Endoscopic drainage of pancreatic fluid collections by use of a novel biflanged stent with electrocautery-enhanced delivery system

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Endoscopic drainage is currently the preferred modality of drainage for pancreatic fluid collections (PFCs) because of the ease of the procedure, reduced cost, shorter hospital stay, and the reduced morbidity and mortality compared with traditional surgical drainage.1 Plastic stents used for endoscopic drainage may become blocked with the passage of time, leading to adverse events requiring reinterventions, especially in PFCs with significant debris (ie, walled-off necrosis [WON]). Novel large-caliber metal stents (LCMSs) are less prone to spontaneous occlusions and therefore, provide efficient drainage of PFCs. Large-caliber metal stents have been broadly classified as either lumen-apposing metal stents (LAMSs) or biflanged metal stents (BFMSs). The safety and efficacy of these stents have been established in multiple studies.2,3

The deployment of novel metal stents involves a series of well-coordinated steps including real-time endosonography, fluoroscopy, and endoscopic imaging. Recently, LAMSs with an electrocautery-enhanced delivery system (Hot AXIOS; Boston Scientific Corp, Marlborough, Mass, USA) have been introduced. The stent assembly has inbuilt multiple steps for deployment, making the drainage procedure easier.4-6

In this study, we aimed to evaluate the feasibility and safety of a novel BFMS with electrocautery-enhanced delivery system (EC-BFMS) (Video 1, available online at www.VideoGIE.org).

METHODS

Five patients with symptomatic PFCs undergoing drainage with the EC-BFMS were included in the analysis. The PFCs were classified as WON or pseudocyst according to the revised Atlanta guidelines.7 The data were extracted from a prospectively collected database and analyzed retrospectively. The study was approved by the institution’s review board.

Drainage technique

All the PFCs were drained under EUS guidance after thorough assessment and choice of an appropriate site for drainage. The standard sequence of steps for EUS-guided drainage of PFCs with conventional BFMSs are (1) puncture of the PFC with a 19-gauge needle, (2) coiling of a guidewire inside the PFC, (3) creation of a cystogastrostomy fistula by use of a 6F cystotome over the guidewire, (4) dilation of the fistula with a small-caliber balloon, and (5) deployment of the stent under EUS, fluoroscopic, and endoscopic guidance.2

The important differences in drainage technique when the EC-BFMS was used are as follows. First, the cyst wall was punctured either with a 19-gauge regular FNA needle or directly with the electrocautery-enabled stent assembly with a free-hand technique, depending on the operator’s preference. Second, steps 3 and 4 (see above), including the use of a cystotome and balloon for creating a cystogastrostomy tract were omitted. Third, the guidewire was not coiled in all cases, and the decision to coil the guidewire inside the cyst cavity was left to the endoscopist’s discretion.

Technical success was defined as successful deployment of the EC-BFMS. Clinical success was defined as resolution of symptoms along with >50% reduction in the size of the PFC cavity. All intraprocedural and postprocedural adverse events were recorded.

Postprocedure follow-up

All the patients were followed up clinically and radiologically. If clinical symptoms persisted at 48 to 72 hours, a nasocystic drainage tube was placed for flushing with diluted hydrogen peroxide and saline solution. Subsequently, direct endoscopic necrosectomy was considered for patients with persistent symptoms.

The stents were removed about 4 weeks after initial placement. MRCP, endoscopic retrograde pancreatography, or both were performed before removal of the stents to delineate pancreatic ductal anatomy. A pancreatic ductal
A stent was placed in case a ductal stricture or leak was demonstrated.

**Electrocautery-enhanced BFMS**

The EC-BFMS (Hot Nagi Taewoong Medical, Gyenoggi-do, Korea) device is a through-the-scope BFMS delivery system (10F) (Fig. 1). The delivery system has a conical hollow stiff metallic tip, which is connected by an internal fine wire to the connector hub handle. This setup allows the operator to place the stent assembly without any dilation of the tract. This allows the operator to place the stent directly without intervening steps like guidewire placement, passage of a cystotome to create a fistula, or balloon dilation to allow passage of a stent assembly. The BFMS is a conventional fully covered metal stent made of nitinol with flared ends and covered with silicone membrane. The EC-BFMS is available in 2 lengths (20 and 30 mm) and 4 diameters (10, 12, 14, and 16 mm). The stent flanges measure 26 mm in diameter. The recommended settings on an electrosurgical generator are 80 to 120 watts on pure cut mode.

**RESULTS**

A total of 5 patients, all men (median age, 31 years; range, 18-39 years), underwent EUS-guided drainage of PFCs by use of an EC-BFMS equipped with an electrocautery-enhanced delivery system. Technical success was achieved in all the patients. Of these, the PFCs in 4 patients were WON, and 1 was a pseudocyst according to the revised Atlanta classification. The median size of fluid collections was 9.8 cm (range, 7.7-17 cm). The mean wall thickness of the PFCs at point of entry was 4.38 ± 1.02 mm (range, 3.2-5.6 mm) (Table 1). In 2 cases, a 16- × 30-mm stent was used; in the other 3 cases, a 16- × 20-mm stent was used.

**Procedure details**

A 19-gauge EUS-FNA needle was used to puncture the cyst wall in the first 3 patients, in whom the PFC wall thickness at the entry point was 5.1, 4.5, and 5.6 mm, respectively (Fig. 2A). In the remaining 2 patients, the cyst wall was punctured directly with the electrocautery-enhanced...
stent delivery system (Fig. 2B). The wall thickness in the latter patients was 3.2 and 3.5 mm, respectively. After the cyst wall puncture, a guidewire was coiled inside the cyst wall cavity in 4 patients. In 1 case, the entire drainage procedure was performed in a single step without needle puncture and guidewire placement (Fig. 2C). The median procedure time (from PFC wall puncture to stent placement) was 383 seconds (range, 115-445 seconds). The mean time taken for the first 3 procedures where a needle was used for puncture was 416 seconds (range, 383-445 seconds). In the last 2 cases, where the EC-BFMS system was used directly for PFC wall puncture, the time taken was 200 and 115 seconds, respectively (Table 1). There was no technical failure, nor were there intraoperative adverse events. One patient had a large PFC extending up to the paracolic gutter, where “combined drainage” was performed (ie, a percutaneous drain was placed from the flanks, followed by cystogastric EC-BFMS placement at the same session).

**Postprocedure follow-up**

Nasocystic tube placement and lavage with diluted hydrogen peroxide was performed in 3 patients for infected WON. Of these, direct endoscopic necrosectomy was
performed in 2 patients. Clinical success was achieved in all 5 patients.

All the EC-BFMSs were successfully removed at 4 weeks. The pancreatic duct was demonstrated to be normal on MRCP/endoscopic retrograde pancreatography in 3 patients. In 2 patients, a disconnected pancreatic duct was present. At a mean follow-up time of 10 months (range, 3–21 months), there were no recurrences of PFCs.

Statistical analysis
The data are presented as median or mean ± standard deviation.

DISCUSSION

In this series, we demonstrated the feasibility and safety of drainage of PFCs using a BFMS with a new electrocautery-enhanced delivery system. The endoscopic drainage of PFCs, especially WON, has been revolutionized with the introduction of novel metal stents. These stents have a wide caliber for efficient drainage and are either biflanged or lumen-apposing in design, which gives them antimigration properties. We have previously demonstrated the utility of BFMSs for the drainage of PFCs in adults and also in children.

The conventional deployment of metal stents under EUS guidance involves a series of steps, including puncture of the PFC wall with a regular FNA needle, coiling of a guidewire inside the cyst cavity, dilation of the cystogastric tract with a cautery and balloon, and finally deployment of the stent. These steps, in turn, require the exchange of several accessories like a cystotome and a balloon over the guidewire for the dilation of the cystogastric tract. The operator and the assistant have to act in synchrony, being vigilant to avoid losing access to the PFC cavity during these exchanges of accessories.

The recently introduced LAMS on an electrocautery-enhanced delivery system carries the advantage of eliminating most of the steps required for deployment of the stent. Rinninella et al. evaluated a novel LAMS (Hot AXIOS; Boston Scientific Corp) for the drainage of PFCs. This device is a through-the-scope stent delivery system with an electrocautery wire at the distal tip. Technical success was achieved in 98.9% of cases. Importantly, the PFC was punctured directly with the device in three-fourths of patients. The authors concluded that EUS-guided drainage with the electrocautery-enhanced delivery system is safe and easy to perform.

In the present pilot study, we report the initial use of an electrocautery-enabled BFMS for the drainage of PFCs. Stent deployment was easy and successful in all cases. In our study, an FNA needle was used for puncture in the first 3 cases to avoid maldeployment or adverse events while we were getting accustomed to the new device. Direct puncture with the stent delivery system was done in the last 2 cases, where the PFC wall was thinner (<4 mm) and direct puncture appeared easier. With more experience using the novel stent delivery system, it is probable that an FNA needle might not be required for cyst puncture even in patients with thick-walled collections.

The main advantage of the electrocautery-enabled system is that it simplifies the procedure and reduces the need for exchange of accessories. The operating time is considerably reduced, making the procedure efficient, which is especially important in sick patients. In this study, the median procedure time (PFC wall puncture to deployment of stent) was about 6 minutes. In the last case, in which the entire procedure was completed in a single step, the procedure time was about 2 minutes. In our experience, the approximate time to deploy a conventional Nagi stent is longer, averaging about 15 to 20 minutes. A recent study compared a BFMS (NAGI; Taewoong Medical, Gyenoggi-do, Korea) and a LAMS (Hot AXIOS; Boston Scientific Corp) with an electrocautery-enhanced delivery system. Technical and clinical success were similar in both groups. However, the median in-room procedure time was significantly shorter in the LAMS group (BFMS 62.5 minutes vs LAMS 45 minutes).

The other advantage of the EC-BFMS system is its intuitive delivery system, which is analogous to conventional biliary and luminal metal stent delivery systems. This reduces the chances of losing access to the PFC cavity. Moreover, the additional cost of accessories involved at various steps is avoided. The currently available LAMSs with electrocautery-enhanced delivery system (EC-LAMS) (Hot AXIOS; Boston Scientific Corp), although efficient, has a complex nonintuitive delivery system. In one study, there was no significant difference in cost between the BFMS and the EC-LAMS. However, the cost efficiency of EC-BFMSs compared with conventional BFMSs remains to be established.

In conclusion, endoscopic drainage of PFCs is feasible and safe by use of a novel biflanged metal stent with an electrocautery-enhanced delivery system. Larger studies are required to establish the utility of this novel stent delivery system for drainage of PFCs.

DISCLOSURE

Dr Reddy designed the Nagi stent used in this study for Taewoong Medical, Gyenoggi-do, Korea. All other authors disclosed no financial relationships relevant to this publication.

Abbreviations: ANP, acute necrotizing pancreatitis; BFMS, biflanged metal stents; CP, chronic pancreatitis; EC-BFMS, BFMS with electrocautery-enhanced delivery system; LAMS, large-caliber metal stents; EC-LAMS, LAMS with electrocautery-enhanced delivery system; PFC, pancreatic fluid collection; WON, walled-off necrosis.

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