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Feasibility and safety of a novel plastic stent designed specifically for endoscopic ultrasound-guided pancreatic duct drainage: a case series

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Abstract:
Background/study aim: Endoscopic ultrasound-guided pancreatic duct drainage (EUS-PD) is emerging as an effective alternative treatment for obstructive pancreatitis after unsuccessful endoscopic retrograde pancreatography (ERP). However, the high incidence of adverse events associated with EUS-PD (approximately 20%) remains an issue. Recently, we developed a novel plastic stent for EUS-PD, with a radiopaque marker positioned at approximately one-third of the length from the distal end of the stent and side holes positioned exclusively distal to the marker. This study aimed to evaluate the feasibility and safety of using this stent in EUS-PD.
Patients/materials and methods: We retrospectively reviewed data from 10 patients who underwent EUS-PD with the novel plastic stent at the National Cancer Center Hospital between March 2021 and October 2023. Technical and clinical success, procedure times, adverse events, recurrent pancreatic duct obstruction (RPO), and time to RPO were assessed.
Results: Of the ten patients, five had postoperative benign pancreaticojejunal anastomotic strictures and five had malignant pancreatic duct obstruction. The technical and clinical success rates were both 100% (10/10). An adverse event (self-limited abdominal pain) occurred in one (10.0%) patient. Two (20.0%) patients died of their primary disease during the follow-up period (median, 44 days; range, 25–272 days). The incidence of RPO was 10.0% (1/10), and the 3-month non-RPO rate was 83.3%.
Conclusion: The novel plastic stent shows potential as a useful and safe tool in EUS-PD.

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INTRODUCTION

Endoscopic retrograde pancreatography (ERP) is considered the primary drainage procedure for symptomatic obstructive pancreatitis and pancreatic duct disruption [1]. However, technical failure of ERP occurs when the main pancreatic duct (MPD) cannot be cannulated due to severe MPD stenosis, duodenal stricture, or surgically altered anatomy [2].

Recently, endoscopic ultrasonography-guided pancreatic duct drainage (EUS-PD) has emerged as an effective alternative treatment for patients in whom ERP has failed to achieve successful drainage [3-11]. Although two meta-analyses found technical success rates of 81.4–84.8% and clinical success rates of 84.6–89.2%, the incidence of adverse events (AEs) remained relatively high, ranging from 18.1 to 21.3% [12, 13]. Therefore, EUS-PD is currently considered a procedure best performed by highly experienced endosonographers in advanced medical centers.

Various types of plastic and covered metal stents have been used in EUS-PD; however, few suitable dedicated stents have been developed for EUS-PD [7, 8, 14]. In March 2021, we introduced a novel plastic stent designed specifically for EUS-PD (Figure 1). This study aimed to evaluate the feasibility and safety of using this stent in EUS-PD.

PATIENTS AND METHODS

Study population

We retrospectively reviewed data from ten patients who underwent EUS-PD using the novel plastic stent at the National Cancer Center Hospital between March 2021 and October 2023. The study was approved by the Institutional Review Board (IRB) of the National Cancer Center (No. 2018-149). The IRB waived the requirement for informed consent, and all patient information was de-identified.

Endoscopic procedures

EUS-PD was indicated for patients with symptomatic obstructive pancreatitis or pancreatic fistulae/pseudocysts caused by pancreatic duct disruption following failed ERP drainage. Oblique-viewing (GF-UCT260 and GF-UCT-240; Olympus, Tokyo, Japan; EG-580UT; Fujifilm, Tokyo, Japan) and forward-viewing (TGF-UC260J; Olympus) echoendoscopes were used. After confirming the absence of intervening vessels by Doppler mode of EUS, the pancreatic duct was transgastrically punctured with a 19-gauge fine-needle aspiration (FNA) needle (EZ Shot 3 Plus; Olympus). The puncture site of the MPD was chosen to be distal and far enough from the stenosis to allow stent placement in the MPD. A 0.025-inch guidewire (M-Through and Fielder 25; Asahi Intecc., Aichi, Japan) was placed in the MPD and pancreatography was performed. After removal of the needle, an injection catheter (SHOREN; Kaneka, Osaka, Japan) was inserted into the MPD over the guidewire. A 7-Fr bougie dilator (ES Dilator; Zeon Medical, Tokyo, Japan) or a 7-Fr spiral dilator (Tornus ES; Asahi Intecc.) was used as the first choice for fistula dilation, supplemented by a 4-mm balloon dilator (REN; Kaneka) if dilation was insufficient.

In cases where passage through the stricture was possible, the distal end of the stent was placed in the duodenum or jejunum and the proximal end in the stomach. In cases where passage through the stricture was difficult, the distal end of the stent was placed in the MPD and the proximal end in the stomach. Plain computed tomography (CT) was performed immediately after, or on the day after, the procedure to evaluate the stent position and detect any AEs.

Novel plastic stent for EUS-PD

We recently developed a new plastic stent for EUS-PD (Harmo Ray, ERP-USR-60-150-200-SH8-MK-025 and

ERP-USR-60-120-200-SH6-MK-025; Silux, Saitama, Japan) (Figure 1). This straight-type plastic stent has an outer diameter of 6 Fr, an effective length of 15 or 12 cm, two anti-migration flaps at each end, and three main features. First, and most importantly, it incorporates a radiopaque marker positioned approximately one-third of the length from the distal end of the stent, along with side holes exclusively in the distal region (eight and six for the 15- and 12-cm effective lengths, respectively). Placing the stent such that the marker is positioned in the MPD prevents leakage of pancreatic juice into the abdominal cavity while maintaining flow from the branch pancreatic duct. Second, the stent is compatible with a 0.025-inch guidewire to reduce the gap between the stent and the inner sheath, and the stent tip is highly tapered (Figure 1b). Furthermore, the small diameter (6 Fr) and moderate rigidity of the stent facilitate smooth insertion into the MPD and traversal of the stricture. Third, the stent is preloaded onto the delivery catheter and features small flaps at the distal end, making it easy to pull back and safely adjust its position.

Reinterventions

Reinterventions (RIs) were performed for recurrent pancreatic duct obstruction (RPO) or scheduled stent exchange. Scheduled stent exchange was performed after approximately three months. In cases where the stenosis could not be crossed and the distal end of the stent was implanted in the MPD, an earlier (approximately 1-2 months) stent exchange was performed to try to place a stent across the stenosis. Ultimately, the decision to perform RI was based on the patient's general condition.

There were two methods of placing the guidewire into the MPD via the fistula during stent exchange: a guidewire through the side of the stent (alongside method), and a guidewire through a new side hole created with a cutting device (Loop Cutter; Olympus) (side-hole method) [15]. The side-hole method was used when the alongside

method had failed. In cases of insufficient fistula formation (less than 2 weeks), the side-hole method should be used. After the guidewire was placed in the MPD, the stent was removed, and an injection catheter was inserted into the MPD. The subsequent stenting procedure was as described above. Retrograde stenting using the rendezvous method could be performed based on endoscopists' discretion, in cases where the guidewire was advanced across the papilla/anastomosis.

Outcomes and definitions

The endpoints included technical and clinical success rates, procedure times, AEs, incidence of RPO, and time to RPO (TRPO). Technical success was defined as successful transgastric pancreatic duct stenting using the novel plastic stent. Clinical success was defined as the improvement of either the primary symptom that necessitated the procedure or that of a pancreatic fistula/pseudocyst on a CT scan within 1 week. The procedure time was defined as the time from the start of MPD puncture to the placement of the novel plastic stent. AEs were defined according to the TOKYO Criteria 2014 [16]. The severity of AEs was classified according to the American Society for Gastrointestinal Endoscopy Lexicon [17]. RPO was defined as the recurrence of obstructive pancreatitis, pancreatic fistulae, or pseudocysts requiring additional interventions. TRPO was defined as the time from the initial procedure to the occurrence of RPO.

Statistical analyses

Continuous variables were presented as medians and ranges, whereas categorical variables were presented as numbers and proportions. TRPO with a 95% confidence interval (CI) was calculated using the Kaplan–Meier method. Patients were censored when they experienced scheduled stent exchange on the last day of follow-up, or death before RPO. Statistical analyses were performed using SPSS, version 27.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Patient characteristics

Table 1 presents the characteristics of the patients included in the study, highlighting key demographic and clinical information. Ten patients (median age, 69 years [range 17–84 years]; 6 men) underwent EUS-PD using the novel plastic stent. The primary diseases were benign stenosis in five (50.0%) patients (all had pancreaticojejunal anastomosis strictures) and malignant stenosis in five (50.0%) (three patients with pancreatic cancer, one had ampullary cancer, and one had gastric cancer). The indications for pancreatic duct drainage were obstructive pancreatitis in seven (70.0%) patients and pancreatic fistula or pseudocyst in three (30.0%). The stricture sites were pancreaticojejunal anastomoses in five (50.0%) patients, MPD in two (20.0%), and papilla in three (30.0%). The main reasons EUS-PD was needed were as follows: in five (50.0%) patients, attempts to approach via the pancreaticojejunal anastomosis had been unsuccessful (three unsuccessful cannulations and two unreachable ones); in five (50.0%) patients, attempts to approach via the papilla were unsuccessful (three unsuccessful cannulations and two unreachable ones).

Procedure details

The details of the procedures are presented in Table 2. Oblique- and forward-viewing echoendoscopes were used in eight (80.0%) and two (20.0%) patients, respectively. The median MPD diameter was 4.0 (range, 2.0–12.0) mm, and all patients underwent transgastric puncture. The puncture needle was a 19-gauge FNA needle with a 0.025-inch guidewire in all patients. A bougie dilator was used as the fistula-dilating device in all patients: eight (80.0%) patients underwent dilation using 7-Fr mechanical dilators, whereas two (20.0%) underwent dilation using a new 7-Fr spiral

dilator. One (11.1%) patient required additional dilation using a 4-mm balloon dilator. The outer diameter of the new stent was 6 Fr in all patients, with a stent length of 12 cm in five (50.0%) patients and 15 cm in five (50.0%). In four (40.0%) patients, the distal end of the stent was successfully placed in the intestine across the stenosis (Figure 2), and in six (60.0%), the distal end of the stent was deployed into the MPD because the stenosis could not be traversed (Figure 3). In all patients, the stent was placed such that the radiopaque marker was in the MPD.

Clinical outcomes

Table 3 presents the main results of this study. Both the technical and clinical success rates for EUS-PD using the novel stent were 100% (10/10). The median procedure time was 28 (range, 19–47) min. An AE (worsening of abdominal pain) occurred in one (10.0%) patient; the abdominal pain was mild and improved with conservative treatment. During the follow-up period (median, 44 days; range, 25–272 days), the RPO rate was 10.0% (1/10), and the median TRPO was not reached (Figure 4). The non-RPO rates at 30 and 90 days were 100% (9/9) and 83.3% (5/6), respectively.

The clinical course after stenting is shown in Figure 5. RI was performed in three (30.0%) patients, and all patients underwent scheduled stent exchange or removal. One (10.0%) patient experienced spontaneous stent dislodgement 141 days after stent placement but remained asymptomatic and did not require RI. One (10.0%) patient who developed RPO could not undergo RI due to the deterioration of his general condition. Two (20.0%) patients died of their primary disease during the follow-up period.

DISCUSSION

EUS-PD was first reported by Francois et al. in 2002 [18]. This procedure is technically challenging and carries a high risk of AEs. Various stents have been developed to improve the feasibility and safety of the procedure. Matsunami et al. performed EUS-PD using a novel 7-Fr plastic stent in 30 patients [7]. The results demonstrated excellent technical and clinical success rates (both 100%). However, the incidence of early AEs was relatively high at 23.3% (abdominal pain, 16.7%; mild pancreatitis, 3.3%; and bleeding requiring transcatheter arterial embolization, 3.3%). These AEs may have occurred because 83.3% of the patients required a 4 mm-diameter balloon dilator or electrocautery dilator. This could have led to pancreatic juice leakage into the abdominal cavity or injury to the surrounding pancreatic parenchyma or blood vessels.

Oh et al. also performed EUS-PD using a novel 6 mm-diameter fully covered metal stent in 23 patients and achieved technical and clinical success in all patients [8]. However, the early-AE rate (17.4%) was not low (abdominal pain, 13.0%; peripancreatic fluid collection, 4.3%). The placement of a large-diameter metal stent in a poorly dilated MPD is thought to be the main cause of these AEs. This can result in the overexpansion of the MPD and obstruction of branch pancreatic ducts. Therefore, stents for EUS-PD must have the following characteristics: ability to pass through the stenotic or fibrotic pancreatic parenchyma, long patency, and mechanisms to prevent migration, blockage of the branch duct, and leakage of pancreatic juice into the abdominal cavity. In particular, failure of pancreatic duct stent placement after fistula dilation or early migration after stent placement carries a high risk of serious complications, including pancreatic fistula and peritonitis. The top priority in EUS-PD is the development of a dedicated stent with high efficacy and safety.

In this study, we evaluated the efficacy of EUS-PD using a novel plastic stent and observed technical and

clinical success in all patients (100%). This rate is higher than the technical (81.4–84.8%) and clinical (84.6–89.2%) success rates reported in two prior meta-analyses [12, 13]. One important factor contributing to the excellent outcomes was the minimization of the gap between the stent and guidewire. This was possible because the stent is compatible with the 0.025-inch guidewire, which is standard in interventional EUS, despite its small diameter of 6 Fr. In this study, only one (10.0%) patient required balloon dilation due to difficulty in stenting after fistula dilation with a bougie dilator. Another factor contributing to the high success rates was the presence of a radiopaque marker and side holes in the novel stent. This stent has a radiopaque marker positioned approximately one-third of the length from the distal end and multiple side holes only distal to the marker. Therefore, by placing the stent such that the marker is in the MPD, determining the position where the branch pancreatic duct is unobstructed becomes safe and easy. Additionally, this prevents pancreatic juice leakage into the abdominal cavity.

The rate of AEs in the present study was relatively low (10.0%) compared with those in two previously reported meta-analyses (18.1–21.3%) [12, 13]. Furthermore, in the current study, only one patient experienced increased abdominal pain, a relatively small number compared with previous reports of 16.0–33.0% [4, 8, 10]. Although balloons were mainly used for fistula dilation in previous reports, a 7-Fr mechanical dilator was the first choice in this study. This approach minimizes fistula dilation and reduces the risk of intraoperative and postoperative leakage of pancreatic juice into the abdominal cavity. This may be the main reason for the low incidence of abdominal pain in this study.

During the follow-up period (median, 44 days; range, 25–272 days), the incidence of RPO was 10.0% (1/10), and the non-RPO rates were 100% (9/9) and 83.3% (5/6) at 30 and 90 days, respectively. In contrast, previous reports showed RPO rates of 25–55%, with a median observation period of 14.5–37 months [6, 19, 20]. The method and timing

of RI after EUS-PD varied among reports because no established strategy exists; however, we performed RI before RPO, followed by stent exchange or retrograde stenting using the rendezvous technique. Therefore, the follow-up period was shorter than that in previous reports. This makes comparing the incidences of RPOs between the present and previous studies difficult. Nonetheless, one can say that fewer early RPOs occurred herein.

The new stent was designed with an effective length of 15 or 12 cm. If stent placement across the stricture is possible, stent length contributes to a reduction in dislodgement and migration. However, in some cases, the stent cannot pass through the stenosis and is placed in the MPD. Therefore, selecting a puncture position that allows sufficient distance from the puncture point to the stenosis is crucial to avoid dislodgement. In one case, spontaneous stent dislodgement without any symptoms was observed 141 days after placement. However, in this case, the distal end of the stent was placed in the MPD without crossing the stricture. To effectively prevent dislodgement, the stent should be placed across the papilla. However, during EUS-PD, performing prolonged procedures and repeated pancreatography to avoid leakage of pancreatic juice from the MPD puncture site into the abdominal cavity can be challenging. Additionally, in many cases, crossing the stenosis during the first session can also pose difficulties. In these patients, stenting across the stricture is planned during the second session. In this study, two patients successfully underwent stent placement across the papilla or pancreaticojejunal anastomosis at the first RI several months after EUS-PD. Therefore, to prevent stent dislodgement, early RI after fistula formation may be considered in cases where the distal end of the stent is placed in the MPD. In addition, the migration rate of this straight-type stent (10%) was not higher than that of previously reported single pigtail stent (20%) [7].

The main limitations of this study are its single-center setting, retrospective design, and small sample size. In

addition, as the follow-up period was short, long-term outcomes could not be comprehensively evaluated. Furthermore, some patients underwent scheduled stent exchange or retrograde transpapillary/transanastomotic stent replacement after a certain period, and an accurate evaluation of RPO was not yet possible. Therefore, establishing more appropriate RI strategies through the accumulation of cases and evaluation of long-term outcomes is necessary.

In conclusion, this study demonstrated that the newly developed plastic stent for EUS-PD may be feasible and effective. Although these findings are encouraging, further research is needed to validate our results and establish the potential role of the stent in clinical practice. Prospective, multicenter studies with larger patient populations will be essential to confirm the safety and efficacy of the stent. This represents a promising step toward improving the management of patients with pancreatic duct disorders.

FIGURE LEGENDS

Figure 1. Novel plastic stent designed for EUS-PD

(a) The novel plastic stent designed for EUS-PD. The stent has a radiopaque marker positioned at approximately one-third of the length from the distal end of the stent, with side holes (8 and 6 holes for 15- and 12-cm effective lengths, respectively) positioned exclusively distal to the radiopaque marker. (b) The stent has a highly tapered tip and inner sheath dedicated for a 0.025-inch guidewire, reducing the gap between the stent and inner sheath. (c) A fluoroscopic image shows the novel plastic stent with the radiopaque marker. EUS-PD, endoscopic ultrasound-guided pancreatic duct drainage.

Figure 2. EUS-PD using the novel plastic stent (across the stenotic pancreatojejunal anastomosis)

(a) An endosonographic image shows a 19-gauge needle being advanced into the pancreatic duct. (b) A fluoroscopic image demonstrates a transgastric pancreatogram. (c) A 0.025-inch guidewire is advanced into the MPD across the stenotic anastomosis. (d) A fluoroscopic image shows the novel plastic stent being placed in the MPD across the stenotic anastomosis. (e) A fluoroscopic image shows successful stent placement. (f) An endoscopic image shows successful stent placement. EUS-PD, endoscopic ultrasound-guided pancreatic duct drainage; MPD, main pancreatic duct.

Figure 3. EUS-PD using the novel plastic stent (above the stricture of the pancreatic duct)

(a) A fluoroscopic image demonstrates a transgastric pancreatogram, and a 0.025-inch guidewire cannot be passed across the stricture of the MPD. Thus, the guidewire is inserted downstream to the papilla as far as possible for the stenting that follows. (b) A fluoroscopic image shows the novel plastic stent being placed into the pancreatic duct above the stricture

of the MPD. (c) A fluoroscopic image shows successful stent placement. (d) An endoscopic image shows successful stent placement. EUS-PD, endoscopic ultrasonography-guided pancreatic duct drainage; MPD, main pancreatic duct.

Figure 4. Kaplan–Meier curve illustrating the time to recurrent pancreatic obstruction

The median follow-up period is 44 days (25–272 days). The median time to RPO is not reached (95% CI: 43–NA). RPO-free rates at 30 and 90 days are 100% and 83.3%, respectively. RPO, recurrent pancreatic duct obstruction; CI, confidence interval

Figure 5. Timeline of the clinical course

AC, ampullary cancer; GC, gastric cancer; PC, pancreatic cancer; PJAS, pancreaticojejunal anastomosis strictures; RI, reintervention; RPO, recurrent pancreatic duct obstruction

TABLES

Table 1. Patient characteristics

Patient characteristics	**N=10**
Age, years	69 (17–84)
Male sex	6 (60.0%)
Primary disease	
- Benign stricture	5 (50.0%)
- Pancreaticojejunal anastomotic stricture	5 (50.0%)
- Malignant stricture	5 (50.0%)
- Pancreatic cancer	3 (30.0%)
- Ampullary cancer	1 (10.0%)
- Gastric cancer	1 (10.0%)
Indication for pancreatic duct drainage	
- Obstructive pancreatitis	7 (70.0%)
- Pancreatic fistula or pseudocyst	3 (30.0%)
Stricture site	
- Pancreaticojejunal anastomosis	5 (50.0%)
- Main pancreatic duct	2 (20.0%)
- Duodenal papilla	3 (30.0%)
Reason EUS-PD was needed	
- Failure to approach through the anastomosis	5 (50.0%)
- Unsuccessful cannulation	3 (30.0%)
- Unreachable	2 (20.0%)

- Failure to approach through the papilla	5 (50.0%)
- Unsuccessful cannulation	3 (30.0%)
- Unreachable	2 (20.0%)

Data are presented as n (%) or medians (ranges).

EUS-PD, endoscopic ultrasound-guided pancreatic duct drainage

Table 2. Procedural details of EUS-PD

Procedural details	N=10
Type of echoendoscope	
- Oblique-viewing	8 (80.0%)
- Forward-viewing	2 (20.0%)
MPD diameter, mm	4.0 (2.0–12.0)
Puncture site	
- Stomach	10 (100%)
Puncture needle	
- 19-gauge FNA needle	10 (100%)
Guidewire	
- 0.025-inch	10 (100%)
Device for tract dilation	
- 7-Fr bougie dilator	8 (80.0%)*
- 7-Fr spiral dilator	2 (20.0%)
- 4 mm-diameter balloon dilator	1 (11.1%)*
Stent diameter	
- 6-Fr	10 (100%)
Effective length of the stent	
- 12 cm	5 (50.0%)
- 15 cm	5 (50.0%)
Stenting style	
- From the stomach to the MPD	6 (60.0%)

- From the stomach to the intestine	4 (40.0%)

Data are presented as n (%) or medians (ranges).

*Duplicated number

EUS-PD, endoscopic ultrasound-guided pancreatic duct drainage; MPD, main pancreatic duct; FNA, fine-needle aspiration

Table 3. Clinical outcomes

Clinical outcomes	N=10
Technical success	10/10 (100%)
- Obstructive pancreatitis	7/7 (100%)
- Pancreatic fistula or pseudocyst	3/3 (100%)
Clinical success	10/10 (100%)
- Obstructive pancreatitis	7/7 (100%)
- Pancreatic fistula or pseudocyst	3/3 (100%)
Procedure time, min	28 (19–47)
Adverse events	1 (10.0%)
- Mild abdominal pain	1 (10.0%)
RPO	1 (10.0%)
TRPO, median (95% CI), days	not reached (43–NA)
Reintervention*	3 (30.0%)
Asymptomatic stent dislodgement	1 (10.0%)
Death	2 (20.0%)
Follow-up period, days	44 (25–272)

Data are presented as n (%) or medians (ranges).

* All patients underwent scheduled stent exchange or removal; one patient with RPO did not undergo reintervention due to a deteriorating general condition.

RPO, recurrent pancreatic duct obstruction; TRPO, time to recurrent pancreatic duct obstruction; NA, not available; CI, confidence interval

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