A new lumen-apposing metal stent for endoscopic transluminal drainage of peripancreatic fluid collections

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The endoscopic management of peripancreatic fluid collections (pancreatic pseudocysts, pancreatic abscesses, and walled-off pancreatic necrosis) has historically been technically challenging and associated with significant shortcomings. Traditional management included the use of endoscopic accessories including balloon dilators, stents, needle-knives, guidewires, and papilotomes, which were not specifically designed for transluminal drainage. Multiple 10French plastic stents were conventionally used for drainage, but were associated with the need for multiple revisions frequently due to the small lumen of the devices and consequent loss of patency.[1,2] Biliary fully covered-self expanding metal stents (SEMS) have been employed with the hope that a large luminal diameter would facilitate more effective and lasting drainage. Unfortunately, SEMSs may migrate and have been reported to cause tissue injury and bleeding when the end of the stent abuts the lumen wall.[3,4]

The AXIOS lumen-apposing stent (Xlumena Inc., Mountain View, California, USA) attempts to overcome the limitations of current endoscopic accessories with a removable fully covered, 10 or 15-mm diameter, nitinol, braided stent that is deployed under endoscopic ultrasound guidance [Figure 1]. A "dumbbell" configuration with two large flanges aims to avoid stent migration. When fully expanded the stent has a flange diameter twice that of the "saddle" section permitting apposition of the tissue layers. Stent delivery occurs under combined endoscopic and imaging guidance [Figure 2a and b] and requires an endoscope with a 3.7-mm working channel.[5]

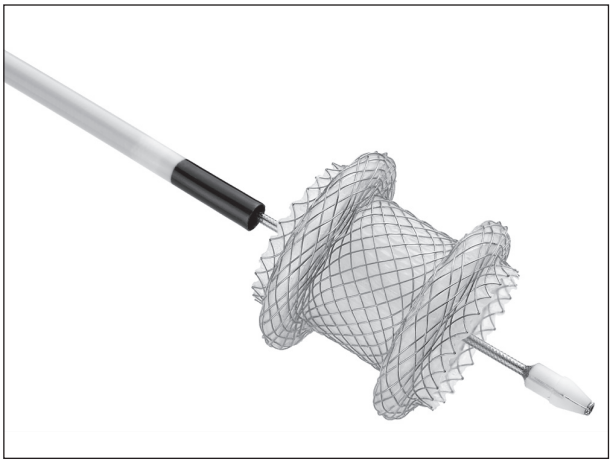

Figure 1. The AXIOS lumen-apposing metal stent

Several studies to date have looked at safety and effectiveness of the AXIOS delivery system (Xlumena Inc., Mountain View, California, USA) and lumen-apposing stent, including successful placement of stent, stent migration, patency and resolution of pancreatic fluid collections (PFC). Itoi *et al.*[6] first reported use of AXIOS stent for symptomatic pancreatic pseudocysts (15 patients). All stents were successfully deployed without complication (median time of removal 15 days). All patients had complete peripancreatic fluid collection resolution following initial procedure and

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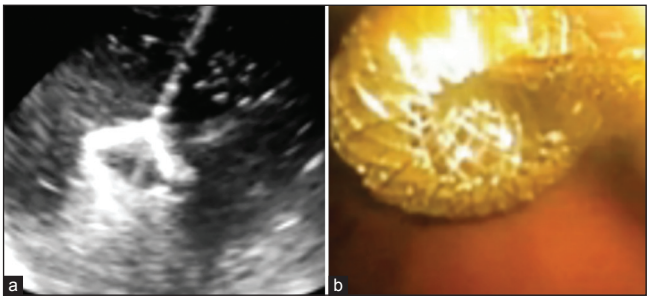

Figure 2. (a) Proximal AXIOS flange deployed in cyst cavity under endoscopic ultrasound visualization. (b) Distal AXIOS flange deployed in the gastric lumen

no recurrence during the 11.4 months median follow-up. One complication occurred with stent migration into the stomach without medical consequence. The remainder of the stents was found to be patent at the time of removal. In addition, endoscopists were able to perform pancreatic necrosectomy through the deployed AXIOS stent.

Similar success rates were achieved by Gornals *et al.*[7] comparing the AXIOS with plastic double pigtail stents. The technical success rate for AXIOS was 88.8% (8/9) with one failure of the delivery system. One pneumothorax was reported following transesophageal drainage. All patients achieved complete PFC resolution initially following the procedure (stent retrieval 33 ± 40 days). During a median 50 weeks follow-up, one patient experienced recurrence of their pseudocyst 4 weeks after stent removal. When compared to plastic pigtail stents (10 cases), the AXIOS stent showed similar technical and clinical success. However, patients with double pigtail stents experienced increased stent migrations (2), recurrences (2), and complications (2).

Shah *et al.* performed the largest AXIOS trial to date.[8] The multicenter study included 33 patients with pancreatic pseudocysts >6 cm in diameter. The AXIOS stent was successfully placed in 91% (31/33) of cases with 93% stent patency at 60 days follow-up. PFC resolution was observed in 94% (31/33) of cases. All stents were removed without complications. Spontaneous stent migration was observed in one case.

In conclusion, the AXIOS SEMS utilizes a single-step stent deployment system to effectively drain peripancreatic fluid collections and perform endoscopic necrosectomy through the stent. Success rate and PFC resolution are comparable to pigtail stent with fewer complications. Larger trials are required to determine the final role of AXIOS stent.

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