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Review Article

Self-expandable metal stents for endoscopic ultrasound-guided drainage of peripancreatic fluid collections

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A B S T R A C T

Endoscopic ultrasound (EUS)-guided transmural drainage has evolved as an important treatment modality for peripancreatic fluid collections (PFCs). Recently, self-expandable metal stents (SEMS) have been introduced as an alternative for the traditionally used double-pigtail plastic stents, for endoscopic drainage. Due to the larger diameter (>10 mm) of SEMS, a wide drainage opening can be created, with a potentially reduced risk of stent occlusion and associated complications, and a direct access route if endoscopic necrosectomy is indicated. The use of different types of SEMS has been reported in several case reports and small case series. Although the results of these studies seem promising, the available results to date are limited and need critical appraisal. Large prospective and randomized trials are needed to evaluate the efficacy and safety of the placement of SEMS for endoscopic drainage of PFCs.

Keywords: Pancreatic necrosis, Pancreatic pseudocyst, Peripancreatic fluid collection, Self-expandable metal stents, Transmural drainage

Introduction

Peripancreatic fluid collections (PFCs) may complicate the course of acute and chronic pancreatitis, pancreatic surgery or trauma. They develop due to disruption of the pancreatic duct, with subsequent fluid leakage, or as a consequence of maturation of (peri)pancreatic necrosis.[1–3] Over the past decade, endoscopic ultrasound (EUS)-guided transmural drainage has evolved as an important treatment modality for PFCs.[4]

The aim of this review is to give an overview of EUS-guided treatment modalities for the different types of PFCs, with special focus on the use of self-expandable metal stents (SEMS).

Definitions of peripancreatic fluid collections

The use of precise terminology and strict definitions for different types of PFCs is important, since each form requires a distinct treatment strategy. Moreover, a universal classification system is essential for comparing results of studies. In 1992, the widely accepted Atlanta Classification was introduced as a clinically based classification system for PFCs that occur as a complication of acute pancreatitis.[1] Definitions were proposed for the following types of collections: acute fluid collection, pseudocyst, pancreatic abscess and pancreatic necrosis. In order to describe the evolution of pancreatic necrosis and acute fluid collections to a more organized, partially encapsulated state, Baron et al subsequently introduced the term, organized pancreatic necrosis, in 1996.[2] Although this term for describing PFCs was not defined in the 1992 Atlanta Classification, it has been widely adopted from then on.[5]

The original Atlanta Classification is considered to be a milestone in the classification of PFCs. Nonetheless, new insights into the pathophysiology of acute pancreatitis, improved imaging techniques, and the emergence of minimally invasive techniques for the management of PFCs, made it necessary to revise the Atlanta Classification in 2008 (Table 1).[6,7] In the revised Atlanta Classification, PFCs were defined by the presence or absence of necrosis. This distinction between fluid and nonliquefied collections is important, as the therapeutic strategy and clinical outcome differ between collections containing fluid alone and those containing necrotic debris as well. Subsequently, collections were further subdivided according to whether the contents are infected or sterile.[8–11]

Acute collections, developing within the first 4 weeks after the onset of acute pancreatitis, are referred to as either acute peripancreatic fluid collections (APFC) or as acute necrotic collections (ANC). APFCs are extrapancreatic homogeneous collections without nonliquefied components, i.e., debris or necrosis, and lack a well-defined wall. The majority of these APFCs are reabsorbed spontaneously within several weeks and only a minority matures into a pancreatic pseudocyst (PP). Drainage is only indicated in the rare

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Table 1 Comparison of Atlanta Classification 1992 and Revised Atlanta Classification 2008

Atlanta Classification – 1992	Working Group Classification – 2008
<4 wk after onset of acute pancreatitis	
Acute fluid collection	Acute peripancreatic fluid collections (APFC)
	Sterile
	Infected
Pancreatic necrosis	Acute necrotic collection (ANC)
	Sterile
	Infected
≥4 wk after onset of acute pancreatitis	
	Pancreatic pseudocyst (PP)
Pancreatic pseudocyst	Sterile
Pancreatic abscess	Infected
Organized pancreatic necrosis*	Walled-off pancreatic necrosis (WOPN)
	Sterile
	Infected

* Introduced by Baron et al. (1996).

case that an APFC becomes infected.[7,12] In contrast, ANCs contain both fluid and necrotic material in various proportions, due to gradual liquefaction of necrotic tissue. These collections are not encapsulated and infected necrosis in these collections is an indication for drainage.[7,11]

Within a period of approximately 4 weeks, acute collections mature and become encapsulated. These mature collections are subdivided into a PP and walled-off pancreatic necrosis (WOPN). PPs are defined as homogeneous fluid collections surrounded by a well-defined nonepithelialized fibrous wall, without nonliquefied components. They usually contain increased amylase and lipase levels, due to communication with the pancreatic ductal system. Sealing of such ductal disruptions explains the spontaneous resolution of the majority of PPs. Intervention is only indicated for PPs causing pain, jaundice or gastric outlet obstruction, due to compression on the biliary or gastrointestinal tract or fever due to infection.[13–15]

WOPN represents the late stage of an AFPC, previously referred to as organized pancreatic necrosis.[2] A thickened wall, without an epithelial lining, forms the interface between necrosis and adjacent viable tissue. Infected WOPN usually require drainage to effectively control sepsis, whereas in patients with sterile WOPN, the need for drainage is based on the same symptoms as for a PP.[7,12,13]

Treatment modalities

The management of PFCs has changed considerably over the last decades. Until the introduction of endoscopic drainage of PFCs in the late 1980s, treatment options were limited to surgical and percutaneous drainage. Since then, endoscopic transmural drainage has emerged as an important minimally invasive treatment modality.[4,16,17]

Surgical drainage

Surgery of PP involves internal drainage by creating an anastomosis between the cyst and a small-bowel loop, a cyst-enteric anastomosis. Although success rates are excellent, the procedure is associated with significant morbidity and mortality rates of 24% and 5.8%, respectively.[18,19] Furthermore, surgical drainage of PP is associated with a longer hospital stay compared to EUS-guided drainage.[20] The main role of surgical drainage for PP is, therefore, adjunctive to an endoscopic procedure or as salvage therapy.[4]

The traditional surgical approach for WOPN is an open surgical necrosectomy. This invasive procedure is associated with high morbidity (34–95%) and mortality (11–39%) rates.[21] Minimally invasive surgical techniques, including laparoscopic necrosectomy and video-assisted retroperitoneal debridement (VARD), have gained wide popularity as alternatives due to lower morbidity and mortality rates (25–88% and 0–25%, respectively).[21,22] A recent randomized pilot study, comparing surgical necrosectomy to endoscopic necrosectomy, showed a higher pro-inflammatory response as well as higher morbidity and mortality rates for the surgical approach in cases of infected necrosis.[23] Despite these results, to date, surgical necrosectomy still has an important role in the step-up treatment algorithm for WOPN.[21,24]

Percutaneous drainage

A less invasive alternative to surgery is percutaneous drainage, performed under radiological guidance. Although clear fluids can be drained effectively via the percutaneous drain, a drawback of this technique is the inability to clear the necrotic content from the cyst.[4] In approximately half of patients with infected WOPN, drainage of the infected fluid provides adequate control of sepsis and the necrotic material will be reabsorbed without formal necrosectomy. However, additional necrosectomy is needed in the other patients.[21,24–27] Risks associated with percutaneous drainage include puncture of adjacent viscera, secondary infection and bleeding. Furthermore, a prolonged need for an external draining catheter may result in a considerable risk of developing a pancreaticocutaneous fistula. For collections which cannot be accessed endoscopically, or those without a mature wall, percutaneous drainage may be of additive value.[4,26]

Endoscopic drainage

As mentioned above, endoscopic transmural drainage of PPs was introduced in the 1980s.[16,17] The first endoscopic necrosectomy for WOPN followed in 1996, by Baron et al.[2] Since the first reports, much more experience has been gained and endoscopic techniques have evolved. Endoscopic drainage entails the creation of a fistulous tract between the PFC and the lumen of the upper gastrointestinal tract, followed by placement of double-pigtail stents and eventually a nasocystic catheter to facilitate drainage. To be eligible for this approach, PFCs should have a well-defined wall and be located within 1 cm of the duodenal, esophageal or gastric wall. Furthermore, the presence of a luminal bulge is a prerequisite when performing endoscopic drainage without EUS-guidance, since this is a relatively blind approach. Due to direct sonographic visualization, the introduction of EUS-guidance enables drainage of nonbulging PFCs, without an increased risk of perforation or puncture of other organs. Moreover, intervening vessels can be identified by using Doppler ultrasound and avoided at the puncture site, with a potential reduction of the bleeding risk.[4,28] Apart from access and safety, performing EUS before endoscopic drainage can provide essential information to rule out alternative diagnoses and differentiate between WOPN and PPs.[29,30]

Two randomized trials have compared endoscopy-guided, with EUS-guided, drainage for PPs. In the EUS-guided group, fewer complications were reported; however, this difference was not statistically significant. The technical success rates were significantly higher for EUS-guided drainage (94–100%) than for endoscopy-guided drainage (33–72%) ($P < 0.05$). This difference was mainly due to a high failure rate for nonbulging PP in the endoscopy group.[31,32] Although some other studies have reported technical success rates to be equal for both endoscopy-guided and EUS-guided drainage, EUS-guidance is increasingly being used for drainage.[28,33]

The success rate of EUS-guided drainage is highly dependent on the type of PFC drained. The use of different nomenclature, leads to

Table 2 EUS-guided Drainage of Peripancreatic Fluid Collections (PFC) Using Self-expandable Metal Stents (SEMS)

Authors	No.	Type of stent	Stent lumen (mm)	Type of collection (*n*)	Technical success (%)	Puncture site (*n*)*	Clinical success *n* (%)	Complications (*n*)
Fully covered biliary SEMS								
Talreja et al (2008)[43]	18	VIABIL	10	PFC	94%	–	17 (94%)	Bleeding (2) Stent migration (1) Superinfection (5)
Tarantino et al (2009)[37]	1	Wallstent	10	WOPN	100%	TD	1 (100%)	–
Fabbri et al (2012)[38]	20	WallFlex/Niti-S	10	Abscess (6) Infected PP (12) Infected WOPN (2)	100%	TG (12) TD (6) TG + TD (2)	19 (95%)	Superinfection (2) Stent migration (1) Surgical stent removal (1)
Berzosa et al (2012)[39]	7	VIABIL	10	PP (5) WOPN (2)	100%	TG	7 (100%)	–
Tarantino et al (2012)[42]	1	Taewoong	8	PP	100%	TG + TD	1 (100%)	–
Penn et al (2012)[40]	20	WallFlex	10	PP (20)	100%	TG	17 (85%)	Stent migration (3) Superinfection (2) Post-drainage fever (1)
Weilert et al (2012)[41]	18	WallFlex	10	Abscess (8) Acute collection (7) PP (3)	100%	–	14 (78%)	Superinfection (3)
Partially covered biliary SEMS								
Barresi et al (2012)[44]	1	Wallstent	10	PP	100%	TG	1 (100%)	Surgical stent removal (1)
Nici et al (2012)[45]	1	WallFlex	10	PP	100%	TG	1 (100%)	–
Other SEMS								
Antillon et al (2009)[47]	1	Alimaxx-E Esophagus	22	Infected WOPN	100%	TG	1 (100%)	–
Belle et al (2010)[48]	4	Leufen	18–25	Infected WOPN (4)	100%	TG (3) TD (1)	1 (100%)	–
Perez-Miranda et al (2007)[46]	4	Hanaro tracheal (2) Hanaro enteral (2)	15–18	Abscess (1) WOPN (3)	100%	TG	3 (75%)	Piece-meal stent removal (1)
Transmural SEMS								
Itoi et al (2012)[49]	15	AXIOS	15	PP (15)	100%	TG (12) TD (3)	15 (100%)	Stent migration (1) Oozing at stent removal (3)
Itoi et al (2012)[50]	1	NAGI	16	Infected WOPN	100%	TG	1 (100%)	–
Total	112		8–25		111/112 (99%)		99/112 (88%)	

PP, pancreatic pseudocyst; TD, transduodenal; TG, transgastric; WOPN, walled-off pancreatic necrosis.

a direct comparison of studies not always being easy, although it is clear that adequate treatment of WOPN is much more challenging than draining PPs.[8,9] In larger series, the technical success rate of EUS-guided drainage of PPs ranges from 90% to 100%. Treatment success, defined as clinical improvement or complete resolution on imaging, is observed in >90% of patients. Complication rates range from 0% to 31%, and include bleeding, infection, pneumoperitoneum and stent-related complications, such as stent migration or occlusion.[4]

The need for necrosectomy in addition to drainage alone, in most cases of (infected) WOPN, makes the treatment of this type of PFC more challenging. For endoscopic drainage alone, success rates as low as 25% have been reported.[4] A much higher resolution rate (76%) has been reported for WOPN treated with endoscopic necrosectomy. Furthermore, with a mortality rate of 5% and a morbidity rate of 30%, this can be considered as a relatively safe procedure.[34]

SEMS

To further improve endoscopic treatment of PFCs, SEMS have recently been used as an alternative for the traditionally used double-pigtail stents (Table 2). The use of plastic pigtail stents is limited by the small diameter of the stent lumen (7–10F). Several studies have shown that placement of multiple stents ensures a wider drainage opening, with a low risk of obstruction of the fistula tract, resulting in better clinical success rates. Furthermore, there is a reduced risk of stent migration, which also reduces the risk of premature closure of the fistula tract.[35,36] Since SEMS have a larger diameter (>10 mm), placement of a single SEMS can already provide a wide drainage opening. Furthermore, due to the larger stent lumen, there is a reduced risk of stent occlusion, especially for collections containing a significant amount of debris. As a result, complications due to stent occlusion, for example, infection of the PFC, are expected to be reduced. Lastly, SEMS can provide an enduring direct access route for endoscopic transmural necrosectomy. The use of different types of SEMS has been described in several case reports and small case series.

Biliary SEMS

Fully covered biliary SEMS with a 10 mm diameter, are the most frequently used SEMS for endoscopic drainage of PFCs. Experience with this type of stent has been reported in seven reports comprising 85 patients with PFCs.[37–43] All but two stent placements were performed under EUS-guidance and placement failed in one patient. To prevent migration of the fully covered stents, plastic pigtail stents were placed through or alongside the SEMS in 38 patients[40,43] and a plastic stent with flaps was placed through the stent in one patient.[42] Stent migration was reported in four (10%) patients with an anchoring stent to prevent migration, whereas only one (3%) stent migration was reported in patients without additional stents. Clinical success, defined as complete resolution of symptoms and resolution on imaging, was achieved in 76 of 85 patients (89%).[37–42] In five of these, endoscopic necrostomy was performed before resolution was achieved. The SEMS was removed before necrosectomy and replaced by plastic pigtails after the procedure.[41] Surgery was required in the other patients to effectively control sepsis.[38,40,41,43] In one patient, endoscopic stent removal was not possible due to inflammatory tissue ingrowth, and surgical removal was indicated.[38]

The use of partially covered biliary SEMS has been reported in two case reports.[44,45] Tissue ingrowth in the uncovered stent end was thought to reduce the risk of migration in these stents. However, severe tissue ingrowth may cause problems during stent removal. Barresi et al reported this as early as 1 month after placement of the SEMS. The stent was embedded in the gastric wall and completely covered by gastric mucosa, which was described as a buried stent. The stent was removed through a surgical procedure.[44] Nici et al did not experience any problems with removal of the partially covered SEMS 3 weeks after placement.[45]

Other SEMS

To provide an even wider drainage opening than with biliary SEMS, other types of SEMS have been used for PFC drainage. Perez-Miranda et al report on the use of a 15-mm covered tracheal SEMS ($n = 2$) and a 18-mm covered enteral SEMS ($n = 2$) for EUS-guided drainage of PFCs. Double pig-tail stents, and/or a nasocystic drain, were placed through the stent to reduce migration risk, although one stent migration was reported. Endoscopic irrigation and necrosectomy was performed through the lumen of the SEMS. Clinical success was seen in three of four patients (75%) while in one patient, the stent had to be removed in a piece-meal way.[46] A 22-mm esophageal SEMS with flared ends was used by Antillon at al to facilitate drainage in one patient. Previously placed double-pigtail plastic stents and a nasocystic drain were left in place alongside. With ongoing irrigation, symptom resolution was achieved within 2 weeks and all stents could easily be removed.[47] Belle et al reported their experiences with specially designed 18-mm to 25-mm partially covered SEMS in four patients. Subsequent endoscopic procedures, including necrosectomy and lavage, were performed through the stent. Resolution of symptoms was achieved in all patients and the partially covered SEMS were easily removed.[48]

Dedicated transmural stents

To overcome the limitations associated with the use of tubular SEMS for transmural drainage, such as migration and tissue ingrowth, novel drainage SEMS have been developed. Both the AXIOS stent (Xlumena Inc, Mountain View, CA, USA) and the NAGI stent (Taewoong Company, Seoul, Korea) are specifically developed for transmural drainage (Fig. 1). They both have a saddle-shape design, with bilateral flanges, and a stent length between those flanges of 10-mm and 20-mm, respectively. The flanges are designed to provide lumen-to-lumen anchoring, thereby reducing the risk of migration and leakage alongside the stent. Furthermore, both stents are fully covered to prevent tissue ingrowth and to enable easy removal. The diameter of the stents, 10-mm or 15-mm for the AXIOS stent and 16-mm for the NAGI-stent, enables direct necrosectomy through the lumen of the stent.

Itoi et al[49] retrospectively reported on the use of the AXIOS stent in 15 patients with symptomatic PFCs. Stents were successfully placed in all patients and the stents were used as access portals for a diagnostic endoscope (<10 mm) to perform necrosectomy and irrigation. Dislodgement or removal of the stent during these interventions was not observed. However, stent migration to the stomach was reported in one patient. The cystogastrostomy tract in this patient was dilated up to 15-mm before placement of a 10-mm stent, which might be an explanation for migration. Resolution of the PFCs was achieved in all patients and stents could be removed without complications.

The experience with the NAGI stent is limited to one case report, for drainage of an infected WOPN, also by Itoi et al.[50] Stent placement was performed using a transgastric approach. Necrosectomy was performed during two subsequent endoscopy sessions, whereby a standard upper endoscope was inserted through the stent. No complications were reported and the stent was easily removed after 3 weeks.

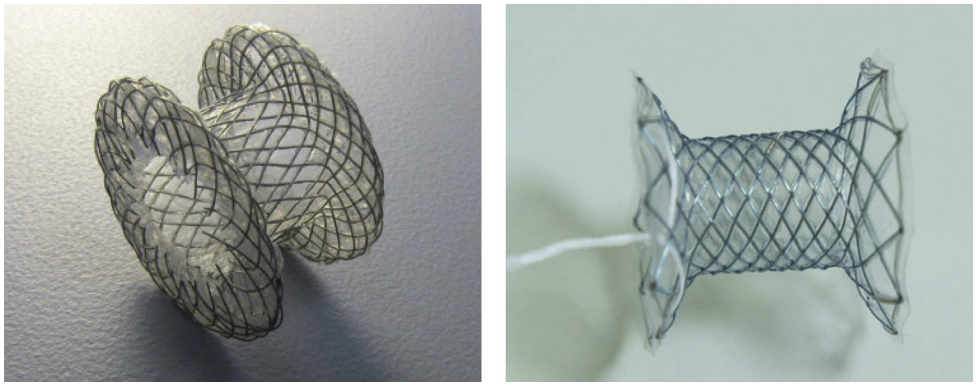

Fig. 1. Dedicated transmural stents: the AXIOS-stent (Xlumena Inc, Mountain View, CA, USA) and the NAGI-stent (Taewoong Company, Seoul, Korea).

Discussion

The use of SEMS for EUS-guided drainage of PFCs seems promising, based on the overall clinical success rate of 88% and only one placement failure in the above mentioned studies. However, the available results to date are limited and need critical appraisal.

First, the use of SEMS has been reported for drainage of both WOPN, containing significant amounts of necrotic debris, as well as for PPs. However, as for drainage of PPs with plastic stents, excellent clinical success rates have been reported, it remains to be established whether the use of SEMS has any added clinical value for this indication.

Second, the use of SEMS is, in many cases, probably not cost-effective, as they are far more expensive than plastic stents. It is thought, however, that the higher initial costs for SEMS will be offset by a reduction in the number of repeat endoscopies. This reduction will than probably be more distinctive for WOPN than for PPs. However, the number of repeat endoscopies is difficult to compare, since in some studies, necrosectomy and irrigation was performed at preset moments, whereas in other studies, repeat endoscopy was only performed based on clinical symptoms.

Third, a wide variety of SEMS is currently available. Fully covered SEMS are the most commonly used stents, mainly since they have the lowest risk of tissue ingrowth. To prevent migration of the stent, some preventative measures can be used, including placement of double pigtail plastic stents in or alongside the stent, the use of stents with bilateral flares, or not performing dilation before stent placement. Also, partially covered SEMS have been used, as they are less prone to migration, which is thought to be due to tissue ingrowth at the uncovered stent ends. However, hyperplastic tissue ingrowth can also lead to significant problems during endoscopic removal, and in some cases, surgery is required.[44] In order to prevent tissue ingrowth as well as migration, dedicated SEMS for transmural drainage have been developed. However, even with these devices, stent migration has been reported as well.[49]

Last, the studies that have been published on the use of SEMS for PFC drainage all have limitations, such as the inclusion of small numbers of patients, the lack of a control group, the use of different stent designs, the absence of preset endpoints, no long-term follow-up results, a retrospective design, etc. Well designed prospective studies and randomized trials are therefore needed to validate the initial promising results on the use of SEMS for endoscopic drainage of PFCs. A comparison should be made with conventional drainage using plastic stents and also a clear distinction should be made for the different types of PFCs, using well established criteria. Apart from the efficacy and safety, a cost analysis should be performed to elucidate whether the more expensive SEMS are indeed cost-effective, as compared to plastic stents, when used for the drainage of PFCs.

Conflicts of interest

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