

## New devices and techniques for management of pancreatic fluid collections

*The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of new or emerging endoscopic technologies that have the potential to have an impact on the practice of GI endoscopy. Evidence-based methodology is used, performing a MEDLINE literature search to identify pertinent preclinical and clinical studies on the topic, and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. For this review, the MEDLINE database was searched through August 2012 by using the keywords "pseudocyst and device," "endoscopic pseudocyst drainage," and "endoscopy and pseudocyst."*

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### BACKGROUND

Pancreatic fluid collections (PFCs) include acute fluid collections, pseudocysts, walled-off necrosis, and abscesses. Endoscopic management of PFCs can be difficult and technically challenging. Accessories such as papillotomes, guidewires, balloon dilators, stents, needle-knives, and other devices originally intended for other purposes have been

used for the treatment of symptomatic PFCs. This report focuses on new techniques and devices designed specifically for the endoscopic treatment of PFCs.

### EMERGING TECHNOLOGIES

#### Forward-viewing echoendoscope

Therapeutic linear array echoendoscopes were developed for PFC drainage. The large 3.7/3.8-mm working channel allows placement of large-diameter (10F) stents through the echoendoscope. These echoendoscopes are oblique viewing, which can hamper visualization and technical success. An echoendoscope with forward-viewing optics and US has been developed but is not yet commercially available (Olympus Medical Systems, Center Valley, Pa); it has a narrower plane of US compared with standard linear array echoendoscopes (90 degrees vs 180 degrees), lacks an elevator, and has a working channel diameter of 3.7 mm. Initial evaluation of this endoscope was described in a series of 7 patients; all procedures were successful, including 2 that were not able to be performed with a standard echoendoscope because of the location of the PFC.<sup>1</sup> A prospective, randomized, multicenter trial of 52 patients with PFCs compared the use of a prototype forward-viewing echoendoscope with a standard, oblique-viewing linear array echoendoscope.<sup>2</sup> PFC drainage was feasible and effective with the forward-viewing echoendoscope, but no differences were found in safety, technical success, and ease or duration of the procedure compared with the standard instrument. The authors noted that the time to initial puncture was longer with the forward-viewing echoendoscope because of the smaller US viewing plane (90 degrees vs 180 degrees) and unusual orientation of the scanning plane, but the time on stent placement after puncture was shorter with the novel device. Another prospective study of 21 patients compared the standard oblique-viewing linear array echoendoscope with the forward-viewing device.<sup>3</sup> All patients underwent examinations with both devices for a variety of indications, including 2 cystogastrotomies, and the images were viewed by independent ultrasonographers in a blinded fashion. There were no differences in visualization or image quality between the 2 devices, except that the common hepatic duct was better visualized with the forward-viewing echoendoscope. The cystogastrotomies were both successful with the forward-viewing echoendoscope.

#### PFC puncture devices

Transmural endoscopic drainage of PFCs is achieved by creation of a fistulous tract between the cyst and GI tract

lumen by using sequential steps of cyst puncture, dilation of the tract, and placement of transmural stent(s). This process requires multiple steps and device exchanges over a guidewire and may also require endoscope exchange over the guidewire for a side- or forward-viewing endoscope after cyst puncture.

Endoscopic pseudocyst puncture devices are designed for pseudocyst drainage and are intended to facilitate the procedure either with fewer steps or by addressing some of the common challenges associated with the procedure.

**EUS needle.** A variety of EUS needles are commonly used for initial puncture of PFCs. Occasionally, a standard guidewire can be sheared as it is passed through the needle into the PFC. One 19-gauge needle (EchoTip Ultra; Cook Medical, Bloomington, Ind) has a sharp stylet with a blunt needle. The PFC is punctured with the stylet in place; after the stylet is removed, the blunt hollow needle does not shear the guidewire as it is manipulated within the cyst. There are no publications comparing the use of this needle for PFC drainage with standard EUS needles.

### Combination devices

**The cystotome.** The Cystotome (Cook Endoscopy, Winston-Salem, NC) is a through-the-scope device with an inner, 5F retractable needle-knife catheter and an outer sheath, which can be used to create a 10F fistulous tract at initial puncture. The distal end of the outer sheath has a metal electrocautery ring. The inner needle-knife is used to puncture the PFC. The outer sheath with the metal tip is then advanced through the gut wall while applying diathermy current, creating a 10F cystenterostomy. The needle-knife diathermy wire is withdrawn, leaving the outer sheath in place within the cyst, and a guidewire is inserted. The Cystotome is then withdrawn, leaving the guidewire in place. The cystgastrostomy tract may then be dilated with standard endoscopic dilation balloons, and transmural stents may be placed. The Cystotome has been shown to be effective in transgastric and transduodenal pseudocyst drainage.<sup>4-7</sup> There are no studies directly comparing its use with other equipment commonly being used for PFC drainage.

**The NAVIX access device.** The NAVIX device (Xlumena Inc, Mountain View, Calif) consists of a catheter with a 19-gauge trocar, a small “switchblade” knife that extends perpendicular to the trocar, an 8-mm anchoring balloon, a 10-mm dilating balloon, and 2 guidewire ports. The trocar punctures the cyst and is advanced into it while the switchblade cuts a 3.5-mm enterostomy at the puncture site. The anchoring balloon is passed into the cyst and used to maintain position, and a guidewire is passed through it into the cyst. The trocar is removed. The device catheter also has a 10-mm dilation balloon that is used to dilate the enterostomy. A second guidewire can be placed at this point if desired, and the NAVIX device is removed over the guidewire. A stent or stents can then be placed over the guidewires. The NAVIX device has U.S. Food and Drug Administration clearance for use in PFC drainage.

Several series have demonstrated the effective use of the NAVIX device for PFC drainage from either the duodenum or stomach.<sup>8-11</sup> A study of 18 patients with PFCs that were of indeterminate adherence (eg, the PFC was not clearly adherent to the intestinal lumen) underwent cystenterostomy by using the NAVIX device. All procedures were technically successful. There was 1 dehiscence after tract dilation that was treated with a fully covered self-expandable metal stent (SEMS).<sup>12</sup>

**Other combination devices.** There are several prototype devices, not commercially available, that have been described in case series. One series of 3 patients outlines a prototype system with a diathermy needle and 8.5F, double-pigtail stent already loaded and deployable without the need for guidewires, needle-knife enlargement of the puncture site, or catheter exchange.<sup>13</sup> Another prototype device, described in a series of 6 patients, is composed of a wire-guided, 18-mm esophageal dilation balloon in which the guidewire is replaced with a 1-cm retractable, diathermic needle-knife.<sup>14</sup> This eliminates the need for needle-knife exchange. It is unknown whether either of these prototype instruments offers a clear advantage over the standard approach.

### Devices for maintenance of cystenterostomy

A variety of stents designed for other indications have been used to maintain patency of the fistulous tract between the gut lumen and the PFC. Traditionally, 2 or more double-pigtail stents are deployed across the tract. Recently, the use of temporary fully covered SEMSs has been reported.<sup>15,16</sup> Plastic stents and SEMSs may occlude, migrate, or cause bleeding (in the case of SEMSs), or there may be leakage around the fistulous tract from poor apposition of the intestinal lumen to the PFC. These issues have led to interest in the development of larger diameter stents with antimigration features. This review is limited to devices designed for the express purpose of PFC drainage.

**AXIOS stent.** The AXIOS stent (Xlumena) is a fully covered, removable metal stent with wide, nearly spherical flanges at each end in a “dumbbell” configuration. The design is intended to anchor it securely in the cystenterostomy to prevent migration as well as provide good apposition of the tissue layers (eg, stomach wall to cyst). It is 10 mm in diameter with 20-mm diameter flanges on either end and is available in 3 lengths (6, 10, and 15 mm).<sup>17</sup> The stent is constrained within a 10.5F delivery catheter and is delivered through the endoscope; it requires an endoscope with a 3.7-mm working channel. A case series describes use of the AXIOS stent in 8 patients who underwent transenteric pseudocyst drainage and 2 patients who underwent transduodenal cholecystostomy.<sup>18</sup> A recent retrospective study described 15 patients with symptomatic pancreatic pseudocysts and 5 patients who had acute cholecystitis who underwent cystenterostomy or cholecystoduodenostomy/gastrostomy by using the AXIOS stent. All stents were deployed successfully and were removed at a median of 35

days.<sup>19</sup> All instances of acute cholecystitis resolved immediately after stenting, and all pseudocysts remained resolved at average follow-up of 11.4 months. One stent migrated into the stomach. There is a single case report of use of the AXIOS stent to drain a PFC that had herniated into the mediastinum.<sup>20</sup> The AXIOS has CE Mark (European approval) for treatment of pancreatic pseudocysts as well as for biliary tract drainage. It is not currently approved by the U.S. Food and Drug Administration and is not commercially available in the United States.

**Aixstent.** The Aixstent (Leufen Medical, Aachen, Germany) is a fully covered metal stent with wide flanges on each end to prevent migration; the flanges have an atraumatic folded-wire design to prevent tissue damage from the end of the stent. The stent is 30 mm in length with a diameter of 10 or 15 mm and 25-mm wide flanges. It is passed through the endoscope for placement. A case series describes transgastric or transduodenal puncture of peripancreatic fluid collections with necrosis followed by placement of through-the-scope, fully coated SEMS in 4 patients.<sup>21</sup> In 2 of the 4 patients, a standard 18 × 60-mm stent was used, but in the other 2, a custom-made SEMS was used (Leufen Medical). This is now commercially available in Europe only (Aixstent). There are no other human data published at this time.

### New techniques for the management of complex pseudocysts and necrosis

Pancreatic necrosis in need of débridement has traditionally been managed surgically. In recent years, endoscopic débridement or necrosectomy has become an option for well-circumscribed areas of necrosis.<sup>22-24</sup> The method involves gaining transduodenal or transgastric access to the necrotic area, dilating the tract between the PFC and GI tract lumen to a large caliber (eg, 18 mm), then driving the endoscope itself into the PFC. A variety of tools, such as baskets, snares, and nets, are used to débride and remove the nonviable tissue. A nasocystic drain may be left in place to enable cyst lavage. A retrospective comparison of endoscopic necrosectomy with conventional transmural endoscopic drainage for walled-off pancreas necrosis found that successful resolution was greater in the necrosectomy group (88% vs 45%,  $P < .01$ ) with equivalent minor complication rates.<sup>25</sup> New methods have been described that attempt to improve endoscopic management of necrosis.

The multiple transluminal gateway technique (MTGT) involves puncture of the necrotic area at 2 or 3 sites rather than 1, leaving multiple stents as well as a nasocystic drain for repeated flushing of the PFC. This was first described in a case report.<sup>26</sup> A retrospective review of 60 patients with walled-off pancreatic necrosis who had either the MTGT or the conventional method of drainage (1 puncture site) found that treatment success was more likely with the MTGT (adjusted odds ratio 9.24; 95% confidence interval, 1.08-79.02;  $P = .04$ ) after adjusting for area of necrosis and placement of a pancreatic duct stent.<sup>27</sup>

A combined approach of using a percutaneously placed drain for flushing the necrotic PFC and endoscopically

placed stents (without endoscopic necrosectomy) was described in a case series of 15 patients. The investigators reported resolution of the PFC in 13 patients after a median of 56 days with no instances of cutaneous fistulae.<sup>28</sup> A subsequent retrospective review of 102 patients, approximately half of whom underwent the combined approach and half who had a percutaneous drain alone, found that the combined procedure was associated with shorter length of hospitalization and fewer ERCPs and CT scans.<sup>29</sup>

Another variation on endoscopic drainage includes the use of natural orifice transluminal endoscopic surgery techniques. There is 1 case series of 6 patients with large symptomatic pseudocysts who had transoral surgical cystgastrostomy creation by using a surgical stapling device.<sup>30</sup> Access to the cysts was obtained transgastrically under EUS guidance. The puncture site was dilated to a large caliber (18-20 mm). Endoscopic débridement was performed when possible. After placement of an overtube, a surgical stapler (SurgAssist SLC 55; Power Medical Interventions, Langhorne, Pa [no longer commercially available]) was passed perorally into the stomach near the site of the cyst puncture. A gastroscope was passed alongside it and used to visualize and manipulate the stapler to create a large cyst gastrostomy measuring 5.5 to 8 cm in diameter.

The procedural morbidity and mortality rates were high in 1 study (26% and 7%).<sup>31</sup>

### AREAS OF FUTURE RESEARCH

Multicenter studies are needed to assess the applicability of these devices in general practice. Development of better techniques and devices for the safe and efficacious management of walled-off pancreatic necrosis is desirable.

### SUMMARY

Endoscopic management of PFCs is technically challenging. Therapeutic endoscopists are tackling increasingly complex cases, providing minimally invasive treatment for patients who previously required surgery. New techniques and devices intended to facilitate endoscopic drainage have been developed. More research is needed to demonstrate comparative outcomes, collect long-term efficacy data, and develop additional, simpler equipment for PFC drainage.

### DISCLOSURE

*The authors disclosed no financial relationships relevant to this publication.*

*Abbreviations: MTGT, multiple transluminal gateway technique; PFC, pancreatic fluid collection; SEMS, self-expandable metal stent.*

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