

ORIGINAL ARTICLE OPEN ACCESS

Balloon Catheter Versus Drill Dilator for EUS-Guided Hepaticogastrostomy Stent Placement: A Randomized Clinical Trial

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Received: 17 February 2025 | **Accepted:** 27 February 2025

Keywords: balloon catheter | balloon dilation | biliary drainage | drill dilator | EUS-guided hepaticogastrostomy | self-expandable metal stent | stent placement | tract dilation

ABSTRACT

Objectives: A novel partially self-expandable metal stent (PCSEMS) with an anti-migration system has recently become available during Endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) but requires tract dilation. No previous study has compared the performance of dilation devices during EUS-HGS. The aim of this randomized controlled trial was to evaluate the technical success rate of tract dilation between a balloon catheter and drill dilator technique during EUS-HGS prior to insertion of SEMS with an anti-migration system.

Methods: A single-center, randomized controlled trial comparing the balloon dilation and drill dilator techniques for first-line tract dilation during EUS-HGS. The primary outcome was the initial technical success rate of tract dilation for each technique during EUS-HGS. The secondary outcome was adverse events associated with the procedures.

Results: Of 54 randomized patients who underwent EUS-HGS at our center, there were 27 in the balloon dilation group and 27 in the drill dilation group. The initial technical success rate was 92.6% (25/27) in the balloon dilation group and 100% (27/27) in the drill dilation group ($p = 0.1495$). The technical success rate of stent delivery system insertion was significantly higher in the balloon dilation group (88%, 22/25) than in the drill dilation group (45%, 13/27; $p = 0.0013$). Procedure time was significantly shorter in the balloon dilation group (mean, 9.7 min) than in the drill dilation group (mean, 14.0 min; $p = 0.047$). Adverse events were more frequent in the drill dilation group (7.4% vs. 29.6%, $p = 0.038$).

Conclusions: Balloon dilation appears more suitable than drill dilation for PCSEMS with 8.5 Fr stent delivery system deployment.

Clinical trial registration number: University Hospital Medical Information Network 000049550.

1 | Introduction

Endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) is widely attempted for patients in whom endoscopic retrograde

cholangiopancreatography (ERCP) is unsuccessful due to duodenal obstruction or surgically altered anatomy [1–3]. Among EUS-HGS stents, longer stent patency has been shown for self-expandable metal stents (SEMS) than for plastic stents

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Summary

- Summarize the established knowledge on this subject
 - Endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) is widely attempted for patients in whom endoscopic retrograde cholangiopancreatography (ERCP) is unsuccessful. To avoid stent migration, a novel partially covered SEMS (PCSEMS) with an anti-migration system has recently become available. To deploy PCSEMS, tract dilation can be performed using a balloon catheter or drill dilator. However, no previous study has compared the efficacy and safety of drill dilation and balloon catheter during EUS-HGS.
- What are the significant and/or new findings of this study?
 - Of 54 randomized patients who underwent EUS-HGS, there were 27 in the balloon dilation group and 27 in the drill dilation group. The technical success rate of stent delivery system insertion was significantly higher in the balloon dilation group (88%, 22/25) than in the drill dilation group (45%, 13/27; $p = 0.0013$). Procedure time was significantly shorter in the balloon dilation group (mean, 9.7 min) than in the drill dilation group (mean, 14.0 min; $p = 0.047$). Adverse events were more frequent in the drill dilation group (7.4% vs. 29.6%, $p = 0.038$). Therefore, balloon dilation appears more suitable than drill dilation.

[4–6]. In addition, if bile duct puncture cannot be performed through a sufficient depth of hepatic parenchyma [7], bile leakage can occur when a plastic stent is deployed because of the gap between the fistula and the stent [8]. In contrast, with SEMS deployment, stent migration into the abdominal cavity is a critical associated adverse event. To avoid this occurrence, a novel partially covered SEMS (PCSEMS) with an anti-migration system has recently become available, and excellent results have been reported [9–11]. Therefore, SEMS might be a suitable stent for EUS-HGS. Compared with SEMSs that have a fine-gauge stent delivery system [12–14], those with an anti-migration system have a large diameter and generally require tract dilation prior to deployment. Dilation can be performed by mechanical or electrocautery dilation devices. Although co-axial type electrocautery dilation is useful for obtaining tract penetration to a certain depth, previous comparison studies using needle knife type have reported its association with adverse events such as bleeding [14, 15]. The balloon catheter technique has a low risk of bleeding and is more commonly used for this purpose [16]. As a third dilation technique, a recently developed drill dilator has been shown to facilitate easy and safe tract dilation [17–19]. Although dilation of the stomach and bile duct walls requires insertion of the dilation device into the biliary system through these walls, the drill dilator can be easily and accurately inserted into the biliary system with an extremely high technical success rate. However, no previous study has compared the efficacy and safety of drill dilation and mechanical dilation during EUS-HGS before SEMS with an anti-migration system. In this randomized controlled trial, we aimed to evaluate the technical success rate of tract dilation

using the balloon catheter technique and the drill dilator during EUS-HGS before SEMS with an anti-migration system.

2 | Patients and Methods

2.1 | Patients

Consecutive patients with obstructive jaundice who required biliary drainage at our hospital were eligible for enrollment in the study. The inclusion criteria were as follows: (1) age > 18 years, (2) failed ERCP, and (3) performance status 0–2. The exclusion criteria were as follows: (1) total gastrectomy, (2) presence of ascites, (3) bleeding tendency, and (4) refusal to participate in this study.

2.2 | Study Design and Randomization

This single-center, randomized controlled trial compared balloon dilation with the drill dilator as the first-line tract dilation device during EUS-HGS. The study was conducted according to the tenets of the Declaration of Helsinki for biomedical research involving human subjects (clinical trial registration number: University Hospital Medical Information Network 000049550), and all patients provided written informed consent. A priori approval was given by the Human Research Committee of Osaka Medical and Pharmaceutical University (IRB No. 2022-210).

Patients were randomly divided according to dilation device into the balloon dilation and drill dilation groups in a 1:1 fashion. Randomization was conducted with respect to age (> 75 years old), gender (male or female), disease (malignant or benign), and factors associated with successful tract dilation such as bile duct diameter (> 3 mm) and length of hepatic parenchyma (> 25 mm) at the puncture site on EUS imaging. Randomization was conducted using a web-based system designed by an independent research organization (Tofield Company Limited, Tokyo, Japan).

2.3 | Devices and Procedure Protocol

The dilation devices are shown in Figure 1. The PCSEMS with an anti-migration system (8 mm × 12 cm Spring Stopper; Tae-woong Medical, Seoul, Korea) has a 1.5-cm uncovered portion at the distal end, and the proximal end has a lumen-apposing shape as an anti-migration system (Figure 1a). The diameter of the stent delivery system is 8.5 Fr. The single-lumen balloon catheter (REN biliary dilation catheter; KANEKA, Osaka, Japan) is coaxial type with a 3 Fr tip (Figure 1b), and a 4-mm balloon catheter is used. The drill dilator (Tornus ES; Asahi Intecc, Aichi, Japan) is also coaxial type, and the body is 7F (Figure 1c). The tract is easily dilated by clockwise rotation of the device without applying pushing force. If counterclockwise rotation is attempted, movement of the drill dilator is in the proximal direction. Each dilation device was dedicated for 0.025-inch guidewire.

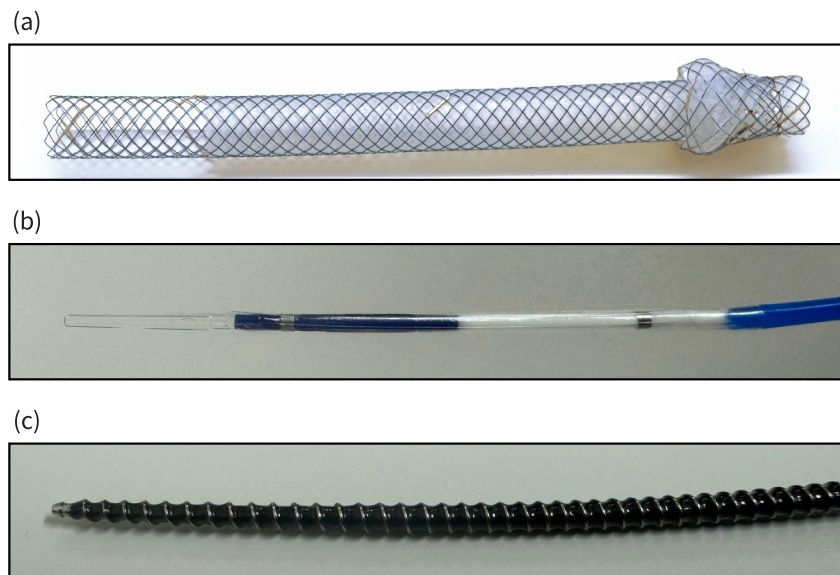


FIGURE 1 | (a). Partially covered self-expandable metal stent with an anti-migration system (8 mm × 12 cm Spring Stopper; Taewoong Medical, Seoul, Korea). There is a 1.5-cm uncovered portion at the distal end. (b). Balloon catheter (REN biliary dilation catheter; KANEKA, Osaka, Japan). This coaxial catheter has a 3 Fr tip. (c). Drill dilator (Tornus ES; Asahi Intecc, Aichi, Japan). The drill dilator is also coaxial type, and the body is 7F.

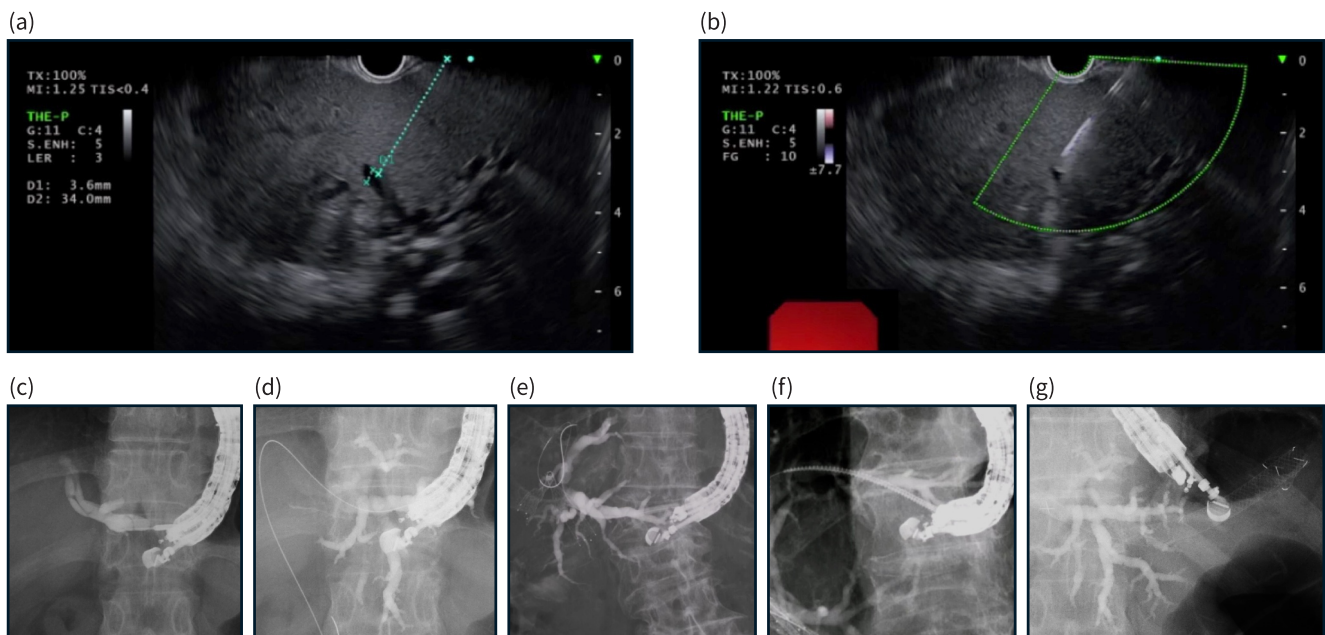


FIGURE 2 | (a). Endoscopic ultrasound image shows measurement of the puncture diameter and the depth of the hepatic parenchyma at the puncture site. (b). The intrahepatic bile duct is punctured using 19G needle. (c). Contrast medium is injected. (d). Guidewire is deployed. (e). Tract dilation is performed using the balloon catheter. (f). Tract dilation is performed using the drill dilator. (g). A partially covered self-expandable metal stent with an anti-migration system is deployed.

Figure 2 illustrates technical tips for EUS-HGS. To exclude bias due to operator experience, EUS-HGS was performed by an experienced endoscopist (T.O) who has performed more than 500 biliary drainage procedures under EUS guidance. Prior to bile duct puncture, we measure the diameter of the bile duct at the puncture site and measure the depth of the hepatic parenchyma on EUS imaging (Figure 2a). At this time, the patients are randomly divided into the balloon dilation group or drill dilation group. The intrahepatic bile duct is punctured using a

19G needle (EZ Shot 3 Plus, Olympus, Tokyo, Japan) (Figure 2b) and contrast medium is injected until a cholangiogram is obtained around the confluence of B2 and B3 (Figure 2c). A 0.025-inch guidewire (VisiGlide, Olympus; J-Wire, JMIT, Shiga, Japan) is inserted into the biliary tract and the needle is then removed (Figure 2d). The bile duct and stomach wall are dilated using a balloon catheter (Figure 2e) or drill dilator (Figure 2f). In the case of unsuccessful dilation device insertion into the biliary tract, tract dilation is attempted using another device. If

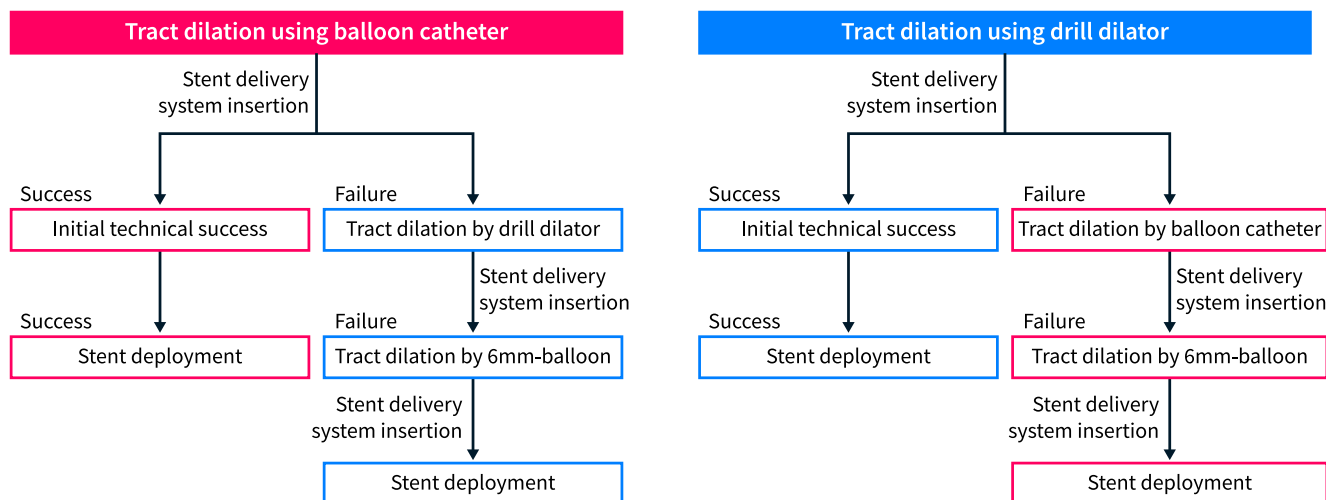


FIGURE 3 | Procedural protocol.

tract dilation is unsuccessful with both techniques, tract dilation using a 6-mm balloon catheter is attempted (Figure 3). After successful tract dilation, insertion of the stent delivery system is attempted. If unsuccessful, additional tract dilation is performed using a balloon catheter or drill dilator. Finally, the stent is deployed from the bile duct to the stomach using the intrascopy channel release technique (Figure 2g). Post-procedural computed tomography (CT) is obtained the day after EUS-HGS and evaluated for adverse events such as stent dislocation or migration.

2.4 | Outcome Measurements and Definitions

The primary outcome was the initial technical success rate of tract dilation during EUS-HGS. Technical success was defined as insertion of the dilation device into the biliary tract followed by successful dilation of the bile duct and stomach wall.

The secondary outcome was the technical success of stent delivery system insertion and adverse events associated with the procedures. The technical success of stent delivery system insertion was defined as successful stent delivery system insertion after tract dilation using a definitive dilation device such as a drill dilator or balloon catheter. Peritonitis was diagnosed if fever, elevated inflammatory markers on blood examination, and abdominal pain were observed the day after EUS-HGS. Bile peritonitis was defined as bile leak or peritonitis observed around the HGS stent on the post-procedural CT. Intraoperative bleeding events were defined as puncture-site hematoma, continuous bleeding that required endoscopic and/or intravenous and/or surgical hemostasis around the puncture site, or bleeding on cholangiography. Postoperative bleeding events were defined as bleeding requiring blood transfusion, melena, hematemesis, bleeding confirmed on CT, or a decrease in hemoglobin ≥ 2 g/dL. Adverse events were graded according to the severity grading system of the American Society for Gastrointestinal Endoscopy lexicon [20]. Final technical success was defined as the successful deployment of PCSEMS with an anti-migration system. Procedure time was measured from bile duct puncture to stent deployment. The angle between the puncture

needle and the bile duct was measured retrospectively on a fluoroscopic image.

2.5 | Sample Size and Statistical Analysis

The primary analysis was a comparison of balloon dilation versus drill dilation in terms of the initial technical success rate. Although no prospective randomized trial has evaluated tract dilation in terms of drill dilation technique, previous studies have indicated that the initial technical success rate of the drill dilator might be 100% [17, 18]. In our recent retrospective evaluations prior to the present study, the initial technical success rate of balloon catheter dilation was 95% (81–85). The margin was set at 10% in accordance with the US FDA recommendations. To achieve a statistical power of 80%, with a one-sided type I error of 5% based on the normal approximation test of proportions, a total of 50 patients (25 per group) were needed. To allow for possible dropout patients, we estimated that a final sample size of 54 (27 per group) was required.

Descriptive statistics are presented as the mean $\pm$ standard deviation (SD) or the median and range for continuous variables, and as frequencies for categorical variables. The two study arms were compared using analysis of variance for continuous factors, the Kruskal–Wallis test for number of events, and Pearson's chi-square test or Fisher's exact test for categorical factors. All data were statistically analyzed using SPSS version 13.0 statistical software (SPSS, Chicago, IL).

3 | Results

3.1 | Patient Enrollment and Participant Flow

A total of 121 patients underwent EUS-HGS between December 2022 and March 2024 (Figure 4). Of these, 67 were excluded because of total gastrectomy ($n = 49$), presence of ascites ($n = 8$), or refusal to participate in the study ($n = 10$). A final total of 54 patients, 27 in the balloon dilation group and 27 in the drill dilation group, were included in the analysis.

3.2 | Patient Characteristics

In the balloon dilation group (median age, 79 years; 14 males, 13 females), the primary disease was malignancy in 21/27 (77.8%) and the main reason for EUS-HGS was duodenal obstruction or surgically altered anatomy (26/27, 96.3%). In the drill dilation group (median age, 79 years; 16 males, 11 females), the primary disease was malignancy in 22/27 (81.4%) and the main reason for EUS-HGS was duodenal obstruction or surgical altered anatomy (26/27, 96.3%). There were no significant differences between the groups in terms of patient background, inflammatory markers, or liver enzymes (Table 1).

3.3 | Procedural Outcomes

There were no significant differences between the groups in terms of puncture site, diameter of bile duct, or length of hepatic parenchyma at the puncture site. The angle between the puncture needle and the bile duct was 140.8° in the balloon dilation group and 149.7° in the drill dilation group ($p = 0.4128$). The patient outcomes are shown in Figure 5 and Table 2. The initial technical success rate was 92.6% (25/27) in the balloon dilation group and 100% (27/27) in the drill dilation group (no significant difference, $p = 0.1495$). For the two patients in whom balloon dilation was unsuccessful, tract dilation was performed

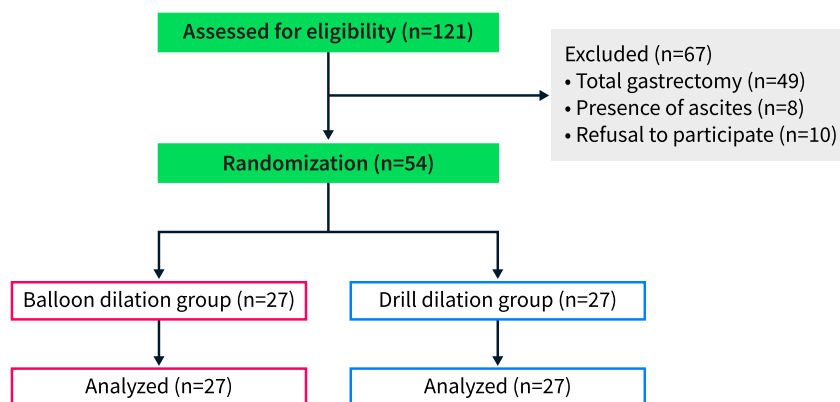


FIGURE 4 | Flow chart of participant selection.

TABLE 1 | Patient demographics and clinical characteristics.

Characteristic	Balloon	Drill	p-value
Total patients (n)	27	27	—
Median age (y, range)	79 (45–94)	79 (63–94)	0.7007
Sex (male: female)	14/13	16/11	0.5839
Final diagnosis			0.5750
Pancreatic cancer	8	7	
Bile duct cancer	7	7	
Gallbladder cancer	2	2	
Gastric cancer	1	5	
Benign biliary stricture	6	5	
Other	3	1	
Reason for EUS-HGS			0.3546
Surgically altered anatomy	7	12	
Duodenal obstruction	19	14	
Failed ERCP	1	1	
T-bilirubin (mg/dL, mean ± SD)	5.42 ± 5.56	5.15 ± 6.22	0.8616
AST (U/L, mean ± SD)	107.9 ± 75.3	104.7 ± 95.9	0.8925
ALT (U/L, mean ± SD)	101.6 ± 84.0	94.7 ± 92.6	0.7746
White blood cell count (/μL, mean ± SD)	6841.1 ± 2817.7	7269.6 ± 5022.6	0.7006
C-reactive protein (mg/dL, mean ± SD)	4.42 ± 5.63	5.47 ± 6.81	0.5412

Abbreviations: ALT: alanine aminotransferase, AST: aspartate aminotransferase.

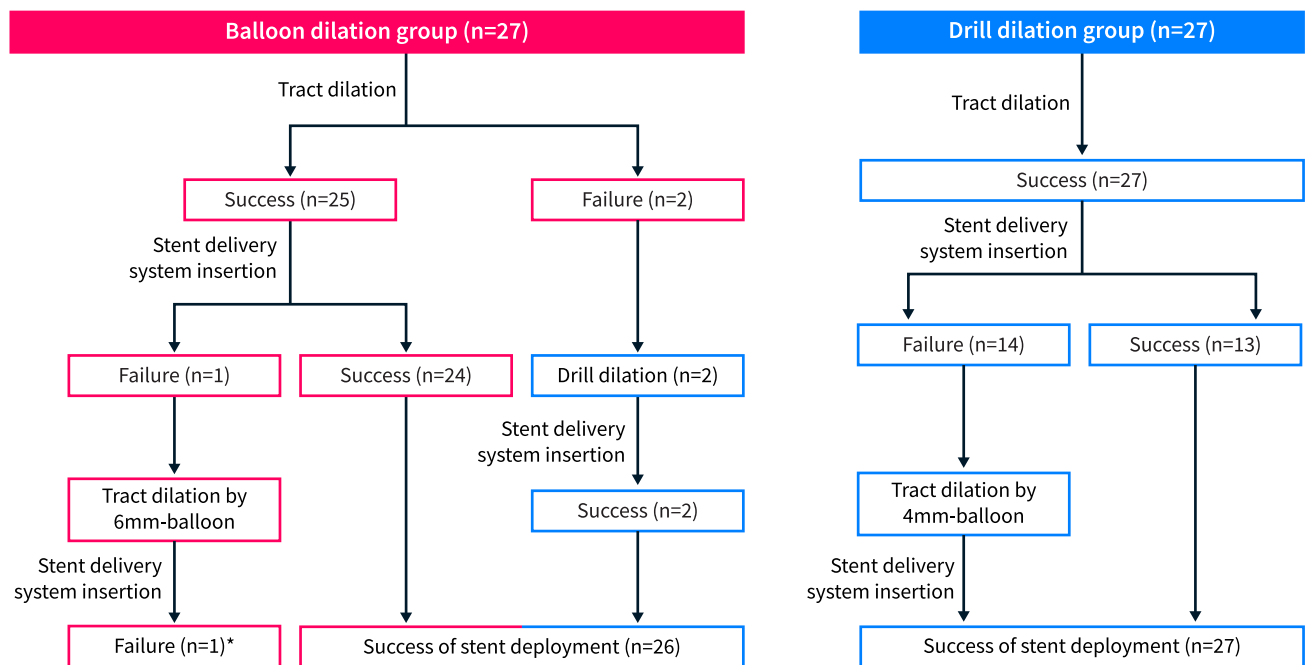


FIGURE 5 | Patient outcomes.

TABLE 2 | Procedural characteristics according to dilation technique.

Characteristic	Balloon (n = 27)	Drill (n = 27)	p-value
Puncture site			0.4835
B2	4	6	
B3	23	21	
Diameter of bile duct at puncture site (mm, mean ± SD)	3.80 ± 1.67	4.19 ± 2.18	0.4613
Length of hepatic parenchyma at puncture site (mm, mean ± SD)	22.7 ± 7.31	21.7 ± 6.34	0.5773
Angle between puncture needle and bile duct (axis, mean ± SD)	140.8 ± 34.77	149.7 ± 43.83	0.4128
Procedure time (min, mean ± SD)	9.70 ± 5.01	14.0 ± 9.67	0.0473
Initial technical success rate of tract dilation, % (n)	92.6 (25/27)	100 (27/27)	0.1495
Type of secondary dilation device			—
Balloon catheter	0	0	
Drill dilator	2	0	
Additional tract dilation required to insert stent delivery system, n (%)	1/25 (4.0)	14/27 (51.9)	0.0001
Type of additional dilation device, n			—
Balloon catheter	1	14	
Drill dilator	0	0	
Electrocautery dilator	0	0	
Final technical success rate, % (n)	96.2 (26/27)	100 (27/27)	0.3128
Adverse events, n			0.0382
Peritonitis	1	5	
Difficult delivery system removal	1	2	
Intraoperative bleeding	0	1	

successfully using the drill dilator. The technical success rate of stent delivery system insertion was significantly higher in the balloon dilation group (88%, 22/25) than in the drill dilation group (45%, 13/27) ($p = 0.0013$). The one in the balloon dilation group for whom stent delivery system insertion was unsuccessful underwent additional tract dilation using a 6-mm balloon catheter. After tract dilation, stent deployment was successful in 26 patients (96.2%). In one patient, however, the stent delivery system could not be inserted even after tract dilation using the 6 mm balloon catheter, and this patient then underwent EUS-HGS using another PCSEMS with a fine-gauge stent delivery system (5.9 Fr) (8 mm diameter, 12 cm length; HANARO Benefit, M.I Tech., Seoul, S. Korea). In the drill dilation group, 14 patients underwent additional tract dilation using a balloon catheter, and stent deployment was successful in all patients. Procedure time was significantly shorter in the balloon dilation group (mean, 9.7 min) than in the drill dilation group (mean, 14.0 min) ($p = 0.047$). Adverse events were observed more frequently in the drill dilation group ($p = 0.038$). Also, difficult delivery system removal was observed in 3 cases. For all 3 cases, the tip of stent delivery system was stacked within the EUS-HGS stent. The stack site was around the intrahepatic bile duct because bile duct wall dilation might be insufficient. Therefore, we removed the echoendoscope and inserted a duodenoscope. The stack site was then dilated using a balloon catheter as has been described previously [21]. We successfully removed the stent delivery system in all patients. Any cases of peritonitis or intraoperative bleeding resolved with conservative treatment.

4 | Discussion

The technical steps in performing EUS-HGS are bile duct puncture, guidewire insertion, tract dilation, and stent deployment. One-step stent deployment technique has been reported as a method for avoiding bile leakage from the fistula that can occur after tract dilation [12, 13]. However, the risk of stent migration into the abdominal cavity is a critical disadvantage of this metal stent because there is no anti-migration function for SEMS using a fine-gauge stent delivery system. PCSEMS with an anti-migration system is therefore a more suitable stent for use in EUS-HGS, but tract dilation is required because of its larger diameter.

Tract dilation is performed as follows. The dilation device itself is inserted into the biliary tract through the stomach and bile duct walls, which requires the dilation device to have a penetration function. It is then necessary to dilate the walls sufficiently to enable insertion of the stent delivery system. As bile leak can occur as an adverse event following tract dilation, tract dilation should be performed in a one-step manner using one device. Therefore, an ideal dilation device must perform highly in terms of penetration and dilation functions. Various dilation devices have been used in clinical practice. Honjo et al. conducted a comparison study between an ultra-tapered mechanical dilator ($n = 26$) and electrocautery ($n = 23$) during EUS-HGS [14]. There was no significant difference in the technical success rate for tract dilation between the ultra-tapered mechanical dilator (92.3%, 24/26) and electrocautery (100%, 23/23);

however, before stent deployment, additional dilation was required in several cases before stent deployment. Okuno et al. evaluated the technical feasibility of a drill dilator as a dilation device during EUS-HGS in 20 patients. The drill dilator could be successfully inserted into the biliary tract in all cases; however, various heterogeneous factors were present in their study, including use of a 22G needle, 0.018-inch guidewire, several stent types, and forward-viewing echoendoscope; and several patients required additional tract dilation. Therefore, despite the excellent penetration function of each of ultra-tapered mechanical dilator, drill dilator, and electrocautery, the dilation function may not be sufficient to deploy the stent. In contrast, Yagi et al. compared a balloon catheter (balloon dilation group, $n = 17$) with several types of bougie dilators (non-balloon dilation group, $n = 21$) during EUS-HGS [22]. SEMS with an 8.5 Fr stent delivery system was successful in 100% of the balloon dilation group but in only 71.4% of the non-balloon dilation group ($p = 0.024$). Therefore, they concluded that dilation using a balloon catheter before SEMS with an 8.5 Fr delivery system placement is most effective in EUS-HGS. However, due to the retrospective nature of the study, they did not take the penetration function into account. The following factors should be taken into consideration when inserting a dilation device or stent delivery system. First, if the diameter of the bile duct at the puncture site is small, device insertion might be challenging because the extension of the bile duct is low compared with the dilated bile duct. Second, device insertion can be difficult in the case of a long insertion depth into the hepatic parenchyma and large volume of hepatic parenchyma. Third, several studies have reported that the angle between the needle and bile duct is an important factor for successful device insertion [23, 24]. In the present study, we excluded these biases by conducting a randomized study in which the diameter of the bile duct and the length of the hepatic parenchyma were adjusted at the puncture site. As we found no significant difference regarding the angle between the puncture needle and bile duct, our study might truly reflect the penetration and dilation functions. Mean procedure time was shorter and there were fewer adverse events in the balloon dilation group because additional dilation was required in 51.9% of patients in the drill dilation group. The lower rate of device exchange in the balloon dilation group might have influenced this result because bile leakage can occur continuously during device exchange after tract dilation. Therefore, in the deployment of PCSEMS with an anti-migration system, a balloon catheter might be an ideal dilation device. In the present study, during stent delivery system removal after stent deployment, the tip of the stent delivery system was stacked around the bile duct in 3 cases. Although stacking stent delivery system might be relatively frequent events, stent delivery system design might also be influenced. We should evaluate this frequency after tract dilation by using another stent.

Our study has several limitations. It was conducted as a single-center study and the sample size was small. The diameter of the drill dilator is 7Fr, therefore, our comparison study may not be fair. However, according to a previous study [22], an 8.5 Fr stent delivery system can be inserted in some cases after tract dilation using a 7 Fr dilator. According to our findings, because of prolonged procedure time or adverse events, selecting balloon dilation might be recommended. The present study may be the

first randomized trial to compare dilation devices for deployment of PCSEMS with an anti-migration system; however, our findings may be beneficial for EUS-HGS using specific stents. If EUS-HGS is performed using PCSEMS with fine-gauge stent delivery or an electrocautery-enhanced delivery system, tract dilation before stent delivery system insertion may not be needed. However, stent migration is sometimes critical; therefore, anti-migratory system should be provided. If anti-migratory system is provided, the diameter of stent delivery system may be increased. In addition, during EUS-HGS using PCSEMS with an electrocautery-enhanced delivery system, the cardiac pacemaker should be stopped. This might be unfavorable for patients. Therefore, we believe that our findings might still benefit the selection of dilation devices, although we should evaluate this finding using various kinds of stents.

In conclusion, balloon dilation might be more useful than drill dilation for PCSEMS deployment with an 8.5 Fr stent delivery system.

Author Contributions

Takeshi Ogura wrote the paper. T Takeshi Ogura, Saori Ueno, Akitoshi Hakoda, Atsushi Okuda, Nobu Nishioka, Jun Sakamoto, Jun Matsuno, Yuki Uba, Mitsuki Tomita, Nobuhiro Hattori, Junichi Nakamura, Kimi Bessho, Taro Iwatsubo, Toshifumi Yamaguchi, Ahmad F Aboelezz, 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.

Ethics Statement

Approval of the research protocol by an Institutional Reviewer Board was obtained (IRB No. 2022-210).

Consent

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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