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CLINICAL ENDOSCOPY

Safety and efficacy of endoscopic ultrasound-guided pancreatic duct drainage using a drill dilator: a retrospective study in Japan

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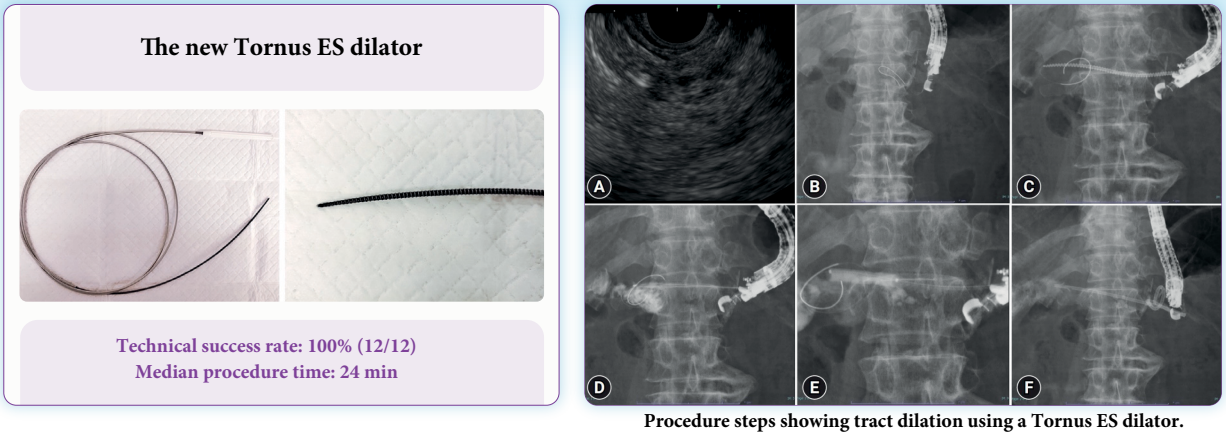
Safety and efficacy of endoscopic ultrasound-guided pancreatic duct drainage using a drill dilator: a retrospective study in Japan



Procedure steps showing tract dilation using a Tornus ES dilator.

The novel drill dilator seems to be safe and practical device in EUS-guided interventional procedures.

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Background/Aims: Dilation of the tract before stent deployment is a challenging step in endoscopic ultrasound-guided pancreatic duct drainage (EUS-PDD). In this study, we examined the effectiveness and safety of a novel spiral dilator, Tornus ES (Asahi Intec), for EUS-PDD.
Methods: This was a retrospective, single-arm, observational study at Aichi Cancer Center Hospital. The punctured tract was dilated using a Tornus ES dilator in all EUS-PDD cases. Our primary endpoint was the technical success rate of initial tract dilation. Technical success was defined as successful fistula dilation using a Tornus ES followed by successful stent insertion. Secondary endpoints were procedure times and early adverse events.
Results: A total of 12 patients were included between December 2021 and March 2023. EUS-PDD was performed in 11 patients for post-pancreaticoduodenectomy anastomotic strictures and one patient with pancreatitis with duodenal perforation. The technical success rates of stent insertion and fistula dilation using a Tornus ES dilator was 100%. The median procedure time was 24 minutes. No remarkable adverse events related to the procedure were observed, apart from fever, which occurred in 2 patients.
Conclusions: Tract dilation in EUS-PDD using a Tornus ES is effective and safe.

Keywords: Drainage; Endoscopy, gastrointestinal; Endosonography; Pancreatic ducts; Pancreaticoduodenectomy

INTRODUCTION

After successfully puncturing the main pancreatic duct (MPD) for endoscopic retrograde pancreatography (ERP), Bataille et al.[1] published the first description of endoscopic ultrasonography-guided pancreatic duct drainage (EUS-PDD) in 2002. Since then, some reports on EUS-PDD have been published, and the role of EUS in pancreatic duct (PD) drainage has increased to include many indications and technical interventions.

Endoscopic treatment is the standard treatment for PD obstruction via transpapillary or transanastomotic PD drainage,[2] but when the papilla or anastomotic site is anatomically inaccessible, or the procedure is technically difficult, EUS-guided drainage provides an efficient treatment option.

EUS-PDD is indicated in cases of obstruction of the PD with chronic pancreatitis, inaccessible major and minor papillae by endoscopic retrograde cholangiopancreatography (ERCP), anastomotic stricture at the pancreaticojejunostomy site following pancreatic surgery, and PD disruption after severe acute pancreatitis or PD stricture.[3,4]

Currently, EUS-PDD includes 2 main approaches: the first one is EUS-assisted rendezvous (EUS-RV) ERCP, which is performed either when the papilla is accessible by conventional duodenoscope (transpapillary) or from the anastomotic site after pancreatic surgery (transanastomotic) either by balloon-assisted endoscopes or a colonoscope. The second approach is EUS-transmural drainage (EUS-TMD). It includes EUS-guided pancreatico-enterostomy, in which a stent is placed between the PD and the stomach, duodenum, or jejunum, and transenteric antegrade stenting, in which further advancement of the stent through the ampulla or anastomotic site is performed (ring drainage).[4,5]

EUS-TMD procedure involves the puncture of the MPD using a fine-needle aspiration needle, guidewire (GW) insertion and negotiation, fistula dilation, and, finally, stent placement.

Before stenting, needle tract dilation is mandatory and demanding. Dilation devices are categorized mainly into 2 types, namely non-electrocautery and electrocautery. The non-electrocautery devices comprise mechanical and balloon dilators, whereas electrocautery devices are classified as either noncoaxial or coaxial.

Sometimes, a hard tract's resistance or misalignment between the direction of the pushing force and the needle tract axis makes it difficult or impossible for a mechanical dilation or balloon catheter to be advanced. Additionally, electrocautery catheters can cause a severe "burn effect" around the tract, which can result in pancreatitis, leakage of pancreatic juice, hemorrhage, and perforation.[3,5]

Needle tract dilation is the most challenging step, even for experts, and may lead to EUS-PDD failure and the occurrence of severe adverse events (AEs). After GW insertion, the introduction of the next device is sometimes difficult in a hard pancreas. To overcome this problem, we adopted the initial use of a novel drill dilator. This study aimed to evaluate the utility of a novel drill dilator in EUS-PDD.

This paper represents the first report on the use of a novel drill dilator in EUS-PDD in a large number of patients.

METHODS

A retrospective analysis was performed on 12 patients who underwent EUS-PDD with the new dilator between December 2021 and March 2023. Early AEs, main procedure details, and short-term outcomes were all assessed. An intention-to-treat analysis was performed to assess the technical success rate.

Procedure

1) The novel drill dilator

The Tornus ES innovative drill dilator (Fig. 1) is produced by Asahi Intec in Aichi, Japan, and comes in 2 sizes that are compatible with 0.018- and 0.025-inch GW. It has a hydrophilic composition with a drill-like form at 30 cm from the tip and tapers from 7 Fr at 3 cm to 0.77 mm at the tip in the 0.018-inch GW-compatible type and to 0.90 mm in the 0.025-inch GW-compatible type. The shaft component of this dilator is made up of a coil sheath, and turning the Tornus ES clockwise makes it simple to dilate the track to 7 Fr without using excessive pressure or worrying about pushback. Upon completion of the dilation procedure, the Tornus ES is removed through counterclockwise rotation. We have previously documented the efficacy of the Tornus ES in EUS-guided pancreatic drainage and EUS-guided hepaticogastrostomy (EUS-HGS).[6-8]

EUS-PDD steps

First, the PD was visualized using linear EUS (GF-UCT260; Olympus Medical Systems), and then a 22-gauge needle (Expect Slimline; Boston Scientific Co.) preloaded with a 0.018-inch wire (Fielder; Asahi Intec) and contrast medium, or a 19-gauge needle (EZ Shot 3 Plus; Olympus Medical Systems) preloaded with 0.025-inch guidewire were used to puncture the PD. The choice of needle gauge depends on the size of the PD; a smaller needle is preferred when the PD is small and difficult to puncture.

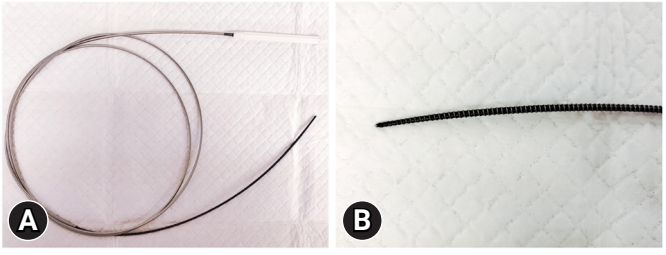

Fig. 1. Tornus dilator. (A) Tornus ES (Asahi Intecc.) (0.025-inch guidewire-compatible type). (B) The drill like part with tapering end at 3 cm from the tip.

The GW was advanced as far as possible to pass through the pancreatico-jejunal anastomotic stricture in post-pancreaticoduodenectomy or the duodenal papillae in patients with pancreatitis. The needle tract was dilated using a Tornus ES drill dilator catheter (0.018-inch or 0.025-inch GW-compatible type, according to the needle used for puncturing the MPD and the GW used initially). The Tornus ES was then rotated clockwise to dilate the fistula, as previously mentioned. After dilation, the Tornus ES was removed using counterclockwise rotation. A biliary catheter (uneven double-lumen cannula; Piolax, 6 Fr diameter), or Tandem XL triple lumen ERCP Cannula (Boston Scientific Co.; 5.5 Fr diameter) was used for injecting the contrast medium and for changing the GW to a 0.025-inch type (VisiGlide 2; Olympus Medical Systems), which is stiffer and allows easier GW negotiation to pass the anastomotic stricture. When necessary, we used another dilator as a second dilation device, either an ES dilator (Zeon Medical Co., 7 Fr diameter) or a balloon dilator (REN; KANEKA Medics, 4 or 6 mm) if track dilation was not adequate. To dilate the anastomotic stricture in cases of successful GW passage, we used a balloon dilator. Finally, according to the EUS-guided pancreatogram and whether GW negotiation to the anastomotic stricture was successful or not, EUS-PDD with transenteric antegrade stenting (ring drainage) or EUS-PDD with transmural metal stenting only (pancreaticogastrostomy) was performed. The procedure steps are illustrated in Figure 2 and Supplementary Video 1.

In cases of failure of GW passage through the anastomosis due to complete anastomotic stricture or failure of stent insertion through the anastomosis, we placed a transmural stent only. We used a fully covered self-expandable metal stent (FCSEMS), 6 mm/12 cm HANARO stent Benefit (5.9 Fr delivery system; M. I. Tech), for the pancreaticogastrostomy (transmural) stent.

In cases of successful GW negotiation through the anastomotic stricture, transenteric antegrade stenting (ring drainage) with transmural and transanastomotic stent is used. We used a 7 Fr/14 cm single pigtail type plastic stent (CX-T stent, Type IT; Gadelius Medical Co.) or a 6 mm/12 cm HANARO stent Benefit for transenteric antegrade drainage so that the proximal end of the stent is in the gastric side and the distal end of the stent is in the small intestinal side.

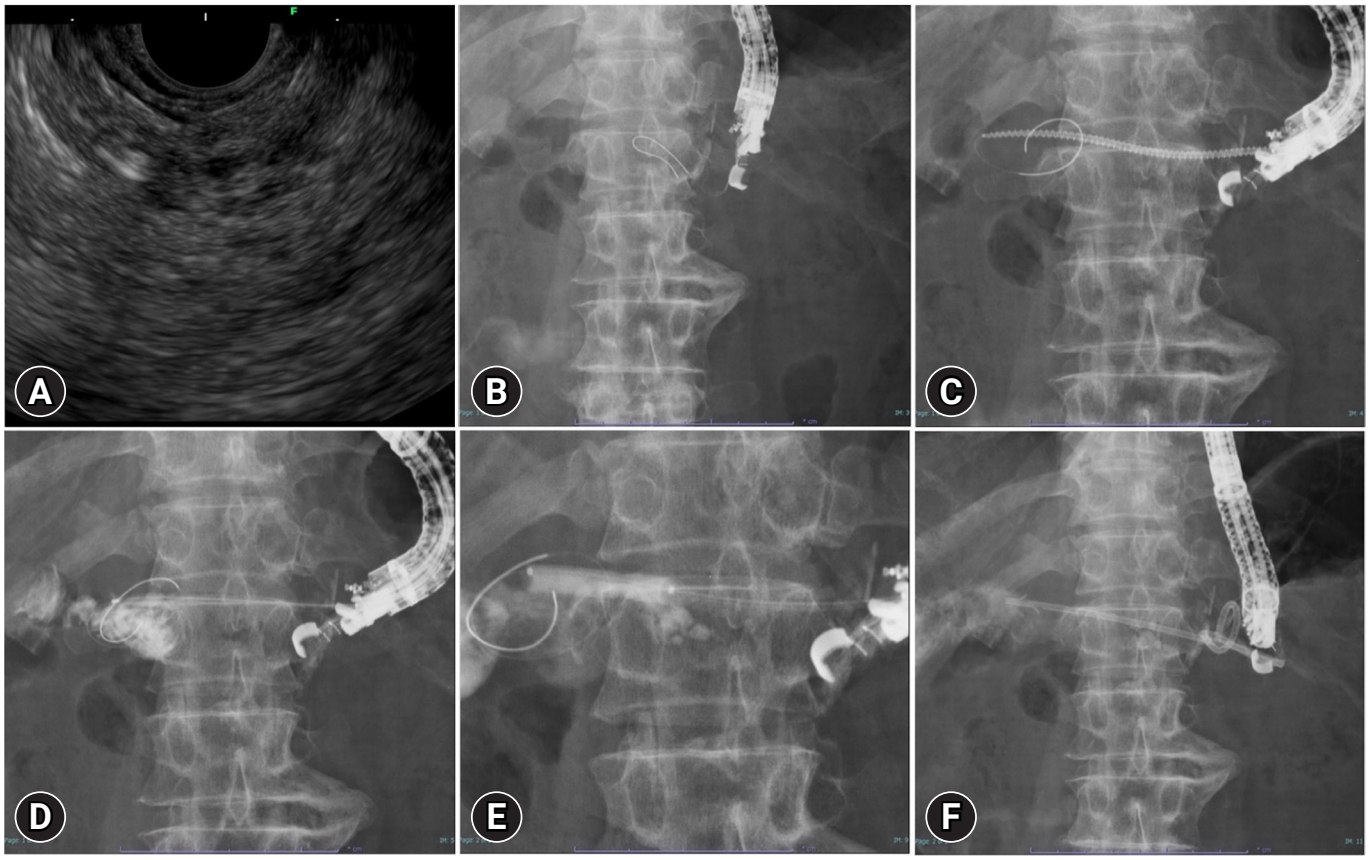

Fig. 2. Endoscopic ultrasound-guided pancreatic duct drainage procedure steps. (A) Main pancreatic duct (MPD) puncture using a 22 G fine-needle aspiration needle. (B) 0.018-inch guidewire insertion in the MPD. (C) Dilation of the tract using a Tornus ES dilator (0.018-inch guidewire-compatible type). (D) Guidewire passed the anastomotic stricture with contrast in the jejunum. (E) Balloon dilation for the anastomotic stricture. (F) A plastic stent (single pigtail) was inserted from the stomach into the jejunum (ring drainage).

Patient follow-up

For patients with anastomotic strictures, transmural stent exchange was scheduled every 2 to 3 months or earlier if the symptoms of PD obstruction recurred.

For patients in whom the GW could pass through the anastomotic stricture and transenteric antegrade stenting was achieved, dilation of the anastomotic stricture was attempted at every scheduled stent exchange using a balloon dilator. After one year, the stent was removed, and the patient was kept stent-free with no further stent exchange.

For patients in whom an FCSEMS (either a gastropancreatic or gastropancreaticojejunal stent) was inserted, the stent was exchanged with a plastic stent on the first scheduled stent exchange date. Patients with PD stones were scheduled for stone extraction one or 2 months after EUS-PDD.

A computed tomography scan was regularly performed for early AEs the day after EUS-PDD and for late AEs every 6 months at least. Short-term outcomes, including AEs, were recorded until the first scheduled stent exchange procedure.

Definitions

Our primary endpoint was the technical success rate of initial tract dilation using a Tornus ES. Secondary endpoints were procedure times and early AEs. The procedure time, measured from puncture of the PD to stent deployment, was assessed by reviewing the video recordings of each case. According to the American Society for Gastrointestinal Endoscopy lexicon, the initial adverse effects that may have been caused by the procedure, occurring up to 14 days after the procedure were described.[9]

Ethical statement

The study was approved by the regional institutional review board of Aichi Cancer Center Hospital after each patient pro-

vided informed consent for the procedure (approval number: 2023-0-171).

RESULTS

Twelve patients (6 males and 6 females) with a median age of 73 years (range, 37–81 years) underwent EUS-PDD at Aichi Cancer Center Hospital during the study period.

The primary disease was neoplastic in 11 patients treated with pancreaticoduodenectomy with Child reconstruction and complicated by anastomotic strictures, whereas only one patient had symptomatic chronic pancreatitis complicated by rupture of a pancreatic abscess and duodenal perforation.

The neoplastic disorders included 3 branch duct-intraductal papillary mucinous neoplasms, 2 intraductal papillary mucinous cancers, 2 pancreatic adenocarcinomas, 2 ampullary neuroendocrine tumors, 2 duodenal gastrointestinal stromal cell tumors, and one serous cystic neoplasm.

EUS-PDD was indicated because of an inaccessible anastomotic site in 11 patients and duodenal perforation with a nonvisualized papilla in one patient. Patient characteristics are summarized in Table 1.

We initially used a Tornus ES (0.018 type) in 10 patients. A Tornus ES (0.025 type) was used in the remaining 2 patients, where MPD puncture was performed using a 19 G needle preloaded with a 0.025-inch GW. We successfully performed the initial gastropancreatic tract dilation in all patients using a Tornus ES (technical success rate, 100%). In 4 patients, to facilitate tract dilator, we used the ES dilator (2 patients) and balloon dilator (2 patients). No electrocautery dilator was used in any patients.

Among the 11 patients with anastomotic strictures post-pancreaticoduodenectomy surgery, Tornus ES was used in 4 patients and efficiently dilated the anastomotic stricture without the need to use a balloon dilator, while a balloon dilator was needed in 7 patients. Procedure times ranged from 13 to 52 minutes (median 24 minutes). The outcomes of dilation are shown in Table 2.

The median MPD diameter was 2.8 mm (range, 0.9–6.9 mm). In our study, the MPD was not dilated in 10/12 patients; however, all patients had symptoms such as abdominal pain, indigestion, diarrhea, and abdominal discomfort. For PD puncture, we used a 22 G needle in 10 patients and a 19 G needle in the remaining 2 patients. In 10 patients, we initially used a 0.018-inch guidewire after PD puncture and then shifted to a 0.025-inch guidewire in only 7 patients. In the remaining 3 patients, the 0.018-inch guidewire passed the anastomotic stricture easily, so we did not have to exchange it with the 0.025-inch GW. A 0.025-inch guidewire was used initially in 2 patients where we used a 19 G needle for puncturing the PD. In one patient, we changed to a 0.035-inch GW after tract dilation.

In 10 patients, we successfully negotiated the guidewire across

Table 1. Patient characteristics (n=12)

Characteristic	Value
Age (yr)	73 (37–81)
Sex	
Male	6 (50.0)
Female	6 (50.0)
Primary disease	
BD-IPMN	3 (25.0)
Intraductal papillary mucinous cancer	2 (16.7)
Pancreatic cancer	2 (16.7)
Serous cystic neoplasm	1 (8.3)
Ampullary NET	2 (16.7)
Duodenal GIST	1 (8.3)
Pancreatitis	1 (8.3)
Indication for pancreatic drainage	
Pancreaticojejunostomy anastomotic stricture	11 (91.7)
Pancreatitis	1 (8.3)
Indication for EUS-PDD	
Inaccessible anastomotic site	11 (91.7)
Duodenal perforation, nonvisualized papilla	1 (8.3)

Values are presented as median (range) or number (%).
BD-IPMN, branch duct-intraductal papillary mucinous neoplasm; NET, neuroendocrine tumor; GIST, gastrointestinal stromal cell tumor; EUS-PDD, endoscopic ultrasound-guided pancreatic duct drainage.

Table 2. Outcomes of dilation

Variable	Value
Technical success rate of initial gastropancreatic fistula dilation	12 (100)
Dilator used for fistula	
Tornus 0.018	10/12
Tornus 0.025	2/12
Bougie dilator (ES dilator)	2/12
Balloon dilator	2/12
Electrocautery	0/12
Dilator used for anastomotic stricture	
Tornus only	4/11
Balloon dilator needed	7/11
Procedure time (min)	24 (13–52)

Values are presented as number (%), number/total number, or median (range).

the anastomosis after pancreaticoduodenectomy (9 patients) and the minor papilla (1 patient). Gastropancreaticojejunal or gastropancreaticoduodenal stents were used in 10 patients.

We used a single pigtail plastic stent (CX-T stent, Type IT; Gadelius Medical Co.) in 8 patients, while in the remaining 2 patients, the FCSEMS 6 mm/12 cm HANARO stent Benefit (M. I. Tech) was used. In the remaining 2 patients, only a transmural stent (gastropancreatic) could be inserted because there was a stone in the MPD, which rendered stent advancement difficult in the first patient. In the other patient, the guidewire could not be inserted through the anastomotic stricture. We used a FCSEMS 6 mm/12 cm (HANARO stent Benefit). The procedural details of EUS-PDD are shown in Table 3.

Low-grade fever occurred in 2 of the 12 patients. The fever lasted for 1 to 2 days and was managed with antibiotics. No pancreatitis or bleeding occurred during or after the procedures. No stent-related AEs requiring stent revision in the form of stent migration or occlusion were observed. Pancreatic juice leakage was not observed. Early AEs are shown in Table 4.

DISCUSSION

Since first being described in 2002 by Bataille et al.,[1] EUS-PDD has been considered an effective substitute for surgical or percutaneous drainage when ERCP fails in patients with pancreatic ductal obstruction.

EUS-PDD is an advanced intervention that requires sufficient experience to ensure the safety and success of the procedure because it has many technical challenges that can lead to failure of the procedure and lower technical and clinical success rates, starting from puncture of the PD, guidewire negotiation, tract dilation, and finally stent deployment.

In their meta-analysis, which included 22 studies (714 patients), Chandan et al.[10] reported that the technical success rate of EUS-PDD (defined as PD puncture and GW insertion) was 84.4% (95% confidence interval [CI], 79.1-89.2) while the rate of successful pancreatic drainage (defined by resolution of PD obstruction by drainage) was 77.5% (95% CI, 63.1-87.4). However, this meta-analysis included studies with patients who underwent both EUS-TMD and EUS-RV, which do not involve tract dilation.

The first step in the EUS-PDD procedure is the PD puncture. This was achieved using either a 22 G or 19 G needle. In previous reports on EUS-PD, the 19 G needle was preferred because it allows the use of a 0.025-inch or 0.035-inch GW, which has better radiological visibility and provides easier insertion of subsequent devices.[3,11] In contrast, the 22 G needle makes it easier to puncture a fibrotic pancreas and in cases with less-dilated MPD.

In our study, a 22 G needle (preloaded with a 0.018-inch GW) was used in 10 patients, and in all of them, successful MPD puncture was achieved, followed by fistula dilation using a Tornus ES (0.018-inch GW-compatible type).

In accordance with this result, Matsunami et al.[12] have reported that the utilization of a 22 G needle may account for their high technical success rate (100%) with EUS-PD, despite the modestly sized targeted MPD with a median diameter of 3.5 mm.

Tract dilation is the most crucial step in EUS-PDD. To obtain successful fistula dilation, attention should be paid to each step. For example, the guidewire should be advanced to a sufficient depth so the rigid portion can reach inside the MPD to ensure

Table 3. Details of endoscopic ultrasound-guided pancreatic duct drainage procedure

Variable	Value
Main pancreatic duct diameter (mm), median (range)	2.8 (0.9–6.9)
Needle gauge	
22 Gauge	10
19 Gauge	2
Guidewire	
Initial guidewire	
0.018 inch	10
0.025 inch	2
Second guidewire	
0.025 inch	7
0.035 inch	1
Stent location	
Transmural	2
Indwelling up to anastomosis/papilla (gastropancreaticojejunal/gastropancreaticoduodenal)	10
Type of stent	
Fully covered self-expandable metal stent 6 mm/12 cm	4
Plastic stent (single pigtail, 7 Fr/14 cm)	8

Table 4. Adverse events

Variable	Value
Fever	2
Pancreatitis	0
Bleeding	0
Pancreatic juice leakage	0
Stent migration	0
Total	2/12

safe procedures thereafter. To achieve this, it is crucial to exert a force of guidewire advancement in the same puncture direction guided by a fluoroscopic image of the scope position. As mentioned previously, dilation devices include electrocautery and non-electrocautery dilators. Non-electrocautery dilators include bougie and balloon dilators.

For deciding the appropriate dilation device, the puncture angle should also be considered. In cases where the puncture direction is perpendicular to the MPD, advancing stiff devices such as electrocautery and mechanical dilators into the MPD is sometimes difficult or even impossible because of angulation. In these cases, multiple dilation devices can be used in a stepwise approach. Initially, a stiff electrocautery device can be used for tract dilation up to the MPD wall then using the more flexible mechanical dilator devices such as balloon dilators.[13] However, using multiple dilation devices can prolong the procedure time and lead to serious AEs, especially with electrocautery dilators, such as late bleeding or leakage due to the burning effect.

Matsunami et al.[12] retrospectively analyzed 30 patients who underwent EUS-guided PDD using only EUS-TMD. They used an electrocautery dilator, namely a 6.5 Fr, Cyst-Gastro set (Endoflex), or a bougie dilator with additional balloon dilation if needed. In accordance with our results, technical and clinical success rates were 100% during the short-term follow-up period; however, they reported that severe bleeding occurred in one patient in whom an electrocautery dilator was used. Transcatheter embolization was required to control the bleeding, and moderate pancreatitis was observed in another patient treated with conservative therapy.

Honjo et al.[14] compared the outcomes of an ultra-tapered (up to 2.5 Fr) mechanical dilator (ES dilator DC7R180S; Zeon Medical Co., Ltd.) and an electrocautery dilator (6 Fr Cyst-Gastro set; Endoflex) in patients who underwent EUS-HGS (n=49) and EUS-PDD (n=15). In the EUS-PDD patients, they showed that there was no significant difference in the success rate of tract dilation between the electrocautery dilator group (90%, 9/10) and the mechanical dilator group (100%, 5/5) (p=0.71). However, the overall success rates of stent placement in the electrocautery dilator group and mechanical dilator group were 90% (9/10) and 80% (4/5), respectively, so even with successful tract dilation in the mechanical dilator group, they failed to deploy the stent in one patient. In both groups, 3 patients experienced AEs, one of them in the electrocautery dilator group had severe bleeding that required arterial embolization.

In a study conducted by Park et al. they investigated the determinants of AEs among 57 patients who underwent EUS-guided biliary drainage (EUS-BD) with transluminal stenting. Their findings revealed that the application of an electrocautery-assisted device, namely a needle knife (noncoaxial dilator device), was an independent predictor of AEs (odds ratio, 12.4; p=0.01). The authors concluded that the use of a needle knife for fistula dilation should be avoided whenever possible.[15]

In this study, we focused on tract dilation as a key step for successful EUS-PDD procedure. Here, we describe the utility of the novel Tornus ES dilator in EUS-PDD by retrospectively analyzing 12 patients who underwent EUS-PDD. The procedure was successful in all patients, so we achieved 100% clinical and technical success rates. Moreover, the 0.018-inch GW-compatible type of Tornus ES was sufficient for fistula dilation in all patients in whom we used the 22 G needle (10 patients) with a 0.018-inch guidewire. We did not have to use the 0.025-inch GW-compatible type except initially if the MPD was punctured with a 19 G needle with a 0.025-inch guidewire (2 patients).

We have already explained the use of a Tornus ES dilator in EUS-HGS in our retrospective analysis of 20 patients who underwent EUS-HGS in which we achieved 100% technical success rates for the initial tract dilation.[8]

Use of the Tornus ES was also reported by Ogawa et al.,[16] in their prospective study using Tornus ES as an initial tract dilator in 7 cases of EUS-BD (6 cases of EUS-HGS and one case of EUS-hepaticojejunostomy) and 3 cases of EUS-guided gallbladder drainage, and again they achieved 100% success rates regarding tract dilation and stent insertion.

In our study, the tract could be dilated to 7 Fr very easily using the new drill dilator (we did not need to push hard, and only rotation was needed even with hard stenosis). None of the patients required cautery dilation. Moreover, apart from tract dilation, the Tornus ES alone was successful in dilating the anastomotic stricture in 4 patients without the need for balloon dilation, which allowed us to minimize device exchange during the procedure and minimize possible complications.

In 2 patients, we used ES dilator because insertion of the Tornus was difficult at the puncture point, so that the ES dilator simply facilitated the entry of the Tornus afterwards (the ES dilator was used to simply expand the puncture point). This can be explained by the non-sharp tip of the Tornus, which may cause difficulty in penetrating the gastrointestinal mucosa or the hard surface of the pancreas. In such cases, expanding only the puncture site with an ES dilator can facilitate further insertion of the Tornus.

In the present study, the median procedure time was 24 minutes, which is a relatively short time that minimizes the risk of AEs such as pancreatic juice leakage and pancreatitis.

In 10 patients, successful guidewire negotiation through the anastomotic stricture or minor papilla was performed to achieve ring drainage. Ring drainage has been considered an important technique for preventing stent migration in EUS-PDD because the proximal and distal ends of the stents are in the gastric and small intestine, respectively, providing more stability for the stent, allowing easy future stent exchange, and reducing the risk of stent-induced ductal changes.[5,17]

To determine the type of stent in EUS-PDD, multiple stents are available, including plastic stents (straight and pigtail stents with diameters ranging from 5 to 7 Fr) and FCSEMS. Uncovered stents are contraindicated because of the high risk of leakage and difficulty in future exchange afterward due to tissue ingrowth.[17]

In cases of successful GW negotiation through the anastomosis, a transenteric antegrade stent was placed (ring drainage). Our preference was a pigtail plastic stent 7 Fr/14 cm (Type IT; Gadelius Medical Co.). It was used in 8/10 patients, while in the remaining 2 patients, the FCSEMS 6 mm/12 cm HANARO stent Benefit (M. I. Tech) was used.

The efficacy of plastic stents for EUS-PDD was reported before by Matsunami et al.[12] who assessed the efficacy of a 7 Fr single pigtail plastic stent (CX-T stent, IT; Gadelius Medical Co.) in the context of EUS-PDD. A stent with a total length of 20 cm and effective length of 15 cm was deemed appropriate for this procedure. Moreover, no inward stent migration or pancreatic juice leakage was observed. The authors attributed this to the new stent's pigtail anchor, in addition to its 4 flanges and side holes at the proximal and distal ends, but not in the middle part of the stent.

Dalal et al.[18] retrospectively analyzed 44 patients who underwent EUS-PDD (EUS-RV in 23/44 patients and EUS-TMD in 21/44 patients). Overall technical and clinical success rates were seen in 88.6% and 81.8% of patients, respectively. They predominantly used straight plastic stents with anti-migration flaps and single- or double-pigtail plastic stents in largely dilated PD after pancreaticogastrostomy.

In cases of failure to negotiate the GW through the anastomotic stricture, only a gastropancreatic stent was inserted, and we chose the FCSEMS because inserting a plastic stent without passing the anastomosis increases the risk of pancreatic fluid leakage.

There are few reports on the utility of FCSEMS in EUS-PDD in contrast to EUS-BD. Compared to plastic stents, a large-diameter FCSEMS may offer the benefits of efficient drainage, lower risk of leakage, and simple re-intervention. Additionally, the tamponade action of FCSEMS, when used with electrocautery dilators, may lower the risk of bleeding.[19] However, metal stent migration may lead to serious complications and require urgent surgery.

Due to recurrent pancreatitis, only mild dilation of the MPD may occur after FCSEMS use. However, even with mild dilation and thinning of the pancreatic parenchyma, the risk of pancreatitis with FCSEMS is believed to be low. Oh et al.[20] assessed the outcomes of EUS-PDD in 23 patients with pancreatico-jejunal anastomotic strictures after pancreaticoduodenectomy. Technical and clinical success were 100%. They used a modified 6 or 8 mm FCSEMS (M. I. Tech) with blunt ends and both proximal and distal anti-migration anchoring flaps in 20 patients and plastic stents in the remaining 3 patients. Early AEs developed in 3/20 patients using FCSEMS (15%), and all of them had mild abdominal pain. However, evidence for EUS-PDD using FCSEMSs is limited, and further evaluation of FCSEMS use is necessary.

The retrospective design and single-center location, along with the limited number of subjects, pose limitations to our study. Furthermore, a control group was not included. However, this study is valuable because it evaluated the safety and usefulness of the new drill dilator device for PD drainage.

In conclusion, the novel drill dilator intended for EUS-guided treatment is safe and practical. Additional prospective randomized controlled studies with a larger number of participants are necessary.

Supplementary Material

Supplementary Video 1. Endoscopic ultrasound-guided pancreatic duct drainage.

Supplementary materials related to this article can be found online at https://doi.org/10.5946/ce.2023.272.

Conflicts of Interest

The authors have no potential conflicts of interest.

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Author Contributions

Conceptualization: KH; Formal analysis: TK, YY; Methodology: NO; Project administration: NO; Resources: AS, TF, MU, KT; Supervision: KH; Validation: SH, TK; Writing–original draft: all authors; Writing–review & editing: all authors.

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