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

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ABSTRACT

Background and study aims Endoscopic ultrasound-guided pancreaticogastrostomy (EUS-PGS) is performed for patients who have failed ERCP. Tract dilation is one of the challenging procedural steps during EUS-PGS. Recently, a bougie dilator, the drill dilator, has become available. With this device, tract dilation can be easily performed without push-back 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.

Patients and methods 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 first evaluated. Overall technical success rate, procedure time, and adverse events were evaluated as secondary outcomes.

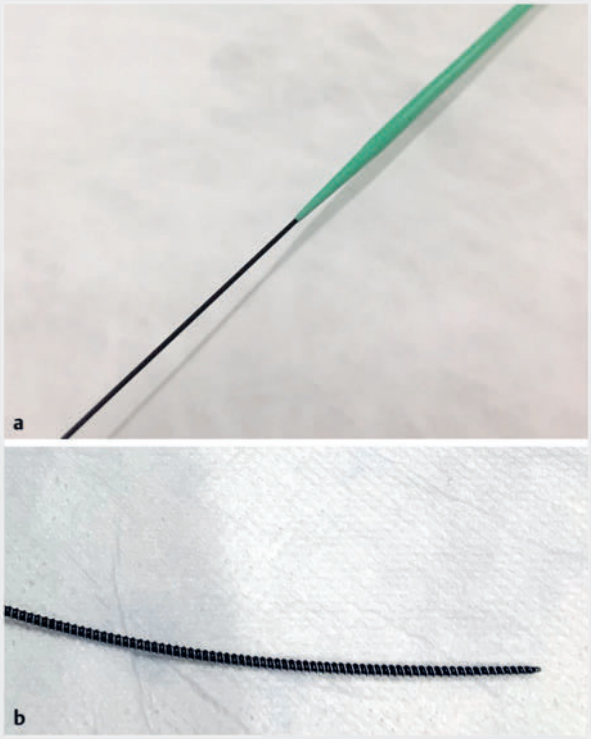
Results The technical success rate of initial device insertion into the MPD was higher with the Tornus ES (100%, 12/12) compared with the ES dilator (60%, 9/15) ($P=0.013$). Additional tract dilation rate to deploy the stent was needed in 86.7% (13/15) in the ES dilator group, and 8.3% (1/12) in the 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 the initial dilation device during EUS-PGS.

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, because EUS-guided pancreaticogastrostomy (EUS-PGS) is per-

formed if the guidewire cannot be passed through the stricture site, this procedure is probably more frequently performed compared with other procedures. There are four technical steps in EUS-PGS: pancreatic duct puncture, guidewire insertion, tract dilation, and stent deployment [3,4,5,6,7]. The technical success rate for EUS-PGS has been reported as being lower than that for 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 a 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.



▶ **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).

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) symptoms 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.

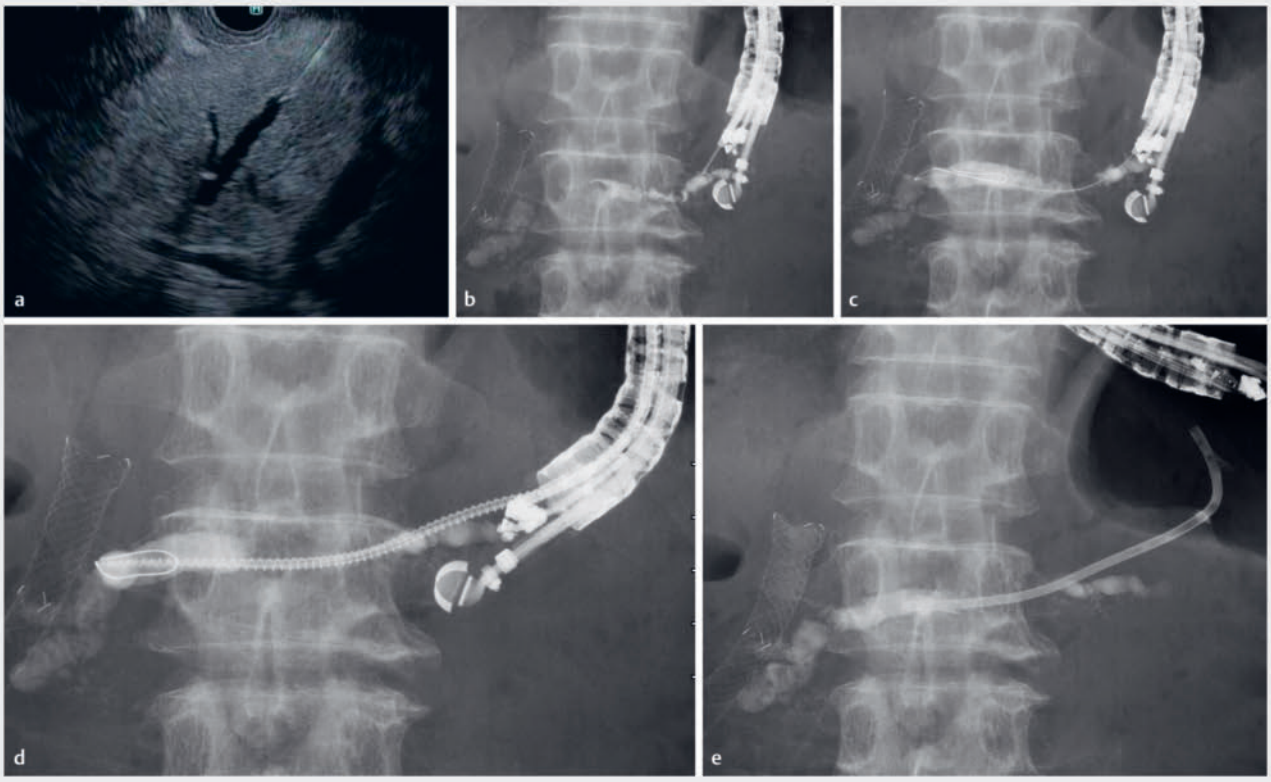
Dilation devices and EUS-PGS procedure

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 onward, 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 the Tornus ES, operators managed 30 cases of EUS-guided biliary drainage using the Tornus ES. Briefly, the tip of the ES dilator is extremely tapered to 2.5F and the maximum diameter of the body is 7F. 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 7F. 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 the 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 9 cm length) is attempted (▶ **Fig. 2e**). If this also fails, additional tract dilation is attempted (▶ **Video 1**).

Definitions and statistical analysis

The technical success rate for tract dilation was first 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 (AEs) were next 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 deploy-



▶ **Fig. 2** **a** The main pancreatic duct is punctured using a 19G needle. **b** The contrast medium is injected into the main pancreatic duct. **c** A 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** 7F plastic placement is performed from the main pancreatic duct to the stomach.

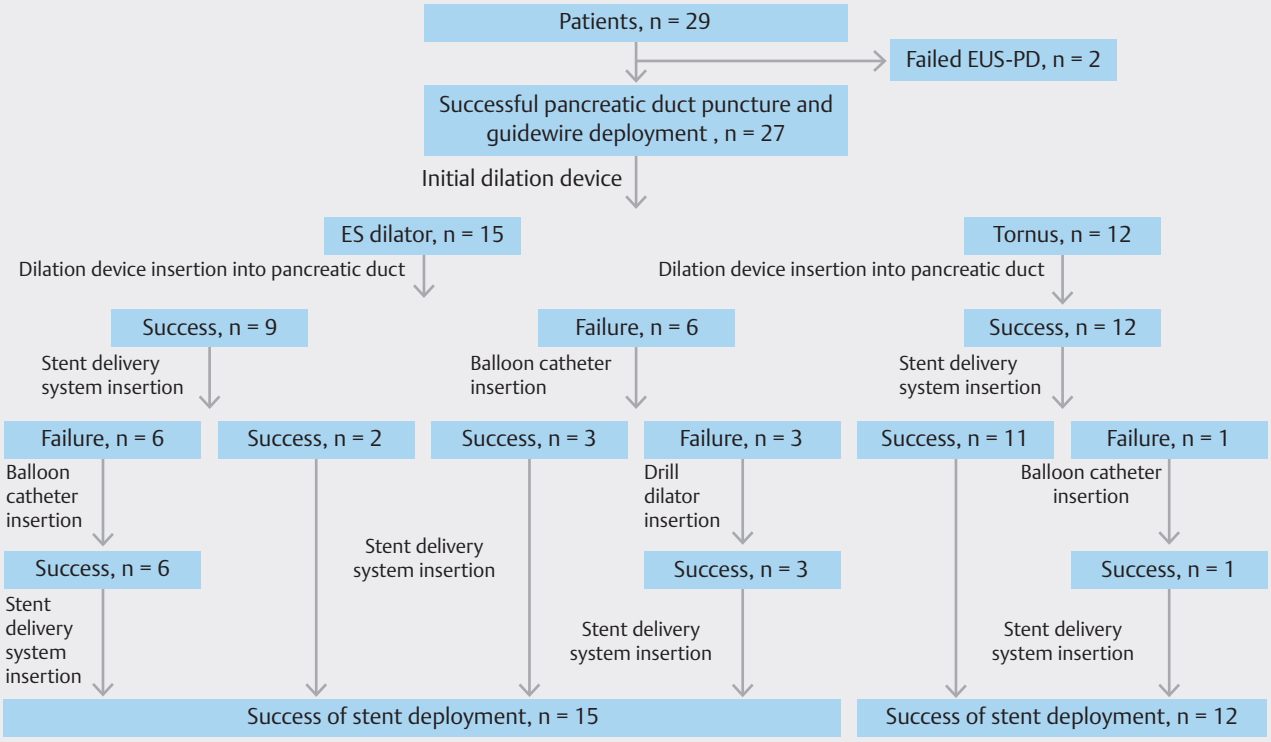
VIDEO

▶ **Video 1** The main pancreatic duct is punctured using a 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, 7F straight plastic stent deployment from the main pancreatic duct to the stomach is successfully performed.

ment. Procedure time was measured using recorded video. The diameter of the MPD was measured by EUS. AEs 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 (ASA) physical status [13]. Descriptive statistics are presented as the mean ± standard deviation 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. $\chi 2$ 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, Illinois, United States).

Results

During the study period, a total of 29 patients (median age, 71 years, 18 males) were enrolled. Table 1 shows patient 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 CP (n = 17) and pancreaticojejunal anastomotic stricture (n = 6). The primary diseases in cases with malignant MPD strictures were cholangiocarcinoma



▶ **Fig. 3** Flow chart for patients in this study.

(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 strictures (n = 2). 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).

▶ **Fig. 3** shows the flow chart for patients in this study. Table 2 shows 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 the Tornus ES as the initial dilation device. The technical success rate for 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 with alternative techniques, with tract dilation ultimately successful. Six of the nine patients who successfully underwent tract dilation using the ES dilator as the initial tract dilation device required additional tract dilation for stent insertion. Finally, the overall technical success rate in the ES dilator group was 100% (15/15). In contrast, 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. Additional tract dilation rate to deploy the stent was needed in 86.7% of patients (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 AEs, such as pancreatic fluid leakage, were seen in one patient in the ES dilator group, all AEs were successfully treated conservatively, and the rate of AEs was similar between the two groups. Finally, after EUS-PGS, resolution of obstructive pancreatitis or pseudocyst was achieved in all patients.

Discussion

EUS-PGS can be a challenging procedure. First, the diameter of the puncture site is usually small. In addition, because EUS-PGS is frequently indicated for CP, in which the parenchyma is fibrotic, puncturing the MPD may be challenging compared with puncture of the biliary tract. In cases of other pancreatic diseases, such as pancreaticojejunal anastomotic stricture, although the pancreatic parenchyma itself is not fibrotic, AEs

such as pancreatic fluid leakage can easily occur as a complication during procedures including puncture and tract dilation because of fragility of the pancreas. Second, guidewire insertion and manipulation may 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] can 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 may 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 AEs. Insufficient tract dilation could make stent delivery challenging, and further dilation attempts will prolong 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 may 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, there is a great need for an ideal dilation device.

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 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 AE 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 the Tornus ES with the ES dilator in this study. Our 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, because no pushing force is needed, the endoscope position remains stable. These factors may influence the success rate for tract dilation and reduce procedure time. A similar concept device, the Soehendra stent retriever (SSR; COOK Medical, Bloomington, Indiana, United States), may be considered for dilation. However, the tip of SSR is not tapered; therefore, SSR insertion through the stomach wall may 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 the procedure, 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 achieved 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 cases. 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 may still be insufficient [18, 19]. Yasuda et al first reported successful stenosis dilation for CP under ERCP guidance using the Tornus ES [20]. Sadek et al reported case series of EUS-PGS using the Tornus ES [21]. In their study including 12 patients, technical success with initial gastropancreatic fistula was obtained in all patients without severe AEs. Therefore, they concluded that the Tornus ES may be a 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 the 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 for device insertion into the MPD was higher with the Tornus ES compared with the ES dilator. In addition, because device exchange to attempt additional dilation was not required, procedure time also was shorter with the 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 design with a small number of patients. Also, enrollment of patients during different periods introduced potential confounding factors such as technical experience, technician experience, and technological evolution. In addition, an electrocautery dilator may be commonly used for EUS-PGS; therefore, it should be compared with the Tornus ES in a future study.

Conclusions

In conclusion, the Tornus ES may be considered as the initial dilation device during EUS-PGS because it is associated with reduced procedure time and a higher technical success rate for tract dilation as compared with the ES dilator, although further randomized controlled trials are needed to confirm our results.

Conflict of Interest

The authors declare that they have no conflict of interest.

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