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Review

Endoscopic ultrasonography-guided drainage of pancreatic fluid collections

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Endoscopic ultrasound (EUS)-guided drainage is now firmly established as the best option for drainage of walled-off pancreatic fluid collections (PFC). It has high clinical efficacy, similar to surgical and percutaneous approaches, but with lower morbidity and costs. It is superior to non-EUS-guided approaches because even collections without endoluminal bulging can be successfully drained. Transmural drainage alone is sufficient for pseudocysts, but in the context of walled-off pancreatic necrosis (WON), adjunctive direct endoscopic necrosectomy (DEN) may be required. Traditionally, double pigtail plastic stents (PS) were used for transmural drainage, but, recently, fully covered self-expandable metallic stents (FCSEMS) customized for PFC drainage have become available and are increasingly used, especially in the management of WON, because the larger-diameter stent facilitates drainage and insertion of an endoscope into the WON cavity for DEN. The present review will discuss the evidence for EUS-guided drainage and DEN, the technical problems involved, and the roles of PS and FCSEMS in PFC drainage.

Key words: endoscopic necrosectomy, endoscopic ultrasound, pseudocyst, self expandable metallic stents, walled-off necrosis

INTRODUCTION

WALLED -OFF PANCREATIC FLUID collections (PFC) can be categorized into pseudocysts (PC) and walled-off necrosis (WON). PC can arise as a consequence of severe acute pancreatitis, chronic pancreatitis, trauma and pancreatic surgery. WON is a late complication of acute severe necrotizing pancreatitis. The key difference between PC and WON is the presence of solid necrotic debris within WON.[1,2] Drainage is required when symptoms such as mass effect or infection occur (Fig. 1). In addition to drainage of the collection, one must consider problems such as management of persistent pancreatic duct disruption and, in the context of WON, the need for adjunctive measures such as surgical necrosectomy or direct endoscopic necrosectomy (DEN).[3] Endoscopic ultrasound (EUS)-guided drainage is now firmly established as the best option for drainage of walled-off PFC.[3,4] It has high clinical efficacy, similar to surgical and percutaneous approaches, but with lower morbidity and costs. A prerequisite for EUS-guided drainage and DEN is the presence of a well-defined mature wall. This usually requires a time frame of 4–6 weeks from onset of disease. Traditionally, double pigtail plastic stents (PS) were used for transmural drainage, but, recently, fully covered self-expandable metallic stents (FCSEMS) customized for PFC drainage have become available and are increasingly used. Significant controversy still exists in the best management of PFC and the establishment of Asian EUS group consensus guidelines is in progress. This review will discuss the evidence for EUS-guided drainage and DEN, the technical issues involved and the roles of PS and FCSEMS.

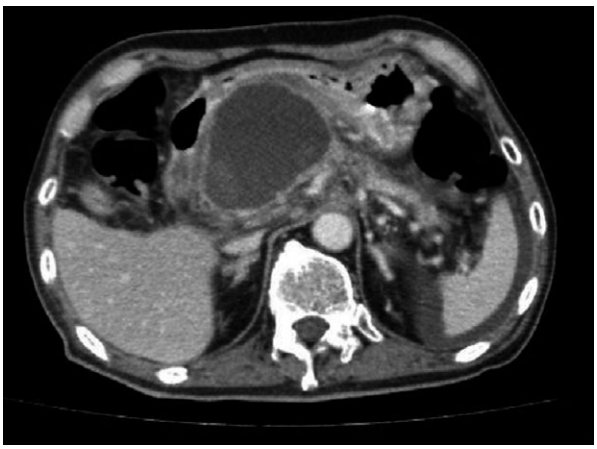

Figure 1 Computed tomography view of infected walled-off pancreatic necrosis.

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ROLE OF EUS-GUIDED DRAINAGE

WITH THE USE of EUS, the nature of the PFC, and its suitability for endoscopic drainage, can be assessed.[4,5] EUS can evaluate for interposed vessels prior to endoscopic drainage, potentially reducing the risk of vessel puncture and bleeding.[6] EUS provides real-time ultrasonic guidance of the drainage procedure. Two randomized controlled studies compared EUS-guided with non-EUS-guided endoscopic transmural drainage of PC. EUS was shown to achieve significantly higher success rates (14/14 [100%] *vs* 5/15 [33%], $P < 0.001$,[7] and 29/31 [94%] *vs* 21/29 [72%], $P = 0.039$[8]) as a result of the ability of EUS to visualize PC without endoluminal bulging and guide access to the PC cavity. Cases that failed non-EUS-guided drainage were all successfully treated with EUS-guided drainage. The two cases that failed EUS-guided drainage had PC located at the uncinate region and these were successfully treated with simple aspiration.[8] A prospective non-randomized study assigned non-EUS-guided drainage to PC with endoluminal bulging, whereas the rest of those without luminal bulging underwent EUS-guided drainage. Similar success rates were achieved in both groups (93% *vs* 94%), highlighting the fact that the main value of EUS is to visualize and guide access to non-bulging PC.[9] One randomized study compared EUS-guided PC drainage with surgical cystogastrostomy.[10] Clinical outcomes between EUS-guided drainage and surgery were similar (success rate: 19/20 [95%] *vs* 20/20 [100%], $P = 0.5$; complications: 0 *vs* 2/20 [10%], $P = 0.24$). However, patients who underwent EUS-guided drainage had a significantly shorter median hospital stay (2 days *vs* 6 days, $P < 0.001$) and incurred significantly lower mean costs (US$7011 *vs* US$15052, $P = 0.003$). This study confirmed the results of an earlier retrospective study by the same authors.[11] Another retrospective study that compared EUS, laparoscopic and open cystogastrostomy reported primary success rates of 51.1% versus 87.5% *vs* 81.2%, with the surgical success rates significantly higher than the EUS success rate ($P < 0.01$). However, the rate of clinical success in the EUS group was unusually low at 51.1% with a high rate of complications, in contrast to published prospective studies.[12] This may indicate that endoscopists carrying out the procedures were still overcoming their learning curves and the difference in outcomes may not be truly representative of the techniques. No study has specifically compared EUS-guided drainage with percutaneous drainage.[4] However, endoscopic drainage has been compared with percutaneous drainage in retrospective studies. Percutaneous drainage was associated with higher rates of re-interventions including surgery and longer lengths of hospital stay compared to endoscopic drainage.[13,14] In contrast, a systemic review comparing the outcomes of endoscopic, percutaneous and surgical pancreatic pseudocyst drainage has identified 10 comparative studies. Based on a large-scale national study, surgical drainage appeared to reduce mortality and adverse events rate as compared to the percutaneous approach. Regarding EUS-guided and surgical drainage, clinical success and adverse events rates appeared to be comparable, but the EUS approach reduced hospital stay, cost and improved quality of life. EUS- and esophagogastroduodenoscopy (EGD)-guided drainage were both feasible for pseudocyst drainage but the success rate of the EUS approach was better for non-bulging cyst and the approach conferred additional safety benefits. Thus, the systematic review concluded that EUS-guided drainage appeared to be advantageous in drainage of pancreatic pseudocysts located adjacent to the stomach or duodenum. In patients with unfavorable anatomy, surgical cystojejunostomy or percutaneous drainage could be considered.[4]

TECHNIQUE OF EUS-GUIDED DRAINAGE

EUS-GUIDED DRAINAGE IS carried out in the endoscopy center with the patient in the left lateral position and under conscious sedation. A therapeutic linear echoendoscope is used to visualize the PFC and target the access site for puncture and drainage, with interposed blood vessels being excluded by Doppler. A 19-G needle is inserted into the collection (Fig. 2), the inner stylet withdrawn and then a 0.035" guidewire is inserted through the needle and coiled within the PFC, under concomitant fluoroscopic guidance (Fig. 3). The puncture tract is then dilated using either coaxial dilators such as the 6 Fr

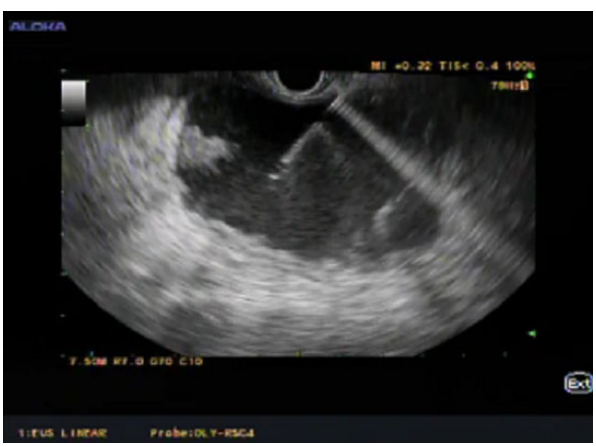

Figure 2 Pseudocyst punctured by a 19 G needle under endoscopic ultrasound guidance.

Soehendra dilator, or a cautery device such as a 6 Fr cystotome, before further balloon dilatation to 8 or 10 mm. A double pigtail PS (7 or 10 Fr diameter) is then inserted for transmural drainage under combined endoscopic and fluoroscopic guidance.[3] To facilitate insertion of multiple transmural PS or additional nasocystic drainage catheter, variations of double guidewire techniques have been described (Fig. 4). These techniques essentially allow insertion of two guidewires simultaneously into the cavity prior to stent placement, and obviate the need to cannulate and regain access to the PFC after placement of the first PS, which can be challenging as a result of the tangential puncture tract and poor visibility from the fluid pouring out into the gut lumen.[15–17]

FCSEMS designed for EUS-guided drainage are now available.[18–20] These FCSEMS include the AXIOS stent[18] (Boston Scientific, Natick, MA, USA) (Fig. 5), NAGI™ stent[19] (Fig. 6) and SPAXUS™ stent[20] (Fig. 7) (Taewoong Medical, Gyeonggi-do, South Korea). They have diameters ranging from 10 to 16 mm, and lengths ranging from 10 to 30 mm. The stents are designed for EUS-guided deployment and are characterized by the presence of flanges at both ends and a short stent length. In an *ex-vivo* study in which 64 anastomoses were created (cholecysto-gastric, cholecysto-duodenal, gastro-gastric and gastro-jejunal), the lumen-apposing forces measured were significantly higher for the AXIOS and SPAXUS stents and it was suggested that these stents should be used for non-adherent organs.[21] In terms of stent insertion, the delivery system of these FCSEMS is inserted into the cavity along the guidewire, similar to PS. Radiopaque markers to guide placement are present for these stents. The NAGI™ and SPAXUS™ stents are deployed by simple retraction of a catheter sheath, whereas deployment of the AXIOS stent is characterized by a Luer lock mechanism that allows independent deployment of distal and proximal stent anchors. A hot AXIOS stent comes with an electrocautery wire at the distal tip of the delivery system (Fig. 8). The electrocautery tip allows passage of the catheter into the PFC (Fig. 9) without the need for prior dilation of the tract. It can be advanced along a guidewire that is inserted after initial puncture with a 19 G needle, or it can be used to directly access the PFC under EUS guidance.[22]

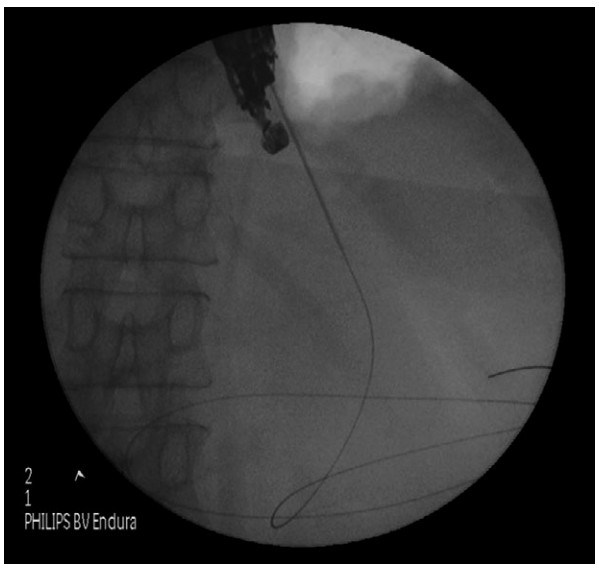

Figure 3 Fluoroscopic image of guidewire inserted into the pancreatic collection.

ROLE OF DIRECT ENDOSCOPIC NECROSECTOMY

WHEN THERE IS a lack of clinical response to antibiotics and transmural drainage, additional DEN is indicated.[23,24] This is the so-called step-up approach. The concept and success of DEN was first reported in 2000 in three patients.[25] This was followed by a case series of 13 patients from Hamburg by Seewald *et al.*, where an aggressive endoscopic approach was detailed and which generated significant widespread clinical interest.[26] Treatment was successful in all 13 patients, thus avoiding emergency surgery as the initial treatment. In the long term, surgery was completely avoided in nine patients; it was required because of either abscess extension into the paracolic gutter or disconnected pancreatic duct syndrome with recurrent collections. A retrospective study compared

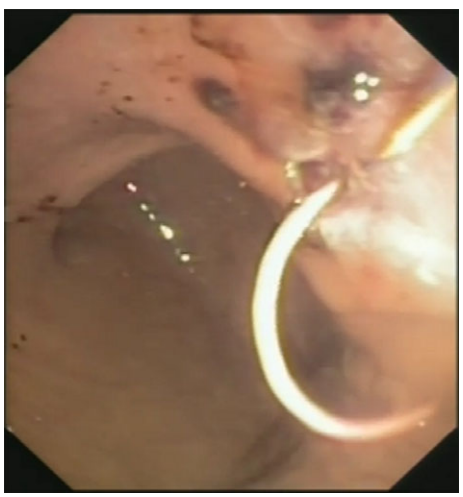

Figure 4 Endoscopic view showing a deployed double pigtail stent next to a guidewire which can facilitate insertion of a second plastic stent.

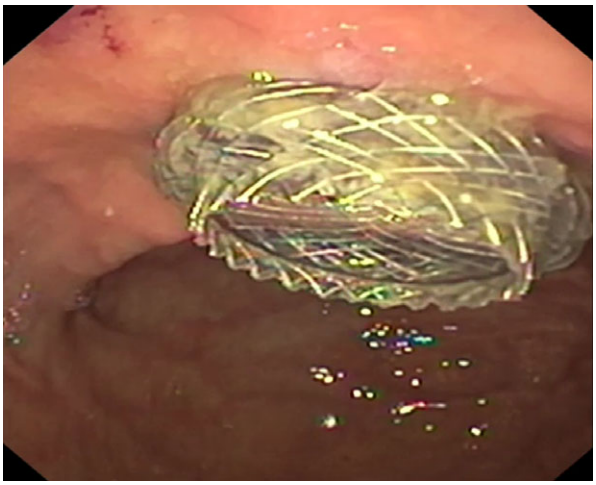

Figure 5 Endoscopic view of AXIOS stent (Boston Scientific, Natick, MA, USA).

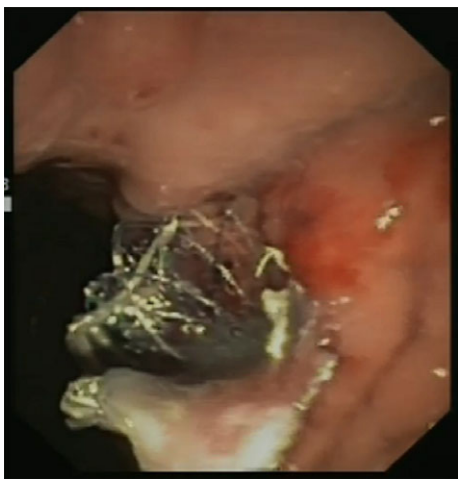

Figure 6 Endoscopic view of NAGI stent (Taewoong Medical, Gyeonggi-do, South Korea).

DEN (n = 25) with endoscopic drainage using PS (n = 20). Successful resolution of WON was accomplished in 88% who underwent DEN compared to 45% who received standard drainage ($P < 0.01$). Complications were limited to mild peri-procedural bleeding with equivalent rates between groups.[27] Several large single and multicenter series have been published.[28–31] Reported clinical success rates ranged from 75% to 91%. It must be remembered that potentially serious complications such as severe bleeding and perforation may occur, and that an aggressive approach towards necrosectomy may not be needed in the majority of patients such that even if DEN were to be carried out, clinical resolution may be achieved with less extensive debridement.

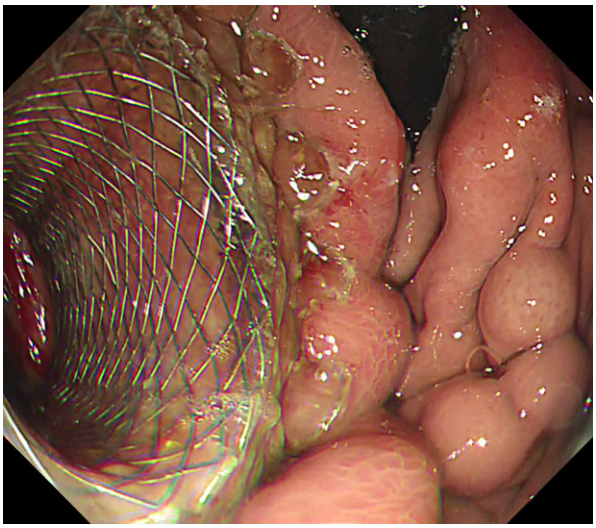

Figure 7 Endoscopic view of SPAXUS stent (Taewoong Medical, Gyeonggi-do, South Korea).

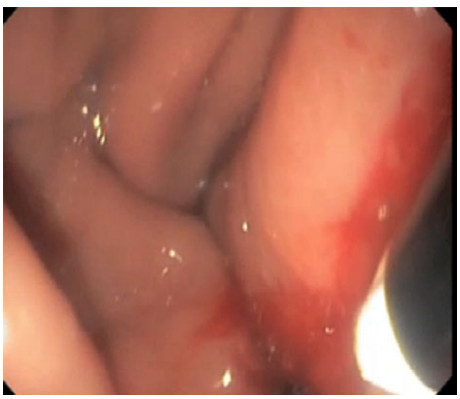

Figure 8 Endoscopic view of the tip of the hot AXIOS stent (Boston Scientific, Natick, MA, USA).

Other treatment approaches such as combined modality treatment that uses both endoscopic transmural drainage and percutaneous drainage and irrigation,[32] and the multiple transluminal gateway technique[33] have been reported. These techniques appear cumbersome and may be associated with a longer hospital stay.

TECHNIQUE OF DIRECT ENDOSCOPIC NECROSECTOMY

IF A DOUBLE pigtail PS has been inserted for initial drainage, the opening into the WON cavity will have narrowed and a large-diameter balloon dilatation to 15 mm must be carried out in order to insert a gastroscope into the

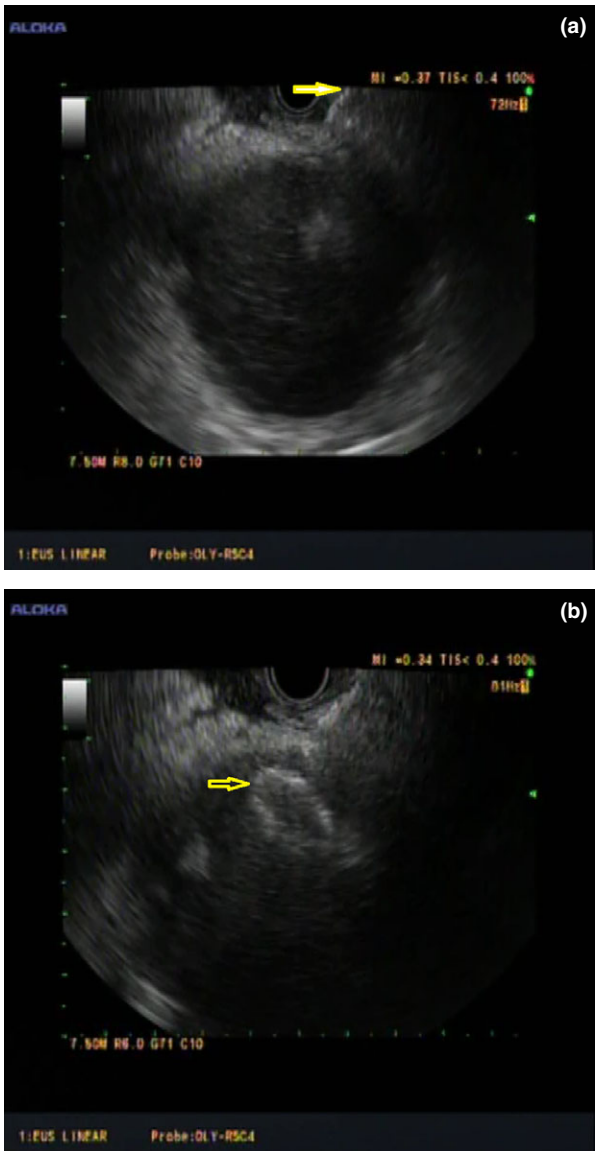

Figure 9 (a) Endoscopic ultrasound view of the tip of the hot AXIOS stent (Boston Scientific, Natick, MA, USA) at the wall of the infected walled-off necrosis (WON). (b) Endoscopic ultrasound view showing the inner flanges of the hot AXIOS stent opening up after insertion into the infected WON.

WON cavity for DEN. If a FCSEMS with a diameter of 15–16 mm has been inserted, it is easy to directly gain access to the WON cavity without further balloon dilatation. Irrigation helps to loosen solid material partially adherent to the wall and small debris may also be removed by suctioning. Accessories such as a Dormia basket and retrieval nets are used to gently remove the solid material from the cavity

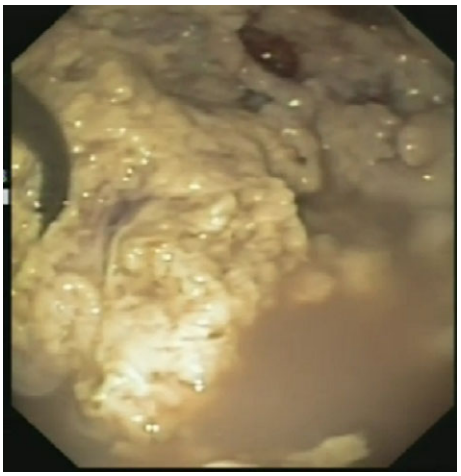

Figure 10 Endoscopic view of the interior of the walled-off necrosis before endoscopic necrosectomy.

(Figs 10,11). The use of large-diameter FCSEMS may even reduce the need for DEN as it may allow effective drainage, including passage of small debris out from the WON cavity. DEN may need to be staged over a few sessions. Access is easily maintained by FCSEMS, otherwise repeat balloon dilatation of the puncture tract prior to each DEN session may be needed. FCSEMS should be removed within 2 to 3 months, when the collection is expected to fully resolve, and before tissue overgrowth or membrane breakdown occurs.[34] Conversely, PS may be left in place for a longer period of time to reduce the risk of PC recurrence, in the context of disconnected pancreatic duct syndrome.[35]

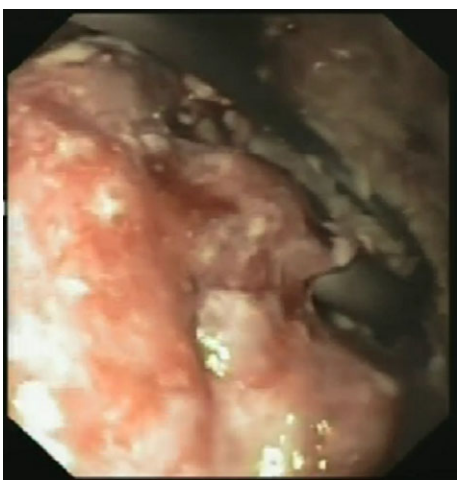

Figure 11 Endoscopic view of the interior of the walled-off necrosis after endoscopic necrosectomy.

SELF-EXPANDABLE METALLIC STENTS VERSUS PLASTIC STENTS

FCSEMS HAVE LARGER diameters than PS and may provide more effective drainage. Biliary FCSEMS were used initially but were suboptimal because of the higher risk of migration, excessive length and lack of lumen apposition.[36] More recent studies that used either NAGI™, SPAXUS™ or AXIOS stents revealed technical success rates that ranged from 91% to 100%.[19,20,22,34,37–41] As the treated PFC involved both PC and WON, actual clinical success rates in these series ranged from 77% to 100% (Table 1).

A randomized study compared FCSEMS with PS for drainage of PC. Both groups achieved technical success in all cases. However, median procedure time with FCSEMS was significantly shorter than with PS (15.0 *vs* 29.5 min, $P < 0.01$).[42] Another large retrospective study on 230 patients compared biliary SEMS with PS. Use of SEMS was associated with significantly higher resolution rates and lower adverse events. Adverse events were 2.9-fold higher when plastic stents were used.[43] Four retrospective studies have compared FCSEMS with PS in the treatment of patients with WON. Mukai *et al.* reported no statistically significant differences in rates of technical success, clinical success, and adverse events between both groups. However, mean procedure times for the first EUS-guided drainage and for re-intervention were significantly shorter in the FCSEMS group. There was no statistically significant difference in the total cost between both groups.[44] In contrast, significantly higher success rates with FCSEMS were reported by Bapaye *et al.* (94% *vs* 73.7%, $P < 0.05$)[45] and Siddiqui *et al.* (95% *vs* 81%, $P = 0.001$).[46] Ang *et al.* reported a less frequent need for repeat drainage (34.2% *vs* 6.3%, $P = 0.032$) and less frequent need for balloon dilatation prior to DEN, and similar costs as PS.[47] Results of these comparative studies are summarized in Table 2.

Although FCSEMS is easier and faster to deploy than PS, it is probably not routinely indicated for PC drainage, given the fact that it is several-fold more costly than PS and similar clinical success rates can be achieved with PS.[48] In the context of WON, with the need for more effective drainage, and the potential role for DEN and similar overall costs compared to PS, FCSEMS should probably be the preferred drainage device. Amount of necrosis present may be useful as a guide for the potential need for FCSEMS and DEN. A study published only in abstract form arbitrarily graded the amount of solid debris as mild (<10%), moderate (10–50%) and profound (>50%). It found that whereas the majority of acute necrotic collections (72.2%) had profound solid

Table 1 Treatment outcome with the use of fully covered self-expandable metallic stents designed for drainage of pancreatic fluid collection

Author	*N*	PFC	Stent	Technical success (%)	Clinical success (%)	Complications
Itoi *et al.*[19]	15	PC	AXIOS	100	100	Migration: 1
Yamamoto *et al.*[38]	9	PC: 5 WON: 4	NAGI	100	77 (7/9)	Late: 2 (22%) Bleeding: 1; migration: 1
Moon *et al.*[20]	4	PC: 3 WON: 1	SPAXUS	100	100	0
Chandran *et al.*[39]	48	PC: 39 WON: 9	NAGI	98.1	76.6	Early: 10 (21%) Late: 14 (29.7%)
Shah *et al.*[40]	33	PC: 22 WON: 11	AXIOS	91	93	Pain: 3; migration: 1; dislodgement: 1
Walter *et al.*[41]	61	PC: 15 WON: 46	AXIOS	98	93	Migration: 3; infection: 4; dislodgement: 3; perforation: 1
Dhir *et al.*[34]	47	PC	NAGI	91.4 (43/47)	87.2	Fever: 2 (4.6%)
Rinninella *et al.*[22]	93	PC: 37 WON: 52 AFC: 4	Hot AXIOS	98.9 (92/93)	93.5 (87/93)	5/93 (5.4%) (perforation [1] and massive bleeding [1] caused by nasocystic catheter; pneumoperitoneum [1]; stent dislodgement during DEN [1]; post-drainage infection [1])

AXIOS stent, Boston Scientific, Natick, MA, USA; NAGI™ stent, SPAXUS™ stent, Taewoong Medical, Gyeonggi-do, South Korea.
AFC, acute fluid collection; DEN, direct endoscopic necrosectomy; PC, pseudocyst; PFC, pancreatic fluid collection; WON, walled-off pancreatic necrosis.

Table 2 Comparison of plastic with metallic stents in the management of walled-off necrosis

Author	Types of stent	Outcomes (FCSEMS *vs* PS)
Mukai *et al.*[44]	BFMS (AXIOS; Niti-S; Hanaro): 43 PS: 27	Clinical success: 97.7% *vs* 92.6%; $P = 0.31$ Mean procedure time for EUS-guided drainage (min): 28.8 *vs* 42.6; $P < 0.001$ Mean procedure time for re-intervention: 34.9 *vs* 41.8; $P < 0.001$ Total cost: $6274 *vs* $5352; $P = 0.25$
Bapaye *et al.*[45]	NAGI: 72 PS: 61	Clinical success: 94% *vs* 73.7%, $P < 0.05$ DEN sessions: 1.46 *vs* 2.74, $P < 0.05$ Adverse events: 5.6% *vs* 36.1%, $P < 0.05$ Salvage surgery: 2.7% *vs* 26.2%, $P < 0.05$ Hospital stay: 4.1 *vs* 8 days, $P < 0.05$
Siddiqui *et al.*[46]	WallFlex: 121 AXIOS: 86 PS: 106	WallFlex *vs* AXIOS *vs* PS Resolution: 95% *vs* 90% *vs* 81%, $P = 0.001$ No. treatment sessions: 3 *vs* 2.2 *vs* 3.6, $P = 0.04$
Ang *et al.*[47]	NAGI: 18 PS: 31	Repeat drainage: 34.2% *vs* 6.3%, $P = 0.032$ Median no. balloon dilations for DEN sessions: 1 (range: 1–3) *vs* 0; $P = 0.022$

AXIOS stent, Boston Scientific, Natick, MA, USA; Hanaro stent, MI Tech, Seoul, Korea; NAGI™ stent, Taewoong Medical, Gyeonggi-do, South Korea; Niti-S stent, Taewoong Medical, Seoul, Korea; WallFlex stent, Boston Scientific, Natick, MA, USA.
BFMS, biflanged metallic stent; DEN, direct endoscopic necrosectomy; FCSEMS, fully covered self-expandable metallic stent; PS, plastic stent.

debris, the majority of WON (62%) had only moderate solid debris ($P < 0.001$). Among WON, the need for intervention was present in all patients with profound solid debris, in 40% with moderate solid debris and in none with minimal solid debris.[49] Hence, there is a case for consideration of FCSEMS insertion when there is at least 10% solid debris. It must be qualified that to carry out endoscopic drainage and DEN, there must be adequate liquefactive necrosis and fluid within the WON. If the WON is mainly solid, endoscopic intervention is not feasible. WON with profound solid debris would therefore not be suitable for FCSEMS insertion. To allow FCSEMS insertion, the volume of fluid within the WON cavity must be able to accommodate the size of the inner flanges as well as the length of the FCSEMS. For instance, if a 15-mm diameter AXIOS stent with 10 mm length and end flanges of 24 mm were to be used, depth of fluid in the WON must be at least 5–6 cm to be able to accommodate the stent easily without the end of the stent impacting upon the opposite wall which will impede drainage, and allow space for insertion of an endoscope for DEN. Morphology of the WON also affects the feasibility of FCSEMS insertion. A large but shallow collection with vertical depth of <2–3 cm is not suitable for FCSEMS insertion and the use of multiple PS which can be angulated at different directions for drainage may be preferred. One important point to note would be that unlike PS which can be left in place for a prolonged period of time to reduce the risk of recurrent PFC in disconnected pancreatic duct syndrome, FCSEMS need to be removed within 4–12 weeks to prevent the risk of migration and the possibility of the membrane breaking down and the stent being permanently embedded.[50] In this context, PS may need to be inserted in place of FCSEMS at end of DEN, or the patient should be closely monitored for recurrence of PFC such that drainage can be done promptly when indicated.

CONCLUSION

EUS-GUIDED DRAINAGE IS the preferred modality for drainage of symptomatic PFC. In the context of PC, use of single or multiple PS would suffice, with high treatment efficacy. FCSEMS customized for PFC drainage are now available. Although FCSEMS permits more effective drainage with its larger diameter, because of its higher costs than PS, its main role is probably in the context of WON. DEN is an important adjunctive technique that can increase the treatment success rate of endoscopic management of WON. There is ongoing work to establish Asian consensus guidelines and harmonize best practices in the management of PFC.[51,52]

CONFLICTS OF INTEREST

AUTHORS DECLARE NO conflicts of interest for this article.

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