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Technical outcomes between a drill dilator and ultra-tapered mechanical dilator during EUS-guided pancreaticogastrostomy; a comparative study

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Abstract:

Background

EUS-guided pancreaticogastrostomy (EUS-PGS) is performed for patients who are failed ERCP. Tract dilation is one of challenging procedural step during EUS-PGS. Recently, a bougie dilator, the drill dilator, has become available. With this device, tract dilation can be easily performed without pushback of the echoendoscope, allowing stable scope positioning to be achieved during tract dilation. However, comparative studies between ultra-tapered mechanical and drill dilators have not been reported. The aim of this study was to compare the technical outcomes of these dilation devices.

Patient and method

Symptomatic patients with main pancreatic duct (MPD) strictures from January 2021 to November 2023 were included in this retrospective study. The technical success rate of tract dilation was firstly evaluated. Overall technical success rate, procedure time and adverse events were evaluated as secondary outcomes.

Results

The technical success rate of initial device insertion into the MPD was higher with the Tornus ES (100%, 12/12) compared with the ES dilator (60%, 9/15) (P=0.013). Additional tract dilation rate to deploy the stent was needed in 86.7% (13/15) in the ES dilator group, and 8.3% (1/12) in the Tornus group (P=0.001), and the overall technical success rate in the Tornus ES group was 100% (12/12). Mean procedure time was shorter in the Tornus ES group (13.38 ± 3.80 min) compared with the ES dilator group (21.40 ± 1.54 min) (P=0.0013).

Conclusions

In conclusion, Tornus ES might be considered as initial dilation device during EUS-PGS.

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard technique for treating symptomatic pancreatic duct obstruction due to chronic pancreatitis (CP), malignant tumor and, sometimes, anastomotic stricture [1]. However, pancreatic duct cannulation or guidewire passage through the stricture, or stent deployment across the stricture might be challenging in cases with surgically altered anatomy, severe main pancreatic duct (MPD) stricture, or duodenal obstruction. For such cases, an endoscopic ultrasound (EUS)-guided approach has recently been developed. EUS-guided access for the MPD can be divided into two techniques, EUS-guided drainage/anastomosis (EUS-D/A) and transpapillary drainage with EUS-assisted pancreatic rendezvous [2]. Among EUS-D/A, since EUS-guided pancreaticogastrostomy (EUS-PGS) is performed if the guidewire cannot be passed through the stricture site, this procedure is probably more frequently performed compared with other procedures. The technical steps of EUS-PGS can be divided into the following four steps: pancreatic duct puncture, guidewire insertion, tract dilation, and stent deployment [3-7]. The technical success rate of EUS-PGS has been reported as being lower than that of EUS-guided biliary drainage [8]. This

could be because of several reasons, including tract dilation [5, 7]. There are two main types of tract dilation devices: bougie and electrocautery dilators. Compared with electrocautery dilators, bougie dilators, such as the ultra-tapered mechanical dilator, appear to be safer because of a reduced risk of bleeding [9]. However, a disadvantage of the bougie dilator is that it might lead to pushback of the echoendoscope during insertion of the device, which could result in misalignment between the scope and the correct axis between the puncture angle and devices. Recently, a bougie dilator, the drill dilator, has become available. With this device, tract dilation can be easily performed without pushback of the echoendoscope [10], allowing stable scope positioning to be achieved during tract dilation. However, comparative studies between ultra-tapered mechanical and drill dilators have not been reported. The aim of this study was to compare the technical outcomes of these dilation devices.

Patients and Methods

Patients with MPD strictures from January 2021 to November 2023 were included in this retrospective study, in which the indications for EUS-PGS were: (1) symptomatic patients such as obstructive pancreatitis or complicating pseudocyst, (2) inaccessible papilla due to surgically altered anatomy or duodenal obstruction, and (3) failed ERCP due to pancreatic duct cannulation or guidewire passage into the MPD through the

stricture. Patients who underwent EUS-PGS using a 22G needle were excluded. The study protocol was approved by the institutional review board of our hospital and conformed to the ethical guidelines of the 2013 Declaration of Helsinki. A priori approval was given by the human research committee of Osaka Medical and Pharmaceutical University.

Dilation devices and EUS-PGS procedure

In our study, an ultra-tapered mechanical dilator (ES dilator; Zeon Medical Co., Ltd., Tokyo, Japan) (Fig. 1a) was used as the first-line tract dilation device from January 2021 to December 2022 (ES dilator group). From December 2022 onwards, the drill dilator (Tornus ES; Asahi Intecc, Aichi, Japan) was used as the first-line tract dilation device (Fig. 1b) (Tornus ES group). Before EUS-PGS using Tornus ES, operators experienced 30 cases of EUS-guided biliary drainage using Tornus ES. Briefly, the tip of the ES dilator is extremely tapered to 2.5 Fr, and the maximum diameter of the body is 7 Fr. The device is characterized by good push ability and a smaller difference in diameter compared with a 0.025-inch guidewire. The tip of the Tornus ES is also tapered, with a drill-like shape 30 cm from the tip. If clockwise rotation is attempted, the track can very easily be dilated to 7Fr. Pushback of the echoendoscope does not occur with this device because it does not require application of pressure.

In the EUS-PGS procedure, the echoendoscope (UCT260; Olympus Optical, Tokyo, Japan) is inserted into the stomach, and the MPD is identified. The MPD is punctured using a 19G needle (EZ shot 3 plus, Olympus) under color Doppler visualization to prevent vessel injury (Fig. 2a). Following injection of contrast medium (Fig. 2b), a 0.025-inch guidewire (VisiGlide, Olympus; J-Wire, JMIT, Shiga, Japan) is inserted into the MPD (Fig. 2c). Next, insertion of the dilation device such as Tornus ES or ES dilator into the MPD is attempted (Fig. 2d). If this step fails, the procedure is attempted using another device. After successful tract dilation, insertion of one plastic stent (QuickPlaceV; Olympus, REGLUS; Japan Lifeline Co., Ltd., Tokyo, Japan) (7Fr, straight type, 7 or 9cm length) is attempted (Fig. 2e). If this also fails, additional tract dilation is attempted (Video).

Definitions and statistical analysis

The technical success rate of tract dilation was firstly evaluated. Technical success of tract dilation was defined as successful insertion of the dilation device into the MPD. Overall technical success rate, procedure time and adverse events were secondary evaluated. Overall technical success was defined as successful stent deployment from the MPD to the stomach. Procedure time was measured from MPD puncture to stent deployment. Procedure time was measured using recorded Video. The diameter of the

MPD was measured by EUS. Adverse events associated with ERCP or EUS-PGS procedures were evaluated according to the severity grading system of the American Society for Gastrointestinal Endoscopy lexicon [11]. Also, we evaluated Charlson comorbidity index [12] and American Society of Anesthesiologists Physical Status (ASA) [13]. Descriptive statistics are presented as the mean ± standard deviation (SD) or the median and range for continuous variables, and as frequencies for categorical variables. Continuous variables are expressed as medians and ranges and were evaluated using the Mann-Whitney U test. χ2 test or Fisher's exact test was used to evaluate the nominal variables. . All data were statistically analyzed using SPSS version 13.0 statistical software (SPSS, Chicago, IL).

Results

During the study period, a total of 29 patients (median age, 71 years, 18 males) were enrolled. Table 1 shows the patients' baseline characteristics. Charlson comorbidity index was mainly 0 (n=25) and ASA was also mainly 1 (n=24). The primary diseases in cases with benign MPD strictures were chronic pancreatitis (n=17) and pancreaticojejunal anastomotic stricture (n=6). The primary diseases in cases with malignant MPD strictures were cholangiocarcinoma (n=2), pancreatic cancer (n=2), and ampullary cancer (n=2). The most frequent stricture site was the MPD (n=21), followed

by pancreaticojejunal (n=6) and ampulla (n=2) strictures. The main indication for pancreatic duct drainage was obstructive pancreatitis (n=28), and the reason for EUS-PD was mainly failed guidewire passage through the stricture (n=19), followed by inaccessible papilla (n=6), duodenal obstruction (n=2), and failed pancreatic duct cannulation (n=2).

Figure 3 shows the flow chart for patients in this study. Table 2 shows the technical results of EUS-PGS. Although MPD puncture was attempted in 29 patients, it was unsuccessful in two patients due to insufficient MPD dilatation. These patients subsequently underwent EUS-PD using a 22G needle. Among the 27 patients, 15 patients underwent tract dilation using the ES dilator as the initial dilation device, and 12 patients underwent tract dilation using Tornus ES as the initial dilation device. The technical success rate of initial device insertion into the MPD was higher with the Tornus ES (100%, 12/12) compared with the ES dilator (60%, 9/15) (P=0.013). Among the six patients with failed ES dilator insertion, insertion of a 4-mm balloon catheter (REN biliary dilation catheter; KANEKA, Osaka, Japan) was alternatively attempted, and tract dilation was successful in three patients. However, in the remaining three patients in whom the 4-mm balloon catheter could not be inserted, tract dilation was attempted by alternative techniques, with tract dilation ultimately successful. Among the nine patients

who successfully underwent tract dilation using the ES dilator as the initial tract dilation device, additional tract dilation for stent insertion was needed in six patients. Finally, the overall technical success rate in the ES dilator group was 100% (15/15). On the other hand, among the Tornus ES group, stent deployment was successful in 11 patients without additional tract dilation, although the procedure was unsuccessful in one patient. Therefore, this patient underwent additional tract dilation using a 4-mm balloon catheter. As results, additional tract dilation rate to deploy the stent was needed in 86.7% (13/15) in the ES dilator group, and 8.3% (1/12) in the Tornus group (P=0.001), and the overall technical success rate in the Tornus ES group was 100% (12/12). Mean procedure time was shorter in the Tornus ES group (13.38 ± 3.80 min) compared with the ES dilator group (21.40 ± 1.54 min) (P=0.0013). Although severe adverse events, such as pancreatic fluid leakage, were seen in one patient in the ES dilator group, all adverse events were successfully treated conservatively, and the rate of adverse events were similar between the two groups. Finally, after EUS-PGS, obstructive pancreatitis or pseudocyst resolution was obtained in all patients.

Discussion

EUS-PGS could be a challenging procedure. First, the diameter of the puncture site is usually small, in addition, because EUS-PGS is frequently indicated for chronic

pancreatitis, in which the parenchyma is fibrotic, puncturing the MPD might be challenging compared with puncture of the biliary tract. On the other hand, in cases of other pancreatic diseases, such as pancreaticojejunal anastomotic stricture, although the pancreatic parenchyma itself is not fibrotic, adverse events, such as pancreatic fluid leakage, might easily occur as a complication during procedures including puncture and tract dilation because of fragility of the pancreas. Second, guidewire insertion and manipulation might be difficult with EUS-PGS. During EUS-PGS, the length of the pancreatic parenchyma en route to the puncture site is short. Therefore, the impaction technique [14] could be challenging. As a result, there is a greater risk of guidewire shearing in EUS-PGS compared with EUS-BD. To prevent guidewire shearing during EUS-PGS, a needle-free technique might be useful, although this technique itself is challenging, especially in non-expert hands [15]. Third, the stability of the echoendoscope is poor. During EUS-PGS, angle is not so used, and the scope shape is almost straight. Therefore, EUS-PGS should be performed with an unstable scope position. Indeed, according to a meta-analysis of EUS-PGS including 22 studies (714 patients), the pooled technical success rate was 84.8% (95% confidence interval 79.1 – 89.2) [16].

Although overcoming the above factors is important for enhancing the technical success

of EUS-PGS, successful and adequate tract dilation for stent insertion might be more important for obtaining technical success and preventing adverse events. Insufficient tract dilation could make stent delivery challenging, and further dilation attempts will prolong the procedure time. In addition, continuous leakage of pancreatic juice is a frequent complication of tract dilation. Moreover, because of the unstable scope position, the pushing force of the dilation device might not be effectively transmitted. If the pushing maneuver is repeatedly attempted, it could displace the echoendoscope from its appropriate position, leading to loss of the correct axis of the entry route. Therefore, an ideal dilation device is much needed.

Various dilation devices are currently available. Electrocautery dilation is a promising technique for obtaining definitive penetration of the stomach and MPD wall. However, electrocautery dilation carries the risk of bleeding, as previously described [17]. Honjo et al previously compared the ES dilator (n=5) and electrocautery dilator (n=10) as the initial dilation device during EUS-PGS [9]. Although there were no significant differences in tract dilation success rate, successful stent deployment, rate of additional dilation and adverse event rates, bleeding was only observed in the electrocautery dilation group. Therefore, due to similar efficacy of dilation between the ES dilator and electrocautery dilator, we compared Tornus ES with the ES dilator in this study. Evaluation showed that

the Tornus ES has several advantages during tract dilation. When using clockwise rotation, the tip automatically advances toward the MPD due to the screw structure, resulting in an extremely strong penetration ability compared with bougie dilators [10]. In addition, since a pushing force is not needed, the position of the echoendoscope remains stable. These factors might influence the success rate of tract dilation and reduction of procedure time. As similar concept device, Soehendra stent retriever (SSR; COOK Medical, Bloomington, USA) might be considered to sue as dilation device. However, the tip of SSR is not tapered, therefore, SSR insertion through the stomach wall might be challenging.

The Tornus ES device has already been evaluated in EUS-BD. Okuno et al retrospectively evaluated this device during EUS-HGS [10]. In their study of 20 patients who underwent EUS-HGS, although heterogeneous factors, such as use of a 22G needle, 0.018-inch guidewire, several stent types, and forward-viewing echoendoscope were included, technical success in initial tract dilation was obtained in all patients. Ogawa et al conducted a prospective feasibility study of this device during EUS-HGS [17]. Although only 10 patients were included in their study, technical success with tract dilation was obtained in all patients. This device has been shown to provide definitive penetration during EUS-HGS, as previously described [17]; however, clinical evaluation of the Tornus

ES for EUS-PGS might remain still insufficient [18, 19]. Yasuda et al firstly reported a successful stenosis dilation for chronic pancreatitis under ERCP guidance using Tornus ES [20]. Sadek et al reported case series of EUS-PGS using Tornus ES [21]. In their study including 12 cases, technical success rate of initial gastropancreatic fistula was obtained in all patients without severe adverse events. Therefore, they concluded that Tornus ES may be useful dilation device for EUS-PGS. Mizumachi et al reported a case of successful antegrade lithotripsy through a fistula created by EUS-PGS for a pancreatic duct stenosis following a Whipple procedure [22]. During EUS-PGS, they used Tornus ES, and successfully dilated tracts.To the best of our knowledge, the present study is the first comparative look at the Tornus ES versus ES dilator during EUS-PGS. In our study, the technical success rate of device insertion into the MPD was higher with Tornus ES compared with the ES dilator. In addition, because device exchange to attempt additional dilation was not required, the procedure time was also shorter with Tornus ES. Therefore, we believe that the Tornus ES is a favorable first-line dilation device during EUS-PGS. However, our study had several limitations such as a retrospective, single-center with small number of patients. Also, because patients were enrolled in different period, our study has introducing potential confounding factors such as technical experience, technician experience, and technological evolution. In addition,

electrocautery dilator may be commonly used, therefore, we must compare with Tornus ES as further study.

In conclusion, Tornus ES might be considered as initial dilation device during EUS-PGS because of the reduction in procedure time and greater technical success rate for tract dilation as compared with the ES dilator, although further randomized controlled trials are needed to confirm our results.

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Figure Legends

Fig 1

a. An ultra-tapered mechanical dilator (ES dilator; Zeon Medical Co., Ltd., Tokyo, Japan).

b. The drill dilator (Tornus ES; Asahi Intecc, Aichi, Japan).

Fig 2

a. The main pancreatic duct is punctured using 19G needle.

b. The contrast medium is injected into the main pancreatic duct.

c. 0.025-inch guidewire is deployed within the main pancreatic duct.

d. The pancreatic duct and stomach wall are dilated using the drill dilator.

e. 7Fr plastic placement is performed from the main pancreatic duct to the stomach.

Fig 3

The flow chart for patients in this study.

Video Legends

The main pancreatic duct is punctured using 19G needle, and the contrast medium is injected. Then, 0.025-inch guidewire deployment is attempted. However, the guidewire is inserted into the tail side of main pancreatic duct. The guidewire manipulation is gently attempted, and successfully deployed into the intestine across the anastomotic stricture site. The pancreatic duct and stomach wall are dilated using the drill dilator. Finally, 7Fr straight plastic stent deployment from the main pancreatic duct to the stomach is successfully performed.

Table 1. Patients' characteristics

	n
Total cohort (n)	29
Median age (y, range)	71 (39 - 88)
Sex (male / female)	18 / 11
Charlson comorbidity index , n (%)	
0	25 (86.2)
1	3 (10.3)
2	1 (3.4)
American Society of Anesthesiologists Physical Status	
1	24 (82.8)
2	5 (17.2)
Primary disease, n (%)	
• Benign stricture	6 (20.7)
Pancreaticojejunal anastomotic stricture	17 (58.6)
Chronic pancreatitis	
• Malignant stricture	2 (6.9)
Cholangiocarcinoma	2 (6.9)
Pancreatic head cancer	2 (6.9)
Ampullary cancer	
Stricture site, n (%)	
• Main pancreatic duct	21 (72.4)
• Pancreaticojejunal stricture	6 (20.7)
• Ampulla	2 (6.9)
Indication for pancreatic duct drainage, n (%)	
• Obstructive pancreatitis	28 (96.6)
• Pseudocyst	1 (3.4)
Reason for performing EUS-PD, n (%)	
• Inaccessible stricture site	6 (20.7)
• Duodenal obstruction	2 (6.9)
• Failed pancreatic duct cannulation	2 (6.9)
• Failed guidewire passage through the stricture	19 (65.6)

Table 2. Technical results of EUS-PGS

	ES dilator	Tornus ES	P-value
Number of patients	15	12	-
Mean diameter of pancreatic duct, mm (±SD)	5.39 ± 1.54	5.54 ± 1.42	0.7897
Technical success rate of device insertion into main pancreatic duct, % (n)	60 (9/15)	100 (12/12)	0.013
Additional tract dilation rate to deploy the stent, % (n)	86.7 (13/15)	8.3 (1/12)	0.001
Overall technical success rate, % (n)	100 (15/15)	100 (12/12)	-
Mean procedure time, min (±SD)	21.4 ± 1.54	13.38 ± 3.80	0.0013
Adverse events, n			0.5552
Pancreatitis	0	1	
Pancreatic fluid leakage	1	0	
Abdominal pain	1	1	

Fig 1

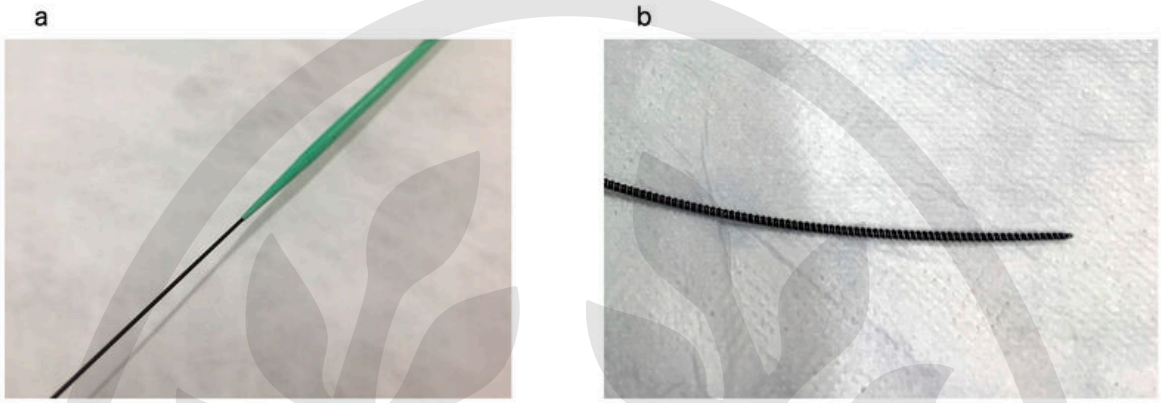

Fig 2

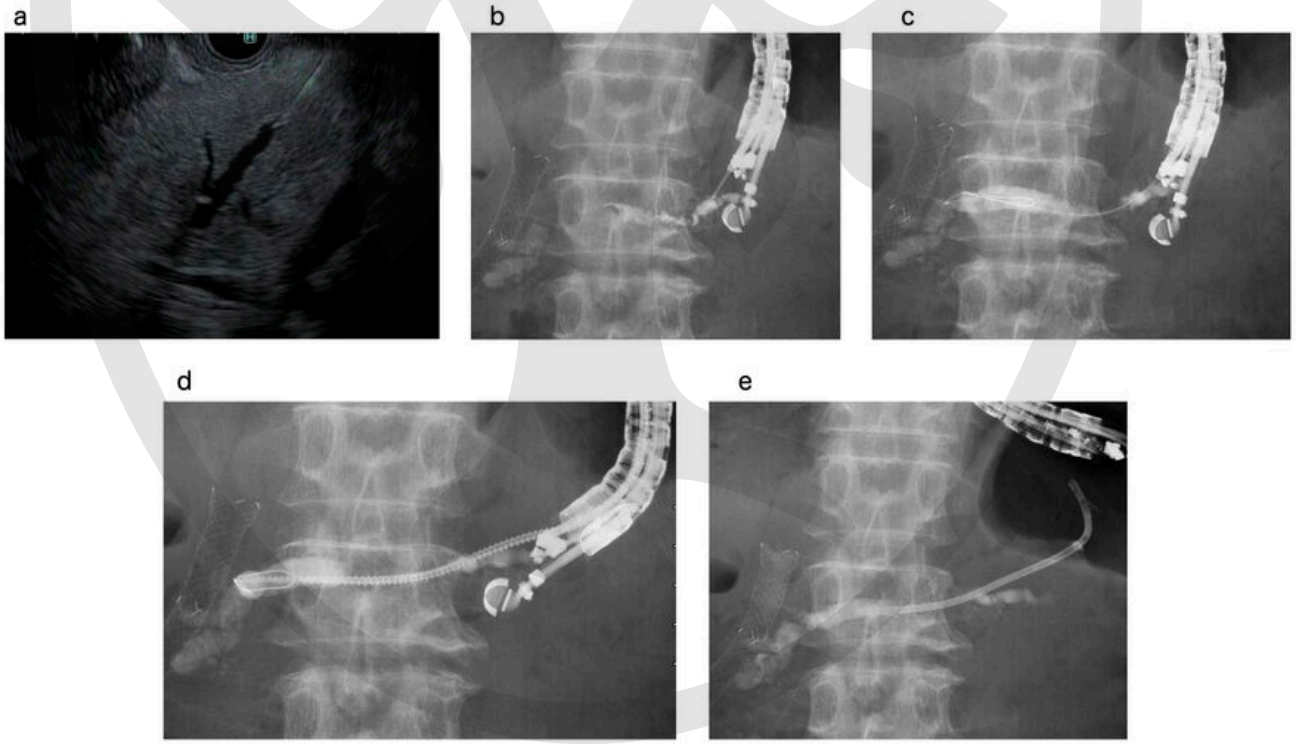

Fig 3