

A two-center comparative study of plastic and lumen-apposing large diameter self-expandable metallic stents in endoscopic ultrasound-guided drainage of pancreatic fluid collections

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ABSTRACT

Background and Objectives: Endoscopic ultrasound-guided drainage of walled-off pancreatic fluid collections (PFCs) (pseudocyst [PC]; walled-off necrosis [WON]) utilizes double pigtail plastic stents (PS) and the newer large diameter fully covered self-expandable stents (FCSEMS) customized for PFC drainage. This study examined the impact of type of stent on clinical outcomes and costs. **Patients and Methods:** Retrospective two-center study. Outcome variables were technical and clinical success, need for repeat procedures, need for direct endoscopic necrosectomy (DEN), and procedure-related costs. **Results:** A total of 49 (PC: 31, WON: 18) patients were analyzed. Initially, PS was used in 37 and FCSEMS in 12. Repeat transmural drainage was required in 14 (PS: 13 [9 treated with PS, 4 treated with FCSEMS]; FCSEMS: 1 [treated with PS]) due to stent migration (PS: 3; FCSEMS: 1) or inadequate drainage (PS: 10). Technical success was 100%. Initial clinical success was 64.9% (25/38) for PS *versus* 91.7% (11/12) for FCSEMS ($P = 0.074$). With repeat transmural stenting, final clinical success was achieved in 94.6% and 100%, respectively ($P = 0.411$). Compared to FCSEMS, PS was associated with greater need for repeat drainage (34.2% *vs.* 6.3%, $P = 0.032$). The need for and frequency of DEN was similar between both groups, but PS required more frequent balloon dilatation. PS was significantly cheaper for noninfected PC. Costs were similar for infected PC and WON. **Conclusion:** PS was associated with a higher need for a second drainage procedure to achieve clinical success. The use of FCSEMS did not increase procedural costs for infected PC and WON.

Key words: Endosonography, endotherapy, necrosectomy, pancreatic necrosis, pseudocyst

INTRODUCTION

Pseudocysts (PCs) may arise after severe acute pancreatitis, chronic pancreatitis, or surgery while

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walled-off necrosis (WON) may complicate acute severe necrotizing pancreatitis.^[1] These walled-off pancreatic fluid collections (PFCs) require drainage when symptomatic, such as in the case of infection or mass effect.^[2] Endoscopic ultrasound (EUS)-guided drainage is now firmly established as the best option for drainage of walled-off PFC.^[2] It has high clinical efficacy, similar to surgical and percutaneous approaches, but with lower morbidity and costs.^[3,4] It is superior to non-EUS-guided approaches because even collections without endoluminal bulging can be successfully drained.^[5,6] When intervention is required for symptomatic PFC, specific steps must be considered: (1) drainage of the collection; (2) treatment of persistent pancreatic duct disruption; and (3) in the context of WON, the need for adjunctive measures such as direct endoscopic necrosectomy (DEN).^[7,8] Double pigtail plastic stents (PS) are used traditionally for transmural drainage, and these are removed after resolution of the PFC.^[1] In recent years, with the development of removable fully covered self-expandable stents (FCSEMS) customized for PFC drainage, FCSEMS are increasingly utilized, especially in cases of infected PC and WON, because these large diameter stents facilitate drainage and repeat entry of the endoscope into the cavity for DEN.^[9-13] Limited comparative studies suggest similar efficacy between PS and FCSEMS.^[14,15] The higher cost of FCSEMS compared to PS is a concern. This two-center study examined the impact of type of stent on procedural and clinical outcomes and overall procedure-related costs.

PATIENTS AND METHODS

Study design and patient selection

This was a retrospective study involving Changi General Hospital, Singapore, and King Chulalongkorn Memorial Hospital, Thailand. All patients who underwent EUS-guided drainage of PFC during the period from November 2006 to December 2015 were identified from a database, and the clinical data were reviewed. Inclusion criteria were all patients with PC or WON who underwent EUS-guided drainage. Exclusion criteria were intra-abdominal collections which were not PFC and non-EUS-guided drainage procedures. The study was approved by the institutional review boards.

Definitions of outcome measures and complications

Technical success was defined as successful placement of a transmural stent. Clinical success was defined as

complete resolution or a decrease in size of the PFC to 2 cm or smaller on follow-up imaging associated with the resolution of symptoms. Recurrence was defined as a PFC found on imaging associated with symptoms after initial resolution. Reintervention was defined as the need for repeat surgery or endoscopy due to persistent symptoms in association with a residual PFC that was not <50% of the original size on follow-up imaging.^[4,16]

Perforation was diagnosed when there was pneumoperitoneum on imaging studies associated with peritoneal signs. Bleeding was defined as any hemorrhagic event that required intervention, blood transfusion, or inpatient observation. Secondary infection was diagnosed if septic events characterized by new-onset fever, elevated inflammatory markers such as C-reactive protein or procalcitonin, positive blood or fluid cultures, occurred after the initial drainage and were attributed to contamination of the PFC.^[4-6,16] Stent migration was defined as the movement of the stent completely into the PFC or out into the enteral lumen, resulting in persistence and nonresolution of the PFC. Depending on whether the migrated stent had passed out spontaneously, it may or may not require endoscopy for removal.

Technique of endoscopic therapy

EUS-guided drainage was performed under sedation using combination of intravenous midazolam and fentanyl. Patients received prophylactic intravenous antibiotics such as ceftriaxone or ciprofloxacin before drainage if the collection was sterile, and in the case of infected collections, they were continued on the appropriate antibiotics before and after drainage, until clinical resolution of the infection. The PFC was visualized using a therapeutic linear echoendoscope and punctured by a 19G needle [Figure 1]. A 0.035" guidewire was introduced through the needle and coiled within the PFC. The puncture tract was dilated to allow stent placement. The devices used for tract dilation were at the discretion of the endoscopist and included mainly a 6-Fr biliary dilator, as well as cautery-based devices such as wire-guided needle knife or cystotome catheter. Further dilation was performed using an over-the-wire balloon dilator to 8 mm and either PS [Figure 2] or 16 mm diameter, 20–30 mm long FCSEMS (Nagi™ Stent Taewoong-Medical Co., Seoul, South Korea) [Figure 3] were inserted under combined endoscopic and fluoroscopic guidance. The number of PS inserted was at discretion of the endoscopists



Figure 1. Endoscopic ultrasound image of puncture of walled-off necrosis by 19G needle

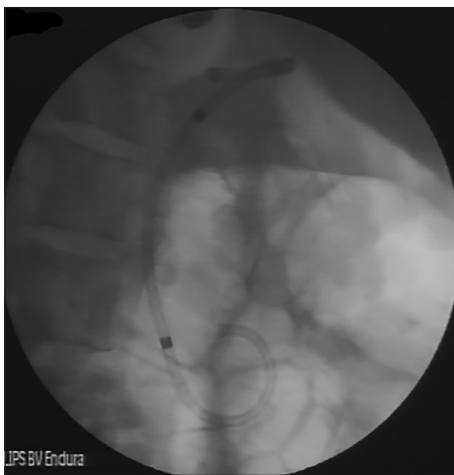


Figure 2. X-ray image of a double pigtail stent deployed for transmural drainage of pseudocyst



Figure 3. Endoscopic image of NagiTM stent inserted for drainage of infected walled-off necrosis

and ranged from 1 to 2, with most having one PS inserted. Short-term nasocystic drainage was used in some patients to provide additional irrigation especially in the context of infection during the initial cases,

but this was not routine. Patients were then followed up clinically and with cross-sectional imaging. In the event of lack of resolution, due to stent migration or inadequate drainage from a single PS, repeat drainage procedures were performed, such as repeating the entire EUS-guided drainage or gastroscopy and insertion of additional PS or change of type of stent through the opening to the PFC, with or without repeat balloon dilatation. When there was a lack of clinical response to transmural drainage alone in the context of infected PC or WON, DEN was performed. When available, CO₂ insufflation was used during DEN, which was performed under sedation using combination of intravenous midazolam and fentanyl. If PS had been inserted for initial drainage, balloon dilatation of the opening of the WON cavity to 15 mm was performed to allow insertion of a gastrocope. If FCSEMS had been inserted, it was possible to insert the endoscope across the FCSEMS into the WON cavity without the need for balloon dilatation. The first step was to irrigate and aspirate the smaller loose debris. Accessories such as dormia basket and retrieval net were used to gently remove the solid material within the cavity. DEN sessions were repeated until removal of most solid debris was achieved [Figures 4 and 5]. Among patients with PS, repeat balloon dilatation of the WON opening was performed if narrowing occurred in between DEN sessions. Cross-sectional imaging was performed to document resolution of the PFC before stent removal. All FCSEMS were removed within 3 months. The pancreatic duct was assessed by endoscopic retrograde cholangiopancreatography (ERCP) or magnetic resonance cholangiopancreatography and stented if disruption was present.

Assumptions for cost analysis

The procedure-related costs were determined by the procedural and facility fees, and costs of accessories and medication used [Table 1]. As there were differences in the accessories used for different patients such as types of puncture needles, guidewires, as well as intrinsic healthcare cost differences between Singapore and Thailand, a standardized drainage technique with common accessories was assumed and all costs were based on current treatment costs in Singapore. The accessories included for cost analysis were those most frequently used. The premise was full costs involved from a private payee perspective, without taking into account national subsidization. The cost for EUS drainage procedure involved facility, professional and reprocessing charges, and the use of 19G Echotip®



Figure 4. Endoscopic image of the solid debris within the cavity of the infected walled-off necrosis, before endoscopic necrosectomy

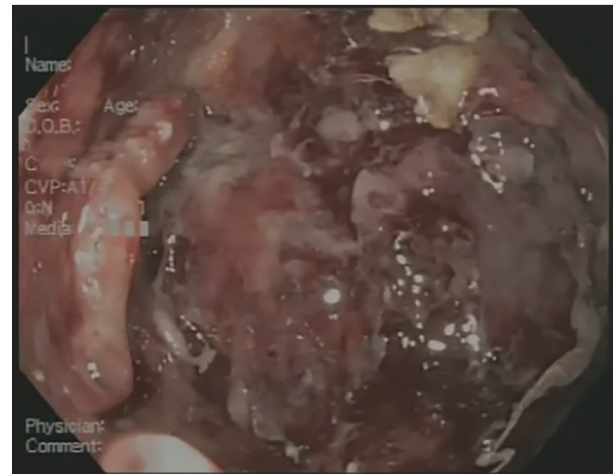


Figure 5. Endoscopic image of the clean granulating wall within the cavity of the infected walled-off necrosis after successful endoscopic necrosectomy

Table 1. Cost assumptions for procedures and accessories

Endoscopic accessories and procedures	Cost (Singapore \$)
19G Echetip® needle (Cook Medical, Winston-Salem, USA)	320
0.035” Jagwire™ (Boston Scientific, Natick, MA, USA)	140
6-Fr Soehendra® Biliary Dilation Catheter (Cook)	90
CRE™ Balloon Dilatation Catheter system (Boston Scientific)	540
Solus® Double Pigtail Stent (Cook Medical)	230
Nagi™ Stent (Taewoong-Medical Co., Seoul, South Korea)	1800
Classic ERCP Catheter (Cook Medical)	100
EUS drainage procedure (excludes cost of stents)	3209
DEN using Dormia basket	1125
Gastroscopy guided stent insertion (excludes cost of stents)	639

DEN: Direct endoscopic necrosectomy, EUS: Endoscopic ultrasound

needle (Cook Medical, Winston-Salem, USA), 0.035” Jagwire™ (Boston Scientific, Natick, MA, USA), 6-Fr Soehendra® Biliary Dilation Catheter (Cook Medical), CRE™ Balloon Dilatation Catheter (Boston Scientific), and then 1 or more Solus® double pigtail stent (Cook Medical) or a single Nagi™ stent (Taewoong-Medical Co., Seoul, South Korea). In the case of salvage drainage procedures to insert additional PS or change of stent type, the costs were that of gastroscopy charges and costs for a standard ERCP catheter (Cook Medical), 0.035” Jagwire™, and then 1 or more Solus® double pigtail stents or a single Nagi™ stent. DEN was assumed to be performed using a gastroscope with dormia basket only, and the cost of dormia basket was assigned as zero as it could be reprocessed. If

additional balloon dilatation to facilitate gastroscope entry into the cavity for DEN was needed, the costs would be that of gastroscopy and use of standard ERCP catheter, 0.035” Jagwire™, CRE™ Balloon Dilatation Catheter, and dormia basket.

Statistics

The outcome measures to be evaluated were technical and clinical success rates, need for repeat procedures, need for and frequency of DEN, complications, and procedure-related costs. The differences in clinical outcomes between FCSEMS and PS were analyzed using Chi-square or Fisher’s exact test. The difference in costs was analyzed using *t*-test. *P* < 0.05 was considered statistically significant. All statistical analyses were performed by SPSS version 19.0 software for Windows (SPSS Inc., Chicago, Illinois, USA). All authors had access to study data and approved the final manuscript.

RESULTS

Clinical demographics

A total of 49 patients (Singapore 34, Thailand 15) with PFC (PC with mass effect: 24, infected PC: 7; infected WON: 18) were analyzed. The mean diameter of PFC was 10.8 cm (range: 4–19). The locations of the PFC were pancreatic head (3), body (4), body and tail (38), and tail (4). The underlying etiologies were severe pancreatitis (34), postpancreatic surgery (5), postabdominal trauma (1), and chronic pancreatitis (9). FCSEMS were used in 16 cases (12 had FCSEMS inserted as the initial drainage device, and 4 had

FCSEMS insertion after unsuccessful drainage with PS) while 33 were treated with only PS. Adjunctive PD stenting was required in 33% (16/49) due to the presence of PD disruption. Significantly more patients in the PS group underwent PD stenting compared to the FCSEMS group (45.5% [15/33] vs. 6.3% [1/16], $P = 0.006$). The PD disruption resolved after stenting in all patients, except for one in the PS group who underwent additional successful cyanoacrylate sealing of the persistent leak during ERCP. The baseline clinical data were similar between those treated with PS and FCSEMS [Table 2].

Clinical outcomes

The initial drainage device used was PS in 37 (1 PS: 27; 2 PS: 10 [PC with mass effect: 2/18; infected PC: 1/6; WON: 7/13]) and FCSEMS in 12. Repeat endoscopic transmural drainage was required in 14 (PS: 13 [9 treated with PS, 4 treated with FCSEMS]; FCSEMS: 1 [treated with PS]) due to stent migration (PS: 3; FCSEMS: 1) or inadequate drainage (PS: 10). The technical success rate of EUS-guided drainage was 100%. Clinical success after the index drainage was 64.9% (25/38) for PS versus 91.7% (11/12) for FCSEMS ($P = 0.074$). With repeat transmural stenting,

on intent to treat basis, clinical success was achieved by PS group in 94.6% (35/37) and by FCSEMS group in 100% (12/12) ($P = 0.411$). The overall clinical success rate was 95.9% (47/49). One patient had perforation after PS insertion and needed surgery while another opted for surgery after recurrence of PFC following PS migration. When PS was compared to FCSEMS, the stent migration rate tended to be higher (18.4% [7/38] vs. 6.3% [1/16], $P = 0.250$) and the need to repeat drainage despite correct stent placement with no migration was significantly greater (26.3% [10/38] vs. 0; $P = 0.023$). Overall, the need for repeat drainage after PS compared to FCSEMS was significantly higher (34.2% [13/38] vs. 6.3% [1/16], $P = 0.032$). There was no difference in the need for DEN for those treated by PS compared to FCSEMS (40.5% [15/37] vs. 33.3% [4/12], $P = 0.656$). DEN was performed in 19/49, with mean of 2 sessions (range: 1–7). The number of DEN sessions was similar between PS and FCSEMS groups but there was more frequent balloon dilatation of the WON opening before each DEN session in the PS group due to narrowing of the opening in between DEN sessions (median: 1 [range: 1–3] vs. 0; $P = 0.022$). Complications occurred in 5 after PS insertion (perforation: 1; bleeding needing transfusion: 2; pneumoperitonum: 1; secondary infection of PC: 1) but not after FCSEMS insertion ($P = 0.117$) [Table 3].

Table 2. Clinical data of patients who underwent endoscopic drainage of pancreatic fluid collections

Parameters	PS (n=33)	FCSEMS (n=16)	P
Mean age (years)	56	50	0.231
Male:female ratio	18:15	7:9	0.478
Type of PFC (PC with mass effect:infected PC:WON)	17:6:10	7:1:8	0.310
Mean diameter of PFC (cm)	10.9	10.7	0.849

FCSEMS: 12 inserted at 1st procedure, 4 inserted at 2nd procedure. FCSEMS: Fully covered self-expandable stent, PC: Pseudocyst, PFC: Pancreatic fluid collection, PS: Plastic stent, WON: Walled-off necrosis

Table 3. Clinical outcome after endoscopic drainage of pancreatic fluid collections

Parameters	PS (37) (%)	FCSEMS (12) (%)	P
Technical success rate	100	100	1
Stent migration rate*	18.4 (7/38)	6.3 (1/16)	0.250
Need for repeat drainage due to stent migration*	7.9 (3/38)	6.3 (1/16)	0.833
Rate of inadequate drainage despite correct stent placement with no migration*	26.3 (10/38)	0	0.023
Initial clinical success rate	64.9 (24/37)	91.7 (11/12)	0.074
Final clinical success rate after repeat drainage	94.6 (35/37)	100 (12/12)	0.411
Complication	5/37	0	0.179
Mean procedural cost**	\$5402	\$5894	0.516

*Cross-overs of stents included in analysis, **Cost was based on Singapore dollars. FCSEMS: Fully covered self-expandable metallic stent, PS: Plastic stent

Differences in procedure-related costs

The total procedure-related costs between those initially treated with PS and FCSEMS were compared. These costs include the costs of repeat drainage procedures and adjunctive DEN. Overall for all PFC, the mean procedural costs of PS versus FCSEMS were \$5402 versus \$5894 ($P = 0.516$). The cost of drainage of different types of PFC for PS versus FCSEMS was then analyzed. In the context of all PC, infected PC only, PC with mass effect only, and PFC needing DEN, the costs were \$4340 versus \$5164 ($P = 0.009$), \$4816 versus \$5554 ($P = 0.575$), \$4182 versus \$5190 ($P = 0.038$), and \$7362 versus \$6916 ($P = 0.760$), respectively.

DISCUSSION

Transmural drainage of PFC has traditionally been achieved with the use of double pigtail PS, and high efficacy has been demonstrated. In recent years, there are increasing reports concerning the use of FCSEMS.

The initial reports utilized short biliary FCSEMS such as the Wallflex stent (Boston Scientific). Apart from higher costs compared to PS, these FCSEMS are also not optimal for drainage because of the higher risk of migration due to a lack of lumen apposition and excessive length. Subsequently, FCSEMS customized for PFC drainage were designed.^[17] These FCSEMS had shorter lengths of 1–3 cm to reduce the degree of protrusion, a diameter of 10–16 mm to allow effective drainage and wide flanges at the ends to reduce the risk of migration and even facilitate to some degree lumen apposition.^[9,12,18]

In a recently published systematic review, Bang *et al.* reported that there was no difference in overall treatment success between patients treated with PS and FCSEMS (81% vs. 82%) for both PC (85% vs. 83%) and WON (70% vs. 78%) and that there was no difference in the rates of adverse events (16% vs. 23%) or recurrence (10% vs. 9%).^[19] In this review, there were 9 cohort studies that utilized FCSEMS and 8 that utilized PS. None of these were direct comparative studies between FCSEMS and PS; these studies examined different patient populations with procedures performed by different endoscopists. In addition, among the 9 FCSEMS studies, only 3 noncomparative studies utilized FCSEMS customized for PFC (Itoi *et al.*: AXIOS [Xlumena Inc., Mountain View, CA, USA], $n = 15$;^[9] Gornals *et al.*: AXIOS, $n = 8$;^[20] Yamamoto *et al.*: Nagi™ stent, $n = 9$).^[21] In contrast, in a retrospective comparative study of PS with short (40–60 mm long) biliary FCSEMS (WallFlex biliary stent [Boston Scientific] or a GORE VIABIL stent [GORE, Utica, NY, USA]), Sharaiha *et al.* reported that complete resolution of PFC using PS was lower compared to FCSEMS (89% vs. 98%; $P = 0.01$), and procedural adverse events were higher in the PS group (31% vs. 16%, $P = 0.006$).^[22] The results of recent noncomparative cohort studies that evaluated the use of customized FCSEMS for drainage of PFC are summarized in Table 4.^[9-13,21,23-26]

Our study is the first study that compared directly PS with the Nagi™ stent, FCSEMS designed specifically for drainage of PFC. It was clear that the Nagi™ stent facilitated the drainage, with there being a significantly lower need to intervene a second time for drainage. The clinical success rate after the initial PS placement in our study was somewhat lower than other published studies. This could be explained by the presence of infected necrotic collections as well as early stent

migration, necessitating a repeat drainage procedure, which ultimately increased the final clinical success rate. In addition, FCSEMS also facilitated DEN, decreasing the need for balloon dilatation of the WON opening. In terms of costs, overall, there was no difference between the use of PS and FCSEMS. However, PS was significantly cheaper in the context of PC, in particular noninfected PS. Costs were similar in the context of infected PC and WON. In fact, there was a nonsignificant trend to lower cost with FCSEMS in patients requiring DEN. Although costs were lower with the use of PS for uninfected PC, given the greater need for reintervention with the use of PS and the ease of insertion of FCSEMS, the decision on type of stent to be used should be individualized. We acknowledge the limitations of our study. It was retrospective in nature and the sample size was relatively small. We did not examine the issue of long-term recurrence because this would be a reflection of the presence of persistent PD disruption and not be dependent on the type of stent.

Apart from our study, only two other studies have directly compared PS with FCSEMS customized for PFC drainage. Lee *et al.* performed a prospective randomized study that compared PS with the BONA-Soo stent (Standard Sci. Tech. Inc., Seoul, South Korea), FCSEMS with a flare at the proximal end and a flap at the distal end that had a 90° angulation intended to prevent proximal migration after stent placement. The technical success rate (100%) and clinical success rates (20/23 vs. 20/22) were similar between FCSEMS and PS. However, the procedural time for FCSEMS was significantly shorter.^[14] In a retrospective study, Mukai *et al.* compared PS with various biflanged FCSEMS (AXIOS, 16 mm Niti-S [Taewoong Medical, Seoul, Korea] and 12 mm Hanaro [MI Tech, Seoul, Korea]) in the drainage of WON. There were no differences in rates of technical success, clinical success, and adverse events between PS and FCSEMS. However, the mean procedural times were significantly shorter with FCSEMS. Total costs were similar in both groups.^[15] The AXIOS FCSEMS were recently modified to include an electrocautery-enhanced delivery system. This allowed large diameter stent insertion in a single step, without the need for additional puncture tract dilation and could even bypass the traditional initial step of 19G needle puncture and guidewire insertion.^[25] The Wallflex FCSEMS were previously used in the drainage of PFC with indeterminate adherence to the luminal wall. It

Table 4. Summary of published clinical outcome data after endoscopic drainage of pancreatic fluid collections using lumen-apposing fully covered self-expandable metallic stents'

Author	n	PFC	Stent	Success rate (%)		Complication
				Technical	Clinical	
Itoi <i>et al.</i> ^[9]	15	PC	AXIOS	100	100	Migration: 1
Yamamoto <i>et al.</i> ^[21]	9	PC: 5 WON: 5	Nagi™	100	77	Bleeding: 1 Migration: 1
Moon <i>et al.</i> ^[12]	4	PC: 3 WON: 1	Niti-S Spaxus	100	100	0
Chandran <i>et al.</i> ^[13]	47	PC: 39 WON: 9	Nagi™	98.1	76.6	Early: 10 (21%) Late: 14 (29.7%)
Walter <i>et al.</i> ^[10]	61	PC: 15 WON: 46	AXIOS	98	93	Migration: 3 Dislodgement: 3 Infection: 4 Perforation: 1
Shah <i>et al.</i> ^[11]	33	PC: 22 WON: 11	AXIOS	91	93	Pain: 3 Migration: 1 Dislodgement: 1
Dhir <i>et al.</i> ^[23]	47	PC	Nagi™	91.4	87.2	Fever: 2
Bapaye <i>et al.</i> ^[24]	19	AFC: 1 PC: 9 WON: 11	Nagi™	100	100	Splenic artery erosion and bleeding: 1
Rinninella <i>et al.</i> ^[25]	93	PC: 37 WON: 52 AFC: 4	Hot AXIOS	98.9	93.5	Perforation: 1 Massive bleeding: 1 Pneumoperitoneum: 1 Stent dislodgement: 1 Secondary infection: 1
Siddiqui <i>et al.</i> ^[26]	82	PC: 12 WON: 68	AXIOS	97.5	PC: 100 WON: 88.2	Stent maldeployment: 2 (1 perforation treated with surgery) Minor bleeding: 1

AFC: Acute fluid collection, PC: Pseudocyst, PFC: Pancreatic fluid collection, WON: Walled-off necrosis

would be expected that lumen-apposing FCSEMS would be even for suited for this indication.^[27]

In our study, 5 of the PFC occurred after pancreatic surgery. All were successfully treated endoscopically. In the past, percutaneous drainage had been the main modality for treatment, but the results of published data and our data have shown that EUS-guided drainage is highly effective and safe, once these postoperative collections have walled-off, similar to PFC occurring after pancreatitis.^[28,29] In fact, as these are fluid collections without any solid debris, it may be expected that the overall treatment success rate may be somewhat higher than in the context of PFC due to WON that occur after severe necrotizing pancreatitis.

CONCLUSION

The Nagi™ FCSEMS were highly effective for drainage of PFC. It decreased the need for repeat interventions compared to PS. The costs were similar to PS in the context of infected PC and WON.

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Conflicts of interest

There are no conflicts of interest.

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