Feasibility and safety of a fully covered self-expandable metal stent with antimigration properties for EUS-guided pancreatic duct drainage: early and midterm outcomes (with video)

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Background and Aims: Recently, EUS-guided pancreatic duct drainage (EUS-PD) has been used for patients in whom endoscopic retrograde pancreatography (ERP) has failed. Stent-related adverse events such as stent migrations, failures in stent placement, or pancreatic fluid leakages have been of concern in transmural plastic stenting procedures. The aim of this study is to evaluate the feasibility and safety of EUS-PD with a fully covered self-expandable metal stent (FCSEMS) for patients with obstructive pancreatitis who failed ERP.

Methods: Twenty-five consecutive patients with painful obstructive pancreatitis underwent EUS-PD with a FCSEMS after failed ERP. Technical and clinical success, adverse events, and stent patency were assessed.

Results: EUS-PD was successful in all 25 patients (technical success rate, 100%), and symptoms improved in all patients (clinical success rate, 100%). EUS-guided pancreaticogastrostomy (n = 23), pancreaticoduodenostomy (n = 1), and pancreaticojejunostomy (n = 1) were performed. Pain scores improved significantly after FCSEMS placement ($P = .001$). Early mild grade adverse events occurred in 5 patients (20%), 4 with self-limited abdominal pain and 1 with minor bleeding. No other adverse events related to FCSEMS, including stent migration, stent clogging, pancreatic sepsis, and stent-induced ductal stricture, were observed during follow-up periods. Mean stent patency duration was 126.9 days during mean follow-up periods (221.1 days).

Conclusions: EUS-PD with an FCSEMS may be technically feasible and relatively safe for patients who fail conventional ERP. Further randomized trials comparing EUS-PD with long-term FCSEMS and plastic stents for patients with painful obstructive pancreatitis after failed ERCP should be encouraged. (Gastrointest Endosc 2016;83:366-73.)

Endoscopic retrograde pancreatography (ERP) is a conventional method for treating pancreatic ductal obstruction caused by strictures, stones, or congenital anomalies. ERP may not be technically possible in approximately 3% to 10% of patients because of surgically altered anatomies, tight strictures, complete ductal obstructions, or disrupted ducts.[1] Repeat endoscopic attempts and/or percutaneous radiologic or surgical intervention may be required for failed ERP.[1,2]

EUS-guided pancreatic duct drainage (EUS-PD) is a promising diagnostic and therapeutic modality for patients

Abbreviations: ERP, endoscopic retrograde pancreatography; EUS-PD, EUS-guided pancreatic duct drainage; FCSEMS, fully covered self-expandable metal stent; IQR, interquartile range; MPD, main pancreatic duct.

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with painful obstructive pancreatitis in whom endoscopic transpapillary drainage has failed.[3] According to the approach of stent placement, EUS-guided antegrade (transanastomotic/transpapillary and/or transmural) or rendezvous stent placement can be completed.[1,4] Of the 2, the rendezvous approach seems to be more safe and effective than the EUS-guided antegrade approach.[5] However, it is not possible to advance a guidewire across the anastomosis site or the major papilla under complete pancreatic obstruction or a tortuous configuration of the main pancreatic duct (MPD).[1,5] For this situation, EUS-PD with transmural plastic stenting may be performed. However, stent migration, failed stent placement, or pancreatic fluid leakage are possible in the transmural plastic stenting procedure.[2,6] Furthermore, plastic stents may clog or have a difficult stent exchange because of the small diameter of the stent and fistula opening.

Self-expandable metal stents, which have a larger diameter, have been used to achieve a prolonged stent patency in benign and malignant biliary strictures.[7,8] In previous reports, the transpapillary placement of a fully covered self-expandable metal stent (FCSEMS) for a pancreatic ductal stricture appeared to be technically feasible and effective.[9-11] However, an FCSEMS has not yet been used for EUS-PD with transmural stenting, because of concerns of stent migration and a cross-stream blockage of the MPD that cover the membrane of the FCSEMS. Here, we report our experience using an FCSEMS with antimigration properties for EUS-PD.

METHODS

Patients

This is a retrospective analysis of prospective data collection. Consecutive patients with painful obstructive pancreatitis underwent EUS-PD after failed ERP between July 2013 and December 2014. All patients provided written informed consent to participate in this study. The institutional review board approved the study protocol, and we obtained specific informed consent from each patient to perform EUS-PD before the procedure.

Our inclusion criteria were failure of pancreatic duct decompression through ERP including deep enteroscopy because of a surgically altered anatomy or failure of an EUS-guided rendezvous caused by the inability of a guidewire to traverse the anastomosis site stricture or major/minor papilla in patients with painful obstructive pancreatitis through recurrent acute pancreatitis, chronic pancreatitis, and anastomotic site strictures. Patients with intermittent pain, induced by meals, and obstruction of the MPD with upstream dilation because of malignancy on CT scan were also included,[12] as were reattempted patients with a migrated transgastric plastic stent (7F single pigtail stent, Cook Medical, Bloomington, Ind) after previous EUS-PD. Our exclusion criteria were patients who refused to participate in the study protocol, who were pregnant, and who were younger than 18 years.

Procedure

An experienced endoscopist (D.H.P.) performed all EUS procedures using a curvilinear echoendoscope (GF-UCT 260-AL 10; Olympus Medical System, Tokyo, Japan). After an evaluation of the MPD, it was punctured with a 19-gauge needle (ECHO-19; Cook Medical) under EUS guidance. After the puncture, needle aspiration was performed to confirm the intraductal portion, followed by a contrast injection to provide a pancreatogram. A .025-inch (Visiglide; Olympus America, San Jose, Calif) or .035-inch guidewire (Tracer; Cook Medical) was inserted through the lumen of the pancreaticogastric or pancreaticoenteric fistula and then advanced across the anastomotic site or major or minor papilla or placed in the MPD, according to the access point of the guidewire. In cases in which the EUS-guided rendezvous technique was not feasible because of a failed pass of the guidewire through the anastomotic site or papilla, EUS-PD with transmural stenting was considered. For this, withdrawal and repositioning of the EUS fine needle for better access to transmural stenting was permitted. For EUS-PD with an FCSEMS placement in a transmural antegrade approach, an EUS scope was repositioned for the targeting of the MPD on the pancreas body. At this point, the axis of the EUS needle may be parallel to the longitudinal MPD of pancreas body or body–tail junction (Supplemental Fig. 1, available online at www.giejournal.org). This access point and oblique angle for stent insertion may be more suitable for transmural FCSEMS placement in terms of stabilization of a guidewire, easy pushability of the dilating device, and a longer length of FCSEMS placement in the MPD (Supplemental Fig. 1).

After successful guidewire manipulation and withdrawal of the needle, a triple-lumen needle knife (Microknife; Boston Scientific, Natick, Mass) with a brief burst of pure cutting current was used to advance through the fistula tract. Then, a 4-mm balloon catheter (Hurricane; Boston Scientific) was placed and dilated through the fistula tract. A modified FCSEMS (commercially available, silicon covered, nitinol wire, 6 or 8 mm in diameter, 6-10 cm in length, 8.5F stent introducer in 8-mm diameter, 8F stent introducer in 6-mm diameter; M.I. Tech, Seoul, Korea) with proximal and distal anchoring flaps was placed through the fistula tract. These anchoring flaps were designed to have the blunt end with a covering membrane for the prevention of a stent-induced ductal injury and to prevent proximal and distal migration (Fig. 1). The diameter (6 or 8 mm) of the metal stent was chosen according to the degree of pancreatic ductal dilatation. With EUS and fluoroscopic guidance, an FCSEMS was placed in the pancreaticogastric or pancreaticoenteric fistula. All enrolled patients were given antibiotics before and after the procedure. Patients were given nothing by mouth for 6 hours after the procedure.