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Review Article

Lumen apposing metal stents: A review of current uses and outcomes

Jeffrey S. Bank, Douglas G. Adler*



ABSTRACT

Lumen-apposing metal stents (LAMS) represent a new innovation in gastrointestinal endoscopy. These devices have a saddle-shaped design and larger inner lumen diameter than either plastic or metal biliary stents, which should decrease the risk of migration and allows for an endoscope to pass into pancreatic fluid collections as well as the ability to perform direct endoscopic necrosectomy. LAMS were originally conceived and designed for transmural pancreatic fluid collection drainage but are currently also being used for many off label indications. There are three different LAMS available at this time around the globe. This manuscript will review the current state of the art with regards to LAMS and their indications, usage, and outcomes.

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Keywords: Axios; Lumen-apposing metal stents; Necrosectomy; Pancreatic necrosis; Pseudocyst

Introduction

Lumen-apposing metal stents (LAMS) have a saddle-shaped design and larger inner lumen diameter than either plastic or metal biliary stents, which theoretically decreases the risk of migration and allows for an endoscope to pass into pancreatic fluid collections (PFCs) as well as the ability to perform direct necrosectomy. LAMS were originally designed for PFC drainage but are currently also being used for many off label indications. There are three different LAMS available at this time around the globe (AXIOS, NAGI, and Niti-S Spaxus). The AXIOS stent (Xlumena Inc., Mountain View, CA, USA) consists of double-walled flanges perpendicular to the lumen that hold the tissue walls in apposition.¹ The NAGI stent (Taewoong Medical Co., Ltd., Goyang, Korea) comes in 3 different lengths, 4 diameters and has flared ends of 20 mm.² The Niti-S Spaxus stent (Taewoong Medical Co., Ltd.) consists of nitinol wire and is fully covered with a silicone membrane.³ This manuscript will review the current state of the art with regards to LAMS and their indications, usage, and outcomes.

Walled Off Pancreatic Necrosis and Pancreatic Pseudocysts

PFCs include pancreatic pseudocysts (PPs) and walled off pancreatic necrosis (WON or WOPN). PPs are composed of fluid collections in the peripancreatic tissues that are covered by a well-defined wall and do not contain significant amounts of solid material. WONs are encapsulated collection of necrotic tissue that typically contain liquid and solid material.⁴ The current options for management of symptomatic PFCs include endoscopic, surgical, and percutaneous drainage.^{5–7} Surgery is definitive but is the most invasive approach and is associated with high rates of morbidity and mortality. Surgical approaches often require multiple trips to the operating room before necrosectomy is felt to be complete.^{8–10} Percutaneous drainage may lead to fistula formation, and infection of the drain track, but is also highly effective.¹¹ Advances in endoscopy over the last ten years with endoscopic ultrasound (EUS)-guided drainage of PFCs using transmural stent placement has become the first-line management of PFCs at many tertiary care centers.⁵ Over the last few years, LAMS have been shown to be both safe and efficacious for endoscopic transmural drainage of PPs and WONs (Fig. 1).^{1–3,12–14}

Due to their increased lumen size, AXIOS and NAGI LAMS are

Division of Gastroenterology and Hepatology, Department of Internal Medicine, University of Utah School of Medicine, Salt Lake City, UT, USA

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* Corresponding author. Division of Gastroenterology and Hepatology, Department of Internal Medicine, University of Utah School of Medicine, 30N 1900E 4R118, Salt Lake City, UT 84132, USA.

E-mail address: douglas.adler@hsc.utah.edu (D.G. Adler).

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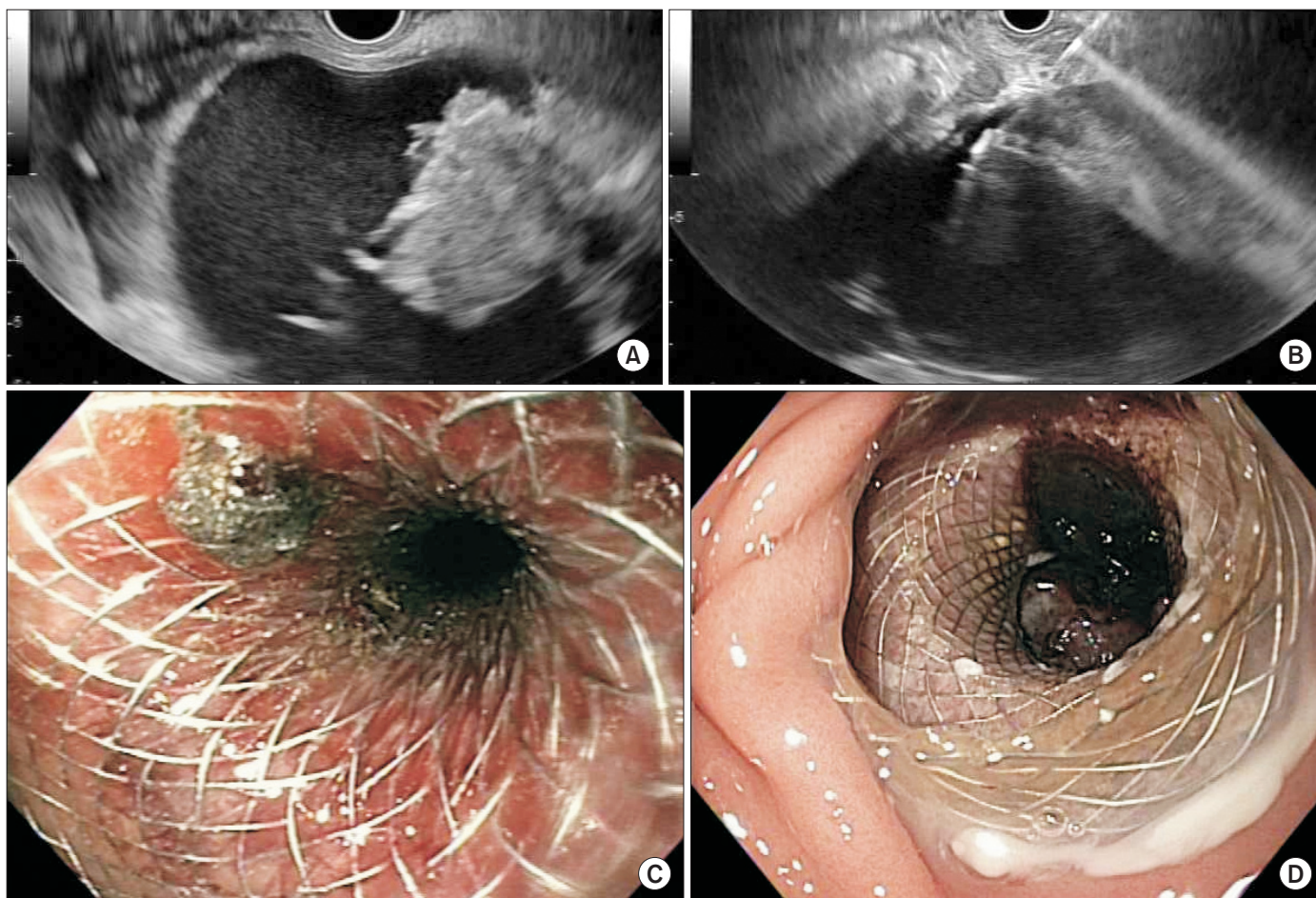


Fig. 1. Lumen-apposing metal stents for walled off pancreatic necrosis access, drainage, and debridement. (A) Endoscopic ultrasound (EUS) image (7.5 MHz) of a large pancreatic fluid collection (PFC) with solid and liquid contents. (B) EUS image (7.5 MHz) of the AXIOS stent (Xlumena Inc.) on its delivery catheter before deployment. (C) AXIOS stent immediately after deployment. Note some solid necrotic debris in stent. (D) AXIOS stent seen 2 weeks after placement. Note direct view into the PFC cavity, where necrosectomy was then performed.

preferable when direct endoscopic necrosectomy (DEN) is required as it allows the endoscopist to pass the scope directly through the stent into the PFC to remove the necrotic material.^{12,13}

In a retrospective case-control study, Bang et al¹⁴ compared 21 patients undergoing PP drainage (7 via LAMS, 14 via conventional plastic double pigtail stents) and 39 patients undergoing WON drainage (13 via LAMS, 26 via plastic stents). To be considered a treatment success, the pseudocyst or WON had to be ≤ 2 cm on computed tomography (CT)/magnetic resonance imaging (MRI) in combination with resolution of the patient's symptoms at 8-week follow-up. With regards to hospital costs, there was no difference seen between WON treated with plastic stents vs LAMS, but hospital costs were significantly decreased for pseudocysts drained with plastic stents (\$18,996 vs \$58,649; $P = 0.03$). The authors achieved treatment success in 80.9% of patients (17/21); of the four patients who had treatment failure, three had WON and one had a PP. This study did not demonstrate improved clinical outcomes for LAMS over plastic stents for the treatment of pseudocysts or WON. The major advantage of LAMS was decreased procedure time.¹⁴

In large cohort studies, LAMS have been shown to have high technical success rates (91%–98%) as well as clinical success rates, defined as resolution of clinical symptoms with a decrease

in PFC size to ≤ 2 cm on cross-sectional imaging (81%–100%). Shah et al¹⁵ examined 33 patients with PFCs (11 with WON and 22 with PPs) and found that 93% of PFCs resolved when treated with LAMS. In a European trial of 61 patients with PFCs (15 with PPs and 46 with WON), Walter et al¹⁶ demonstrated clinical success rates of 81% for patients with WON and 93% for patients with PPs and an overall adverse rate of 9%.

In a large American multicenter retrospective study on 82 patients with symptomatic PFCs, Siddiqui et al¹⁷ evaluated clinical outcomes and safety of EUS-guided drainage of PPs and WON using the LAMS. LAMS were placed successfully in 80 patients (97.5%) with PFCs (12 with PP and 68 with WON). Endoscopic therapy using LAMS was successful for resolution of the PFC in 12 of 12 patients (100%) with PP and 64 of 68 patients (94.1%) with WON. This was defined as complete resolution of the pseudocyst and resolution of the patient's symptoms without requiring reintervention at 3 months after initial treatment; this was assessed at clinical follow-up and imaging with CT or MRI. During the 3-month follow-up period, 1 PFC recurred. Adverse events occurred in 8 patients (9.8%), which included stent maldeployment ($n = 2$), and self-limited bleeding ($n = 6$).¹⁷

In a study of 47 patients with PFCs, Chandran et al¹⁸ demonstrated 76.6% resolution of PFCs using the NAGI LAMS. The

Table 1 Comparison of Clinical Outcomes Using Lumen-Apposing Metal Stents

	No. of patients	PP	WON	Technical success rate (%)	Clinical success rate (%)	Adverse event rate (%)
Bang et al ¹⁴	21	7	14	100.0	80.9	20.0
Shah et al ¹⁵	33	22	11	91.0	93.0	15.2
Walter et al ¹⁶	61	15	46	98.0	84.2	9.0
Siddiqui et al ¹⁷	82	12	68	97.0	95.0	9.8
Chandran et al ¹⁸	47	39	9	98.1	76.6	20.4
Sharaiha et al ¹⁹	124	0	124	100.0	86.3	11.3
Rinninella et al ²⁰	93	N/A	N/A	99.0	92.0	5.0
Gornals et al ²¹	12	0	13	100.0	100.0	33.3

PP, pancreatic pseudocyst; WON, walled off pancreatic necrosis; N/A, not available.

authors attributed their decreased rate of resolution compared with the AXIOS stent as used in the study by Siddiqui et al¹⁷ to their larger subgroup of patients with WON, infected WON, and infected pseudocysts. Adverse events included 4 early and 6 late stent migrations, 4 cases of sepsis, and 1 clinically significant gastrointestinal (GI) bleed.

Sharaiha et al¹⁹ performed a retrospective multicenter case series of 124 patients with WON who had endoscopic transmural drainage using LAMS performed at 17 tertiary care centers. Technical success occurred in 100% of patients and clinical success was achieved in 107 patients (86.3%), which was measured at 3-month follow-up. Stents remained patent in 94.4% of patients (117/124) and migrated in 5.6% of patients (7/124). Complete resolution of the WON with a single endoscopic session occurred in 34 patients. PFCs recurred in six patients (4.8%) after LAMS removal, verified on follow-up imaging. Clinical success occurred six times more frequently if the larger stent diameter (15 mm) was used. Adverse events less than 30 days from intervention occurred in fourteen patients (11.3%); these included re-intervention due to superinfection ($n = 4$), stent occlusion ($n = 5$), and stent migration ($n = 3$). Two patients developed acute hemorrhage during DEN that required interventional radiology embolization.

In a similar retrospective study of 93 patients (80% with complex collections) with PFCs at 13 European centers, Rinninella et al²⁰ successfully placed LAMS in 92/93 patients (98.9%). Overall clinical success occurred in 86/93 patients (92.5%) without evidence of recurrence during average follow-up of 320 days. Treatment failure occurred in 6/93 patients (6.5%) due to persistent infection requiring surgery ($n = 3$), perforation and massive bleeding caused by nasocystic drainage catheter ($n = 2$), and the need for a larger opening to extract large necrotic tissue ($n = 1$). Major adverse events occurred in 5/93 patients (5.4%).

In a prospective study of 12 patients with 13 WOPN collections who underwent endoscopic transmural necrosectomy using LAMS, Gornals et al²¹ accomplished clinical success in 100% of cases after a median of three sessions per patient. No adverse events occurred during the procedures; however, two infections and two bleeds occurred between sessions. The average duration of follow-up was 13 months with only 1 recurrence at 12 months after stent removal (Table 1).¹⁴⁻²¹

With regard to the safety of LAMS versus plastic stents, a recent ongoing randomized trial for drainage of PFCs via LAMS versus plastic stents demonstrated stent-related adverse events in 50.0% (6/12) patients who received LAMS and no adverse events in patients who received plastic stents.²² Similar results were seen in a previous study using both LAMS and plastic stents for drain-

age of PFCs where stent-related adverse events occurred in 10.0% (2/20) of patients who received LAMS and 2.5% (1/40) patients who received plastic stents.¹⁴ Other studies using LAMS for drainage of PFCs with larger numbers of patients ($n = 47$ to $n = 124$), have reported adverse event rates of 5.0%–20.4%.¹⁶⁻²⁰ There are few studies in the literature comparing plastic stents to LAMS for drainage of PFCs. However, performing a CT scan at 3 weeks post-procedure for all patients who received a LAMS followed by stent removal of evidence of PFC resolution may be reasonable as proposed by Bang et al.²²

Bile Duct Drainage

Endoscopic retrograde cholangiopancreatography (ERCP) is currently the standard of care for patients with biliary obstruction. ERCP may not be feasible in patients with malignant gastric outlet or duodenal obstruction, and rarely if there is an inability to cannulate the papilla or transverse a common bile duct (CBD) stricture.²³ When ERCP fails, percutaneous drainage, surgical bypass, and EUS-guided biliary drainage (EUS-BD) are alternative options.²⁴⁻²⁶ The rates of technical and clinical success have been high with EUS-BD (86%–98% and 88%–94%, respectively), although complication rates have been high as well (9%–26%).²⁷⁻³¹ To potentially improve success, LAMS have been developed and are now being used for choledochoduodenostomy (CD), gallbladder decompression, and cholecystoenterostomy.

Choledochoduodenostomy (Fig. 2)

In a retrospective study of 57 patients in seven tertiary European centers with unresectable distal bile duct obstruction after ERCP failure, Kunda et al³² demonstrated technical successful placement of EUS-guided CD (EUS-CD) with AXIOS or Hot AXIOS LAMS in 56/57 patients (98.2%). Average procedure time was 22.4 minutes (range, 11–65 minutes). Clinical success was achieved in 54/56 patients (96.4%; 94.7% of entire cohort). Adverse event rate was 7% and included two duodenal perforations, one bleeding, and one transient cholangitis. These authors used a combination of stent sizes, including 6 × 8 mm (36/56 patients), 8 × 8 mm (2/56 patients), 10 × 10 mm (16/56 patients), and 15 × 10 mm (2/56 patients). During an average follow-up of 151 days, 5/54 patients (9.3%) with clinical success required re-intervention: stent migration in 1 case and sump syndrome in 4 patients. At end of follow-up, the stent was patent without any intervention in 49/54 patients (90.7%).

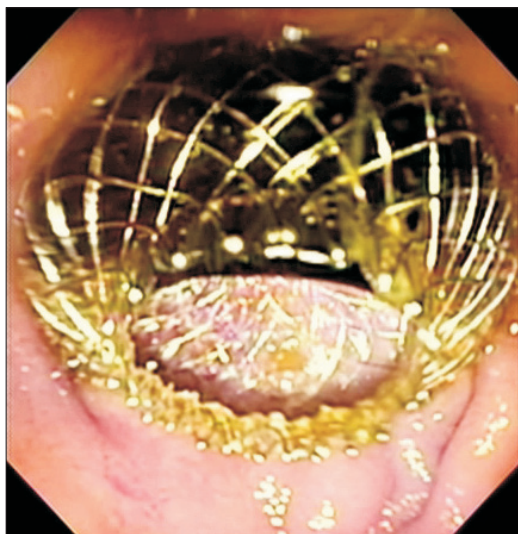


Fig. 2. Endoscopic image of a choledochoduodenostomy created via transluminal placement of an AXIOS stent (Xlumena Inc.) from the duodenal bulb to the common bile duct in a patient with an endoscopically inaccessible ampulla. Note copious bile drainage.

EUS-guided gallbladder drainage

EUS-guided gallbladder drainage (GBD) using LAMS is still in development but has been performed in a limited manner to date with very encouraging results.

In a retrospective review of 15 non-surgical patients at 3 tertiary care centers who underwent EUS-GBD using the AXIOS LAMS to decompress the gallbladder, Irani et al³³ had technical success in 14/15 patients (93.3%) and achieved clinical success in 15/15 patients at a median follow-up of 160 days. They used a 10 × 10 mm stent in 12 patients and a 15 × 10 mm stent in 3 patients. Indications for the procedures included 7 patients with calculous cholecystitis, 4 with acalculous cholecystitis, 2 with biliary obstruction, 1 with gallbladder hydrops, and 1 with symptomatic cholelithiasis. One patient had postprocedure fever for 3 days, otherwise no adverse events were noted. Median time to clinical response was 1 day (range, 0–3 days). No patients had evidence of postprocedure bile leakage or stent migration.

In a multicenter, prospective study of 30 high-risk surgical patients with acute cholecystitis, Walter et al³⁴ performed EUS-GBD using the AXIOS LAMS with technical success in 27/30 patients (90.0%) and clinical success in 26/27 patients (96.3%). Half of the patients did not have LAMS removal performed due to poor functional status and/or patients declining repeat procedures. These stents were left in place for an average time of 364 days, during which time no LAMS-related complications were observed. There were 15 serious adverse events (50.0%), including 4 that were possibly stent-related or procedure-related. Overall mortality was 23.3% (7/30); 30-day mortality was 16.7% (5/30).

Cholecystoenterostomy for internalization of drainage after percutaneous cholecystostomy

EUS-guided cholecystoenterostomy using LAMS has been performed in one case series and the technical success rate was encouraging.

In a prospective study of 7 non-surgical candidates who underwent EUS-guided cholecystoenterostomy with LAMS for inter-

nalization of GBD, Law et al³⁵ demonstrated technical success in all patients in 1 endoscopic session. The authors achieved internal GBD with a percutaneous cholecystostomy catheter.

Other Procedures: Gastrojejunostomy, EUS-directed Transgastric ERCP Procedure

Endoscopic ultrasound-guided gastrojejunostomy

In patients with gastric outlet obstruction (GOO), surgical gastrojejunostomy (GJ) is highly effective, but it has a morbidity rate of up to 39%.³⁶ Another option in widespread use is endoscopic placement of an enteral self-expanding metal stent (SEMS), which have high technical (90%–100%) and clinical success rates (67%–100%).^{37,38} However, SEMS can become obstructed or overgrown by tumor resulting in reduced luminal patency (57% in one study) after 6 months.³⁹ With the recent development of LAMS, Tyberg et al⁴⁰ examined the utility of LAMS for EUS-guided GJ (EUS-GJ) in patients with benign and malignant GOO. In an international, prospective trial of 26 patients with GOO, the authors demonstrated technical success of EUS-GJ using LAMS in 24 patients (92.3%). The authors used EUS to identify a loop of small bowel beyond the level of obstruction and access it via EUS fine needle aspiration (FNA) and guidewire placement, allowing transluminal LAMS placement. Clinical success, in which patients were able to tolerate an oral diet, was achieved in 22 patients (84.6%). Of these 22 patients, 19 underwent EUS-GJ after previous failed attempts at surgical or endoscopic treatments for GOO. Adverse events occurred in 3 patients (11.5%) and included peritonitis, bleeding, and surgery. Misplacement of the LAMS occurred in 7/26 cases (26.9%) and was the only cause of technical failure. The authors felt that EUS-GJ appears to be a less expensive option than its surgical equivalent.⁴⁰ It is not known how LAMS GJ compares to traditional endoscopic treatments for GOO like enteral stents, which do not require transluminal access to work.

EUS-directed transgastric ERCP

It can be difficult to perform ERCP in patients with Roux-en-Y gastric bypass due to their surgically altered anatomy. The technical success rate of deep enteroscopy-assisted ERCP is 63%, but this is dependent on the length of the roux limb and operator experience.⁴¹ These procedures are also time consuming compared to routine ERCPs. An alternative is ERCP through a surgically created gastrostomy into the excluded stomach, which has higher technical success rates (100%). However, the adverse event rate is up to 13% and this procedure requires coordination of multiple teams, leading to increased costs.^{42,43} The EUS-directed transgastric ERCP (EDGE) procedure utilizes EUS to visualize the bypassed stomach, then create a fistulous tract with a LAMS, and perform ERCP through the LAMS.

Kedia et al⁴⁴ report a case series of five patients with Roux-en-Y gastric bypass who underwent EGDE via a LAMS. EUS-guided formation of a gastrogastroic or jejuno gastric fistula via placement of a LAMS was successful in 5/5 patients (100%). ERCP was able to be performed through the fashioned fistula during the index procedure in 3/5 patients (60.0%). During a follow-up ERCP, 2/5 patients had their fistulous tract closed, which was confirmed by contrast injection. Of the 3/5 patients who had their LAMS left in place for continued biliary access, none had adverse events or weight gain at follow-up visits. It is somewhat unclear how the patients did not gain weight with the LAMS in place, of note.

The advantages of the EDGE procedure include its minimally

invasive nature, the ability to be performed entirely within the endoscopy suite, and that it obviates the need for deep enteroscopy or surgically created gastrostomy as the endoscopist may temporarily (in theory) recreate the patients' original upper GI anatomy. Stent dislodgement is a downside as Kedia et al⁴⁴ experienced it in 3/5 cases with the 15 mm LAMS; however, this may be less common with release of a 20 mm LAMS. Another disadvantage is the high cost of LAMS, but eliminating the need for operating room time and the surgical specialty team should also be taken into account. Further studies utilizing the EGDE procedure are needed before recommending widespread use of it for ERCP in patients with a history of Roux-en-Y gastric bypass.

Conclusion

Of the three currently available LAMS, the AXIOS stent is the most commonly utilized in the literature and the only one available in the United States. LAMS have been shown to have high clinical (77%–92%) and technical success (97.5%–100%) rates for drainage of PFCs, including both PPs and WOPNs, along with low adverse event rates (5%–11%). Due to their increased luminal diameter, LAMS are preferable in patients where endoscopic necrosectomy is required. For bile duct drainage in high-risk patients or non-surgical candidates, LAMS have been used for CD, gallbladder decompression, and cholecystoenterostomy in moderate size studies with promising rates of clinical and technical success. Lastly, small case series have demonstrated favorable outcomes for use of LAMS with EUS-GJ and EDGE procedures. Larger studies are required before LAMS have widespread use for the above procedures, but the early results are promising.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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