

# Comparison of time to recurrent biliary obstruction between plastic stents and metallic stents for endoscopic ultrasound-guided biliary drainage

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**Abstract.** Endoscopic ultrasound-guided biliary drainage (EUS-BD) may prevent stent placement at the bile duct stricture. Therefore, whether a plastic stent (PS) or metallic stent (MS) should be used for EUS-BD remains to be undetermined. The present study aimed to clarify whether a PS or MS was more efficient for EUS-BD. Patients with malignant biliary obstruction who were successfully treated with EUS-BD were enrolled in the present study. The clinical characteristics, procedural outcomes and time to recurrent biliary obstruction (TRBO) were compared between patients treated with a PS (PS group) and patients treated with an MS (MS group). Consequently, 28 patients underwent PS placement and 11 patients underwent MS placement. In the PS group, 12 patients also underwent EUS-antegrade stenting (AGS) using an MS. The TRBO was not significantly different between the two groups ( $P=0.25$ ). When the patients with

AGS were excluded, the TRBO was significantly longer in the MS group than in the PS group ( $P=0.036$ ). However, the TRBO was not significantly different between the patients in the MS group and those in the PS group who underwent AGS ( $P=0.61$ ). In EUS-BD, MS is expected to be associated with a longer TRBO than PS. However, combining EUS-BD with AGS may help overcome the shorter TRBO associated with the use of PS.

## Introduction

For the treatment of biliary obstruction, endoscopic transpapillary drainage is recommended first. However, endoscopic transpapillary drainage is not always possible. When a patient has a duodenal stricture or a history of upper gastrointestinal surgery, endoscopic transpapillary drainage becomes difficult. In these cases, endoscopic ultrasound-guided biliary drainage (EUS-BD) may be an alternative treatment for biliary obstruction (1).

Metallic stents (MSs) and plastic stents (PSs) are used for endoscopic biliary drainage. A benefit of using MSs instead of PSs in transpapillary drainage is the expectation of a longer time to recurrent biliary obstruction (TRBO) (2). For EUS-BD, covered self-expandable metallic stents (CSEMSs) were originally used (3,4). A drawback of using MSs is the greater risk. Adverse events of EUS-BD using CSEMSs have been reported in 0-30% of cases (5), with severe events involving bile leak sepsis and stent migration that occurred from shortening (6-8). On the other hand, the benefits of using PSs include convenience and safety, and a dedicated PS for EUS-BD that may be easily and safely placed has been developed (3,9). However, the shorter TRBO is a drawback of using PSs in transpapillary drainage (2).

As described above, MSs are superior to PSs in terms of TRBO in endoscopic transpapillary drainage (2). However, in EUS-BD, the stents do not pass through the biliary stricture. Therefore, it has remained elusive whether MSs are superior to PSs in EUS-BD. Comparing MSs and PSs may provide

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**Abbreviations:** EUS-BD, endoscopic ultrasound-guided biliary drainage; PS, plastic stent; MS, metallic stent; TRBO, time to recurrent biliary obstruction; EUS-AGS, EUS-guided antegrade stenting; CSEMS, covered self-expandable metallic stent; CBD, common bile duct; FNA, fine-needle aspiration; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HES, EUS-guided hepaticoenterostomy; SEMS, self-expandable metallic stent; LAMS, lumen-apposing metal stent

**Key words:** endoscopic ultrasound-guided biliary drainage, plastic stent, metallic stent, time to recurrent biliary obstruction, endoscopic ultrasound-guided hepaticoenterostomy, endoscopic ultrasound-guided choledochoduodenostomy

information to aid decision-making regarding which type of stent to use to achieve a longer TRBO. Thus, the present study aimed to clarify whether PSs or MSs are more useful for EUS-BD.

## Materials and methods

**Patients and inclusion and exclusion criteria.** The present study was an observational study performed at Fukushima Medical University (Fukushima, Japan) and Soma General Hospital (Soma, Japan) between May 2005 and July 2022. The inclusion and exclusion criteria were as follows: Patients with malignant biliary obstruction who underwent successful EUS-BD were enrolled in the present study ( $n=39$ ; 26 males and 13 females; mean age,  $70.8\pm9.6$  years); patients who did not undergo successful EUS-BD were excluded from the study. Successful EUS-BD was defined as the procedure in which a biliary stent was placed from the biliary tract to the gastrointestinal tract through the abdominal cavity.

All patients underwent endoscopic transpapillary biliary drainage prior to EUS-BD. Patients who underwent MS insertion for EUS-BD were classified into the MS group, while patients who underwent PS insertion for EUS-BD were classified into the PS group. The requirement for informed consent was waived, as the present study was a retrospective study using anonymized clinical data. All patients agreed to undergo the clinical examination and treatment by providing written informed consent. This study was approved by the Institutional Review Board of Fukushima Medical University (Fukushima, Japan; approval no. 2399).

**Procedure.** After all patients were sufficiently sedated with midazolam, the echoendoscope was gently inserted. After visualizing the hepatic duct or common bile duct (CBD) from the gastrointestinal tract, the target biliary tract was determined. Color Doppler mode was used to confirm the absence of blood flow in the puncture route and the biliary tract was punctured by an EUS-guided fine-needle aspiration (FNA) needle. The biliary tract was visualized under X-ray imaging and a guidewire was successfully inserted into the biliary tract. Fistula dilation was performed through the guidewire and a PS or MS was finally placed from the gastrointestinal tract to the target biliary duct.

X-ray images of EUS-BD are provided in Fig. 1. EUS-guided choledochoduodenostomy (EUS-CDS) was performed for patients with a distal CBD stricture. On the other hand, EUS-guided hepaticoenterostomy (EUS-HES) was performed for patients with a hilar biliary obstruction, an upstream or long CBD obstruction, a history of Billroth-II reconstruction or Roux-en-Y reconstruction, or a duodenal stricture that involved the duodenal bulb. If the duodenal stricture did not reach the papilla of Vater and a guidewire was sufficiently advanced to the duodenum, EUS-guided antegrade stenting (EUS-AGS) was performed with EUS-HES.

The choice of a PS or an MS was made as follows: When just a small amount of ascites was present or the punctured biliary duct was distant from the gastrointestinal wall, a covered MS was selected. When the lumen of the duodenal bulb was narrow or the end of the stent reached the hilar biliary duct, a PS was selected.

The following devices were used: A UCT240-AL5 or UCT260 echoendoscope (Olympus Medical Systems); an SSD-5500, Prosound SSD  $\alpha 10$  (Hitachi Aloka Medical), an EU-ME1 or EU-ME2 ultrasound system (Olympus Medical Systems); a 19 G EZ Shot 3 Plus (Olympus Medical Systems), 22 G NA-11J-KB (Olympus Medical Systems), 19 G SonoTip (Medi-Globe), 19 G EchoTip Ultra (Cook Medical), 19 or 22 G Expect (Boston Scientific Japan) FNA needle; a 0.018 Fielder 18 (Olympus Medical Systems), 0.025 VisiGlide, 0.025 VisiGlide 2 (Olympus Medical Systems), 0.025 Endoselector (Boston Scientific Japan) and 0.025 or 0.035 Jagwire guidewire.

Regarding the dilators, a 6 Fr MTW ERCP catheter taper (MTW Endoskopie), a 4 mm Hurricane RX Biliary Balloon Dilation Catheter (Boston Scientific Japan), a 4 or 6 mm REN biliary dilation catheter (Kaneka Corporation), a 6 Fr Cysto-Gastro-Set (Endo-Flex GmbH) or an ES dilator (Zeon Medical Co.) were used for fistula dilation. A 7 Fr double-pigtail (Cook Medical), 7 Fr Flexima Plus or 7 Fr IT stent (Gadeliuss Medical, Co., Ltd.) stent was used as the PS. A partially covered WallFlex Biliary RX stent, 10 mm HANARO (Boston Scientific), partially covered 10 mm Niti-S Comvi, or 8 mm partially CSEMS (Spring Stopper; Taewoong Medical) stent was used as the MS.

**Outcomes.** The TRBO was the primary outcome of the present study. Patient characteristics [age, sex, history of gastrectomy, diseases, biliary stricture part (hilar or distal), indications for EUS-BD, duodenal stent placement before dysfunction of EUS-BD stent], factors related to the EUS-BD procedure and postprocedural course were the secondary outcomes. As for the factors related to the EUS-BD procedure, the period during which EUS-BD was performed (earlier nine years: 2005-2013, later nine years: 2014-2021), diameter of the target bile duct, puncture route distance, length of the biliary obstruction, method of EUS-BD (CDS or HES, addition of AGS), procedural time and adverse events were selected. As factors of the postprocedural course, chemotherapy, death and overall survival were selected.

The outcomes were defined according to the criteria established by Isayama *et al* (10). TRBO was defined as the duration between the first stent placement and RBO. RBO was defined as recurrent jaundice, hepatic dysfunction or biliary tract dilation on imaging, e.g., computed tomography or percutaneous ultrasonography, which required additional endoscopic therapy. Adverse events and the severity of adverse events were diagnosed according to Cotton's criteria (11). Malignant biliary obstruction was diagnosed by cytology (class IV or V), biopsy, or clinical course and imaging findings. The causal diseases of biliary obstruction were divided into pancreaticobiliary and metastatic according to the report by Jang *et al* (12). The diameter of the punctured biliary bile duct and puncture route distance were measured by EUS imaging or cholangiography. The length of the biliary obstruction was measured by endoscopic cholangiography or CT.

**Statistical analysis.** The TRBO was compared between groups using the log-rank test. Continuous variables that followed a normal distribution were compared by an unpaired Student's

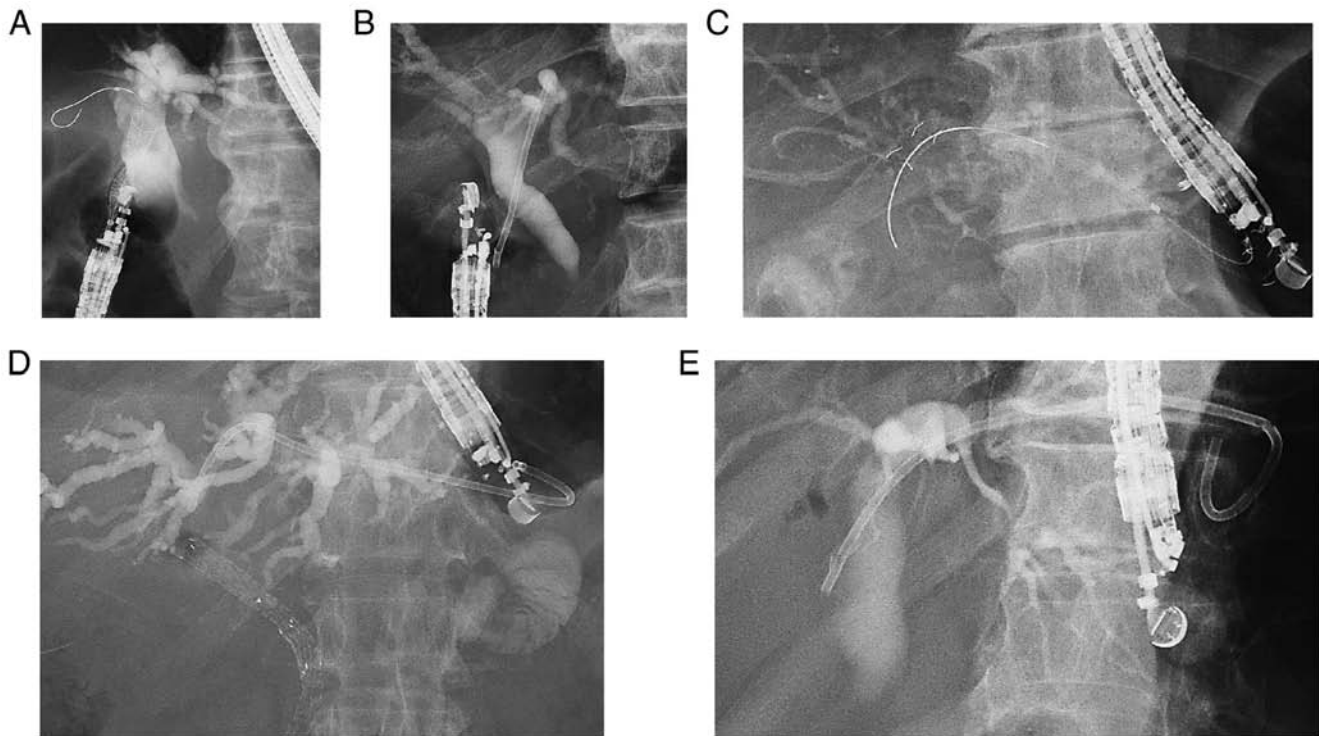


Figure 1. Representative X-ray images for the EUS-BD and related methods. (A) EUS-CDS using MS. (B) EUS-CDS using PS. (C) EUS-HES using MS. (D) EUS-HES using PS with AGS using MS. (E) EUS-HES using PS. EUS-BD, endoscopic ultrasound-guided biliary drainage; CDS, choledochoduodenostomy; MS, metallic stent; PS, plastic stent; HES, hepaticocenterostomy; AGS, antegrade stenting.

t-test. Continuous variables that did not follow a normal distribution were compared by the Mann-Whitney U-test. Nominal variables were compared by Fisher's exact test.  $P < 0.05$  was considered to indicate statistical significance. All statistical analyses were performed using EZR version 1.40 (Saitama Medical Centre).

## Results

**Flow of patients who underwent EUS-BD.** EUS-BD was performed in 41 patients, and the procedure was successful in 39 patients (Fig. 2). Among them, 28 patients underwent PS placement (PS group). In the PS group, 16 patients were treated with a PS only and 12 patients were treated with a PS and underwent AGS with an MS at the stricture. Furthermore, 11 patients underwent placement of an MS only (MS group).

**Comparison of patient characteristics.** The patient characteristics are compared in Table I. There were no significant differences between the two groups in any of the parameters. All five patients who had previously undergone gastrectomy were treated with plastic stents. In addition, all five patients with metastatic lesions were treated with plastic stents. However, the frequency of history of gastrectomy and metastatic diseases were not significantly different between the two groups.

**Comparison of EUS-BD procedure-related factors and postprocedural course.** The results of EUS-BD procedure-related factors and postprocedural course comparison are presented in Table II. EUS-HES was performed significantly

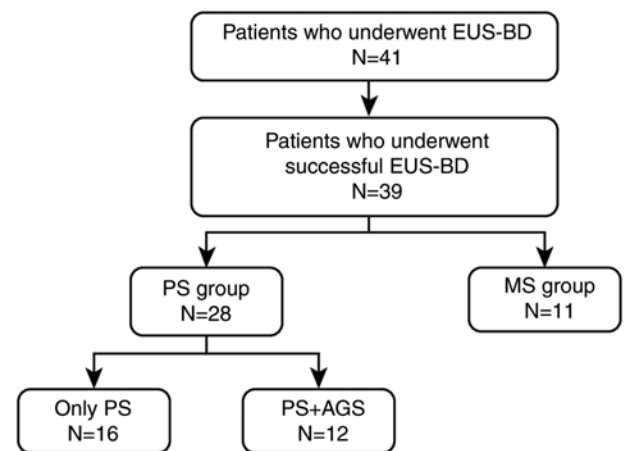


Figure 2. Flowchart of patients who underwent EUS-BD. EUS-BD, endoscopic ultrasound-guided biliary drainage; MS, metallic stent; PS, plastic stent; AGS, antegrade stenting.

more frequently in the PS group than in the MS group [22 patients (78.6%) vs. 3 patients (27.3%),  $P < 0.01$ ]. However, the period during which EUS-BD was performed, diameter of the target bile duct, puncture route distance, length of biliary obstruction, AGS operation, procedural time, adverse events, chemotherapy, death and overall survival were not significantly different between the two groups.

**Comparison of patient characteristics without AGS.** When those patients who had undergone EUS-AGS were removed from the analysis, the patient characteristics were not

Table I. Comparison of patient characteristics between groups.

Parameter	PS group (n=28)	MS group (n=11)	P-value
Age, years	71.5±9.7	69.2±9.4	0.50
Male sex	18 (64.3)	8 (72.7)	0.72
Antithrombotic therapy	4 (14.2)	1 (9.1)	1.00
History of gastrectomy	5 (17.9)	0 (0)	0.30
Distal gastrectomy with Billroth-I reconstruction	1	0	
Distal gastrectomy with Billroth-II reconstruction	2	0	
Distal gastrectomy with Roux-en-Y reconstruction	1	0	
Total gastrectomy with Roux-en-Y reconstruction	1	0	
Diagnosis			
Pancreatic cancer	17	9	
Biliary tract cancer	5	2	
Duodenal cancer	1	0	
Metastatic diseases	5 (17.9)	0 (0)	0.30
Gastric cancer	3	0	
Bladder cancer	1	0	
Urothelial cancer	1	0	
Biliary stricture part, hilar/distal	1/27	1/10	0.49
Reason for EUS-BD			
Duodenal stricture	14	7	
Difficult biliary duct cannulation	7	3	
Gastric stricture	2	0	
Difficult biliary drainage	2	1	
Difficult endoscope insertion	3	0	
Duodenal stent placement	9 (32.1)	6 (54.5)	0.28

Values are expressed as the mean ± standard deviation, n or n (%). EUS-BD, endoscopic ultrasound-guided biliary drainage; MS, metallic stent; PS, plastic stent.

Table II. Comparison of EUS-BD procedure-related factors and postprocedural course.

Parameter	PS group (n=28)	MS group (n=11)	P-value
Later nine years (2014-2021)	22 (78.6)	6 (54.5)	0.23
Diameter of target bile duct, mm	7.9 (2.0-20.0)	10.0 (5.0-20.0)	0.10
Distance of puncture route, mm	15.3±6.8	13.9±4.5	0.52
Length of biliary obstruction, mm	30.6±13.6	33.2±15.1	0.62
Method of EUS-BD			<0.01
CDS	6 (21.4)	8 (72.7)	
HES	22 (78.6)	3 (27.3)	
AGS operation	12 (42.9)	1 (9.1)	0.06
Procedural time, min	48.0 (30.0-157.0)	60.0 (24.0-131.0)	0.34
Adverse events	2 (7.1)	2 (18.2)	0.56
Dislocation	1	2	
Pancreatitis	1		
Chemotherapy	16 (57.1)	4 (36.4)	0.30
Death	19 (67.9)	10 (90.9)	0.23
Overall survival, days	128 (9-874)	75 (18-740)	0.45

Values are expressed as the mean ± standard deviation, median (range), n or n (%). EUS-BD, endoscopic ultrasound-guided biliary drainage; CDS, choledochoduodenostomy; HES, hepaticoenterostomy; PS, plastic stent; MS, metallic stent; AGS, antegrade stenting.

Table III. Comparison of patient characteristics (excluding patients with antegrade stenting).

Parameter	PS group (n=16)	MS group (n=10)	P-value
Age, years	71.5±11.3	70.1±9.3	0.75
Male sex	12 (75.0)	7 (70.0)	1.00
Antithrombotic therapy	3 (18.8)	1 (10.0)	1.00
History of gastrectomy	2 (12.5)	0 (0)	0.51
Distal gastrectomy with Billroth-I reconstruction	1	0	
Distal gastrectomy with Billroth-II reconstruction	1	0	
Diagnosis			
Pancreatic cancer	10	8	
Biliary tract cancer	5	2	
Metastatic disease	1 (6.3)	0 (0)	1.00
Urothelial cancer	1	0	
Biliary stricture location, hilar/distal	1/15	1/9	1.00
Reason for EUS-BD			
Duodenal stricture	6	6	
Difficult biliary duct cannulation	7	3	
Difficult biliary drainage	2	1	
Difficult endoscope insertion	1	0	
Duodenal stent placement	4 (25.0)	5 (50.0)	0.23

Values are expressed as the mean ± standard deviation, n or n (%). EUS-BD, endoscopic ultrasound-guided biliary drainage; PS, plastic stent; MS, metallic stent.

Table IV. Comparison of EUS-BD procedure-related factors and postprocedural course (excluding patients with antegrade stenting).

Parameter	PS group (n=16)	MS group (n=10)	P-value
Later nine years (2014-2021)	10 (62.5)	6 (60.0)	1.00
Diameter of target bile duct, mm	9.7±5.3	12.5±5.9	0.24
Distance of puncture route, mm	13.9±7.4	13.5±4.6	0.87
Length of biliary obstruction, mm	31.9±10.3	31.6±14.9	0.95
Method of EUS-BD			0.051
CDS	6 (37.5)	8 (80.0)	
HES	10 (62.5)	2 (20.0)	
Procedural time, min	38.5 (30.0-157.0)	55.0 (24.0-131.0)	0.27
Adverse events	1 (6.3)	2 (20.0)	0.54
Dislocation	1	2	
Chemotherapy	8 (50.0)	4 (40.0)	0.70
Death	12 (75.0)	9 (90.0)	0.62
Overall survival, days	122 (33-874)	91 (26-74)	0.87

Values are expressed as the mean ± standard deviation, median (range), n or n (%). EUS-BD, endoscopic ultrasound-guided biliary drainage; CDS, choledochoduodenostomy; HES, hepaticoenterostomy; PS, plastic stent; MS, metallic stent.

significantly different between the PS group and the MS group (Table III).

*Comparison of EUS-BD procedure-related factors and postprocedural course without AGS.* When those patients who had undergone EUS-AGS were removed from the analysis,

EUS-BD procedure-related factors and postprocedural course were not significantly different between the PS group and the MS group (Table IV).

*Comparison of the TRBO.* The results of the TRBO comparison between MSs and PSs are provided in Fig. 3. The TRBO was

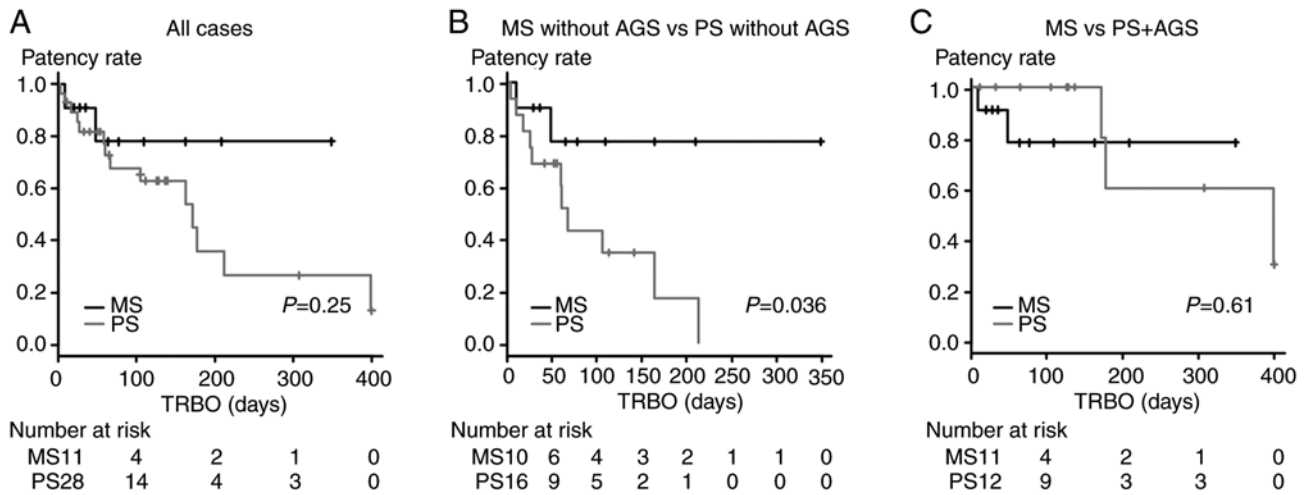


Figure 3. Comparison of TRBO between MSs and PSs. (A) MS vs. PS. (B) MS without AGS vs. PS without AGS. (C) MS vs. combination of PS and AGS. TRBO, time to recurrent biliary obstruction; MS, metallic stent; PS, plastic stent; AGS, antegrade stenting.

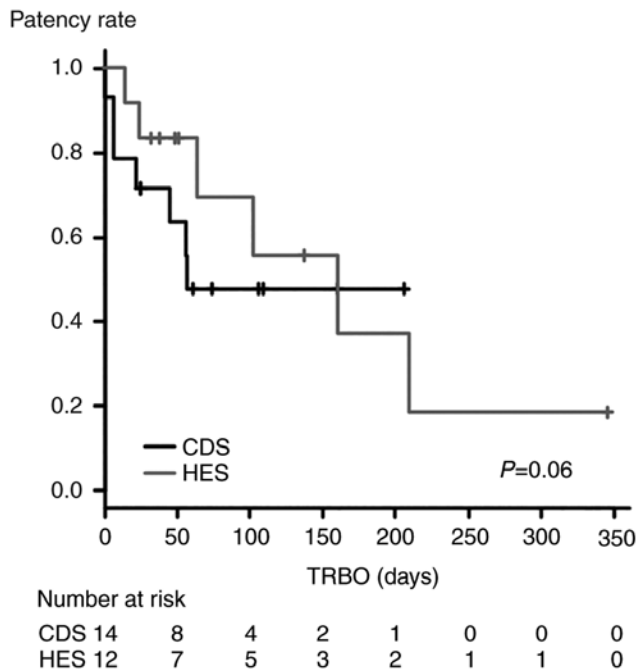


Figure 4. Comparison of TRBO between EUS-CDS and EUS-HES. TRBO, time to recurrent biliary obstruction; EUS-CDS, endoscopic ultrasound-guided choledochoduodenostomy; HES, hepaticoenterostomy.

not significantly different between the PS group and the MS group ( $P=0.25$ , Fig. 3A). When the analysis was limited to patients without AGS, the TRBO was significantly longer in the MS group than in the PS group ( $P=0.036$ , Fig. 3B). When the patients in the PS group were limited to those patients who had undergone PS placement and AGS, the patency period was not significantly different between the groups ( $P=0.61$ , Fig. 3C).

The results of the TRBO comparison between EUS-CDS and EUS-HES are presented in Fig. 4. The TRBO was not significantly different between the two EUS-BD methods ( $P=0.06$ ). In addition, the TRBO was not significantly different between males and females (female vs. male,  $P=0.15$ , Fig. 5A;

female MS vs. male MS,  $P=0.29$ , Fig. 5B; female PS vs. male PS,  $P=0.22$ , Fig. 5C).

## Discussion

EUS-BD is an alternative option for cases in which endoscopic transpapillary biliary drainage is difficult. In endoscopic transpapillary biliary drainage, a longer TRBO is expected with SEMSs as compared to PSs (13). However, the stent does not pass through the biliary stricture in EUS-CDS and HES. Therefore, whether an MS or PS should be used for EUS-BD has remained elusive. The present study indicated that the TRBO was longer with an MS than with a PS in EUS-BD.

The present results indicated that TRBO was not significantly different between the MS and PS groups. Although the EUS-BD method (CDS or HES) did not influence TRBO, the EUS-BD method was significantly different between the PS group and the MS group. Therefore, comparisons that excluded patients with AGS were performed. The results indicated that patient characteristics, EUS-BD procedure-related factors, and postprocedural course were not significantly different between the PS group and the MS group. When the extraneous factors were matched in this way, the TRBO in the MS group was significantly longer than that in the PS group.

As described in the introduction, CSEMSs have been used in EUS-BD (3,4), but several adverse events have been reported, including bleeding, bacteremia, bile leakage and bile peritonitis, stent migration, pneumoperitoneum and biloma. Furthermore, adverse events may at times become severe and fatal (6-8,14). Among these adverse events, bleeding may be decreased by using an ultratapered mechanical dilator called the ES dilator (Zeon Medical Co., Ltd.) for fistula dilation (15,16). In addition, a single-pigtail PS with two flanges on the distal end and proximal end called the IT stent (Gadelius Medical Co., Ltd.) has been reported to address stent migration (9) and be easy to place. However, in the present study, an MS was more appropriate for a longer TRBO than a PS. In a previous study, the combination of EUS-HES with PS placement and EUS-AGS using an MS was expected to result in a long TRBO (17). In the present study, the combination of



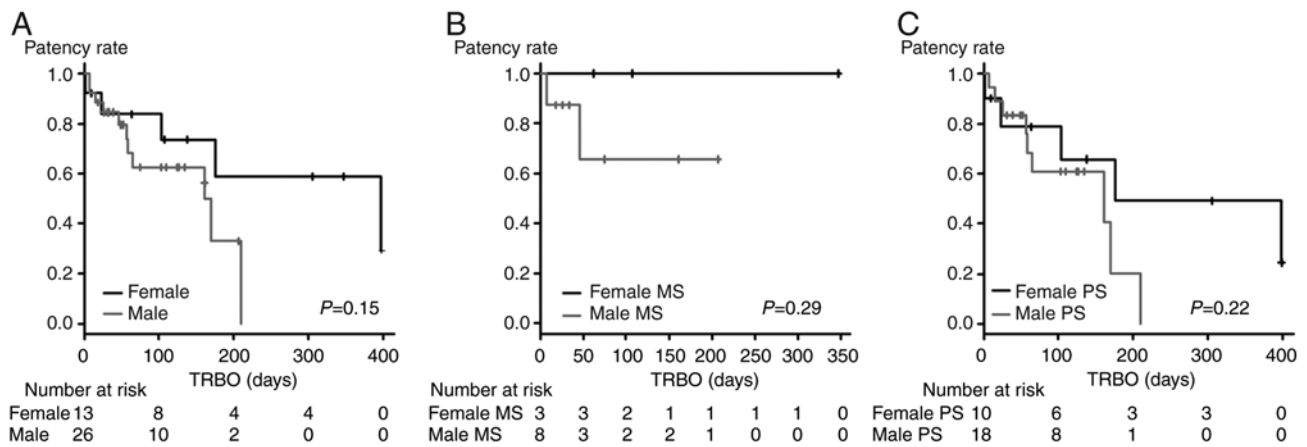


Figure 5. Comparison of TRBO between males and females. (A) Female vs. male. (B) Female MS vs. male MS. (C) Female PS vs. male PS. TRBO, time to recurrent biliary obstruction; MS, metallic stent; PS, plastic stent.

EUS-HES with PS placement and EUS-AGS using an MS was not inferior to EUS-BD using an MS in terms of the TRBO for patients with malignant biliary strictures. Therefore, the disadvantages of EUS-BD using a PS may be overcome by performing EUS-AGS with an MS at the same time.

On the other hand, MSs for EUS-BD have been improved. Lumen-apposing metal stents (LAMSs) have been used for EUS-CDS (18,19). The LAMS delivery system (Hot AXIOS; Boston Scientific) may also be used as an electrocautery dilator. Therefore, the puncture, fistula dilation and stent placement processes may be achieved in one step. In addition, the dumbbell-like shape of the LAMS prevents stent migration. The function of the LAMS as an electrocautery dilator may lead to the possibility of bleeding. However, only a small number of studies have reported bleeding with the use of an LAMS in EUS-CDS (20,21). Of note, the use of LAMSs for EUS-BD is not covered by the National Health Insurance of Japan. Therefore, LAMSs were not used in the present study.

For EUS-HES, the use of a dedicated partially covered SEMS (Spring Stopper; Taewoong Medical) has been reported (22). The distal end of the SEMS is uncovered and the proximal end resembles an umbrella. This shape prevents stent migration to the abdominal cavity. In addition, the delivery system of the stent matches a 0.025 guidewire. Therefore, sufficient trackability to the guidewire and insertion into the bile duct are expected. Improvement in SEMS performance may help to overcome the risk of migration and contribute to achieving a long TRBO in patients treated with EUS-BD.

There are certain limitations to the present study. First, the study was retrospective, performed at a single institution and had a small sample size. Furthermore, different stents were used in each group. In the future, multicenter prospective studies that use a PS or an MS are required to validate these results. In addition, a large proportion of the patients (n=26/39) were male. However, there was no significant difference in patient sex between the MS group and the PS group.

In conclusion, a longer TRBO is expected in EUS-BD with MSs than with PSs. Although MSs had sufficient patency, critical adverse events were reported with EUS-BD using MSs. On the other hand, PSs are easy to place. The use of PSs may help to overcome the disadvantage of a short

TRBO if combined with EUS-AGS using an MS. In the future, improvements to MSs may contribute to the advancement of EUS-BD.

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#### Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

#### Authors' contributions

MS wrote the manuscript, contributed to the study design and performed the research. TT contributed to the study design and supervised the research. RS, YW, NK, HA, YS, HI, JN, MT, MH, TK, RK, TY and TH performed analyses and interpretation of data. HO supervised the study, performed analyses and interpretation of data, and wrote the manuscript. All authors have read and approved the final manuscript. TT and HI confirm the authenticity of all the raw data.

#### Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Fukushima Medical University (Fukushima, Japan; approval no. 2399).

#### Patient consent for publication

Not applicable.

#### Competing interests

The authors declare that they have no competing interests.

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