EDITORIAL

Fully covered self-expandable metal stents: The "be all and end all" for pancreatic fluid collections?

An understanding of the underlying pathophysiology of pancreatic fluid collections (PFCs) is crucial for holistic management. Central to the formation of a collection is the presence of a pancreatic duct disruption, which may be partial or complete. Persistence of duct disruption, especially in disconnected pancreatic duct syndrome (DPDS) in which there is complete disruption, will predispose to recurrence of PFC after drainage procedures. Walled-off PFC can be categorized into pseudocysts (PCs) and walled-off necrosis (WON). The key difference between PCs and WON is the presence of solid necrotic debris within the WON.[1,2] When intervention is required for symptomatic PFCs, specific steps must be considered: (1) drainage of the collection, (2) treatment of persistent pancreatic duct disruption, (3) and, in the context of WON, the need for adjunctive measures such as surgical necrosectomy or direct endoscopic necrosectomy (DEN).[3]

EUS-guided drainage is now firmly established as the best option for drainage of walled-off PFC. It has high clinical efficacy, similar to surgical and percutaneous approaches, but with lower morbidity and costs.[4,5] It is superior to non-EUS–guided approaches because even collections without endoluminal bulging can be drained successfully.[6,7] Indeed, this is the technique for training of the current generation of therapeutic endoscopists. Nonetheless, technical limitations exist, and the design of the linear echoendoscope, as well as the accessories used, certainly can be improved further. Several steps are involved in the conventional technique of EUS-guided drainage, including initial puncture of the PFC by using a 19-gauge needle, tract dilation after the needle puncture, and insertion of double-pigtail plastic stents.[3] The largest plastic stent is 10F (3.3 mm) in diameter. Therefore, depending on the nature of the PFC, multiple plastic stents may be required for adequate drainage or to keep the fistulous tract patent for subsequent DEN. This is a laborious process, and repeat cannulation and multiple stenting may be challenging and time consuming, given the poor visibility because of copious fluids accumulating in the gastric lumen after the initial puncture. Double-wire techniques have been used to maintain continued access during insertion of multiple plastic stents.[8,9] Fully covered self-expandable metal stents (FCSEMSs) have larger diameters than plastic stents and may provide more effective drainage. Biliary FCSEMSs were used initially but were suboptimal because of the higher risk of migration, longer length, and lack of lumen apposition.[10] Subsequently, FCSEMSs customized for PFC drainage were designed.[11-15] These had shorter lengths of 1 to 3 cm to reduce the degree of protrusion, a diameter of 10 to 16 mm to allow effective drainage, and wide flanges at the ends to reduce the risk of migration. The AXIOS FCSEMS (Boston Scientific, Marlborough, Mass) is the only FCSEMS that is truly lumen apposing, unlike other biflanged FCSEMSs designed to prevent migration rather than facilitate lumen apposition.[11-13] Lumen apposition is especially crucial in situations in which the wall of the PFC may not be adequately mature or firmly adherent to the luminal wall. Indeed, the choice of drainage devices is currently a contentious issue.[16] Regardless of the choice of device, multiple steps are required for the drainage procedure. There is a need to simplify the process.

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In the present issue of *Gastrointestinal Endoscopy*, Rinninella et al[17] reported the results of a multicenter retrospective study of the use of the Hot AXIOS system (Boston Scientific) for drainage of PFCs. The Hot AXIOS system is a through-the-scope FCSEMS delivery system with an electrocautery wire at the distal tip. The stent is made up of braided nitinol that is fully covered with silicone, with wide flanges on both ends that provide anchoring within the collection. The stent is delivered through a 9F or a 10.8F catheter. The electrocautery tip allows passage of the catheter into the PFC without the need for prior dilation of the tract. It can be advanced along a guidewire inserted after initial puncture with a 19-gauge needle, or it can be used to directly access the PFC under EUS guidance. Among a cohort of 93 patients with PFCs who underwent drainage with this device, technical success was achieved in all but 1 case (98.9%). In terms of

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site of access, a transgastric approach was used in the majority, with 10 cases (10.8%) using a transduodenal approach. In most cases (74.2%), access to the PFC was obtained directly with the device, whereas in the rest, access was obtained by using the standard technique of initial EUS-guided puncture, followed by insertion of a 0.035-inch guidewire through which the Hot AXIOS device was advanced by using cautery. Clinical success was achieved in all patients with PCs and abscesses (37/37), 3 of 4 patients with acute PFCs, and 47 of 52 patients with WON. The placement of a large-diameter FCSEMS provided effective drainage and facilitated repeat entry of a gastroscope into the cavity for DEN. Only a median of 2.8 sessions of DEN was required. After resolution of the PFCs, successful removal of the FCSEMSs was performed in 83 of 86 (96.5%) cases after a median of 80 days. Stents were left in situ in 2 patients with terminal illnesses and was retained in a patient who defaulted on follow-up for more than 4 months.

These results are relevant because they demonstrated the clinical efficacy of the Hot AXIOS device. The process of EUS-guided drainage is simplified. By incorporating a cautery device at its tip, the Hot AXIOS allows large-diameter stent insertion in a single step, without the need for additional puncture tract dilation by using a cystotome device, graded dilators, or balloon dilators. Indeed, it would seem that even the traditional initial step of 19-gauge needle puncture and guidewire insertion can be omitted safely. A transduodenal approach may be more challenging because of the limited space to maneuver the echoendoscope to optimize the puncture axis and may be associated with a higher bleeding risk. However, this was not encountered in this study among the cases that had transduodenal stenting. Successful deployment of the large-diameter FCSEMS allows rapid drainage of the PFC, and this is especially important in the context of infected PCs and WON. When DEN is indicated, the large-bore FCSEMS can serve as a conduit for repeat endoscope insertion into the cavity. An approach that used multiple transluminal gateways to facilitate effective drainage of necrotic contents by using multiple plastic stents without the need for DEN has been proposed, but it appeared cumbersome and was associated with the need for a long hospital stay.[18] In contrast, a single FCSEMS may be adequate.

What about comparative data between FCSEMSs and plastic stents? A recent randomized study compared FCSEMSs with plastic stents for drainage of PFCs.[19] Both groups achieved technical success in all cases. However, the median procedure time with FCSEMSs was significantly shorter than with plastic stents (15.0 vs 29.5 minutes; $P < .01$). A retrospective study compared FCSEMSs with plastic stents in the treatment of patients with WON. There were no statistically significant differences in rates of technical success, clinical success, and adverse events between groups. However, the mean procedure times for the first EUS-guided drainage and for reintervention were significantly shorter in the FCSEMS group. There was no statistically significant difference in the total cost between groups.[20]

In the light of these data, is it time for us to fully embrace FCSEMSs for drainage of all PFCs? Extreme caution is warranted. The pros and cons should be carefully assessed, with considerations given to the nature of PFCs, the presence of DPDS, and relative efficacy, morbidity, and differences in costs. Let us first consider the case of uncomplicated PC. Double-pigtail plastic stents have been the traditional device used for drainage, and excellent success rates with low morbidity have been demonstrated.[3] The cost of a single plastic stent is a fraction of the cost of an FCSEMS. Unlike the case of infected PFCs, a single plastic stent is probably sufficient for uncomplicated PCs. Thus, even though FCSEMSs may provide larger-diameter drainage and may increase the speed of the drainage process, they may not result in a significant difference in eventual clinical outcome and thus may not be truly cost effective. Further properly designed and adequately powered randomized controlled studies would be warranted, examining specifically the speed of resolution of the PC as well as the relative risks of secondary infection and stent migration. The need for placement of a nasocystic catheter for continuous irrigation of complicated PCs in the initial few days is another issue that should be critically assessed. Next, let us consider the issue of infected WON. If DEN is needed, an FCSEMS certainly will facilitate the process because it maintains a conduit for insertion of the endoscope into the cavity for DEN. Without an FCSEMS, the opening of the fistula may actually narrow between DEN sessions, resulting in a need for repeat balloon dilatation. In fact, as alluded to earlier, compared with plastic stents, it is cost effective to use FCSEMSs in the context of WON that requires DEN.[20] One must be careful when inserting and withdrawing the endoscope from the cavity and when performing DEN, because there is a small risk of dislodgement of the FCSEMS during the process; one such case was encountered by the authors.[17] However, it is probably unnecessary to perform DEN in every case of infected WON. In fact, it is uncertain whether DEN is being performed excessively or whether it would hasten the speed of recovery. It must be remembered that in a randomized study that compared a step-up approach to open necrosectomy, 35% in the step-up approach group could be treated conservatively and did not require necrosectomy.[21] This also was observed in cohort studies in which DEN was not required in all cases of WON undergoing endoscopic drainage,[22] as well as in patients who successfully underwent a combined percutaneous and endoscopic approach (dual modality drainage), with none requiring surgical necrosectomy or surgical treatment of adverse events.[23] There is an ongoing study that examines endoscopic versus minimally invasive surgical step-up approaches to