

## Endoscopic transluminal drainage and necrosectomy by using a novel, through-the-scope, fully covered, large-bore esophageal metal stent: preliminary experience in 10 patients

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**Background:** Interventions for necrotizing pancreatitis have undergone a recent paradigm shift toward minimally invasive techniques, including endoscopic transluminal necrosectomy (ETN). The optimal stent for endoscopic transmural drainage remains unsettled.

**Objective:** To evaluate a novel large-bore, fully covered metal through-the-scope (TTS) esophageal stent for cystenterostomy in large walled-off necrosis (WON).

**Design:** Retrospective case series.

**Setting:** Single tertiary care academic center.

**Patients:** Ten patients with large (> 10 cm) WON collections who underwent endoscopic transmural drainage and ETN.

**Intervention:** Initial cystenterostomy was performed by using EUS, and in the same session, a TTS (18 × 60 mm), fully covered esophageal stent was placed to create a wide-bore fistula into the cavity. In 1 or more later sessions, the stent was removed, and ETN was performed as needed.

**Main Outcome Measurements:** Technical and clinical success rates and adverse events.

**Results:** The TTS stent was successfully deployed at the initial cystogastrostomy in all 10 patients. All patients had large WON (median size 17 cm, range 11-30 cm) and underwent intervention at a median of 30 days (range 12-117 days) after onset of acute pancreatitis. Resolution of WON was achieved in 9 of the 10 patients (90%) after a median of 3 endoscopic sessions. There were no early adverse events. Late adverse events occurred in 3 patients (30%); worsening of infection from stent migration and occlusion of cystogastrostomy (2 patients), and fatal pseudoaneurysmal bleeding from erosion of infected necrosis into a major artery distant from the stent (1 patient). The stent was easily removed in all the cases after resolution or improvement of the necrotic cavity.

**Limitations:** Retrospective, single-center evaluation of a small number of cases. No comparative arm to determine the relative efficacy or cost-effectiveness of these stents compared with conventional plastic stents.

**Conclusions:** Endoscopic therapy using a large-bore TTS, fully covered esophageal stent is feasible for use in the treatment of large WON. Further studies are needed to validate these findings.

*Abbreviations:* ETN, endoscopic transluminal necrosectomy; ETD, endoscopic transluminal drainage; FCSEMS, fully covered self-expandable metal stent; SEMS, self-expandable metal stent; TTS, through-the-scope; WON, walled-off necrosis.

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Endoscopic transluminal drainage (ETD) in conjunction with endoscopic transluminal necrosectomy (ETN) is increasingly recognized as primary therapy for patients with pancreatic/peripancreatic walled-off necrosis (WON) in whom intervention is indicated.<sup>1,2</sup> As originally described, endoscopic cystenterostomy is followed by placement of double pigtail plastic stents to maintain patency and facilitate drainage of fluid and necrotic debris.<sup>3</sup> However, because of their narrow inner lumen and small combined outer diameter, even after placing 2 or three 7F or 10F stents, relatively small cystenterostomy results, which is prone to occlusion and infection, thus requiring serial dilations and stent revisions.<sup>4-6</sup> In addition, spillage may occur between the enteric and cavity walls, which can result in peritonitis.<sup>6</sup> In an attempt to overcome such limitations, fully covered self-expandable metal stents (FCSEMSs) have been used for cystenterostomy.<sup>7</sup> Because a dedicated FCSEMS for cystenterostomy is not currently available in the United States, use of biliary and esophageal stents has been reported.<sup>4,5,7</sup> Biliary stents are limited by their small diameter (10 mm), which is insufficient to allow egress of necrotic material. Esophageal stents have a much larger outer diameter and in theory would create a substantially wider cystogastrostomy. However, the limited reports of fully covered esophageal stents for cystenterostomy involve stents that cannot be passed through the working channel of the endoscope, rendering the procedure cumbersome and technically challenging.

In this series, we report our preliminary experience with a recently released, through-the-scope (TTS) FCSEMS designed for use in the esophagus. This stent has properties that render it suitable for use in cystenterostomy, including full covering, easy removability, a relatively short length (6 cm), a wide inner diameter (18 mm), and pronounced flaring at both ends to prevent migration.

## METHODS

The FCSEMS used in this study was a fully covered TTS Niti-S stent (Taewoong Medical, Seoul, South Korea). Stents are delivered via an introducer sheath with an outer diameter of 10.5F, allowing passage through the working channel of a therapeutic endoscope or duodenoscope. The 6-cm long stent has a dumbbell shape, with a body diameter of 18 mm and flares at both ends to 26 mm to limit migration. A nylon drawstring at the proximal end of the stent allows endoscopic removal by collapsing the upper end of the stent when pulled by forceps.

Indications for intervention in WON included suspected or proven infection, biliary or gastric outlet obstruction, and persistent intractable symptoms.<sup>1,2</sup> Only patients with WON of at least 10 cm in diameter and those accessible through the stomach (as opposed to the duodenum) were considered for placement of the Taewoong stent (Fig. 1). Patients unsuitable for cystogastrostomy because of the location of WON or with a small (<3 cm)

### Take-home Message

- Endoscopic transluminal drainage and necrosectomy by using a large-bore, through-the-scope, fully covered esophageal stent is feasible for use in the treatment of large walled-off necrosis.

endoscopic window were excluded. In addition to cystogastrostomy, selected patients with WON that was very large or extended deep into the pelvis also underwent simultaneous cystoduodenostomy and/or percutaneous catheter drainage via a retroperitoneal approach.

Management decisions for interventions were made by a multidisciplinary team consisting of gastroenterologists, surgeons, and interventional radiologists dedicated to the management of severe acute pancreatitis. All endoscopic procedures were performed on an inpatient basis by 1 of 3 interventional endoscopists with combined experience of more than 100 cases of endoscopic necrosectomy (R.A., M.A., and M.L.F.). Off-label use of the stent was explained to the patients, and informed consent for the procedure was obtained. Broad-spectrum antibiotics were administered before the procedure. All endoscopic procedures were performed with patients under general anesthesia with endotracheal intubation. EUS (curved linear array, 2.8- or 3.7-mm working channel [Olympus America, Center Valley, Pa]) was used for the initial cavity puncture in all cases, by using color Doppler, to avoid any intervening blood vessels. Cystogastrostomy was performed by using a 19-gauge needle with a 0.025-inch guidewire (Visiglide; Olympus America) passed into the cavity under fluoroscopic guidance. The cystogastrostomy was dilated to 15 to 20 mm by using a controlled radial expansion balloon dilator (Boston Scientific, Natick, Mass). In most patients, a single 7F or 10F double pigtail plastic stent was placed through the echoendoscope. After drainage was secured, the echoendoscope was removed and a therapeutic forward-viewing endoscope or duodenoscope (Olympus America) was used to place the Taewoong stent over a guidewire (0.025 Visiglide; Olympus America) that was reinserted alongside of the initial plastic stent if present (Figs. 2 and 4). The stent was positioned so that no more than 3 cm of it extended into the WON. ETN was not attempted in the initial session. Oral intake or tube feedings were resumed if the patient did not have significant pain or any adverse event from the procedure. The size of the necrotic collection was followed by CT scans and/or magnetic resonance imaging, as warranted by the patient's clinical course. ETN was performed in subsequent sessions as determined by clinical symptoms of pain, fever, or lack of resolution of the necrosis as shown by imaging. At repeat procedures for endoscopic necrosectomy, the Taewoong stent was removed and ETN was performed by using cap suction, nets, baskets, and/or forceful irrigation via a forward-viewing

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