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EUS-Guided Transmural Drainage of Pancreatic Fluid Collections: Keeping It Close

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Introduction

Pancreatic fluid collections (PFCs) can develop as a consequence of acute necrotizing pancreatitis, pancreatic duct (PD) disruption due to acute or chronic pancreatitis, pancreatic surgery, and trauma [1-3]. Based on the Revised Atlanta classification, PFCs are classified as acute peripancreatic fluid collections (APFC), pseudocysts, acute necrotic collection (ANC), and walled-off necrosis according to their morphology on imaging [1]. While most of these collections tend to resolve spontaneously, treatment is warranted for symptomatic PFCs. Symptoms, including abdominal pain, early satiety, jaundice, or weight loss, are often secondary to luminal (gastroduodenal) and/or biliary obstruction. Other indications for intervention include infection, bleeding and fistulization [4,5].

Endoscopic transmural drainage has emerged as the first-line therapy for PFCs given its similar efficacy, shorter recovery times, fewer adverse events and improved cost-effectiveness when compared to surgical cystogastrostomy [6]. Endoscopic drainage is achieved by creating a communication between the PFCs and the gastrointestinal lumen; thus facilitating internal drainage and subsequent collapse of the fluid collection [7]. With the evolution of endoscopic ultrasound (EUS) from being primarily a diagnostic tool into a therapeutic modality over the years, conventional endoscopic drainage has been largely replaced by a EUS-guided approach, as the latter is associated with higher technical success and less complications [8,9].

Traditionally, EUS-guided transluminal drainage of PFCs has been achieved by using tubular plastic double pigtail and/or fully-covered self-expandable metal stents (FCSEMSs). This approach has been shown to be both safe and effective in various studies [10-13]. However, since these stents are not specifically designed for transluminal drainage; there are several inherent limitations to their application in this setting. Plastic stents have the disadvantage of a small lumen diameter, which potentially limits drainage, especially in PFCs containing some degree of solid debris. Placement of multiple plastic stents can still be associated with higher rates of stent occlusion necessitating repeat interventions when compared to FCSEMSs [14]. On the other hand, the tubular structure of FCSEMs does not provide lumen apposition between the gastrointestinal wall and the PFC. This physical separation increases the risk of stent migration and leakage of both luminal and PFC contents into the abdominal cavity. To limit FCSEMS migration, plastic double-pigtail stents can be placed within the FCEMS to impart anchorage. However, this multi-step procedure can be technically cumbersome and may obviate the advantage of the large caliber FCSEMS if the indwelling through-the-FCSEMS plastic stents were to occlude prematurely. Furthermore, the straight ends of the tubular FCSEMS protruding into the GI lumen and cavity can also cause stent impaction resulting in ulceration, bleeding, and perforation [12, 15-17].

The Arrival of the Lumen-Apposing Stent

In the setting of the limitations of both conventional tubular plastic and FCSEMS for endoscopic transluminal drainage, new dedicated lumen-apposing metal stents (LAMS) have been recently introduced. These stents impart lumen apposition via their wide flanges, designed to evenly distribute pressure across the fistulous tract thus providing anchorage and reducing the risk for migration. These LAMS are fully covered thereby preventing leakage across the fistulous tract or tissue in growth.

Figure 1a: The Axios™ "saddle" shaped LAMS with bilateral anchoring flanges (a): The LAMS catheter-based delivery system.

The Axios™ stent (Boston Scientific Corporation, Natick, MA, USA) is a "saddle-shaped" LAMS that was initially introduced by Binmoeller and Shah in 2011 (Figure 1a) [18]. In their initial landmark study, the authors demonstrated that the stent was able to withstand various vector forces of movement yet could be easily removed. This stent is 10 mm in length and available in 2 different lumen diameters (10 mm and 15 mm). It is delivered through a dedicated 10.5 Fr catheter-based system that is Luer-locked onto the echoendoscope channel inlet port (Figure 1b). Stent deployment is then achieved by

the controlled independent stepwise release of each flange under visualization.

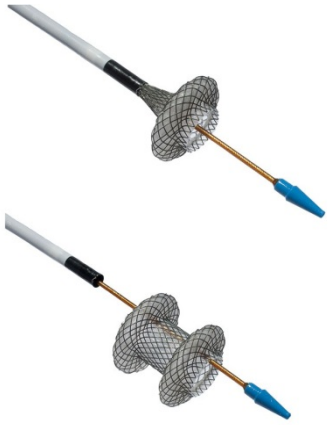

Figure 1b: Images courtesy of Boston Scientific, MA, USA.

The NAGI™ stent (Taewoong Medical Co, Seoul, Korea) is another fully-covered LAMS with large and acute angled anti-migration flares. This stent has a retrieval string which allows easy removal. This stent comes in different lengths (total length 10-30 mm) and diameters (10-16 mm). Similar to the Axios stent, the NAGI stent is delivered through a 10.5 Fr dedicated catheter-based system [19]. Itoi and colleagues reported a case report in which the NAGI stent was successfully placed for an infected WON [20]. The large caliber stent allowed direct endoscope insertion through the LAMS to perform necrosectomy. Likewise, a separate group demonstrated adequate pseudocyst transluminal drainage with the NAGI stent after the PFC had failed to resolve after multiple attempts of endoscopic treatment with placement of plastic stents [21].

Clinical Studies

There have been numerous studies to date evaluating the feasibility, safety and efficacy of the LAMS for endoscopic transluminal PFC drainage. In a multicenter retrospective case series, Itoi and colleagues demonstrated successful endoscopic drainage with the Axios stent in 12 patients with symptomatic pancreatic pseudocysts [22]. Median time to removal was 35 days and there was no pseudocyst recurrence during an 11.4 month median follow-up period. More recently, Shah et al performed a multicenter prospective study of the outcomes of the Axios stent in 33 patients with symptomatic pseudocysts and WON [23]. Technical success was 91% (30/33) and overall PFC resolution was accomplished in 93% (27/29). Furthermore, the indwelling LAMS in patients with WON (n=11) allowed for direct endoscopic debridement resulting in PFC resolution in 10 (90.9%) patients. Complications occurred in 15.2% of the cases, including infection (n=1), stent migration/dislodgement (n=1), fever (n=1), and pain (n=2). Overall, the authors concluded that LAMS was associated with safe and efficient PFC drainage and permitted direct endoscopic debridement in patients with WON. In line with these findings, Siddiqui et al reported their experience on the safety and efficacy of EUS-guided transmural drainage of pseudocysts and WON using the Axios stent [24]. This was a multicenter retrospective review of 82 patients with symptomatic PFCs across 4 centers in the United States. LAMS were successfully placed in 80 (97.5%) of the patients (12 with pseudocysts and 68 with WON). Successful drainage was accomplished in all pseudocysts compared to 88% of patients with WON. There was only 1 patient who had PFC recurrence following stent removal after confirmed initial resolution. Procedure-related adverse events were encountered in 8 patients (9.8%), which included self-limited bleeding (n=6) and stent maldeployment (n=2). In general, this study confirmed the high technical success associated with the use of LAMS for endoscopic PFC drainage and the relative long-term success (median 7 month follow-up) even in patients with WON.

The safety and efficacy of the NAGI stent for the treatment of PFCs was also recently reported in a multicenter retrospective study from Japan [25]. In this study, a total of 9 patients (5 with pseudocysts and 4 with WON) underwent endoscopic drainage with the LAMS. Technical success was achieved in all patients. Clinical success, defined as complete PFC resolution and/or improvement of infection, was attained in 7/9 (77.8%) of the patients. There were no immediate complications whereas there was one case of delayed bleeding (>8 days after the procedure) and one case of spontaneous stent migration. Limitations of this study include small number of cases and short-follow up (10-60 days after stent insertion).

LAMS on an Electrocautery-Enhanced Delivery System: Hot Stuff

Endoscopic transmural drainage has become the standard of care for the initial management of symptomatic PFCs. Yet, the widespread use of EUS-guided PFC drainage has been shorthanded by the lack of dedicated devices. Consequently, endoscopic drainage has traditionally involved multiple procedural steps culminating with transluminal stent deployment. One of the steps involved requires fistulous tract dilation to facilitate advancement of the stent delivery system into the PFC. Enlargement of the fistulous tract can be accomplished by using a cystotome/needle wire or dilating catheter/balloons. However, this is often regarded as one of the most technically challenging steps, especially when the fistulous tract is across the stomach wall.

To overcome this technical hurdle and further streamline the placement of LAMSs, a new electrocautery-enhanced delivery system has been developed (Hot Axios stent and delivery system, Boston Scientific Corporation, Natick, MA, USA). In this system, the LAMS are delivered through a system with an electrocautery wire at the distal tip (Figure 2). The electrocautery tip permits passage of the deployment device without necessitating prior fistulous tract dilation. This novel approach potentially minimizes the risk of complications and failure rate by reducing the number of steps and accessory exchanges required during PFC drainage. The safety and efficacy of this newly developed device was recently evaluated in a European multicenter retrospective analysis [26]. A total of 93 consecutive patients with PFCs underwent endoscopic drainage with the study device. In 24 patients, initial access to the PFC was obtained using a 19-gauge EUS-needle followed by placement of a guidewire over which the device was advanced. In the remaining 69 patients (74.2%), access to the PFC was obtained directly with the study device. Stent placement was technically successful in all but 1 case (98.9%) in which the distal flange of the stent malfunctioned. Complete PFC resolution was obtained in 92.5% of the cases whereas treatment failure occurred in 6 patients due to persistent infection (n=3), perforation/massive bleeding due to nasocystic drainage (n=2) and need for a larger opening for endoscopic necrosectomy (n=1). Adverse event rate was

5.4% with no reported complications associated with the drainage procedure. This study demonstrated that the new electrocautery-enhanced delivery system may allow safe direct penetration of the PFC without requiring prior puncture with a EUS needle and wire placement. These findings substantiate the recent technological advances and the evolution towards a streamlined dedicated system for the endoscopic management of symptomatic PFCs.

Figure 2: The Hot Axios^{TM} delivery system with an electrocautery tip. Image courtesy of Boston Scientific, MA, USA.

Conclusion

The current available data suggests that LAMS are safe and effective for the treatment of symptomatic PFCs and may represent a reasonable alternative to the conventional placement of multiple plastic stents or FCSEMSs. The availability of this dedicated stents and delivery systems for transluminal PFC drainage further simplifies and streamlines the endoscopic procedure. Furthermore, the wider stent diameter may provide enhanced drainage and facilitate endoscopic debridement of WON. Future prospective, randomized comparative trials are needed to further determine if this novel approach is both cost-effective and superior to traditional endoscopic drainage approaches.

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