# Management of pancreatic collections with a novel endoscopically placed fully covered self-expandable metal stent: a national experience (with videos)

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**Background:** Recent medical literature on novel lumen-apposing stents for the treatment of pancreatic fluid collections (PFCs) is limited by small numbers, solo operators, and single-center experience.

**Objective:** To evaluate a recently developed lumen-apposing, fully covered self-expandable metal stent (FCSEMS) in the management of PFCs.

**Design:** Retrospective case series.

**Setting:** Thirteen tertiary and private health care centers across Australia.

**Patients:** Forty-seven patients (median age 51 years) who underwent endoscopic management of PFCs.

**Intervention:** Insertion of FCSEMS after PFC puncture under EUS guidance. A subgroup of 9 patients underwent direct endoscopic necrosectomy.

**Main Outcome Measurements:** Technical and clinical success rate, adverse event rate.

**Results:** The technical success rate was 53 of 54 patients (98.1%), and the initial clinical success rate was 36 of 47 (76.6%), which was sustained for more than 6 months in 34 of 36 (94.4%). Early adverse events included 4 cases (7.4%) of stent migration during direct endoscopic necrosectomy, 4 cases (7.4%) of sepsis, 1 case (1.9%) of bleeding, and 1 case (1.9%) of stent migration into the fistula tract. Late adverse events were 6 (11.1%) spontaneous stent migrations, 3 (5.6%) recurrent stent occlusions, 3 (5.6%) tissue ingrowth/overgrowth, and 2 (3.7%) bleeding into PFC. The majority of stents inserted (48 of 54, 88.9%) and removed (31 of 35, 88.6%) in our study were described by the operator as superior to pigtail stents with regard to ease of use.

**Limitations:** Retrospective study.

**Conclusion:** Although FCSEMSs are technically easier to insert and remove compared with traditional pigtail stents, there are significant limitations to the widespread use of FCSEMSs in the management of PFCs. These include cost, adverse events, and lower-than-expected resolution rates. (Gastrointest Endosc 2015;81:127-35.)

*(footnotes appear on last page of article)*

**This video can be viewed directly from the GIE website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.**

Since its first description, EUS-guided drainage has increasingly become the preferred method in the management of pancreatic fluid collections (PFCs) across many centers.[1-3] The etiology of PFCs includes abdominal trauma, surgical adverse event, and acute or chronic pancreatitis.[1,2,4] Factors that have an impact on the formation and composition of PFCs include pancreatic

duct damage/disruption, pancreatitis severity, and the maturation time of the collection.[1,4] Indications for drainage of these collections include gastric outlet/biliary obstruction, persistent symptoms, and infection.[1,5]

At present, the options for PFC drainage include percutaneous, surgical, and endoscopic approaches.[1,2,6] The previous standard approach was surgical drainage; however, the associated morbidity ranges from 7% to 37%.[1,2] Percutaneous drainage, although attractive in that it is the least-invasive option, is associated with a significant risk of fistula formation caused by the placement of an external drain, and this may complicate subsequent endoscopic/surgical management.[1,2] EUS allows accurate assessment of surrounding vessels, PFC wall thickness, and the shortest transmural distance for access purposes.[3] Advances in the endoscopic approach in the recent past has allowed the drainage of organized necrosis, abscesses, and nonbulging and distant collections.[1,7] Increasingly, direct endoscopic necrosectomy (DEN) has been shown to result in reduced mortality, shorter hospital length of stay, and improved success rates over conventional surgical management.[8,9]

The conventional EUS approach to PFC drainage is via the placement of plastic stents.[2,10,11] However, this has been associated with multiple revisions in as many as 27% of cases in addition to the limitations of drainage capacity by the stent lumen diameter and increased procedural time, especially if multiple plastic stenting is to be performed.[1,4,11,12] Since its first description in 2007,[13] there have been several case series and case reports assessing the role of FCSEMSs in PFCs that suggest that they may be easier to deploy, reduce procedural times, increase resolution rates, provide access to PFCs with indeterminate adherence, and provide large-diameter access for performing DEN.[1,6-8,10-12,14-16] However, current limitations in this medical literature include single operator, expert centers, small stent numbers, and the use of tubular stents not specifically designed for PFC management.[1,6-8,10-12,14-16]

The aim of our study was to assess the national use of a recently developed novel lumen-apposing stent for the management of PFCs including outcomes, ease of use compared with plastic stents, and any associated adverse events.

## METHODS

A retrospective audit was conducted across 13 centers from January to August 2013. A database of practicing endosonographers who had inserted these novel covered metal stents into PFCs was created by using the Pyramed (stent distributor) Australian registry. A standardized datasheet capturing patient demographics, etiology of PFCs, technique used for insertion, ease of use compared with plastic stenting, and early/late adverse events was created.

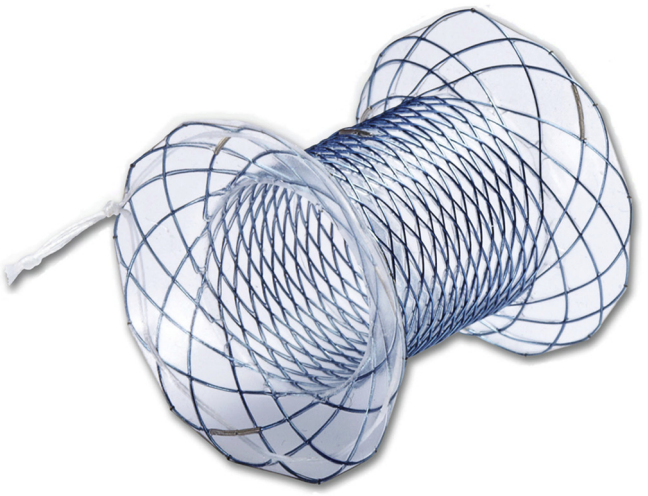

**Figure 1.** The novel lumen-apposing stent with flared ends to prevent migration and drawstring attachment located at the gastric end to aid extraction.

Ethical approval for this study was granted by our institutional review board (Austin Health Human Research Ethics Committee H2012/04908). Data collection was performed in accordance to the provisions of the Declaration of Helsinki.

### Design and definitions

All patients who had this stent inserted under EUS guidance for a PFC were included. The Nagi pseudocyst stent (TaeWoong Medical Co, Ltd, Gyeonggi-do, South Korea) was used in this study. This stent is constructed from nitinol with a silicone coating specifically designed to act as a temporary cystogastrostomy (Fig. 1). The wide flares at both ends of the stent were designed to prevent spontaneous migration. It comes in a variety of lengths (1, 2, and 3 cm) and diameters (10, 12, 14, and 16 mm). A drawstring is present along the gastric flare end of the stent to facilitate removal.

All procedures were performed with the patient under a general anesthetic. A therapeutic linear echoendoscope alone or in combination with a duodenoscope was used in our cohort. To gain access, a 19-gauge needle was used to puncture the cyst and then a 460-cm 0.035-inch ERCP guidewire was advanced to form several loops within the cyst under radiological guidance. The tract was predominantly dilated to 4 to 6 mm with a graduated balloon device and in some cases a cystotome or needle-knife were used to enable the passage of the stent delivery device through the tract (Video 1, available online at www.giejournal.org). The introducing device for the stent requires a long wire system and is constrained onto a 10.5F delivery system. A nasocystic catheter was placed through the