Evaluation of the short- and long-term effectiveness and safety of fully covered self-expandable metal stents for drainage of pancreatic fluid collections: results of a Spanish nationwide registry

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Background and Aims: Initial reports suggest that fully covered self-expandable metal stents (FCSEMSs) may be better suited for drainage of dense pancreatic fluid collections (PFCs), such as walled-off pancreatic necrosis. The primary aim was to analyze the effectiveness and safety of FCSEMSs for drainage of different types of PFCs in a large cohort. The secondary aim was to investigate which type of FCSEMS is superior.

Methods: This was a retrospective, noncomparative review of a nationwide database involving all hospitals in Spain performing EUS-guided PFC drainage. From April 2008 to August 2013, all patients undergoing PFC drainage with an FCSEMS were included in a database. The main outcome measurements were technical success, short-term (2 weeks) and long-term (6 months) effectiveness, adverse events, and need for surgery.

Results: The study included 211 patients (pseudocyst/walled-off pancreatic necrosis, 53%/47%). The FCSEMSs used were straight biliary (66%) or lumen-apposing (34%). Technical success was achieved in 97% of patients (95% confidence interval [CI], 93%-99%). Short-term- and long-term clinical success was obtained in 94% (95% CI, 89%-97%) and 85% (95% CI, 79%-89%) of patients, respectively. Adverse events occurred in 21% of patients (95% CI, 16%-27%): infection (11%), bleeding (7%), and stent migration and/or perforation (3%). By multivariate analysis, patient age (>58 years) and previous failed drainage were the most important factors associated with negative outcome.

Conclusions: An FCSEMS is effective and safe for PFC drainage. Older patients with a history of unsuccessful drainage are more likely to fail EUS-guided drainage. The type of FCSEMS does not seem to influence patient outcome. (Gastrointest Endosc 2016;84:450-7.)

Abbreviations: AE, adverse event; CI, confidence interval; F, French; FCSEMS, fully covered self-expandable metal stent; LAMS, lumen-apposing metal stent; LTCS, long-term clinical success; MRI, magnetic resonance imaging; OR, odds ratio; PFC, pancreatic fluid collection; RSS, required salvage surgery; SBFCSEMS, straight biliary fully covered self-expandable metal stent; SD, standard deviation; STCS, short-term clinical success; TS, technical success; WOPN, walled-off pancreatic necrosis.

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Drainage of pancreatic fluid collections (PFCs)[1,2] has been classically performed by surgical means with good results but with high rates of morbidity.[3,4] For this reason, nonsurgical techniques have emerged, and EUS-guided PFC drainage has become the mainstay for treating these patients.[5-7] Internal endoscopic drainage is preferred over external radiologic drainage owing to better tolerability, lower morbidity rates, increased success rates, and the lower number of reinterventions required.[8-12]

The EUS-guided drainage of PFCs has been traditionally performed with placement of plastic stents, with good results for pseudocysts (clinical success rate, 88%-98%; adverse event [AE] rate, 5%-15%) but worse outcomes for collections with solid debris such as walled-off pancreatic necrosis (WOPN) (success rate, 63%-70%; AE rate, 16%-25%).[7,13] Greater amounts of debris and necrosis results in stent occlusion and treatment failure.[7,13,14] Although preliminary reports suggest that fully covered self-expandable metal stents (FCSEMSs), due to their larger caliber (8-10 mm), may be better suited for draining difficult PFCs (success rate, 78%-100%; AE rate, 0%-33%),[13,15] experience with FCSEMSs in pancreatic pseudocysts and WOPN is limited. Concerns regarding safety, efficacy, and cost have been raised by some experts in the field.[9,13] To our knowledge, there is no population-based study investigating the role of FCSEMSs for PFC drainage in a large cohort of patients. Furthermore, whether lumen-apposing metal stents (LAMSs) may be better than straight biliary FCSEMSs (SBFCSEMSs) is unknown.

The primary aim of this study was to analyze the effectiveness and safety of FCSEMSs for drainage of different types of PFCs in a large cohort study. The secondary aim was to investigate which type of FCSEMS is superior.

METHODS

Patients

All hospitals performing EUS-guided PFC drainage with FCSEMSs in Spain between April 2008 and August 2013 were identified through the national EUS and endoscopy societies and were invited to participate in this nationwide retrospective registry. Institutional review board approval was obtained for medical record and database review and analysis of included patients.

Inclusion and exclusion criteria. We included patients with symptomatic PFCs requiring drainage and patients who had undergone an EUS-guided PFC drainage with placement of an FCSEMS. Patients were excluded if (1) an FCSEMS was not used for PFC drainage and (2) at least 6-month follow-up after drainage was not available. All patients treated at the participating centers who met the study criteria were included and analyzed in an intention-to-treat analysis.

Data analyzed. The following data were extracted from databases and registries at the participating hospitals for analysis: patient demographic information (age and sex), etiology of pancreatitis, history of chronic pancreatitis, size and type of PFC (pseudocyst vs WOPN), previous failed drainage (and technique), time of evolution since diagnosis of PFC until EUS-guided treatment, type of FCSEMS used for drainage (LAMS vs SBFCSEMS), use of a coaxial plastic stent to prevent migration of the FCSEMS, nasocystic tube placement for continuous lavage and/or endoscopic necrosectomy, and coexisting percutaneous drainages. Information regarding previous unsuccessful drainage by any other technique (percutaneous radiology guided, EUS guided, or surgery) also was collected. A previous drainage was considered unsuccessful if, despite that previous therapy, the patient still showed symptoms derived from the PFC and was referred for that reason for EUS-guided drainage.

Patient follow-up. Patients were followed up with periodic clinic visits, laboratory analyses, and imaging techniques at each of the participating hospitals at the discretion of the responsible physicians. Follow-up was not uniform across all centers, but each patient was observed for at least 6 months, and CT and/or magnetic resonance imaging (MRI) within the first 2 weeks and 6 months after EUS-guided drainage were included. Patient feeding (enteral or total parenteral nutrition), antibiotics, and other additional medicines required by the patient were at the discretion of the attending physician at each institution.

Outcomes measured. Technical success and short-term (2 weeks) and long-term (6 months) effectiveness of EUS-guided drainage with an FCSEMS were assessed. All AEs, directly related to the endoscopic intervention or not, were registered and included for analysis. Need for surgical rescue therapy due to technical or clinical failure or AEs was also registered for analysis.

Technical success was accomplished when all steps required for EUS-guided drainage of the PFC with an FCSEMS were accomplished and PFC contents were seen exiting from the FCSEMS during endoscopy. For short-term clinical effectiveness, the patient was asymptomatic and had a greater than 50% decrease in the size of the PFC, as measured by CT or MRI, 2 weeks after the EUS-guided drainage. For long-term clinical effectiveness, the patient was asymptomatic and had a greater than 50% decrease in the size of the PFC, as measured by CT or MRI, 6 months after the EUS-guided intervention. Adverse events were identified by the development of new signs or symptoms (eg, fever or pain) immediately after the EUS-guided drainage or during patient follow-up. Need for surgery was defined as patient requiring a surgical intervention due to AEs or because of ineffective endoscopic drainage.

Technique for EUS-guided PFC drainage with an FCSEMS

The procedure was performed on an inpatient basis by a single operator or a team of 2 endoscopists with experience in EUS and therapeutic endoscopy. Procedures