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# Prospective evaluation of the use of fully covered self-expanding metal stents for EUS-guided transmural drainage of pancreatic pseudocysts

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Endoscopic drainage has become the procedure of choice for the management of symptomatic pancreatic pseudocysts in high-volume centers.[1] In recent years, the use of EUS guidance for transmural pseudocyst drainage has gained popularity because of its ability to locate a suitable puncture site in patients without obvious extrinsic gastric or duodenal compression and its avoidance of intramural vessels during the initial pseudocyst puncture.[1-6]

Although various techniques have been described, the basic transmural drainage is performed by first accessing the pseudocyst; cauterizing the tract, dilating it, or both; and finally inserting multiple plastic stents to facilitate drainage and maintain tract patency.[7,8] Once the patient has improved clinically and the pseudocyst is resolved radiographically, the stents are removed. However, the placement of multiple plastic stents can be technically difficult and tedious because of the need to access the cyst cavity multiple times or the need to use 2 wires simultaneously to maintain access. Furthermore, 10F plastic stents can be hard to deploy through the relatively small 3.7-mm channel of the therapeutic linear echoendoscope scope. Recently, groups have reported the use of fully covered self-expanding metal stents (CSEMSs) for pseudocyst drainage.[9] CSEMSs offer some advantages in that only a single stent may be required rather than multiple plastic stents. Moreover, they provide a larger diameter than do plastic stents. Therefore, they can theoretically allow for faster drainage and a decreased risk of occlusion, which might reduce the need for repeated procedures. In addition, pseudocyst drainage with CSEMSs eliminates the need to access the cyst cavity multiple times and the simultaneous use of 2 guidewires to secure cyst access. To our knowledge, none of these potential advantages of CSEMSs have been rigorously evaluated by prospective studies. Furthermore, there is concern that because of the presence of silicone coating on CSEMSs, they may have a higher migration rate. In this study, we prospectively evaluated the technical feasibility of EUS-guided single-access pseudocyst drainage with a CSEMS anchored with a double pigtail plastic stent inserted through the metal stent lumen. Additionally, we assessed for pseudocyst resolution and adverse events.

*Abbreviation: CSEMS, fully covered self-expanding metal stent.*

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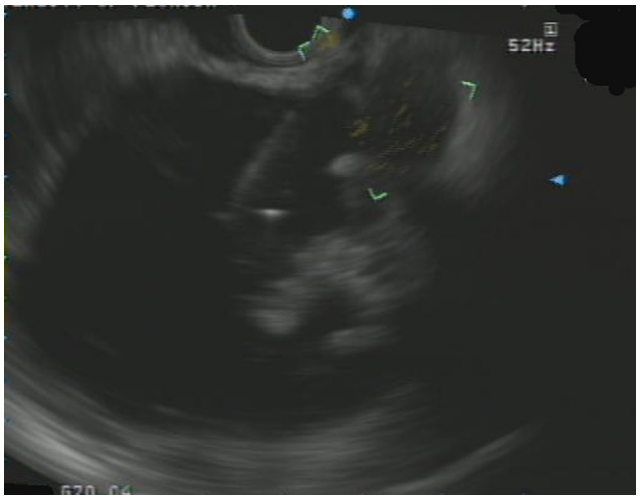


**Figure 1.** Pseudocyst being punctured by FNA needle.

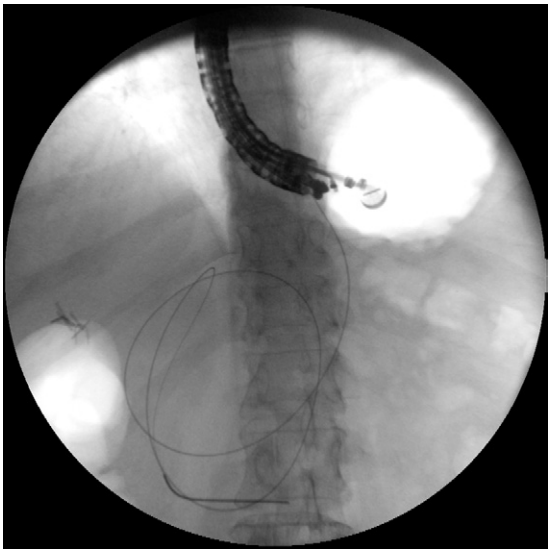

**Figure 2.** Fluoroscopic view of guidewire coiled inside pseudocyst.

## METHODS

### Study design

This prospective cohort study was approved by the Institutional Review Board at the University of Florida. All patients signed research informed consent. The trial was registered with ClinicalTrials.gov (NCT01239056). The study concept, hypothesis, and design were investigator initiated, and no financial support or free devices were received.

### Study population

All patients with symptomatic pseudocysts referred to our institution for transmural drainage were considered eligible for the study. Patients were excluded if there was evidence of preexisting intracystic bleeding, significant solid contents (>50%) or walled-off pancreatic necrosis, clinical or imaging findings suggesting that the lesion was not a pseudocyst, or pseudocyst wall was not in close proximity (>1 cm) to the EUS probe.

### Study protocol

All patients had a clear history of preexisting acute pancreatitis. At the first endoscopy session, EUS-guided transmural drainage was performed with a therapeutic linear echoendoscope (Olympus GF-UCT140, Olympus America, Center Valley, PA) by use of fluoroscopic guidance. If no exclusion criteria were noted on EUS, then an appropriate location for the initial puncture was identified, and the pseudocyst cavity was accessed with a 19-G Echo tip Ultra EUS needle (Cook Endoscopy, Winston Salem, NC) (Fig. 1). The pseudocyst contents were aspirated to reconfirm the needle tip location within the cyst cavity and to exclude the presence of blood. Fluid was sent for standard testing, including carcinoembryonic antigen level, amylase level, and cytology (These results were reviewed later to ensure that we had not inadvertently drained a premalignant or malignant lesion). Then a 0.035-inch 450-cm-long Jagwire (Boston Scientific, Natick, MA) was inserted through the FNA needle and coiled in the pseudocyst cavity by use of fluoroscopic guidance (Fig. 2). Next, the FNA needle was exchanged, and placement of a 10-mm to 40-mm fully covered WallFlex metal biliary stent (Boston Scientific) was attempted. If the CSEMS could not be inserted over the guidewire directly into the cyst cavity, balloon dilation of the tract with either an 8-mm or a 10-mm Fusion Titan biliary dilating balloon (Cook Endoscopy) was performed. After placement of the CSEMS, over the same guidewire, a single 10F or 7F double pigtail biliary stent (Cook Endoscopy) was placed through the CSEMS with the internal pigtail inside the cyst cavity and the external pigtail in the GI lumen, thereby anchoring the CSEMS (Figs. 3 and 4). This was done to reduce the risk of migration. All patients were given intraprocedural intravenous ciprofloxacin 400 mg. This was continued for 3 to 5 days after the procedure. The antibiotic was switched to oral administration in patients who were discharged home immediately after the procedure.

At a second endoscopy session, all patients (except 1) underwent ERCP to evaluate for pancreatic duct disruption. If pancreatic duct disruption was found, pancreatic sphincterotomy and transpapillary pancreatic duct stent placement were attempted.

Pseudocyst resolution was assessed by CT generally 6 to 12 weeks after the initial transmural drainage. If complete resolution of the pseudocyst was noted, all stents (transmural and transpapillary) were subsequently removed. In patients who had documented pancreatic duct disruption on ERCP, repeated pancreatograms were obtained to ensure resolution of the leak before removal of the transpapillary stent. However, if