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Impact of self-expandable metal stent deployment site on stent dysfunction during EUS-guided hepaticogastrostomy

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ABSTRACT

Background and Objectives: Hyperplasia at the distal side of an EUS–guided hepaticogastrostomy (HGS) stent is one of the most frequent causes of stent dysfunction. However, risk factors for hyperplasia during EUS-HGS remain unclear. The aim of the present study was to determine the most appropriate stent site during EUS-HGS to obtain prolonged stent patency.

Method: This study included 100 consecutive patients who underwent successful EUS-HGS using a partially covered, self-expandable, metal stent (PCSEMS) between January 2017 and September 2022. The patients were divided into 2 groups according to the distal site of the PCSEMS at the intrahepatic bile duct, the peripheral side group and the central side group.

Results: There were 30 patients in the peripheral side group and 70 in the central side group. The diameter of the intrahepatic bile duct at the PCSEMS deployment site was significantly greater in the central side group (mean 7.90 mm) than in the peripheral side group (mean 4.25 mm; $P < 0.05$). Stent patency was significantly longer in the central side group than in the peripheral side group (median, 60 days *vs.* 144 days, $P = 0.011$), although overall survival was not significantly different. Hyperplasia was significantly more frequent in the peripheral side group. On multivariate analysis, the site of the PCSEMS (peripheral) was the only risk factor for stent dysfunction.

Conclusions: In conclusion, the distal site of the PCSEMS deployed at the hepatic hilar site from the confluence between B2 and B3 might play a role in obtaining longer stent patency.

Key words: EUS-guided hepaticogastrostomy; EUS-HGS; EUS–guided biliary drainage; ERCP; Biliary drainage

INTRODUCTION

Endoscopic biliary stenting under ERCP guidance is the gold standard technique for treating malignant biliary obstruction. However, biliary drainage under a percutaneous or enteroscopic approach is indicated for patients who fail ERCP or have an inaccessible papilla due to surgically altered anatomy. EUS–guided biliary drainage (EUS-BD) has been indicated for such cases.[1–5] EUS-BD can be mainly divided into 2 kinds of procedures, EUS-guided choledochoduodenostomy (CDS) and hepaticogastrostomy (HGS). EUS-CDS in particular has recently been considered a possible primary drainage technique instead of ERCP.[6] In addition, according to a recent meta-analysis,[7] although EUS-CDS and EUS-HGS are comparable in terms of technical success, clinical success, and adverse event rates, EUS-CDS is better with respect to procedure time and preventing recurrent biliary obstruction (RBO). However, EUS-HGS has several advantages over EUS-CDS, such as for duodenal bule obstruction or surgically altered anatomy.[5] To date, several efforts to prevent adverse events have been reported,[8–12] but efforts to obtain longer stent patency have not been sufficiently reported. As reasons for stent dysfunction, hyperplasia at the distal side of the EUS-HGS stent is one of the most frequent.[13] In clinical practice, we have seen early stent dysfunction due to hyperplasia. This might be similar to stent-induced ductal change during ERCP.[14] However, risk factors for hyperplasia during EUS-HGS remain unclear. The aim of the present study was to determine the most appropriate stent site during EUS-HGS for prolonged stent patency.

PATIENTS AND METHODS

This retrospective, single-center study included consecutive patients who underwent EUS-HGS between January 2017 and September 2022. The inclusion criteria were the following: malignant common biliary obstruction; stent deployment at B3; successful EUS-HGS with clinical success; and placement of a partially covered, self-expandable, metal stent (PCSEMS) (diameter 8 mm, length 12 cm, Niti-S S type; Taewoong Medical, Seoul, Korea). The exclusion criteria were the following: benign biliary stricture; hepatic hilar obstruction; B2 puncture; combined with antegrade stenting; and placement of a plastic stent or other SEMS, such as a fully covered, self-expandable, metal stent (FCSEMS). The study protocol was approved by the institutional review board of our hospital and conformed to the ethical guidelines of the 1975 Declaration of Helsinki. A priori approval was given by the human research

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Technical tips for EUS-HGS and procedure protocol

All procedures were performed by 3 experienced endoscopists (T.O., S.U., and A.O.) who had each performed more than 150 EUS-HGS procedures before the presented study. An echoendoscope (UCT260; Olympus Optical, Tokyo, Japan) was inserted into the stomach, and the intrahepatic bile duct was identified. Then, B3 puncture was performed using a 19-G needle (EZ Shot 3 Plus, Olympus) under color Doppler to prevent vessel injury. After bile juice aspiration, the contrast medium was injected to obtain a cholangiogram. A 0.025-inch guidewire (VisiGlide, Olympus; J-Wire, JMIT, Shiga, Japan) was subsequently inserted into the biliary tract. The stomach and bile duct wall were dilated using an ERCP catheter (MTW Endoskopie, Düsseldorf, Germany), a 4-mm balloon catheter (REN biliary balloon catheter; KANEKA, Osaka, Japan), an electrocautery dilator (Fine025; Medico's HIRATA, Osaka, Japan), or an ultra-tapered mechanical dilator (ES dilator; Zeon Medical Inc., Tokyo, Japan). After tract dilation, a PCSEMS was deployed from the intrahepatic bile duct to the stomach using the intra-scope channel release technique to prevent stent migration into the abdominal cavity.[11] All patients underwent computed tomography (CT) the day after EUS-HGS to evaluate adverse events such as stent dislocation or migration.

Definitions and statistical analysis

In the present study, patients were divided into 2 groups according to the distal site of the PCSEMS at the intrahepatic bile duct. If the distal site of the PCSEMS was deployed at the periphery from the confluence between B2 and B3 [Figure 1A], the patient was assigned to the "peripheral side" group. If the distal site was deployed at the hepatic hilar site from the confluence between B2 and B3 [Figure 1B], the patient was assigned to the "central side" group. The PCSEMS deployment site was evaluated on cholangiography imaging after stent deployment. From January 2017 to April 2019, the EUS-HGS stent was deployed at the peripheral side, and from May 2019 to September 2022, the EUS-HGS stent was deployed at the central side. Technical success was defined as successful stent deployment, and clinical success was defined as a 50% decrease in the bilirubin level within 2 weeks post-stent insertion or achieving a bilirubin value of less than 25% of the preprocedure level within 4 weeks post-stent insertion.

The primary outcome in the present study was stent patency compared between the 2 groups. Stent patency was measured from the day of EUS-HGS to stent dysfunction or the patient's death. Overall survival (OS) was also measured from the day of EUS-HGS to the patient's death. The secondary outcome was the reason for stent dysfunction. Stent dysfunction was considered present if jaundice recurred with clinical imaging findings such as biliary dilatation or cholangitis. If bile duct obstruction at an uncovered site of the PCSEMS was observed on cholangiography, hyperplasia was considered the reason for stent dysfunction [Figure 1C].

The diameter of the bile duct at the PCSEMS deployment site was measured by CT before EUS-HGS. The length between the hepatic parenchyma and the stomach wall and the stent length in the stomach were measured by CT the day after EUS-HGS, according to a previous report.[14] The technical success rate was defined by successful PCSEMS deployment. Procedure time was measured from echoendoscope insertion to successful stent deployment. Peritonitis was diagnosed if fever, elevated inflammatory markers on blood examination, and abdominal pain were observed within 1 day after EUS-HGS. Bile peritonitis was diagnosed based on the CT findings of bile leakage or peritonitis around the HGS stent on imaging performed the day after EUS-HGS. Adverse events associated with EUS-HGS procedures were evaluated according to the severity grading system of the American Society for Gastrointestinal Endoscopy lexicon.[15] A receiver-operating characteristic (ROC) curve was plotted to determine the optimum cutoff score for predicting the risk of stent dysfunction and assess its effect. Potential risk factors for stent dysfunction were examined by univariate analysis and evaluated by hazard ratios (HRs) with 95% confidence intervals (CIs) using logistic regression analysis. Descriptive statistics are presented as mean ± standard deviation (SD) or median and range values for continuous variables and as frequencies for categorical variables. The 2 groups were compared using analysis of variance for continuous variables, the Kruskal-Wallis test for numbers of events, and Pearson's chi-squared test, or Fisher's exact test for categorical variables. Survival curves for stent patency or OS were estimated from Kaplan-Meier curves. Differences with $P < 0.05$ were considered significant. All data were statistically analyzed using SPSS version 13.0 statistical software (SPSS, Chicago, IL).

RESULTS

A total of 100 patients were enrolled. Table 1 shows the patients' characteristics. Of the 100 patients, 30 (median age, 79 years; 19 males, 11 females) were in the peripheral side group, and 70 (median age, 77 years; 44 males, 26 females) were in the central side group. The primary diseases were pancreatic cancer (n = 47),

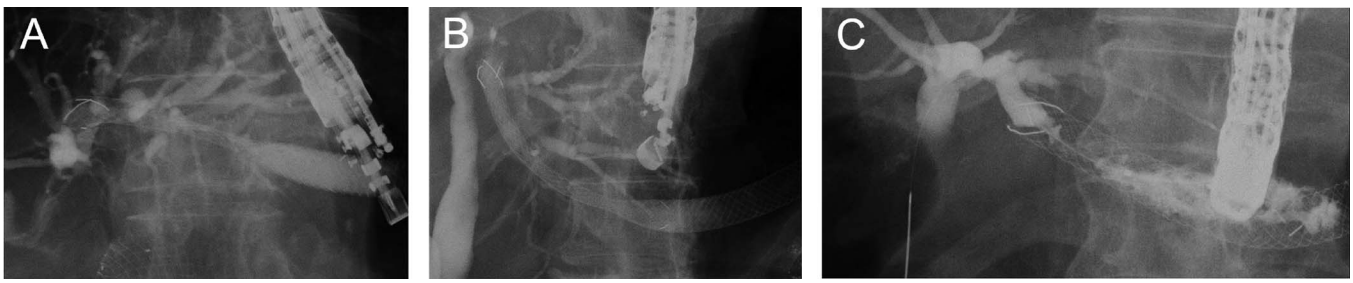

Figure 1. Kinds of stent deployment sites. A, Partially covered, self-expandable, metal stent is deployed at the periphery from the confluence between B2 and B3. B, Partially covered, self-expandable, metal stent is deployed at the hepatic hilar site from the confluence between B2 and B3. C, Hyperplasia is considered the reason for stent dysfunction.

Table 1

Patients' characteristics

	Peripheral Side	Central Side	*P* Value
Total patients (*n*)	30	70	—
Median age (y, range)	79 (54–94)	77 (48–93)	0.5854
Sex (male/female)	19/11	44/26	0.9639
Disease, *n*			0.1996
Pancreatic cancer	15	32	
Cholangiocarcinoma	10	15	
Gallbladder carcinoma	2	5	
Gastric cancer	3	7	
Others	0	11	
Presence of ascites, *n*	10	25	0.8191
Duodenal stent deployment, *n*	8	18	0.553
Diameter of bile duct at stent deployment site, mm (mean ± SD)	4.25 ± 3.13	7.90 ± 2.35	<0.0001
Length between hepatic parenchyma and stomach, mm (mean ± SD)	7.86 ± 9.12	7.49 ± 5.85	0.8062
WBC, /mm (mean ± SD)	6956.9 ± 3618.0	6305.3 ± 4432.0	0.4811
CRP, mg/dL (mean ± SD)	3.93 ± 4.90	5.09 ± 5.44	0.3183
T-Bil, mg/dL (mean ± SD)	8.61 ± 7.39	8.73 ± 6.39	0.9328

cholangiocarcinoma (*n* = 25), gallbladder carcinoma (*n* = 7), gastric cancer (*n* = 10), and other (*n* = 11). Ascites around hepatic parenchyma was observed in 10 patients in the peripheral side group and 25 patients in the central side group, with no significant difference ($P = 0.8191$). A duodenal stent was deployed for 8 patients in the peripheral group and 18 patients in the central group. The diameter of the intrahepatic bile duct at the PCSEMS deployment site was significantly greater in the central side group (mean 7.90 mm) than in the peripheral side group (mean 4.25 mm; $P < 0.05$). The length between the hepatic parenchyma and the stomach wall was similar in both groups (peripheral side *vs.* central side, mean 7.86 mm *vs.* 7.49 mm; $P = 0.8062$). Laboratory data such as white blood cell count, C-reactive protein, and bilirubin levels were not significantly different between the 2 groups.

Table 2 shows the results of the procedures. Technical success was obtained in all patients. Initial dilation devices in the peripheral side group were mainly ERCP catheter (*n* = 15), balloon catheter (*n* = 9), and mechanical dilator (*n* = 4), and in the central side group, they were ERCP catheter (*n* = 40), balloon catheter (*n* = 22), and mechanical dilator (*n* = 6). Procedure time was significantly shorter in the central side group (mean 14.9 minutes) than in the peripheral side group (mean 22.2 minutes; $P < 0.05$). The length between hepatic parenchyma and the stomach wall after EUS-HGS (mean 6.83 mm *vs.* 6.76 mm) and the stent length in the stomach (mean 59.0 mm *vs.* 55.6 mm) showed no significant differences between the peripheral and central side groups ($P = 0.9503$ and 0.3714, respectively). Adverse events were also not significantly different between the 2 groups ($P = 0.2011$), and they were successfully managed by conservative treatment.

Kaplan-Meier curves of OS and stent patency are shown in Figures 2 and 3, respectively. Median overall survival was 177 (95% CI, 92–327) days and 155 (95% CI, 104–NA) days in the peripheral and central side groups, respectively, with no significant difference. On the other hand, stent patency was significantly longer in the central side group than in the peripheral side group (median, 60 days *vs.* 144 days, $P = 0.011$). As reasons for stent dysfunction,

Table 2

Results of the procedures

	Peripheral Side	Central Side	*P* Value
Kind of initial dilation device, *n*			0.5521
Balloon catheter	9	22	
Mechanical dilator	4	6	
ERCP catheter	15	40	
Electrocautery dilator	1	0	
Drill dilator	1	2	
Mean procedure time, min	22.2 ± 11.6	14.9 ± 6.54	0.0001
Length between hepatic parenchyma and stomach after EUS-HGS, mm (mean ± SD)	6.83 ± 4.65	6.76 ± 5.74	0.9503
Stent length in stomach, mm (mean ± SD)	59.0 ± 17.7	55.6 ± 17.1	0.3714
Reason for stent dysfunction, *n*			0.0012
Hyperplasia	9	3	
Debris	1	3	
Stent dislocation	1	0	
Adverse event			0.2011
Peritonitis	2	2	
Pneumonia	1	0	

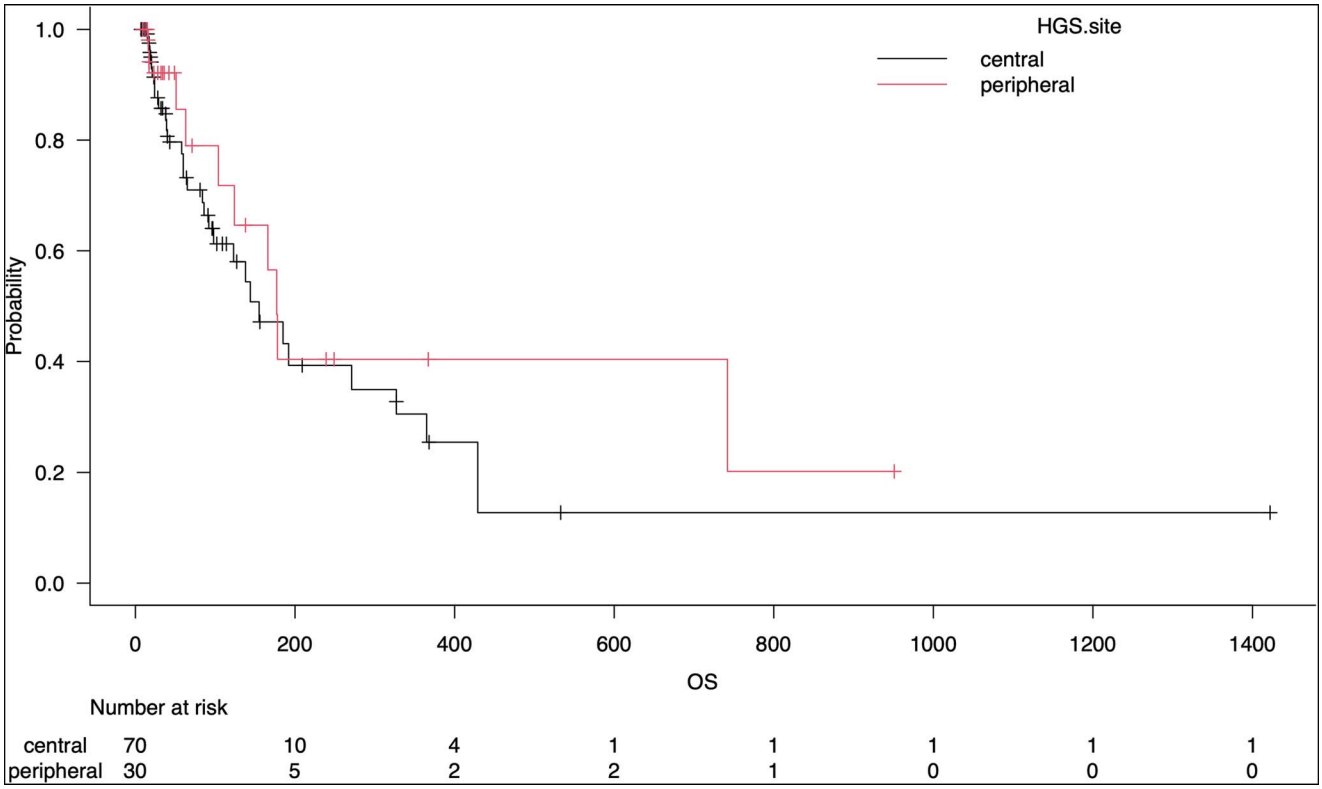

Figure 2. Kaplan-Meier curves of overall survival. Median overall survival is 177 (95% confidence interval [CI] 92–327) days and 155 (95% CI, 104–NA) days in the peripheral and central side groups, respectively, with no significant difference.

hyperplasia at the distal site of the PCSEMS was significantly more frequent in the peripheral side group (n = 9) than in the central side group (n = 3; P < 0.05).

The ROC curve was plotted to evaluate the effect of stent length in the stomach on the risk of stent dysfunction [Figure 4]. A length of 49 mm offered sensitivity of 94.4% and specificity of 30.5% in predicting stent dysfunction. This distance was used as a risk factor in the subsequent multivariate analysis. Table 3 shows the univariate and multivariate analyses of risk factors for stent dysfunction (Figure 5).

Table 3 shows the risk factors for stent dysfunction on logistic regression analysis. On univariate analysis, PCSEMS site (peripheral; HR, 0.144; 95% CI, 0.273–0.428) and stent length in the stomach (<49 mm; HR, 0.136; 95% CI, 0.003–0.964) were significant risk factors for stent dysfunction, but on multivariate analysis, PCSEMS site (peripheral; HR, 0.133; 95% CI, 0.041–0.434) was the only risk factor.

DISCUSSION

In the present study, the patients were divided into 2 groups based on the location of the distal site of the PCSEMS, and several significant findings were observed. First, procedure time was significantly shorter in the central side group than in the peripheral side group. This may be explained by guidewire manipulation into the biliary tract. Compared with the periphery of the intrahepatic bile duct, the diameter of the bile duct is normally dilated near the hepatic hilum. Indeed, in the present study, the diameter of the bile duct was significantly greater in the central side group than in the peripheral side group. Therefore, guidewire insertion into the biliary tract may have been easier in the central side group than in the peripheral side group. In addition, from the periphery of the intrahepatic bile duct to the confluence between B2 and B3, there are several side branch bile ducts. If the guidewire is advanced into the side branch bile ducts, several techniques, such as liver impaction, should be attempted to prevent guidewire sharing.[16] Therefore, guidewire insertion into the common bile duct may have been easier in the central side group than in the peripheral side group. Second, median stent patency was significantly longer in the central side group than in the peripheral side group. Stent dysfunction occurred mainly due to hyperplasia in the present study. This might be explained by a phenomenon similar to stent-induced ductal change. Because a stent damages the normal duct epithelium as a direct result of pressure exerted on it, tissue hyperplasia might occur as stent-induced ductal change.[16,17] In the present study, an 8-mm-diameter PCSEMS was used. Because the diameter of the bile duct where the PCSEMS was placed was smaller in the peripheral side group, the normal bile duct epithelium might have been subjected to high pressure by the stent at the uncovered site of the PCSEMS. Therefore, hyperplasia might have occurred more easily in the peripheral side group than in the central side group.

As reasons for stent dysfunction, sludge or food impaction may also be important factors. Cho et al. conducted a retrospective, multicenter study to evaluate long-term outcomes and predictors of adverse events of EUS-HGS.[18] In their study involving 106

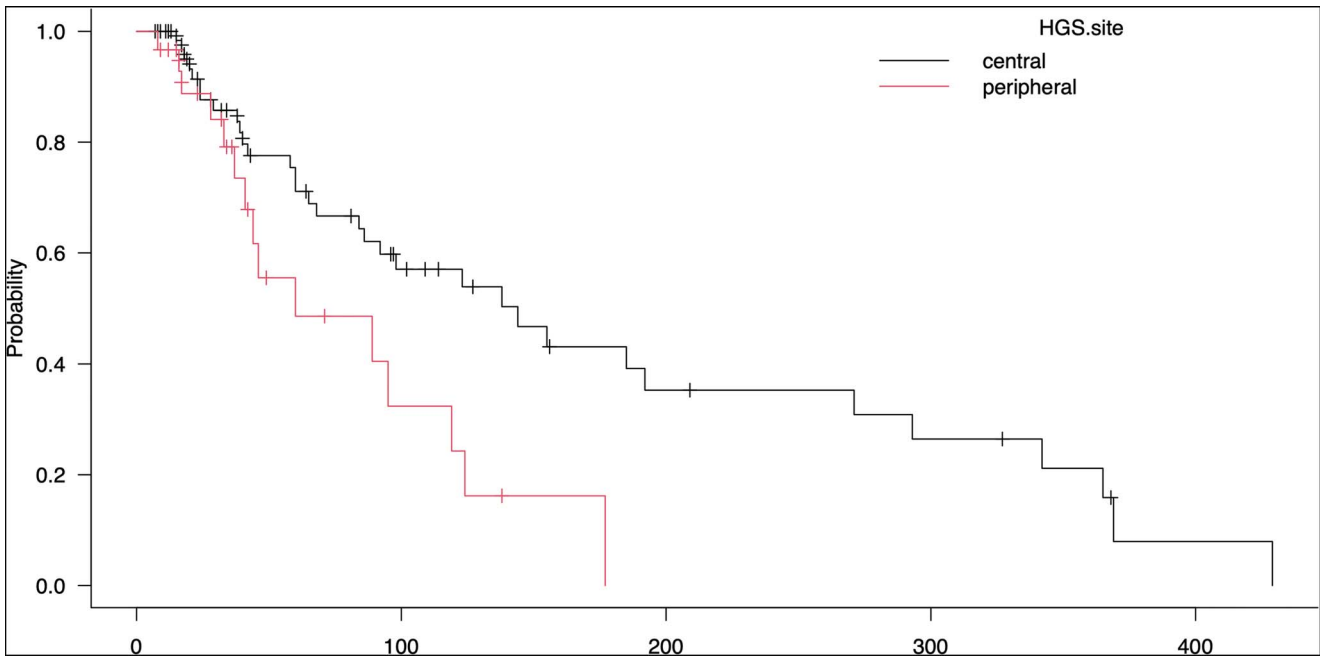

Figure 3. Kaplan-Meier curves of stent patency. Stent patency is significantly longer in the central side group than in the peripheral side group (median, 60 days *vs.* 144 days; $P = 0.011$).

patients, excluding cases of a combination with EUS-guided antegrade stenting, median stent patency was 138 days, and stent dysfunction was observed in 39 patients. The main reason for stent dysfunction was stent obstruction, followed by unknown, sludge (food scraps), and migration. Shibuki et al. compared the time to recurrent biliary obstruction between covered SEMS *versus* plastic stents for EUS-HGS in patients with malignant biliary obstruction.[19] In that study, 109 patients who underwent EUS-HGS using a covered SEMS were included, and recurrent biliary obstruction was observed in 12 patients. Sludge (8/12, 66.7%) was the most frequent reason for recurrent biliary obstruction. However, in the present study, sludge or food impaction was observed in only 4 patients (4/17, 23.5%). The reason for this may be the stent length in the stomach. We previously examined predictors of stent patency in patients who underwent EUS-HGS using a PCSEMS.[12] The median duration of stent patency was significantly shorter with stent length in the stomach <3 cm (52 days) than with stent length ≥3 cm (195 days; $P < 0.01$). On the other hand, the median duration of stent patency did not differ significantly between ≥4 cm (194 days) and <4 cm (127 days; $P = 0.1726$). On multivariate analysis, length of the stent in the luminal portion ≥3 cm (HR, 9.242; 95% CI, 3.255–26.244; $P < 0.05$) was a factor related to longer stent patency. In the present study, stent dysfunction was observed in 8 patients, and sludge was observed in 4 patients; these only occurred in cases with stent length in the stomach <3 cm. Nakai et al. also evaluated long-term outcomes of PCSEMS for EUS-HGS in patients with malignant biliary obstruction.[20] In their study, 110 patients were enrolled; the median stent length in the stomach was 54 mm, similar to the present study. Recurrent biliary obstruction was observed in 36 patients (33%). The major cause of recurrent biliary obstruction was hyperplasia at an uncovered site (25/32). Therefore, sufficient stent length in the stomach may prevent reflux cholangitis, sludge, or food impaction.

To prevent hyperplasia, a fully covered SEMS (FCSEMS) may be considered as an EUS-HGS stent. Okuno et al. conducted a prospective study of EUS-HGS using a 6-mm FCSEMS for primary

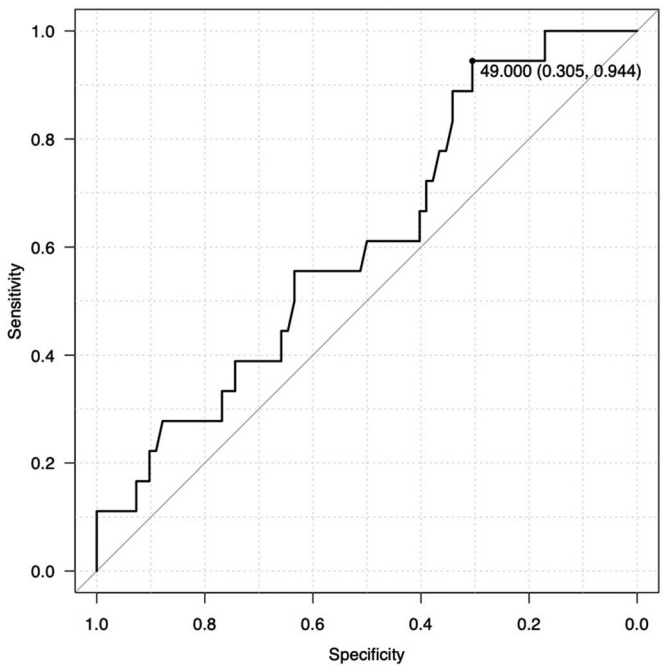

Figure 4. ROC curve to evaluate the influence of stent length in the stomach on the risk of stent dysfunction. A length of 49 mm offers sensitivity of 94.4% and specificity of 30.5% in predicting stent dysfunction. ROC: receiver-operating characteristic.

Table 3

Risk factors for stent dysfunction on logistic regression analysis

	Univariate Analysis		Multivariate Analysis	
Factor, *n* (%)	**HR (95% CI)**	***P* Value**	**HR (95% CI)**	***P* Value**
Age (>70 y)	0.58 (0.178–2.000)	0.39	0.425 (0.120–1.500)	0.185
Sex (male)	1.277 (0.394–4.582)	0.791	1.100 (0.320–3.800)	0.877
Disease (pancreatic cancer)	0.883 (0.273–2.775)	1	1 (0.300–3.350)	0.997
Site of PCSEMS (peripheral)	0.144 (0.039–0.428)	<0.001	0.133 (0.041–0.434)	<0.001
Duodenal stent (deployed)	0.516 (0.088–2.078)	0.388	0.473 (0.099–2.270)	0.349
Stent length in stomach (<49 mm)	0.136 (0.003–0.964)	0.036	0.133 (0.015–1.16)	0.068

drainage.[21] Stent dislocation was observed in 4 of 20 patients, and focal cholangitis due to side bile duct branch obstruction was also observed in 2 patients. We also previously evaluated EUS-HGS using an 8-mm-diameter FCSEMS in 14 patients. However, focal cholangitis that required stent exchange with a plastic stent was observed. Therefore, FCSEMS has a risk of stent dislocation or focal cholangitis, although hyperplasia may be prevented. In particular, early stent dislocation before fistula creation between the hepatic parenchyma and the stomach wall may be a fatal adverse event. On the other hand, a PCSEMS can function as an intrahepatic anchor to prevent stent dislocation out of the liver. In addition, focal cholangitis at B2 can be prevented. If stent dysfunction due to hyperplasia occurs, re-intervention might be feasible. Therefore, a PCSEMS might be as safe as an EUS-HGS stent, although a randomized, controlled study is needed, because the present study had several limitations, such as its retrospective design. Also, the stent length in the stomach was associated with the risk of stent dysfunction; however, the specificity was only 30.5%. Therefore, our results should be evaluated by high quality trial.

In conclusion, the distal site of the PCSEMS deployed at the hepatic hilar site from the confluence between B2 and B3 might play a role in obtaining longer stent patency, although a randomized, controlled trial is needed to confirm this.

Informed Consent

Patient's informed consent is obtained by all patients.

Conflict of Interest

Takeshi Ogura is an Editorial Board Member of the journal. The article was subjected to the standard procedures of the journal, with a review process independent of the editor and his research group.

Author Contributions

Takeshi Ogura wrote the paper. Takeshi Ogura, Saori Ueno, Atsushi Okuda, Nobu Nishioka, Jun Sakamoto, Masanori Yamada, Masahiro Yamamura, Yuki Uba, Mitsuki Tomita, Nobuhiro Hattori,

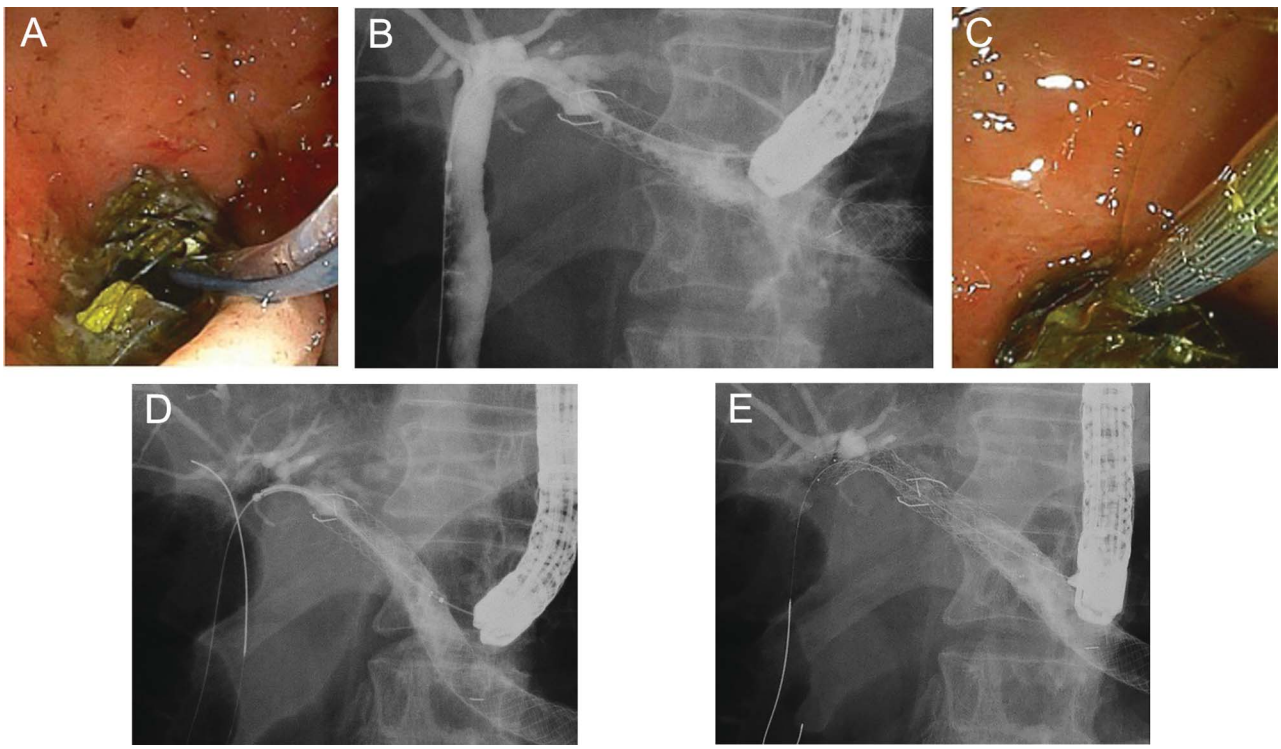

Figure 5. Re-intervention technique for occluded Eus-guided hepaticogastrostomy stent.

Junichi Nakamura, Kimi Bessho, and Hiroki Nishikawa performed data interpretation, revised the work critically for important intellectual content, gave final approval of the version to be published, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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