUS-HES + AS	24/6
Puncture site (B2/B3)	3/27
Bile duct diameter (median, range mm)	2.8 mm (1.2–8.4)
Number of puncture (median, range)	1 (1–3)
Puncture needle (19G/22G)	26/4
Puncture point (transgastric/transjejunum/transesophagus)	(25/5/0)
Double-GW (%)	30 % (9/30)
Dilation (Mechanical [Catheter/Dilater]/Balloon/Electrocautery)	20 (6/14)/10/0
Type of stent (SEMS/PS/PS + AS)	9/15/6
Type of stent (MBO cases) (SEMS/PS/PS + AS)	9/9/6
Type of stent (benign cases) (SEMS/PS/PS + AS)	0/6/0

EUS, endoscopic ultrasound; HES, hepaticoenterostomy; AS, antegrade stenting; GW, guidewire; SEMS, self-expanding metal stent; PS, plastic stent; MBO, malignant biliary obstruction.

Discussion

EUS-BD is now widely used for biliary drainage in patients in whom ERCP is unsuccessful or difficult to perform. Although the reported therapeutic outcomes are good [4–9], only high-volume centers were used.

A previous study found that in the initial introductory period, the technical success rate was low, and the incidence of AEs was high, indicating that caution is required during its initial introduction [12]. However, EUS-BD procedures are now widely employed and have become more standardized. Coupled with advances in the devices, the safety during initial introduction is unknown.



▶ **Fig. 4** The duration of stent patency including stent dysfunction and patient death for EUS-guided hepaticoenterostomy. The median stent patency was 124 days.

In this study, we reported outcomes of introduction of EUS-BD in a medium-sized hospital, which offers a new perspective in light of the situation described above.

In previous reports of its outcomes in institutions where it was newly introduced, the technical success rate of EUS-CDS was high [12] and, therefore, may be preferable for new introduction. In this study, however, only one patient underwent EUS-CDS, and the remaining 30 patients underwent EUS-HES. This may be because EUS-BD was only indicated in patients with duodenal stenosis or postsurgical intestinal reconstruction. A comparison of the stent patency in patients with duodenal stenosis who underwent either EUS-HES or EUS-CDS found that the stent patency was longer for EUS-HES [16], and EUS-HES was often used for treatment. In patients who have undergone postsurgical intestinal reconstruction, it may be difficult for the echoendoscope to reach the duodenum, so EUS-HES is performed. Clinically, patients requiring EUS-BD tend to undergo EUS-HES.

In our study, EUS-HES was attempted in a total of 31 patients. In one patient, EUS-HES was unsuccessful because the diameter was narrow and there were intervening blood vessels in the bile duct. The patient was switched to EUS-CDS immediately with success. As a result, the technical success rate of EUS-HES was 96.7 % and that of EUS-BD was 100 %.

According to Minaga et al., not insisting strictly on a single treatment procedure but being able to switch to a different procedure should it prove unsuccessful is the key to improving the technical success rate of EUS-BD [17]. Because the institutions that introduce the EUS-BD for the first time could experience failure during the procedure, it is important to be flexible rather than sticking to one particular procedure.

In terms of the type of stent used during HES, PSs were placed via the transintestinal route in 70 % of cases. Umeda et al., from Tokyo Medical University, conducted HGS with a special PS and reported a good technical success rate and low incidence of AEs [18]. Because this special PS has a small diameter, it can be inserted with minimum fistula dilation, and the gastric side has a pigtail shape that prevents it from becoming dislodged. Therefore, this stent may be easy for institutions to use when EUS-BD is newly introduced. However, owing to their small diameter, the long-term stent patency of PSs is uncertain. Therefore, in this study, we conducted AS in six patients (20 %) with malignant biliary stenosis using the PSs, with the goal of achieving long-term stent patency.

The additional use of AS prolongs the patency and reduces the incidence of AEs [19–21]. However, in these studies, the stents used for both the AS and transmural stenting were SEMS. Yamamoto et al. reported the results achieved by using a SEMS for AS and a PS for transmural stenting and stated that the stent patency was 263 days, a result not inferior to those of HES with AS when SEMS were inserted using the AS and HES routes [22]. Reintervention was often reported. From these results, we, therefore, suggested that when conducting HES with AS, using a special PS for the HES route may increase the technical success rate and reduce the incidence of AEs because it is feasible with respect to the patency.

The use of a 22G needle for EUS-HES was recently reported [23]. The 22G needle can puncture the narrow bile duct easily. The 22G needle stiffness is reduced, enabling the endoscope to be angled more acutely, thereby expanding the choice of the puncturable bile ducts since the B2 bile duct can be easily punctured. When conducting additional AS, treating the B2 bile duct rather than the B3 bile duct means that the angle of the duct is straighter, which facilitates the procedure, and the use of a 22G needle, therefore, may be advantageous in patients undergoing HES with AS. A disadvantage of using a 22G needle during EUS-HES is that a 0.018-inch GW must be used. With a 0.018-inch GW, maneuverability is poor, making GW placement difficult. Its low stiffness causes the endoscope to become unstable, decreasing its capacity for the delivery of stents and other devices. These difficulties can be addressed effectively with the double-GW technique [14]. This involves inserting another 0.025-inch GW in addition to the 0.018-inch GW to increase the stability of the endoscope and improve its stent delivery performance, making the procedure more reliable. In this study, EUS-HES was conducted with a 22G needle in four patients, and the double-GW technique was used in all the patients. This may have contributed to the technical success rate of 100 %.

The technical success rate and incidence of AEs in this study were not inferior to previously reported results from high-volume centers. This may be explained by the fact that EUS-BD is now more widely used than before, and the procedure is becoming more standardized and organized. The advances in treatment devices may enable it to be conducted more safely.

There are also reports that the treatment success rate increases when the number of experienced cases of EUS-HES exceeded 40 [24]; however, in the present study, even though the number of experienced cases was lower than this, the treatment success rate was sufficiently high. The reason for this was thought to be due to the presence of experienced advisory doctors.

This study had several limitations. First, it was a single-institution retrospective study with a small sample size. In addition, because all the procedures were conducted by a single endoscopist, the outcomes were not standardized. The choice of the EUS-BD procedure was not predetermined but depended on the discretion of the operator, and this may have introduced a bias. Further investigations with a larger sample size are required.

Conclusions

EUS-BD is now more widely used than before, and advances in the devices used have enabled the procedure to be performed more safely. Our results suggest that this new introduction in medium-sized hospitals can be conducted safely.

Competing interests

The authors declare that they have no conflict of interest.

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