Fully covered self-expanding metal stents versus lumen-apposing fully covered self-expanding metal stent versus plastic stents for endoscopic drainage of pancreatic walled-off necrosis: clinical outcomes and success CME

Ali A. Siddiqui, MD,[1] Thomas E. Kowalski, MD,[1] David E. Loren, MD,[1] Ammara Khalid, MD,[1] Ayesha Soomro, MD,[1] Syed M. Mazhar, MD,[1] Laura Isby, BS,[2] Michel Kahaleh, MD,[2] Kunal Karia, MD,[2] Joseph Yoo, MD,[1] Andrew Ofosu, MD,[1] Beverly Ng, MD,[1] Reem Z. Sharaiha, MD[2]

Philadelphia, Pennsylvania; New York, New York, USA

Background and Aims: Endoscopic transmural drainage/debridement of pancreatic walled-off necrosis (WON) has been performed using double-pigtail plastic (DP), fully covered self-expanding metal stents (FCSEMSs), or the novel lumen-apposing fully covered self-expanding metal stent (LAMS). Our aim was to perform a retrospective cohort study to compare the clinical outcomes and adverse events of EUS-guided drainage/debridement of WON with DP stents, FCSEMSs, and LAMSs.

Methods: Consecutive patients in 2 centers with WON managed by EUS-guided debridement were divided into 3 groups: (1) those who underwent debridement using DP stents, (2) debridement using FCSEMSs, (3) debridement using LAMSs. Technical success (ability to access and drain a WON by placement of transmural stents), early adverse events, number of procedures performed per patient to achieve WON resolution, and long-term success (complete resolution of the WON without need for further reintervention at 6 months after treatment) were evaluated.

Results: From 2010 to 2015, 313 patients (23.3% female; mean age, 53 years) underwent WON debridement, including 106 who were drained using DP stents, 121 using FCSEMSs, and 86 using LAMSs. The 3 groups were matched for age, cause of the pancreatitis, WON size, and location. The cause of the patients' pancreatitis was gallstones (40.6%), alcohol (30.7%), idiopathic (13.1%), and other causes (15.6%). The mean cyst size was 102 mm (range, 20-510 mm). The mean number of endoscopy sessions was 2.5 (range, 1-13). The technical success rate of stent placement was 99%. Early adverse events were noted in 27 of 313 (8.6%) patients (perforation in 6, bleeding in 8, suprainfection in 9, other in 7). Successful endoscopic therapy was noted in 277 of 313 (89.6%) patients. When comparing the 3 groups, there was no difference in the technical success ($P = .37$). Early adverse events were significantly lower in the FCSEMS group compared with the DP and LAMS groups (1.6%, 7.5%, and 9.3%; $P < .01$). At 6-month follow-up, the rate of complete resolution of WON was lower with DP stents compared with FCSEMSs and LAMSs (81% vs 95% vs 90%; $P = .001$). The mean number of procedures required for WON resolution was significantly lower in the LAMS group compared with the FCSEMS and DP groups (2.2 vs 3 vs 3.6, respectively; $P = .04$). On multivariable analysis, DP stents remain the sole negative predictor for successful resolution of WON (odds ratio [OR], 0.18; 95% confidence interval, 0.06-0.53; $P = .002$) after adjusting for age, sex, and WON size. Although there was no significant difference between FCSEMSs and LAMSs for WON resolution, the LAMS was more likely to have early adverse events (OR, 6.6; $P = .02$).

Conclusions: EUS-guided drainage/debridement of WON using FCSEMSs and LAMSs is superior to DP stents in terms of overall treatment efficacy. The number of procedures required for WON resolution was significantly lower with LAMSs compared with FCSEMSs and DP stents. (Gastrointest Endosc 2017;85:758-65.)

(footnotes appear on last page of article)

INTRODUCTION

Pancreatic fluid collection (PFC) develops as a result of pancreatic ductal damage in the setting of acute or chronic pancreatitis, iatrogenic causes, or trauma.[1,2] PFC includes pancreatic pseudocysts and walled-off necrosis (WON).[2] WON is a mature, encapsulated collection of pancreatic necrosis that contains both solid and liquid components.

Most WONs are asymptomatic and up to 60% resolve spontaneously.[3] However, they can become symptomatic when they are infected or increase in size, leading to symptoms such as abdominal pain, early satiety, gastric outlet obstruction, biliary obstruction, and sepsis.[3,4]

Currently, the management of symptomatic WONs includes endoscopic, surgical, and percutaneous debridement.[5-7] The surgical approach is invasive and has high mortality and morbidity.[8] WONs drained via the percutaneous approach are at risk of fistula formation, cyst recurrence, and infections.[9]

Endosonography-guided debridement of WONs with placement of transmural stents is often viewed as first-line therapy instead of surgical or interventional radiology approaches.[10,11] EUS-guided debridement has been demonstrated to have a high success rate (87%-97%) with low rates of adverse events (6%-34%) and mortality (0%-1%).[11-13]

In 2007, Papachristou et al[14] reported transmural drainage/debridement of WON using double-pigtail plastic (DP) stents. Later, endoscopists noticed the limitations of plastic stents requiring placement of multiple plastic stents with repetitive wire access via cystenterostomy. Case series have shown successful use of biliary fully covered self-expanding metal stents (FCSEMSs) in EUS debridement of PFCs with a success rate ranging between 78% and 100%. FCSEMSs are larger in diameter than DP stents and permit single-step insertion. However, they do carry the risk of stent migration. The lumen-apposing fully covered self-expanding metal stent (LAMS) with both proximal and distal anchor flanges has been demonstrated to be both safe and effective for endoscopic transmural debridement of WONs.[15-17] It allows direct endoscopic debridement of WONs after stent deployment by passage of the endoscope through the stent lumen, which may improve efficacy and decrease adverse events associated with these procedures.

Currently, no clinical study exists comparing the effectiveness, adverse events, and WON recurrence rate of these stents. Our objective was to perform a retrospective cohort study to compare DP stents, biliary FCSEMSs, and LAMSs for the drainage/debridement of WONs in terms of overall outcomes, success rate, adverse events, and predictors of success.

METHODS

Patients

The endoscopy database at both Cornell and Thomas Jefferson University Hospital was queried for all patients who had undergone EUS-guided drainage/debridement of a pancreatic WON between November 2009 and May 2015. Only patients with follow-up of 6 months or more were included in the study. A pancreatic WON was defined as a mature, encapsulated collection of pancreatic and/or peripancreatic necrosis that had developed a well-defined inflammatory wall (as per the Revised Atlanta Classification).[2]

All WONs were characterized by CT or magnetic resonance imaging. The indications for drainage/debridement of a WON included the following: (1) refractory abdominal pain, (2) gastric outlet or biliary obstruction, (3) ongoing systemic illness, anorexia, and weight loss, (4) a rapidly enlarging WON, and/or (5) an infected WON.[12] Patients who had pancreatic pseudocysts, neoplastic cystic lesions, coagulopathy (international normalized ratio >1.5), and thrombocytopenia (platelets <50,000/mm^3), patients with disconnected pancreatic duct syndrome, or imaging showing that the WON wall was not in close contiguity (>2 cm) to the EUS probe were excluded from the study. Magnetic resonance cholangiopancreatography was performed to evaluate the major pancreatic duct in patients with suspected pancreatic duct disruption.

Procedure

All patients underwent endoscopy with a linear array echoendoscope; all patients were placed under general anesthesia. Patients were administered broad-spectrum antibiotics before and after the procedure. The echoendoscope was used to examine the site of the WON. EUS imaging under Doppler flow guidance was used to assess the local vasculature and determine the cyst puncture site (either transgastric or transduodenal). A 19-gauge needle (Cook Medical, Winston-Salem, NC) was used to perform the primary puncture into the WON cyst cavity. Aspiration of the contents was then done to confirm the location and send the aspirate for microbiology. A 0.889-mm (0.035-inch) guidewire was inserted through the needle and then coiled into the PFC. The needle was then withdrawn and the guidewire was left in the cyst. This was followed by dilation of the tract using a 4-, 6-, or 10-mm diameter controlled radial expansion wire-guided balloon or needle knife.

In patients whose WON was drained using plastic stents, 2 10F DP stents were placed over the wire under endoscopic and fluoroscopic guidance into the WON.

In patients in whom biliary FCSEMSs were placed, a 10-mm by 40-mm or 10-mm by 60-mm WallFlex stent (Boston Scientific, Marlborough, Mass) or a Viabil stent (Gore, Utica, NY) was used. After placement of the FCSEMS, a 7F DP stent was placed over the same wire through the FCSEMS with the internal pigtail inside the WON cavity and the external pigtail in the lumen of the stomach or duodenum to anchor the FCSEMS and prevent stent migration. The plastic stent was left in situ until the biliary metal stent was removed.

In patients who underwent placement of a LAMS (AXIOS; Boston Scientific), the stent delivery catheter was placed over a guidewire under EUS guidance into the PFC. The distal flange was deployed under EUS