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

Sundeep Lakhtakia, MD, DM,[1] Zaheer Nabi, MD, DNB,[1] Jong Ho Moon, MD, PhD,[2] Rajesh Gupta, MD, DM,[3] Radhika Chavan, MD, DNB,[3] Jahangeer Basha, MD, DM,[3] D. Nageshwar Reddy, MD, DM[3]

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 cystogastric 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 cystogastric 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

Written transcript of the video audio is available online at www.VideoGIE.org.

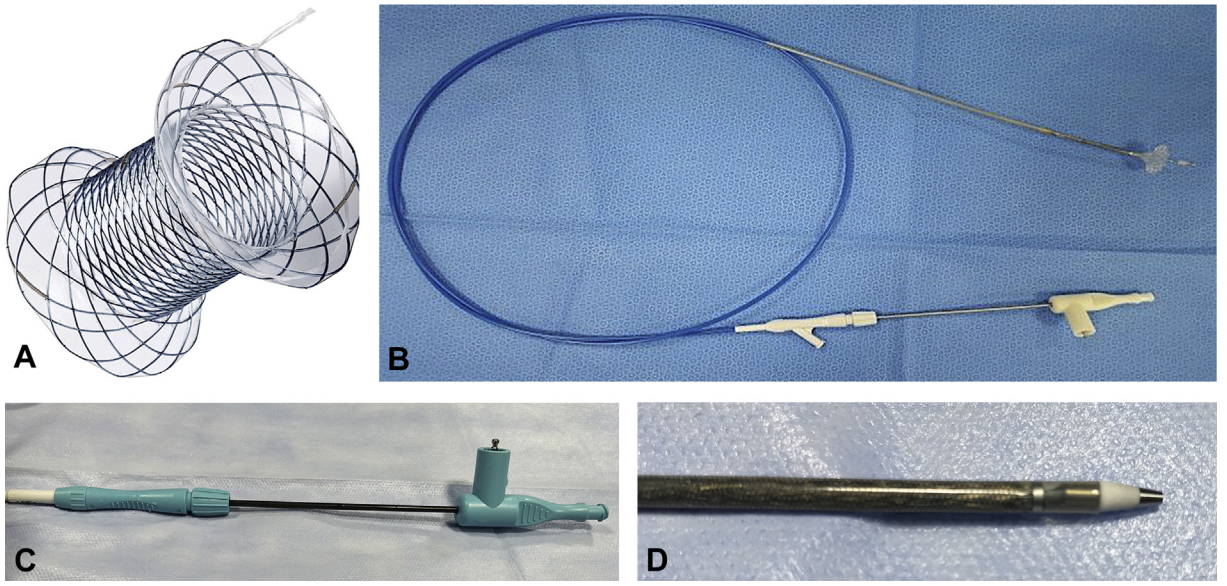

Figure 1. Components of electrocautery-enhanced stent delivery system. **A,** Novel biflanged metal stent. **B,** Electrocautery-enhanced stent delivery system. **C,** Magnified view of electrocautery plug. **D,** Electrocautery-enabled tip of catheter.

TABLE 1. Characteristics of patients who underwent drainage with EC-BFMSs

No.	Age	Sex	Acute or chronic pancreatitis	Type of PFC	Size of PFC (mm)	Wall thickness (mm)	Needle used for puncture	Guidewire secured	Procedure duration (seconds)
1.	26	M	ANP	WON	155 × 116	5.1	Yes	Yes	445
2.	39	M	ANP	WON	170 × 130	4.5	Yes	Yes	420
3.	32	M	ANP	WON	98 × 80	5.6	Yes	Yes	383
4.	18	M	CP	Pseudocyst	77 × 58	3.2	No	Yes	200
5.	31	M	ANP	WON	95 × 55	3.5	No	No	115

EC-BFMSs, BFMSs with electrocautery-enhanced delivery system; *ANP*, acute necrotizing pancreatitis; *CP*, chronic pancreatitis; *PFC*, pancreatic fluid collection; *WON*, walled-off necrosis.

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. The tip enables passage of 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