Mechanical evaluation of the dilation force of dilation devices during interventional endoscopic ultrasound

OPEN ACCESS

Authors
Takeshi Ogura[1], Saori Ueno[1], Akitoshi Hakoda[1], Atsushi Okuda[1], Nobu Nishioka[1], Jun Sakamoto[1], Masahiro Yamamura[1], Nobuhiro Hattori[1], Kimi Bessho[1], Hiroki Nishikawa[1], Rie Kanaoka[2], Youhei Kurose[2]

Institutions
1 2nd Department of Internal Medicine, Osaka Medical and Pharmaceutical University, Takatsuki, Japan
2 Department of Business planning, Kaneka Medix Corporation, Osaka, Japan

Key words
Endoscopic ultrasonography, Intervention EUS, Biliary tract

received 22.4.2024
accepted after revision 13.6.2024
accepted manuscript online 24.6.2024

Bibliography
Endosc Int Open 2024; 12: E955–E961
DOI 10.1055/a-2351-0647
ISSN 2364-3722

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Corresponding author
Dr. Takeshi Ogura, Osaka Medical and Pharmaceutical University, 2nd Department of Internal Medicine, Takatsuki, Japan
oguratakeshi0411@yahoo.co.jp

ABSTRACT

Background and study aims To insert the metal stent delivery system (8.5F) during interventional endoscopic ultrasound (I-EUS), several dilation steps are needed, which may be related to increased bile leakage from a fistula. There have been no definitive studies of dilation force. The aim of the present study was to evaluate dilation force during I-EUS using several dilation devices.

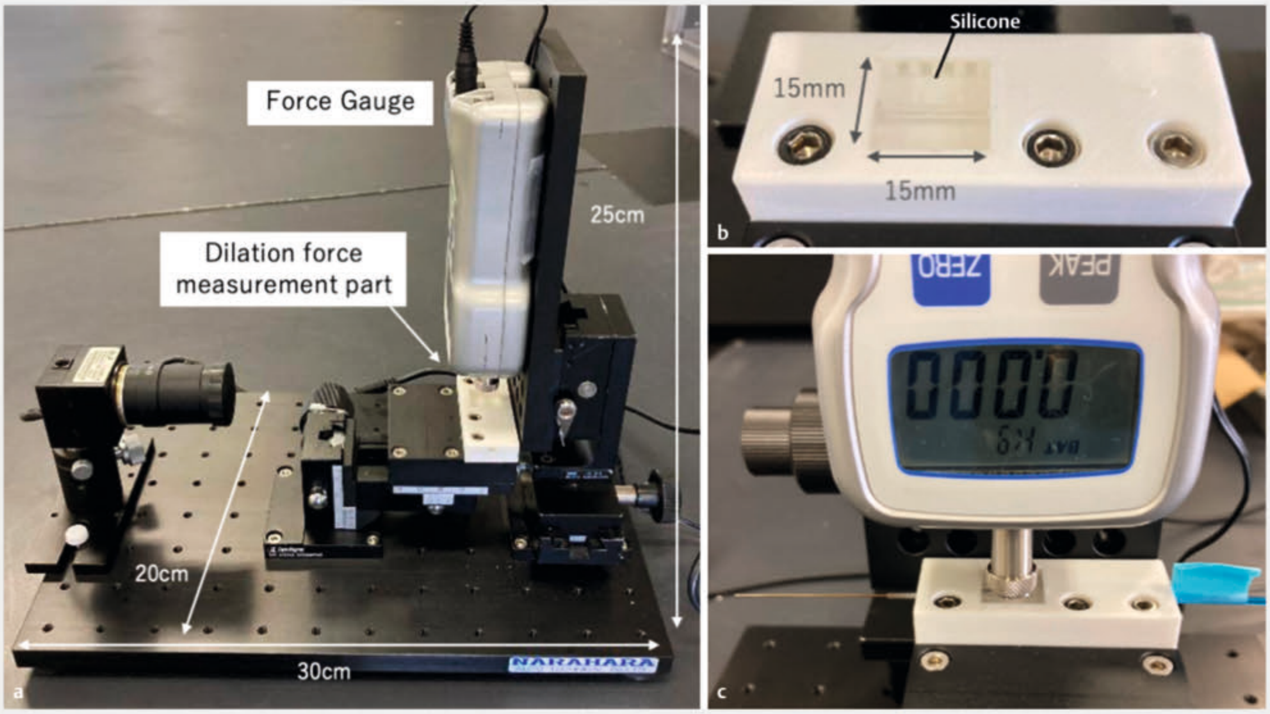
Methods In the present study, seven dilation devices were evaluated including bougie dilators such as a straight-shaped dilator (the ES dilator, Soehendra dilator, a standard ERCP catheter) a screw-shaped dilator (Tornus ES, Soehendra stent retriever), and a 4-mm balloon catheter (REN biliary balloon catheter, Hurricane RX). The diameter of each dilator and dilation force were measured.

Results Of the bougie dilators, the dilation force of the ES dilator was the highest (0.908 ± 0.035 kg). Of the balloon catheters, the dilation force of the Hurricane RX (3.261 ± 0.024 kg) was slightly higher than that of the REN (3.159 ± 0.072 kg). Of the bougie dilators, although the diameter of the ES dilator was not larger than that of the Tornus ES, the dilation force was stronger. Similarly, the diameter of the Soehendra stent retriever was greater than that of the ERCP catheter or Soehendra dilator and the dilation force was lower.

Conclusions Compared with bougie dilators, balloon catheters have stronger dilation force according to our experimental study. The present results should be evaluated in clinical trials.

Introduction

Interventional endoscopic ultrasound (I-EUS), including biliary drainage (BD) or pancreatic duct drainage, has emerged as an alternative technique in patients with failed endoscopic retrograde cholangiopancreatography (ERCP) [1, 2, 3, 4, 5]. For the technique of I-EUS, there are basically four steps: puncture, guidewire deployment, tract dilation, and stent deployment. Before stent deployment, especially when a self-expandable metal stent (SEMS) is deployed, tract dilation should be performed. Various techniques and devices to improve the technical success rate of tract dilation have been reported [6, 7, 8, 9, 10, 11, 12, 13, 14]. Electrocautery dilation is one of the effective techniques to obtain reliable tract dilation, but according to previous studies [11, 15], the adverse event (AE) rate for I-EUS might be high. On the other hand, mechanical dilation techniques using a balloon catheter or bougie dilator may be safe. However, to insert the stent delivery system for SEMS, several dilation steps are needed, and this may be related to increased bile leakage from a fistula. Therefore, a mechanical dilator that



▶ **Fig. 1** Dilation force measurement device. **a** A dilation force measurement device is created using elastic silicone for the dilation force measurement part. **b** The silicone is shaped like a block with a tubular hole (φ2.0 mm). **c** The product is inserted into the hole and allowed to expand, and the force (load) of the expanded silicone pushing against the force gauge attachment 1 s measured (force gauge FGP-5, Nidec, Kyoto, Japan). Glycerin is applied to the hole as a lubricant before each measurement.

can provide one-step dilation for insertion of a stent delivery system should be selected. However, there have been no definitive studies of dilation force. The aim of the present study was to evaluate dilation force during I-EUS using several dilation devices.

Methods

Types of dilation devices

In the present study, seven dilation devices were evaluated. Among bougie dilators, as straight-shaped dilators, the ES dilator (Zeon Medical Co., Tokyo, Japan), Soehendra dilator (SBDC-7, Cook Medical Inc.), a standard ERCP catheter (MTW, Endoskopie, Düsseldorf, Germany), and as screw dilators, Tornus ES (Asahi Intecc Do., Aichi, Japan), and Soehendra stent retriever (SSR-7, Cook Medical Inc., Bloomington, Indiana, United States) were used. Among balloon catheters, two kinds of 4-mm balloon catheters (REN biliary balloon catheter, KANEKA, Osaka, Japan; Hurricane RX, Boston Scientific, Marlborough, Massachusetts, United States) were used. The diameters of 7F and 8.5F plastic stents (SUZAKU (KANEKA), Advanix J (Boston Scientific), QuickPlace (Olympus Medical, Co., Tokyo, Japan), and Flexima (Boston Scientific)) were also measured. To avoid heterogeneity, three samples of each dilation device were measured and the mean values were evaluated.

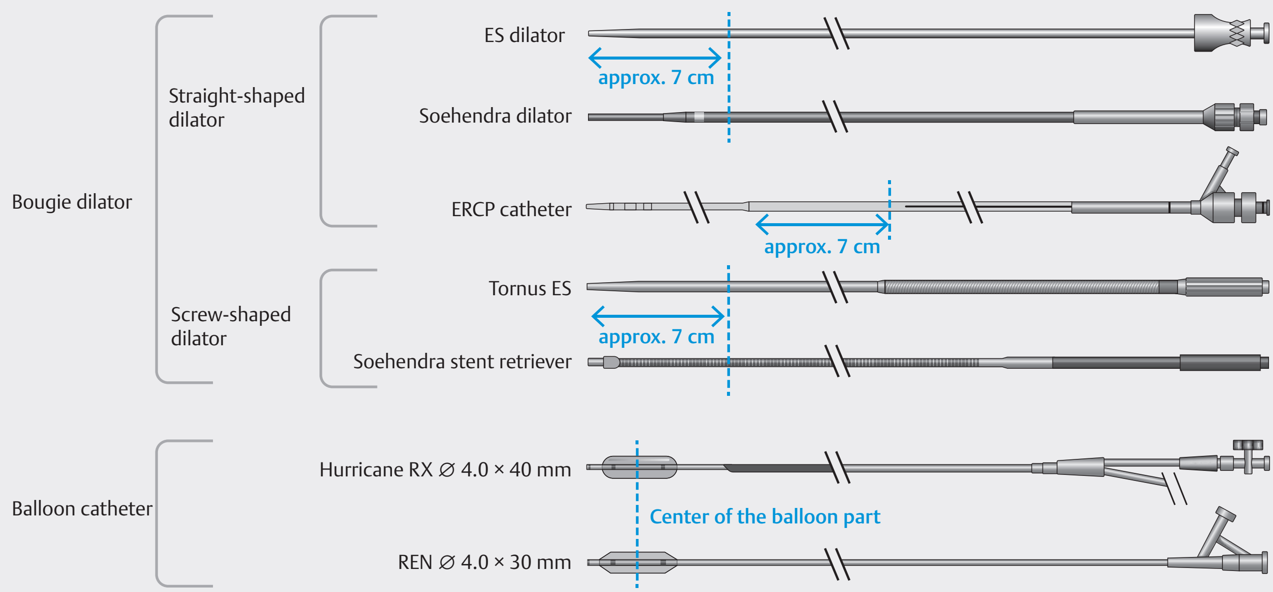
Measurement of the diameter of each dilator

The diameters of the ES dilator, Soehendra dilator, ERCP catheter, and the plastic stents were measured with a laser micrometer (LS-7010 M, KEYENCE, Osaka, Japan). The diameters of the Tornus ES and Soehendra stent retrievers were measured with a digital microscope (VHX-7000, KEYENCE, Osaka, Japan). The diameters of the balloon catheters were measured with a laser micrometer (LS-7070 M, KEYENCE, Osaka, Japan).

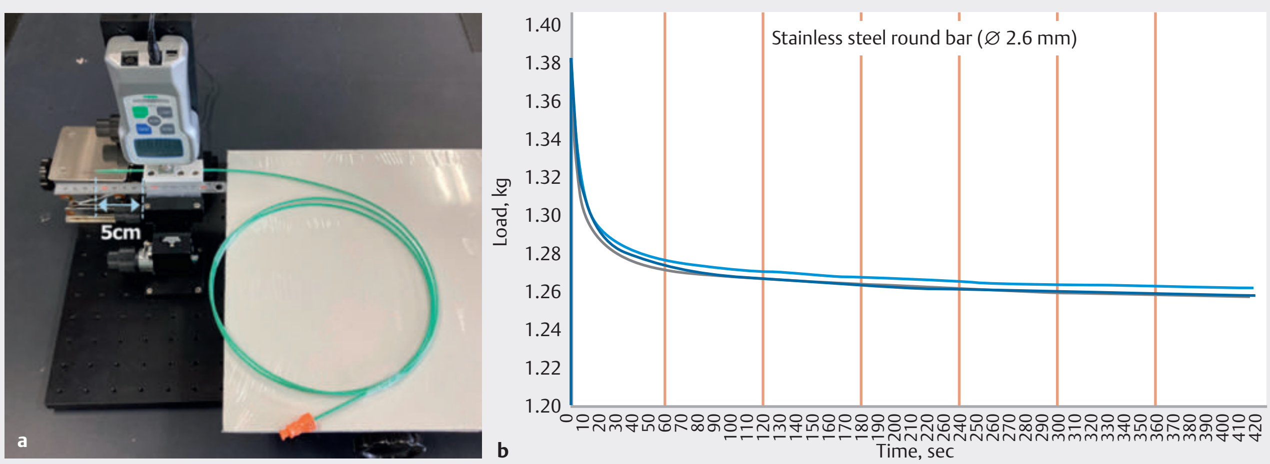
Measurement of dilation force

▶ **Fig. 1** shows the dilation force measurement device. To simulate fistula dilation, a dilation force measurement device was created using elastic silicone for dilation force measurement (▶ **Fig. 1a**). The silicone was shaped like a block with a tubular hole (φ2.0 mm) (▶ **Fig. 1b**). The product was inserted into the hole and allowed to expand, and the force (load) of the expanded silicone pushing against the force gauge attachment was measured (force gauge FGP-5, Nidec, Kyoto, Japan) (▶ **Fig. 1c**). Glycerin was applied to the hole as a lubricant before each measurement. The dilation force was measured approximately 7 cm from the tip of the dilator, with the ERCP catheter as the end of the large diameter part, avoiding the tapered part, and the dilation force of the balloon was measured at the center of the balloon part (▶ **Fig. 2**).

During measurement of the dilator, a stainless steel rod with a compatible guidewire diameter was first inserted from the tip



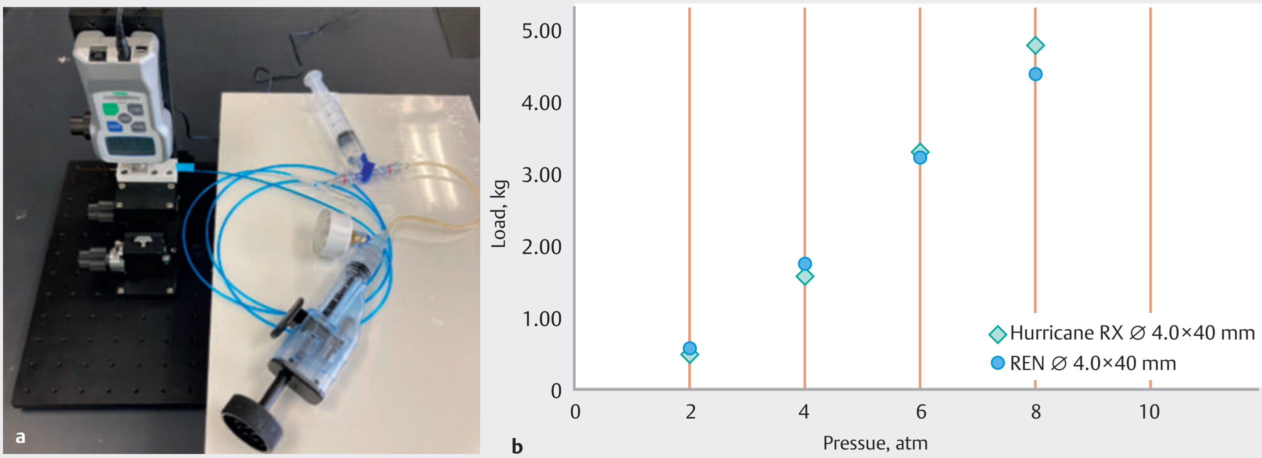
▶ **Fig. 2** Dilation force measurement. The dilation force is measured approximately 7 cm from the tip of the dilator, with the ERCP catheter as the end of the large diameter part, avoiding the tapered part, and the dilation force of the balloon is measured at the center of the balloon part.



▶ **Fig. 3** Dilation force of bougie dilator measurement. **a** The dilator is inserted so that it protrudes approximately 5 cm from the exit of the expansion force measuring section. **b** The load on the force gauge is measured as the expansion force value (measured 10 times for each specimen). When the dilator is inserted into the measurement part, the silicone is temporarily compressed, and the load is increased; therefore, changes in the load over time are investigated.

of the dilator. Then, the dilator was inserted so that it protruded approximately 5 cm from the exit of the expansion force measuring section (▶ **Fig. 3a**). The load on the force gauge was defined as the expansion force value (measured 10 times for each specimen). When the dilator was inserted into the measurement part, the silicone was temporarily compressed and the load was increased; therefore, changes in the load over time were investigated (▶ **Fig. 3b**). For measurements, stainless steel round bars (round bars) with diameters of 2.2 mm and 2.6 mm were used to correspond to the minimum and maximum outer diameters of the dilator. When the round bar was inserted, the load became very high temporarily, and it then dropped significantly after about 1 minute. Thereafter, it decreased over time, but the rate of decrease became very slow after 6 minutes. From this, the load 6 minutes after insertion of the round bar and dilator was defined as the expansion force value.

During balloon catheter measurement, the rod with a compatible guidewire diameter was first inserted from the tip of the balloon catheter (▶ **Fig. 4a**). The balloon was then connected to an indeflator and the air was removed. The balloon catheter



▶ **Fig. 4** Dilation force of balloon catheter measurement. **a** The rod with a compatible guidewire diameter is first inserted from the tip of the balloon catheter. **b** The balloon is pressurized to 6 atm at 0.5 atm/sec and once the value on the force gauge has stabilized, that value is used as the expansion force value. When the balloon catheter is pressurized to its maximum, the maximum load of the force gauge may be exceeded, so the load relative to the inflation pressure was investigated. The balloon catheter is inserted so that the center of the balloon is aligned with the center of the measurement part and the load is recorded every 2 atm when pressurized at 0.5 atm/sec.

was inserted so that the center of the balloon part was aligned with the center of the expansion force measuring part. The balloon was pressurized to 6 atm at 0.5 atm/sec and once the value on the force gauge stabilized, that value was used as the expansion force value (measured 10 times for each sample). If the balloon catheter was pressurized to its maximum, the maximum load of the force gauge might have been exceeded, so the load relative to the inflation pressure was investigated. The balloon catheter was inserted so that the center of the balloon was aligned with the center of the measurement part and the load was recorded every 2 atm when pressurized at 0.5 atm/sec (▶ **Fig. 4b**). The balloon was found to have a load of nearly 5 kg at an inflation pressure of 8 atm. Because clinical inflation is approximately 6 atm and the inflation pressure does not exceed the maximum load of the force gauge, the balloon's inflation force was defined as the load at an inflation pressure of 6 atm. Finally, all measurements were performed 10 times for each device at a temperature of 25 °C.

Statistical analysis

Continuous variables, presented as mean ± standard deviation or median (range) values, were compared using the student's *t*-test and box plots. $P < 0.05$ was considered statistically significant. Statistical analysis was mainly performed using SPSS version 13.0 (SPSS, Chicago, Illinois, United States).

Results

▶ **Table 1** shows the results for the diameter of each dilation device and plastic stent. Of the bougie dilators, the Tornus ES had the largest diameter (2.61 ± 0.015 mm) compared with the ES dilator (2.46 ± 0.012 mm), Soehendra dilator (2.32 ± 0.01 mm), ERCP catheter (2.33 ± 0.02 mm), and the Soehendra stent retriever (2.37 ± 0.006 mm). Because the Tornus ES and the Soehendra stent retrievers have screw shapes, the maximum and minimum diameters were measured. The minimum diameter of the Tornus ES was 2.00 ± 0.06 mm and that of the Soehendra stent retriever was 2.14 ± 0.024 mm.

Because balloons are used at pressures of approximately 6 atm in clinical practice, each balloon catheter was measured after inflation to 6 atm. Compared with the REN balloon catheter (3.87 ± 0.01 mm), the Hurricane RX was larger (3.95 ± 0.025 mm). The diameter of 7F plastic stents ranged from 2.43 to 2.53 mm, and that of 8.5F plastic stents ranged from 2.74 to 2.82 mm.

▶ **Table 2** shows all measured dilation force values. All devices were used in three sets and each measurement was performed 10 times. Of the bougie dilators, the dilation force of the ES dilator was the highest (0.908 ± 0.035 kg) compared with other dilators, such as the Soehendra dilator (0.501 ± 0.036 kg), ERCP catheter (0.548 ± 0.046 kg), Tornus ES (0.504 ± 0.029 kg), and Soehendra stent retriever (0.466 ± 0.010 kg). Among them, the ES dilator was significantly stronger compared with others as shown in ▶ **Fig. 5**. Of the balloon catheters, the dilation force of the Hurricane RX (3.261 ± 0.024 kg) was slightly higher than that of the REN (3.159 ± 0.072 kg).

Regarding the relationship between the dilation force and the diameter of dilation devices, of the bougie dilators, although the diameter of the ES dilator was no larger than that of the Tornus ES, the dilation force was stronger. Similarly, the diameter of the Soehendra stent retriever was greater than that of the ERCP catheter or Soehendra dilator, and the dilation force was lower.

▶ Table 1 Diameters of dilation devices and plastic stents.

	No. 1	No. 2	No. 3	Mean (± SD)
ES dilator	2.47	2.47	2.45	2.46 ± 0.012
Tornus ES (max)	2.63	2.61	2.60	2.61 ± 0.015
Tornus ES (min)	2.00	2.01	2.00	2.00 ± 0.006
Stent retriever (max)	2.38	2.37	2.37	2.37 ± 0.006
Stent retriever (min)	2.14	2.17	2.12	2.14 ± 0.024
Soehendra dilator	2.31	2.33	2.35	2.33 ± 0.02
ERCP catheter	2.31	2.32	2.33	2.32 ± 0.01
Hurricane RX (6atm)	3.98	3.95	3.93	3.95 ± 0.025
REN (6atm)	3.86	3.88	3.87	3.87 ± 0.01
SUZAKU (7F)	2.53	2.53	2.53	2.53 ± 0.004
Advanix J (7F)	2.45	2.45	2.45	2.45 ± 0.003
QuickPlace V (7F)	2.37	2.36	2.37	2.37 ± 0.004
Flexima (7F)	2.43	2.43	2.43	2.43 ± 0.015
SUZAKU (8.5F)	2.82	2.81	2.82	2.82 ± 0.004
Advanix J (8.5F)	2.79	2.79	2.79	2.79 ± 0.004
QuickPlace V (8.5F)	2.86	2.87	2.86	2.86 ± 0.004
Flexima (8.5F)	2.74	2.74	2.74	2.74 ± 0.015

SD, standard deviation.

▶ Table 2 Dilation force.

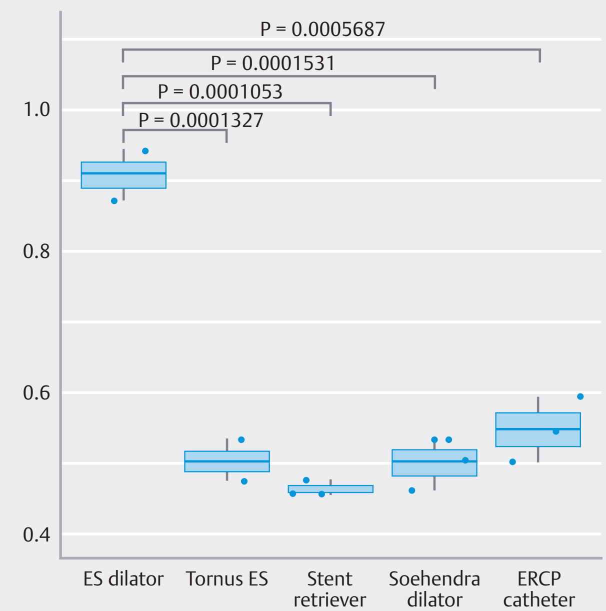
	No. 1	No. 2	No. 3	Mean (± SD)
ES dilator	0.942	0.910	0.872	0.908 ± 0.035
Tornus ES	0.534	0.502	0.477	0.504 ± 0.029
Stent retriever	0.477	0.462	0.458	0.466 ± 0.010
Soehendra dilator	0.463	0.506	0.535	0.501 ± 0.036
ERCP catheter	0.503	0.547	0.594	0.548 ± 0.046
Hurricane RX (6atm)	3.280	3.269	3.234	3.261 ± 0.024
REN (6atm)	3.084	3.227	3.164	3.159 ± 0.072

SD, standard deviation.

Discussion

To the best of our knowledge, the present study is the first to measure the dilation force during pancreato-biliary endoscopy, especially focused on I-EUS. The dilation force was stronger in balloon catheters than in bougie dilators. Of the bougie dilators, the dilation force of dilators with screw shapes was weaker than that of straight-shaped bougie dilators.

Generally, the diameter of a device might affect the dilation force. Indeed, among the straight-shaped dilators, such as the ES dilator, ERCP catheter, and Soehendra dilator, even for the same product, there were differences in dilation force depending on the diameter, and the results showed that straight bougie dilators with larger diameters had higher dilation force. In addition, the dilation force of the Hurricane RX was slightly higher than that of the REN balloon catheter; this may be explained by the finding that, when expanded to 6 atm, the outer diameter of the Hurricane RX (3.95 mm) was slightly larger than that of the REN balloon catheter (3.87 mm). Therefore, one can infer that the dilation force of the Hurricane RX was higher because it had a larger diameter. In addition, even for the same product, there may have been differences in expansion force depending on the diameter at the time of expansion. On the other hand, screw-shaped dilators such as the Tornus ES



► **Fig. 5** Box plots of dilation force among bougie dilators. Among bougie dilators, the ES dilator was strongest, followed by the ERCP catheter, Tornus ES, Soehendra dilator, and stent retriever.

and Soehendra stent retriever had lower dilation force than straight-shaped dilators, even though they had larger diameters. Tornus ES is a screw type, with a small diameter at the base of the screw and a wide width from screw to screw. For this reason, it is presumed that the area of the bulge that pushes out the silicone is small and the expansion force is small. The Soehendra stent retriever is also screw-shaped and has valleys, and as the shaft lengthens, the diameter decreases, which is presumably why the expansion force decreases. Although the Soehendra stent retriever had a smaller diameter than the Tornus ES, the expansion forces of the two were comparable. The Soehendra stent retriever has a narrow peak-to-peak width, and the thread area of the screw that pushes the silicone apart is larger than the Tornus ES. Therefore, we infer that the expansion power of the Soehendra stent retriever is now comparable to that of TornusES.

In clinical practice, various devices were evaluated as dilation devices during I-EUS, especially for EUS-guided BD. According to a multi-institution consensus including various countries [16], during an EUS-guided transhepatic approach such as EUS-guided hepaticogastrostomy (HGS), 47.83% of endoscopists (22/46) recommended a 6F electrocautery dilator to generate a hepatogastric fistula, 15.22% of endoscopists (7/46) recommended 6F and 7F tapered biliary dilator catheters, and 15.22% of endoscopists (7/46) had no preference. They recommended a biliary balloon dilator (4 mm), specific dilator (7F), and a 5–4–3 contour catheter over a 0.025-inch guidewire. In addition, according to consensus guidelines from the Asian EUS group RAND/UCLA expert panel [17], a 6F electrocautery dilator is preferred because it is fast and efficient. If a cystotome is not available in some countries, 5F stiff catheters and 4-mm biliary dilating balloons may be used. Also, electrocautery dilators have several disadvantages. First, bleeding due to vessel injury caused by the burning effect might occur as a complication. Honjo et al conducted a comparison study between ES dilators (n = 31) and electrocautery dilators (n = 33) during I-EUS [11]. Although the technical success rate of I-EUS, procedure time, and the tract dilation success rate were not significantly different between the two groups, the bleeding rate was significantly higher in the electrocautery dilator group. Recently, a balloon catheter with a fine-gauge tapered tip has become available [10]. We previously evaluated this balloon catheter during I-EUS in 20 consecutive patients and found that all patients successfully underwent I-EUS using SEMS without additional dilation using other devices. In addition, the mean procedure time was only 11 minutes (range, 8–16 minutes). Therefore, although the balloon dilation technique may have a risk of bile leakage after tract dilation, as previously described [18], the balloon dilation technique is simple and effective. However, a head-to-head comparison of ballon vs electrocautery dilatation is much needed to determine which technique is optimal.

On the other hand, a screw-shaped dilator might also be useful during I-EUS, especially to penetrate the gastrointestinal wall, bile duct, or pancreatic duct wall. In a comparison study of REN balloon catheters (n = 30) and the Tornus ES (n = 19) [9], the initial technical success rate was 100% in the Tornus ES group, but one patient failed in the REN balloon catheter group. However, 8.5F stent delivery system insertion failed in 14 of the Tornus ES group patients, and those patients underwent additional dilation. On the other hand, additional dilation was not needed in the REN balloon group to insert the 8.5F stent delivery system. As a result, procedure time was significantly shorter in the REN group and AEs were fewer in the REN group. These results might be explained by the findings of our experimental study: Dilation force is lower with a screw-shaped dilator than with a balloon catheter or ES dilator. Insufficient tract dilation might lead to prolonged procedure time, and stent delivery system removal might be difficult, as previously described [19]. Therefore, if insertion of devices with a diameter over 2.74 mm (8.5F) is attempted, balloon dilation might be suitable.

The present experimental study has several limitations. First, the ability to penetrate the gastrointestinal or pancreatobiliary wall could not be considered. This ability might be affected by the ability to insert the dilation device into the duct. Second, the degree of destruction of the gastrointestinal or pancreatobiliary wall could not be considered. This might affect the effectiveness of stent delivery insertion after tract dilation. Indeed, after hepaticojejunostomy stricture dilation using a screw-shaped dilator, fibrotic tissue was scraped off [20]. Third, dilation force was measured in an experimental study. We did not consider various factors such as scope angle or combination with guidewire. Therefore, the present experimental study may not truly reflect clinical practice.

Conclusions

In conclusion, compared with bougie dilators, balloon catheters have stronger dilation force according to our experimental study. The present results should be evaluated in clinical trials.

Conflict of Interest

This experimental study was supported by Kaneka Medix Corporation. N.R and K.Y are employed by Medix Corporation. The other authors declare that they have no conflicts of interest.

References

[1] Giovannini M. EUS-guided hepaticogastrostomy. Endosc Ultrasound 2019; 28: S44–S49 doi:10.4103/eus.eus_47_19

[2] Dell'Anna G, Ogura T, Vanella G et al. Endoscopic ultrasound guided biliary interventions. Best Pract Res Clin Gastroenterol 2022; 60–61: 101810

[3] Ogura T, Ohama H, Higuchi K. Endoscopic ultrasound-guided pancreatic transmural stenting and transmural intervention. Clin Endosc 2020; 53: 429–435 doi:10.5946/ce.2019.130

[4] Ogura T, Itoi T. Technical tips and recent development of endoscopic ultrasound-guided choledochoduodenostomy. DEN Open 2021; 1: e8 doi:10.1002/deo2.8

[5] Ogura T, Higuchi K. Endoscopic ultrasound-guided hepaticogastrostomy: technical review and tips to prevent adverse events. Gut Liver 2021; 15: 196–205 doi:10.5009/gnl20096

[6] Prachayakul V, Aswakul P. Feasibility and safety of using Soehendra stent retriever as a new technique for biliary access in endoscopic ultrasound-guided biliary drainage. World J Gastroenterol 2015; 21: 2725–2730 doi:10.3748/wjg.v21.i9.2725

[7] Kobori I, Hashimoto Y, Shibuki T et al. Safe performance of track dilation and bile aspiration with ERCP catheter in EUS-guided hepaticogastrostomy with plastic stents: A retrospective multicenter study. J Clin Med 2022; 11: 4986

[8] Ogawa T, Kanno Y, Koshita S et al. Prospective feasibility study on the efficacy and safety of a novel spiral dilator for endoscopic ultrasound-guided drainage. DEN Open 2022; 3: e170 doi:10.1002/deo2.170

[9] Hattori N, Ogura T, Ueno S et al. Clinical evaluation of a novel drill dilator as the first-line tract dilation technique during EUS-guided biliary drainage by nonexpert hands (with videos). Gastrointest Endosc 2023; 97: 1153–1157

[10] Amano M, Ogura T, Onda S et al. Prospective clinical study of endoscopic ultrasound-guided biliary drainage using novel balloon catheter (with video). J Gastroenterol Hepatol 2017; 32: 716–720

[11] Honjo M, Itoi T, Tsuchiya T et al. Safety and efficacy of ultra-tapered mechanical dilator for EUS-guided hepaticogastrostomy and pancreatic duct drainage compared with electrocautery dilator (with video). Endosc Ultrasound 2018; 7: 376–382

[12] Ueshima K, Ogura T, Nishioka N et al. Technical feasibility of EUS-guided antegrade dilation for hepaticojejunostomy anastomotic stricture using novel endoscopic device (with videos). United European Gastroenterol J 2019; 7: 419–423

[13] Bessho K, Ogura T, Ueno S et al. Moving scope technique improves technical success rate of device insertion during EUS-guided hepaticogastrostomy (with video). Therap Adv Gastroenterol 2023; 16: doi:10.1177/17562848231207004

[14] Nakamura J, Ogura T, Ueno S et al. Liver impaction technique improves technical success rate of guidewire insertion during EUS-guided hepaticogastrostomy (with video). Therap Adv Gastroenterol 2023; 16: doi:10.1177/17562848231188562

[15] Park DH, Jang JW, Lee SS et al. EUS-guided biliary drainage with transluminal stenting after failed ERCP: predictors of adverse events and long-term results. Gastrointest Endosc 2011; 74: 1276–1284

[16] Guo J, Giovannini M, Sahai AV et al. A multi-institution consensus on how to perform EUS-guided biliary drainage for malignant biliary obstruction. Endosc Ultrasound 2018; 7: 356–365 doi:10.4103/eus.eus_53_18

[17] Teoh AYB, Dhir V, Kida M et al. Consensus guidelines on the optimal management in interventional EUS procedures: results from the Asian EUS group RAND/UCLA expert panel. Gut 2018; 67: 1209–1228

[18] Yamamoto Y, Ogura T, Nishioka N et al. Risk factors for adverse events associated with bile leak during EUS-guided hepaticogastrostomy. Endosc Ultrasound 2020; 9: 110–115

[19] Ogura T, Iwatsubo T, Sakamoto J et al. Troubleshooting for difficult removal of a stent delivery system after endoscopic ultrasound-guided hepaticogastrostomy. Endoscopy 2023; 55: E790–E791 doi:10.1055/a-2094-9374

[20] Ogura T, Uba Y, Tomita M et al. Endoscopic ultrasound-guided antegrade dilation using a drill dilator for hepaticojejunostomy stricture with cholangioscopic findings. Endoscopy 2023; 55: E525–E526