

TECHNOLOGY STATUS EVALUATION REPORT



Lumen-apposing metal stents (with videos)



Prepared by: ASGE TECHNOLOGY COMMITTEE

Ryan J. Law, DO,^{1,*} Vinay Chandrasekhara, MD, FASGE,^{1,*} Amit Bhatt, MD,² Juan Carlos Bucobo, MD, FASGE,³ Andrew P. Copland, MD,⁴ Kumar Krishnan, MD,⁵ Nikhil A. Kumta, MD, MS,⁶ Rahul Pannala, MD, MPH, FASGE,⁷ Mansour A. Parsi, MD, MPH, FASGE,⁸ Erik F. Rahimi, MD,⁹ Monica Saumoy, MD, MS,¹⁰ Guru Trikudanathan, MBBS,¹¹ Arvind J. Trindade, MD, FASGE,¹² Julie Yang, MD, FASGE,¹³ David R. Lichtenstein, MD, FASGE¹⁴ (ASGE Technology Committee Chair)

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

Background and Aims: Lumen-apposing metal stents (LAMSs) are a novel class of devices that have expanded the spectrum of endoscopic GI interventions. LAMSs with their dumbbell configuration, short saddle length, and large inner luminal diameter provide favorable stent characteristics to facilitate anastomosis formation between the gut lumen and adjacent structures.

Methods: The MEDLINE database was searched through April 2021 for articles related to LAMSs by using additional relevant keywords such as "walled-off pancreatic necrosis," "pseudocysts," "pancreatic fluid collection," "cholecystitis," "gastroenterostomy," in addition to "endoscopic treatment" and "endoscopic management," among others.

Results: This technology review describes the full spectrum of LAMS designs and delivery systems, techniques for deployment, procedural outcomes, safety, training issues, and financial considerations.

Conclusions: Although LAMSs were initially introduced for drainage of pancreatic pseudocysts and walled-off necrosis, the versatility of these devices has led to a variety of off-label uses including gallbladder drainage, enteric bypass with the creation of gastroenterostomies, and treatment of luminal GI strictures. (Gastrointest Endosc 2021;94:457-70.)

(footnotes appear on last page of article)

The American Society for Gastrointestinal Endoscopy Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methods are used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a Manufacturer and User Facility Device Experience (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and web-based publications, proprietary publications, and informal communications with pertinent vendors. Technology status evaluation reports are drafted by 1 or 2 members of the American Society for Gastrointestinal Endoscopy Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through April 2021 for articles related to lumen-apposing metals stents by using additional relevant keywords such as "walled-off pancreatic necrosis," "pseudocysts," "pancreatic fluid collection," "cholecystitis," "gastroenterostomy," in addition to "endoscopic treatment" and "endoscopic management," among others. Technology status evaluation reports are scientific reviews provided solely for educational and informational purposes. Technology status evaluation reports on emerging technologies are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

The concept of lumen-apposing metal stents (LAMSs) was inspired by the desire to create a device that facilitates endoscopic transluminal drainage by bringing 2 structures into close apposition.¹ The initial patent for LAMSs was filed in 2007 with a design aimed at reducing adverse events (AEs) and stent malfunction observed with traditional tubular luminal metal and plastic stents.¹ Current LAMSs are made of nitinol wire and are fully covered with a silicone membrane. They have bilateral flanges in a dumbbell configuration with the end diameters 1.5 to 2.9 times larger than the mid-lumen diameter and sufficient axial force to reduce physical separation of the target structure and bowel wall. These design considerations are intended to decrease the rate of leak/perforation and stent migration. The large inner stent diameter was designed to allow fluid drainage and minimize stent occlusion with solid debris. Furthermore, larger-diameter stents permit subsequent direct endoscopic intervention through the LAMS (eg, necrosectomy). These stents are considered magnetic resonance imaging conditionally safe for use with a static magnetic field of 3 T or less. This review focuses on the techniques used for LAMS placement, outcomes, and safety of LAMSs for the endoscopic management of various GI conditions.

TECHNOLOGY UNDER REVIEW

LAMS devices

Table 1 includes a list of available LAMSs that have been used for endoscopic transluminal drainage. The only currently available LAMS in the United States is the Axios stent (Boston Scientific, Marlborough, Mass, USA) (Fig. 1). This has been cleared as a U.S. Food and Drug Administration class II device to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts or walled-off necrosis (WON) >6 cm in size, with \geq 70% fluid content that are adherent to the bowel wall. The Axios deployment system uses a 146cm length wire-guided 10.8F catheter with a constrained stent at its distal end and a delivery system that includes a handle that locks onto the EUS instrument channel to allow for single-operator delivery. The unique handle uses a dual-locking mechanism for advancement of the catheter and stent deployment. Axios stents are available in a variety of configurations. At present there are 1-cm and 1.5-cm saddle-length stents available in the United States with electrocautery-enhanced versions available. The stents are intended for implantation up to 60 days.

The Niti-S Spaxus stents (Taewoong Medical, Gyeonggido, South Korea) are a newer LAMS that are available outside the United States (Fig. 2). These stents are 2 cm in length and are available in a variety of diameters (Table 1). The Spaxus system also has an electrocauteryenhanced version. The Spaxus deployment system has a conventional delivery handle with a 10F catheter. The method of deploying the Spaxus stent is the same as that of conventional self-expanding metal stents (SEMSs) and, unlike the Axios system, allows for recapturing of the stent during deployment. The stent itself has flanges with rounded edges that fold back so the distance between the 2 flanges can shorten to 7 mm.²

LAMSs have been widely used off-label for a variety of nonpancreatic fluid collection (non-PFC) indications. These include biliary drainage (EUS-guided hepaticogastrostomy, EUS-guided choledochoduodenostomy [EUS-CD], EUSguided cholecystostomy), luminal bypass (EUS-guided gastroenterostomy [EUS-GE]), and for treatment of luminal GI strictures as discussed below.

Transluminal LAMS deployment

Cold technique. Before any transluminal LAMS procedure, the operator is encouraged to review crosssectional imaging, which can be used for planning the optimal route and method of drainage and assess for potential intervening vessels (eg, gastric varices) and other intraabdominal abnormalities (eg, pseudoaneurysms). One should strongly consider the use of anesthesia support for sedation and have fluoroscopy capabilities to confirm location and facilitate stent delivery. The noncautery-enhanced deployment technique, also referred to as the "cold technique," typically requires multiple steps to achieve stent placement. For optimal results, the distance between the target area and the lumen wall should be less than 10 mm, and the EUS endoscope position should be stable to allow various deployment steps. Doppler imaging is encouraged to avoid vessels within the drainage tract. The target site is then punctured, typically with a 19-gauge FNA device. Depending on the scenario, fluid may be aspirated and sent for evaluation, and a guidewire is then passed through the needle coiled within the target. The needle sheath is then often advanced over the guidewire to provide further dilation of the tract. The needle is then removed over the guidewire and exchanged for a dilating device. Dilation is most commonly achieved with a 4- to 8-mm dilating balloon but may be performed with a dilating catheter or a cystotome. After successful tract dilation, the device is then exchanged over the wire for the LAMS device.

The LAMS catheter assembly is secured on the echoendoscope channel before stent delivery. The ideal position maintains the same trajectory as needle puncture and tract dilation. Deployment of the stent is then performed in the following fashion under endosonographic, endoscopic, and fluoroscopic guidance. First, the distal end of the stent delivery catheter is advanced as deep into the target area as safely possible and then locked (if applicable). Second, the distal flange is deployed within the desired target. Third, the device is unlocked (if applicable) and withdrawn toward the stomach/bowel such that the inner flange abuts the wall of the target organ, and again the catheter is locked (if applicable). Finally, the proximal flange is

Stent	Manufacturer	Electrocautery- compatible version	Internal diameter (mm)	Flange diameter (mm)	Length (mm)	Delivery catheter profile (F)	Delivery catheter working length (cm)
Lumen-apposing							
Axios	Boston Scientific, Marlborough, Mass, USA	No	10*	21	10†	10.8	138
			15*	24			
Hot Axios	Boston Scientific, Marlborough, Mass, USA	Yes	6	14	8†	9	138
			8	17	8†	9	
			10*	21	10†	10.8	
			15*	24	10†	10.8	
			15	24	15†	10.8	
			20*	29	10†	10.8	
Spaxus	Taewoong Medical, Gyeonggi-do South Korea	No	8	23	20/7†	10	180
			10	25			
			16	31			
Hot Spaxus	Taewoong Medical, Gyeonggi-do South Korea	Yes	8	23	20/7†	10	180
			10	25			
			16	31			
Biflanged							
Nagi	Taewoong Medical, Gyeonggi-do South Korea	No	10	20	10, 20, 30	9	180
			12	22	10, 20, 30	9	
			14	24	20, 30	10	
			16	26	20, 30	10	
Aixstent PPS	Leufen Medical, Berlin, Germany	No	10, 15	25	30	10	230
Hanarostent Plumber	MI Tech, Seoul, South Korea	No	10	22	20/13†, 40/33†	10.5	180
			12	24	20/13†, 40/33†		
			14	26	20/12†, 40/32†		
			16	28	20/12†, 40/32†		
Pseudocyst Stent	Micro-Tech Endoscopy, Nanjing, China	No	16	26 proximal 30 distal	, 15, 20, 25, 30	10.5	180

The non-lumen-apposing biflanged stents have antimigration properties but do not provide concomitant lumen apposition. *Available in the United States as of January 5, 2021.

†Saddle length.

deployed either directly within the stomach/bowel lumen under endoscopic visualization or within the channel of the echoendoscope, and then the catheter is unlocked and the proximal flange pushed out of the channel toward the bowel wall. The Spaxus system does not have a locking mechanism and thus the same steps are performed without locking and unlocking the device.

Hot technique. Recent LAMS iterations have incorporated an electrocautery tip that allows for direct puncture and stent placement using the "hot technique" (Video 1, available online at www.giejournal.org). Electrocauteryenhanced LAMSs use monopolar energy with recommended generator settings of 80 to 120 W using a pure cut mode. Blended or coagulation modes are not recommended because they may result in failure to access the site, prolonged time to access, and tissue distortion/tenting. The main advantage of the hot technique is that it eliminates the need for guidewire exchange and tract dilation



Figure 1. The Axios stent and electrocautery-enhanced delivery system. **A**, The electrocautery-enhanced Axios stent is housed on a 10F catheter with an electrocautery tip. **B**, After cautery entry into the target organ, the distal stent flange is deployed using the hand control. **C**, The catheter is then slowly retracted to allow for release of the proximal stent flange using the same hand control.

before stent deployment. Additionally, this approach allows for procedure completion without the need for fluoroscopy, if preferred. After the stent system is secured on the working channel of the echoendoscope, the LAMS catheter is advanced through the luminal wall, and electrosurgical energy is concurrently delivered. Once the target site has been accessed, steps for stent deployment are similar to the cold technique as above. This approach is known as the "freehand technique." One commonly used variation of the freehand technique is to preload a guidewire into the delivery catheter. This allows for easy advancement and coiling of the guidewire into the target structure after the distal flange has been deployed to secure access and to facilitate placement of a coaxial double-pigtail plastic stent (DPPS). In some instances, the operator may choose to initially access the target with a standard needle and guidewire, as with the cold technique, and then deploy the electrocautery-enhanced LAMS over the guidewire to provide a more stable delivery platform and to allow for additional maneuvers including fluid sampling and easy coaxial DPPS placement. This technique is known as the "over-the-guidewire" technique.

CLINICAL PROCEDURES

Pseudocysts and WON

Many studies evaluating clinical outcomes and safety of PFC drainage with LAMS are retrospective, cohort-based, or single-arm prospective studies that combine results for pseudocysts and WON. Technical success for LAMS deployment has been shown to be greater than 90% for PFCs, with more recent studies demonstrating more than 95%

460 GASTROINTESTINAL ENDOSCOPY Volume 94, No. 3 : 2021

technical success as operators become more familiar with these devices (Fig. 3).³⁻⁶ Definitions for clinical success have varied across studies and have ranged from 84% to 98%, which is similar to clinical success rates observed with DPPS.^{3-5,7,8} At least 2 studies have noted higher, but not statistically significant, rates of clinical success with LAMSs for pseudocysts (93%-100%) than for WON (81%-88%).4,5 AEs with LAMSs have been inconsistently defined and reported across studies, ranging from 8.5% to 24.7%.^{3-5,7,8} Multiple studies have demonstrated higher rates of delayed GI bleeding, in particular higher rates of pseudoaneurysm bleeding with LAMSs compared with DPPSs when used for drainage of PFCs.^{6,7,9,10} A retrospective, international, nested case-control study from 15 centers identified risk factors for AEs associated with LAMSs in 153 patients with pseudocysts and 151 with WON.¹⁰ Technical success was 97.9%, clinical success was 89.5%, and 79 AEs occurred in 75 patients (24.3%), of which 25.3% were mild, 68.4% were moderate, and 6.3% severe according to American Society for Gastrointestinal Endoscopy definitions. The most common AEs were bleeding (27.8%) and stent migration (25.3%), and 43% of all AEs occurred within 14 days of stent placement. The authors also included stent occlusion as an AE and therefore noted a higher rate of AEs with WON compared with pseudocysts (odds ratio, 2.18; 95% confidence interval, 1.09-4.46; P = .028). Small retrospective series have suggested that the placement of 1 or more coaxial DPPSs through a LAMS reduces AEs,^{11,12} but the largest series on this topic found no differences in rates of AEs with coaxial DPPS placement.¹⁰ Similarly, other commonly practiced techniques such as nasocystic drain placement or hydrogen peroxide irrigation, which may improve



Figure 2. The Niti-S Spaxus stent. **A**, Fully deployed Niti-S Spaxus stent in various stent diameters. **B**, The deployment sequence involves release of the distal flange, followed by gentle catheter retraction and release of the proximal flange.

clinical success, have not been shown to reduce AEs when used with LAMSs. $^{5,10,13}_{\ }$

Walled-off necrosis. In theory, the larger-diameter LAMSs have several advantages over DPPSs for the endoscopic treatment of WON, including allowing for spontaneous drainage of solid debris and providing direct access to the collection for necrosectomy through the stent. These perceived design advantages have led to increased off-label use of LAMSs for the endoscopic management of WON with more solid necrosis. An ongoing investigation device exemption study evaluating the safety and effectiveness of the Axios stent for treatment of pancreatic WON with greater than 30% solid component (NCT03525808) may lead to expanded U.S. Food and Drug Administration indications for LAMSs with WON.

When placing LAMSs for WON, it is important to consider the need for future endoscopic necrosectomy, and therefore the site for transluminal drainage should be carefully selected. Some experts have suggested avoiding access through the gastric cardia and preferentially accessing collections closer to the gastric antrum to facilitate subsequent interventions.¹⁴ Others have suggested that it may be safe to remove the LAMS to facilitate

necrosectomy and then redeploy the same LAMS at the end of the session to maintain access to the collection.^{15,16} Reuse of the previously deployed LAMS can be performed by backloading a portion of the LAMS into the working channel of a therapeutic gastroscope. Once the gastroscope is positioned, the LAMS can be delivered through the working channel and into position using a variety of rigid instruments under endoscopic and fluoroscopic guidance. Early studies comparing LAMSs with DPPSs suggested improved clinical success and a lower number of procedures required to achieve WON resolution, but the benefit was partially offset by increased rates of AEs.^{17,18} A recent retrospective study that performed a subgroup analysis of 35 patients with WON noted higher rates of clinical success with LAMSs compared with fully covered SEMSd (95.7% vs 66.7%; P = .04).¹⁹ A pivotal prospective randomized controlled trial of 60 patients demonstrated no differences between LAMSs and DPPSs with regard to total number of procedures required to achieve WON resolution, rates of treatment success, clinical AEs, or length of hospital stay.²⁰ Additionally, LAMSs were associated with shorter procedure duration (15 vs 40 minutes; P < .001) but increased stent-related AEs (32.3% vs 6.9%; P = .01). The authors noted significant LAMS-related AEs after 3 or more weeks, which prompted a protocol amendment to remove the LAMS if the collection had resolved at 3 weeks. After this modification, there were no differences in AEs between the cohorts.

A recent systematic review and meta-analysis evaluating the safety and efficacy of EUS-guided LAMS versus DPPS drainage for WON included 30 studies and 1524 patients. Outcome definitions differed and were inconsistently reported across studies. Nonetheless, LAMSs demonstrated similar rates of WON resolution compared with DPPSs (87.4% vs 87.5%; P = .99) and similar number of procedures to achieve resolution (2.1 vs 1.9; P = .72).²¹ LAMSs were found to have similar rates of AEs compared with DPPSs including bleeding (2.5% vs 4.6%; P = .39), perforation (.5% vs 1.1%; P = .35), stent migration (5.9%) vs 6.8%; P = .79), and stent occlusion (3.8% vs 5.2%; P = .78). A retrospective case-matched study of 306 patients found no differences in rates of clinical success or AEs between 20-mm and 15-mm LAMSs, but individuals receiving the larger-diameter stents required fewer endoscopic necrosectomy sessions (mean 1.3 vs 2.1; P <.001), despite having larger WON collections.²² Last, a multicenter retrospective study of 272 patients with LAMS drainage for WON suggested that proton pump inhibitor use resulted in a greater number of necrosectomy sessions (4.6 vs 3.2; P < .01) but no differences in rates of technical or clinical success.²³ However, the proton pump inhibitor group noted significantly lower rates of stent occlusion compared with the non-proton pump inhibitor group (9.5% vs 20.1%; P = .012), with similar rates of GI bleeding and infection.



Figure 3. EUS-cystgastrostomy using a lumen-apposing metal stent has become the endoscopic standard of care for the management of large pseudocysts and walled-off necrosis.

Gallbladder drainage

EUS-guided gallbladder drainage (EUS-GBD) using LAMSs has been described as a primary intervention in patients with acute cholecystitis who are unfit for urgent surgical intervention (Fig. 1). Although they are not cleared by the U.S. Food and Drug Administration for this indication, a multicenter prospective trial using the Axios stent and electrocautery-enhanced delivery system for acute cholecystitis is currently under investigation (NCT03767881).

In current practice, EUS-GBD is most commonly performed using the hot technique, because many experts believe the additional steps with the cold technique may unnecessarily increase the risk of the procedure. In particular, the coiled guidewire can push the gallbladder away from apposition to the stomach or duodenum. Alternatively, the cautery-enhanced catheter can be preloaded with a guidewire. After direct, cautery-enhanced puncture into the gallbladder lumen, the distal flange can be released and the preloaded guidewire can be coiled within the gallbladder body to serve as a safety net should stent maldeployment occur.

In addition to primary GBD for acute cholecystitis, this technique may be useful in other scenarios including internalization of indwelling percutaneous cholecystostomy tubes in poor surgical candidates²⁴ and palliation of malignant distal biliary obstruction when ERCP fails.²⁵ EUS-GBD may be used to decompress the biliary tree in lieu of EUS-guided biliary drainage only when the cystic duct is patent. Data are limited with regard to both clinical scenarios; however, these techniques may be considered in select patients.

Outcomes of EUS-GBD have been favorable. A prospective, multicenter study to determine efficacy and safety of LAMSs in 30 high-risk surgical candidates with acute cholecystitis demonstrated a technical success rate of 90% and clinical success rate of 96%.²⁶ During a mean follow-up of 298 \pm 82 days, 15 serious AEs were reported, of which 4 (13%) were attributable to the procedure or stent

(gallbladder thrombus, hemobilia, aspiration pneumonia, infection). There were no episodes of stent migration. LAMSs were removed endoscopically in 50% of patients but in the remaining 15 patients, LAMSs were not removed because of tissue overgrowth, patient refusal, and/or poor clinical condition. A retrospective multicenter study of 15 patients undergoing EUS-GBD for various indications demonstrated similarly high technical and clinical success rates (93% and 100%, respectively) with an acceptable AE rate (7%).²⁷ A retrospective multicenter study of 75 patients with acute cholecystitis treated with EUS-GBD using an electrocautery-enhanced LAMS demonstrated similar results with technical and clinical success rates greater than 96% and an AE rate of 10%.28 A recent meta-analysis including 8 studies totaling 393 patients undergoing EUS-GBD demonstrated a pooled AE rate of 12.7% (95% confidence interval [CI], 8.4-18.7) (early <2 weeks postintervention, 6.5%; late >2 weeks postintervention, 8.3%) when using LAMSs.²⁹ The rate of recurrent cholecystitis was 4.6% (95% CI, 2.6-9.5).

A randomized controlled trial comparing EUS-GBD to percutaneous cholecystostomy in very high-risk patients was recently published.³⁰ The AE rate at 1 year, the primary study outcome, was 25% in the EUS-GBD cohort and 77% in the percutaneous cholecystostomy cohort (P < .001). EUS-GBD also significantly reduced 30-day AEs (12.8% vs 47.5%; P = .010), reinterventions after 30 days (2.6% vs 30%; P = .001), number of unplanned readmissions (15% vs 50%; P = .002), and recurrent cholecystitis (2.6% vs 20%; P = .029). Technical success, clinical success, and 30-day mortality were similar.

EUS-GBD was recently compared with laparoscopic cholecystectomy for the management of acute cholecystitis. Sixty patients (30 EUS-GBD, 30 laparoscopic cholecystectomy procedures) were compared using a propensityscore analysis with individuals matched for age, sex, and age-adjusted Charlson score.³¹ No clinically significant differences were noted between groups in regard to



Figure 4. EUS-guided choledochoduodenostomy using a lumen-apposing metal stent (IAMS) performed from the duodenal bulb. When the LAMS is used, apposition of the duodenal bulb to the common bile duct provides drainage of the proximal biliary tree in the setting of distal bile duct obstruction.

clinical/technical success, 30-day AEs, need for reintervention, recurrent biliary events, and mortality after 1 year of follow-up. These results add to data suggesting that EUS-GBD may be considered an alternative to laparoscopic cholecystectomy in selected individuals. Laparoscopic cholecystectomy may not be possible after EUS-GBD with a LAMS because this procedure creates a fistula between the gallbladder and adjacent GI lumen; thus, patients who may be surgical candidates in the future should be considered for alternative interventions. A multidisciplinary discussion including surgical consultation is often necessary before undertaking EUS-GBD.

Biliary drainage

EUS-guided biliary drainage has emerged as a salvage technique in patients who fail conventional ERCP (Fig. 4). EUS-CD has been used primarily in patients with malignant biliary obstruction. Several technical variations have been described using plastic and metal stents. EUS-CD can also be performed using LAMSs with the aforementioned cold and hot techniques. The use of cauteryenhanced LAMSs is most commonly performed using the freehand technique whereby no guidewire is used to direct the LAMS catheter toward the proximal biliary tree. Adequate dilation of the common bile duct (CBD) is needed for safe puncture and stent deployment to prevent injury to the contralateral bile duct wall. Additionally, placement of a coaxial DPPS through the LAMS after deployment into the bile duct should be strongly considered. This technique splints the CBD wall away from the perpendicular relationship of the LAMS, subsequently mitigating the risk of recurrent biliary obstruction from the distal flange of the LAMS as the CBD decompresses. For many endoscopists, these limitations have led to decreased use of LAMSs for EUS-CD.

Despite the described technical challenges when using LAMSs for this indication, the available data are favorable. A recent meta-analysis including 7 studies and 284 patients undergoing LAMS placement for EUS-CD demonstrated high technical (95.7%; 95% CI, 93.2%-98.1%) and clinical (95.9%;

95% CI, 92.8%-98.9%) success rates.³² A wide variety of LAMS diameters were used, ranging from 6 mm to 15 mm. The pooled rate of postprocedural AEs was 5.6% (95% CI, 1.7%-9.5%); however, among the 5 studies that reported details of interventions, 43% of those with AEs required procedural reintervention. Recurrent jaundice occurred in 8.7% of patients (95% CI, 4.5%-12.8%), of which 90% (26 cases) were because of stent obstruction and 10% (3 cases) because of LAMS migration. A subgroup analysis of the cautery-enhanced LAMS revealed no appreciable differences with respect to success rates or AEs.

A more recent meta-analysis on EUS-CD demonstrated similar findings, including technical and clinical success rates of 94.8% and 93.6%, respectively.33 The pooled AE rate was slightly higher at 17.1%, likely because of differences in definition compared with the prior study. A retrospective French multicenter study including 70 patients again noted high technical and clinical success (both 98.6%), a low periprocedural AE rate (3%), short procedure duration (median 5 ± 3 minutes), and acceptable rates of delayed biliary AEs (10%) because of stent obstruction or migration.³⁴ LAMS diameters included 6 mm (n = 60), 8 mm (n = 9), and 10 mm (n = 1). A retrospective U.S. multicenter study of 67 patients who underwent EUS-CD with a 10-mm LAMS provided nearly identical results with regard to technical success (95.5%) and clinical success after 4 weeks (100% in 40 patients with available follow-up).³⁵ Of note, the need for biliary reinterventions for LAMS obstruction was lower in those with a coaxially placed plastic stent through the LAMS (5% vs 50%; P = .02), although conclusions are limited by the small sample size. An ongoing large multicenter, single-blinded, randomized controlled trial (ELEMENT trial) compares EUS-CD using a LAMS with conventional ERCP for first-line intervention of patients with malignant extrahepatic bile duct obstruction (CBD diameter >1.2 cm).³⁶ LAMS size chosen, either $8 \text{ mm} \times 8 \text{ mm}$ or $6 \text{ mm} \times 8 \text{ mm}$, is at the discretion of the endoscopist. It should be noted that 6-mm and 8-mmdiameter LAMSs are not currently available in the United States.



Figure 5. In patients with Roux-en-Y gastric bypass anatomy, an EUS-guided gastrogastromy using a lumen-apposing metal stent (IAMS) can be created through apposition of the gastric pouch and the excluded gastric remnant. Conventional ERCP can then subsequently be performed by passage of the duodenoscope through the IAMS gastrogastrostomy and ultimately into the second duodenum to the level of the major papilla.

Gastrogastrostomy for subsequent intervention in Roux-en-Y gastric bypass anatomy. EUS-directed transgastric ERCP was first described in 2014 as a means of performing ERCP in patients with Roux-en-Y gastric bypass anatomy (Fig. 5).³⁷ This technique involves creation of a fistulous tract by placing a LAMS under EUS guidance between either the jejunum or gastric pouch to the excluded gastric remnant. This allows for a more conventional approach to ERCP through the LAMS.

The technique of EUS-directed transgastric ERCP is performed as follows. An echoendoscope is passed into the gastric pouch or the jejunal blind limb just beyond the gastrojejunostomy to visualize the excluded stomach. An EUS-FNA needle preloaded with water-soluble contrast is used to puncture into the excluded stomach with entry confirmed by contrast injection under fluoroscopic guidance. After significant instillation of dilute contrast (ie, approximately 500 mL), a guidewire is advanced through the needle and coiled within the lumen of the excluded stomach. The tract is typically dilated using a 4- to 6-mmdiameter hydrostatic balloon. The LAMS is then passed over the guidewire followed by stent deployment to create a conduit to the excluded gastric remnant. The electrocautery-enhanced LAMS can be used with or without a guidewire. After deployment of the LAMS and creation of the fistulous tract into the excluded gastric remnant, the LAMS can be dilated with hydrostatic balloons to a diameter of \geq 15 mm if immediate passage of a duodenoscope or echoendoscope is necessary for urgent intervention. The LAMS can also be secured using over-thescope clipping devices or endoscopic suturing to prevent stent migration.³⁸ Alternatively, procedural intervention can be delayed to allow for fistula maturation and to reduce the risk of stent dislodgement. Once transgastric access is no longer required, the LAMS is removed using a standard large-diameter polypectomy snare or grasping forceps. Methods of closure of the gastrogastric fistula include argon plasma coagulation, over-the-scope clipping devices, and endoscopic suturing.

The available outcomes data with respect to creation of a transgastric conduit for intervention in patients with Roux-en-Y gastric bypass anatomy are challenging to interpret. Most results including technical success, clinical success, and AEs are related to the procedure in totality (eg, EUS-guided anastomosis creation + ERCP) and not simply the creation of a luminal fistula using a LAMS. A recent meta-analysis demonstrated high rates of technical and clinical success (both >95%) when ERCP was performed via an EUS-guided gastrogastrostomy.³⁹ However, the overall AE rate was 21% with stent migration/ dislodgment occurring in 13% and bleeding occurring in 6%. There are insufficient data to recommend ERCP in surgically altered anatomy via EUS-guided gastrogastrostomy compared with the other established approaches including enteroscopy-assisted and laparoscopy-assisted.

Gastroenterostomy

EUS-GE has evolved as a viable alternative to luminal SEMSs and surgical GE in patients with both malignant and benign gastric outlet obstruction (GOO). Early data demonstrate favorable technical and clinical success, with acceptable AE rates (Video 2, available online at www. giejournal.org).

Several technical variants of EUS-GE have been described, each with inherent advantages and clinical scenarios where they are preferred. Antegrade (GE) and retrograde (enterogastrostomy) techniques have been performed successfully using LAMSs. The antegrade approaches rely on creation of an endosonographically visible small-bowel target when the echoendoscope is positioned in the gastric lumen. The initial description of this technique (ie, balloon-assisted GE) involves over-the-wire placement of a contrast-filled extraction balloon or hydrostatic dilating balloon into the small bowel beyond the level of the stricture. The balloon is then identified under endosonographic and fluoroscopic visualization. An EUS-FNA needle is used to puncture the small-bowel balloon, which allows guidewire delivery into the downstream small bowel. Ultimately, the EUS-FNA needle is replaced with a LAMS delivery catheter. The LAMS is deployed as described above, thereby creating a GE. Alternatively, after needle puncture with the EUS-FNA needle and guidewire advancement into the small bowel, the echoendoscope can be removed from the mouth, leaving the guidewire in place. Then, typically a forward-viewing gastroscope is passed into the small bowel for guidewire capture using various endoscopic accessories (eg, biopsy forceps, graspers, polypectomy snare, etc) and retrieved through the mouth (ie, rendezvous method). The LAMS is then deployed with traction on both ends of the delivered small-bowel guidewire. This technique was believed to add an additional layer of safety by minimizing the risk of guidewire loss and subsequent stent maldeployment.

The most common method used in current practice is the direct EUS-GE technique, which relies on the newer cautery-enhanced LAMS delivery system. This approach mitigates the need for device exchanges over a guidewire and allows for direct, freehand puncture of the target small bowel after adequate luminal distention. Distention of the small bowel can be achieved in several ways. Some providers prefer direct instillation of dilute contrast or saline solution mixed with methylene blue beyond the level of obstruction using the endoscope working channel, whereas others opt to place a catheter, such as a nasobiliary drain, that can be directly connected to the endoscope irrigation pedal to allow "on command" infusion immediately before EUS-guided puncture of the target small bowel. A third option is wire-guided placement of a dedicated double-balloon catheter into the duodenum or jejunum in an area adjacent to the stomach. Both balloons are insufflated, and an adequate volume of saline solution with a contrast agent is introduced into the space between the 2 balloons to distend the small-bowel lumen for EUS targeting. Intravenous glucagon in a bolus dose of 2 to 4 mg is often given to slow small-bowel peristalsis before EUS-guided puncture of the small bowel.

All prior methods discussed are derivations of the antegrade EUS-GE procedure. A similar anastomosis using a LAMS can be created via a retrograde approach (ie, from small bowel to stomach). This technical variation can be considered in patients with a small-diameter small-bowel lumen or in scenarios where there is concern that the small bowel lacks close apposition to the gastric wall. In this situation, the stomach provides a large, fixed target for LAMS placement. Anastomosis creation with this technique may be challenging because it requires passage of an echoendoscope through the small-bowel stricture.

EUS-GE with LAMSs remains an infrequently performed procedure at many institutions although published results indicate favorable outcomes. A recent systematic review and meta-analysis including 285 patients revealed a technical and clinical success rate of greater than 90%, with a 12% AE rate.⁴⁰ More importantly, symptom recurrence or need for repeat intervention was noted in less than 10% of cases. Long-term outcomes data are sparse; however, 1 study identified an overall reintervention rate of 15% when patients with malignant and benign GOO were followed for \geq 196 days.⁴¹

A retrospective study of 100 patients compared enteral SEMSs (n = 78) with EUS-GE (n = 22) for palliation of

malignant GOO.⁴² Both groups demonstrated 100% procedural technical success; however, clinical success was significantly higher in the EUS-GE cohort (P = .04). More importantly, the AE rate (40% vs 21%; P = .098) and need for reintervention (32% vs 8%; P = .021) were higher in the endoluminal SEMS cohort.

Two multicenter retrospective studies that compared EUS-GE with surgical gastrojejunostomy demonstrated slightly lower, but comparable, technical success rates in the EUS-GE cohort (87% vs 100% and 88% vs 100%). 43,44 However, both studies identified lower AE rates favoring EUS-GE over surgical GE. One of the studies found no difference in the rate of recurrent GOO when comparing the surgical and endoscopic approaches.⁴³ An international, multicenter, retrospective study used a propensity scorematched analysis of 74 consecutive patients undergoing EUS-GE and laparoscopic GE procedures at 3 academic centers from 2015 to 2020.45 Technical success was achieved in 94.6% of EUS-GE patients and in 100% of laparoscopic GE patients. Clinical success, defined as eating without vomiting or a GOO Scoring System score ≥ 2 , was achieved in 97.1% and 89.2%, respectively. Median time to oral intake and median hospital stay were significantly shorter in the EUS-GE group. Overall and severe AEs were significantly higher in the laparoscopic GE group. There were no GE dysfunctions in either group after a median follow-up of 77 days (E-GE) and 123 days (LG-E).

Robust long-term data in patients with benign disease who undergo EUS-GE are lacking. Thus, it remains to be seen if LAMSs can be removed without a resultant increase in AEs or recurrence of symptoms.^{46,47}

Enteroenterostomy

EUS-guided enteroenterostomy using LAMSs has been recently described, but available data are limited to case reports and small case series.^{48,49} The technique is similar to that described for EUS-GE but involves anastomosis creation from small bowel to small bowel and has been used in a variety of clinical scenarios, including treatment of afferent limb syndrome or GOO in the setting of surgically altered GI anatomy. This technique can also be used to create a conduit for subsequent procedures, such as ERCP in the setting of nongastric bypass Roux-en-Y reconstructions.

Treatment of luminal strictures

The use of LAMSs to treat short GI strictures has been described as an alternative to serial balloon dilation or temporary placement of a fully covered SEMS in select patients. LAMSs have been used in patients with benign anastomotic strictures,⁵⁰ benign nonanastomotic strictures,⁵¹ and malignant strictures⁵² involving the esophagus, small bowel, and colon.

The design of LAMSs makes them a suitable treatment option for short luminal GI strictures. The large flared proximal and distal flanges provide adequate anchoring in most cases. A therapeutic channel endoscope is required for stent deployment, either an obliqueviewing linear-array echoendoscope, forward-viewing linear-array echoendoscope, single-channel gastroscope, or double-channel gastroscope. As described above, the LAMS deployment catheter directly attaches to echoendoscopes via a Luer lock when used for EUSguided interventions. The LAMS deployment catheter cannot be attached directly to therapeutic gastroscopes; thus, an assistant is required to manage the free catheter or to hold the gastroscope. The inability to affix the LAMS catheter to a gastroscope allows for direct advancement of the entire catheter and deployment handle down the working channel and beyond the luminal stricture into position for stent deployment. Thus, catheter advancement by unlocking and advancing the LAMS catheter (step 1) is largely unnecessary. A noncautery-enhanced LAMS can be readily used and may reduce the cost of the LAMS device for this indication. After advancement of the catheter beyond the stricture, the initial flange of the LAMS is released (step 2). The catheter is then retracted to create gentle tension and to visualize the black portion of the catheter (step 3) to ensure that the second flange is positioned across the stricture when released (step 4). Balloon dilation of the LAMS after deployment accelerates expansion but has not been shown to improve outcomes and thus remains at the discretion of the endoscopist.

A recent systematic review and meta-analysis including 6 studies totaling 144 patients demonstrated a technical success rate of 98% and clinical success of 73%.⁵⁰ The lowest success rates occurred in esophagogastric (63%) and gastroduodenal strictures (67%) and highest success rates in colonic (85%) and gastrojejunal strictures (77%). The AE rate in this study was 30%, with migration as the most common occurrence in 10% of patients. A second systematic review including 138 patients identified nearly identical rates of technical success, clinical success, and AEs.⁵³ It should be noted that migration of a LAMS may be considered an AE for study purposes but may not always lead to increased morbidity. This is particularly true when LAMSs are placed for colonic strictures. Distal migration is more likely to occur because of colonic peristalsis, which often results in spontaneous passage with defecation or, at worst, passage into the rectum for retrieval with flexible sigmoidoscopy.

TRAINING ISSUES AND ESTABLISHMENT OF COMPETENCY

Individuals acquiring skills in EUS-guided drainage and transmural access with LAMS placement are expected to have achieved competency and a high skill level in diagnostic EUS with fine-needle sampling techniques. This also includes many skills acquired with ERCP training including fluoroscopy and wire manipulation. At present there is limited information regarding optimal approaches to procedural training and no defined competency criteria for performing therapeutic EUS procedures including LAMS placement. Individuals who desire training in these therapeutic applications of interventional EUS are advised to seek additional education through "hands on" endoscopy courses, simulators, industry vendor support, and with mentorship at specialized high-volume medical centers. Ex vivo training models have been described but are limited by availability and cost of the device and supplies, particularly the LAMSs.⁵⁴

Most learning curve or competency assessment data have been published by one investigator group. EUS-GBD data are somewhat difficult to interpret because the studies include marked variation in procedural technique (cold vs hot) and stent placement (IAMSs, fully covered SEMSs, and plastic stents).⁵⁵⁻⁵⁷ A learning curve analysis among a consecutive series of 48 EUS-GBD procedures performed by 1 provider with experience in therapeutic EUS procedures has been reported.54 Efficiency was reached after a learning curve of 19 cases with a mean procedure time of 41 minutes reduced to ≤ 20 minutes during the last 10 patients. More rapid attainment of procedural competency might be achieved with a purely hot LAMS approach to EUS-GBD, because predeployment guidewire placement and tract dilation is unnecessary in most of these procedures. With regard to the effect of level of expertise on achieving procedural competency, 1 study compared outcomes for EUS-GBD performed by endoscopists with limited experience (<25 procedures) and greater experience (>25 procedures).⁵⁸ Outcomes were assessed with AEs, procedure time, and number of unplanned procedural events (which they defined as deviations of the procedure from the planned procedural steps including a dislodged guidewire or misdeployment of the stent). Endoscopists who had performed fewer than 25 EUS-GBD procedures were associated with a longer procedure time (P = .006), more unplanned procedural events (P = .006).012), and more 30-day AEs (P = .031).⁵⁸

The learning curve for the EUS-directed transgastric ERCP procedure was assessed in a series of 19 consecutive patients performed by a single endoscopic provider with expertise in therapeutic EUS.⁵⁶ A cumulative sum control chart demonstrated procedural efficiency after the ninth procedure with progressive reduction in procedure time over successive cases to a median of 54.5 minutes.

For EUS-GE, a similarly performed study involving 23 patients by a single expert provider showed technical and clinical success rates greater than 95%, and using cumulative sum control chart analysis, efficiency was reached at 88 minutes (the median procedure time) at the seventh procedure.⁵⁷ A second study assessing the learning curve of EUS-GE suggested that proficiency could be obtained after 25 procedures and mastery reached after 40 procedures.⁵⁹ These studies focus on reductions in procedural

time as central determinants to learning curves and development of competency in the procedure; however, other parameters such as procedural success and adverse event rates are likely more reflective of proficiency when evaluating the full spectrum of endoscopist's experience rather than published series limited to individuals with a high-level of EUS expertise. Furthermore, the above data suggest that competency can be achieved after a very limited number of procedures, although achieving competency is also largely based on the endoscopist's innate skillset at study initiation, which varies widely. Additional research is warranted to fully explore optimal approaches to training in LAMS procedures and establishment of competency.

FINANCIAL CONSIDERATIONS

The retail cost of currently available LAMSs in the United States ranges from \$8156 to \$8500 per unit, although actual costs may vary by institution. Studies designed to assess the cost-effectiveness of LAMSs are sparse. The results vary based on indication. Cost-effectiveness data comparing LAMSs with a DPPS approach to treat pseudocysts and WON have shown that the DPPS approach is more cost-effective in both conditions.^{60,61} In 2 studies, the use of LAMSs was associated with a significant increase in cost to treat PFCs. The cost per patient was ~\$4000 less for WON and ~\$8000 less for pseudocysts when using DPPSs in lieu of LAMSs. In contrast, EUS-GBD using LAMSs in poor surgical candidates with cholecystitis appears to be cost-effective when compared with percutaneous drainage, but the statistical model was significantly affected by LAMS cost.⁶² EUS-guided gastrogastrostomy creation for ERCP, for which LAMSs are a critical component, has been found to be more cost-effective with lower total costs and higher quality-adjusted life-years compared with device-assisted ERCP and laparoscopicassisted ERCP in patients with Roux-en-Y anatomy.⁶³ Finally, LAMSs may also be cost-effective under select circumstances when used to treat luminal strictures, but the data are very limited. Available data suggest that use of a LAMS to treat an anastomotic stricture is only costeffective after 2 failed conventional endoscopic dilations.⁶⁴ For all other foregut strictures, LAMSs are only costeffective after 3 failed dilation attempts. The data regarding costs when using LAMSs require additional evaluation.

Current procedural terminology (CPT) code 43240 can be used for endoscopic transmural drainage of a pseudocyst with LAMSs, and CPT code 43247 (EGD with foreign body removal) can be used when the LAMS is endoscopically removed. There is no existing CPT code for endoscopic debridement of WON; the use of code 48999 (unlisted procedure, pancreas) is most appropriate, either as a single code or together with the base service(s) to which it is added. To report other therapeutic EUS procedures using LAMS technology, unlisted CPT service codes for the region of anatomy involved can be used (43999, stomach; 44799, small intestine, 47999 biliary tract). For unlisted CPT codes, information submitted should include a cover letter that provides a clear description of the nature, need, time required, and equipment necessary for the procedure as well as supporting medical literature. The cover letter should state why billing cannot be addressed with the standard CPT codes and suggest a reasonably comparable CPT code based on work relative value units and/or percentage of a reasonably comparable CPT. Also, the submission should include the procedure report and indicate that payment is requested as a zero-day service, meaning it is not global to include subsequent visits or other services.

AREAS OF FUTURE RESEARCH

The clinical applications of LAMSs continue to evolve. At present the above-mentioned techniques are most commonly available at tertiary care medical centers. In the near future, additional LAMSs are expected to be available from other industry partners. It is likely that we will see improvements in patient selection, refinements in procedural technique, and development of additional applications for LAMSs. Potential emerging indications include drainage of postoperative and pelvic fluid collections, among others. However, it should be recognized that these procedures are higher-risk techniques that require skill and expertise in various aspects of endoscopy including EUS interpretation, understanding electrosurgical generator settings, utilization of fluoroscopy, and a clear understanding to mitigate and treat AEs.

CONCLUSIONS

LAMSs are a valuable addition for the endoscopic management of a variety of GI conditions, particularly in the transluminal drainage/access of target collections and organs. As newer LAMSs are designed and the worldwide experience continues to expand, these devices will be increasingly used. Further investigation is required to understand how these devices can be used to maximize clinical efficacy and to improve the safety profile.

DISCLOSURE

The following authors disclosed financial relationships: R. Law: Consultant for Olympus America Inc and Medtronic; travel compensation from Olympus America Inc; food and beverage compensation from Olympus America Inc and Boston Scientific Corporation. V. Chandrasekhara: Consultant for Covidien LP; advisory board for Interpace Diagnostics; shareholder in Nevakar, Inc;

grant support from Cook Medical LLC; food and beverage compensation from Olympus America Inc and Boston Scientific Corporation. A. Bhatt: Consultant for Lumendi LLC; patent for a commercial device licensed to Medtronic; food and beverage compensation from Lumendi LLC, Covidien LP, Boston Scientific Corporation, Olympus America Inc, and Shionogi Inc. J. Bucobo: Consultant for Cook Medical LLC; travel compensation from Cook Medical LLC and Olympus Corporation of the Americas; food and beverage compensation from Cook Medical LLC, Olympus Corporation of the Americas, Boston Scientific Corporation, AbbVie, Inc, Janssen Biotech, Inc, Steris Corporation, Ferring Pharmaceuticals Inc, Takeda Pharmaceuticals USA, Inc, Endogastric Solutions, Inc, Merck Sharp & Dohme Corporation, Dova Pharmaceuticals, Pfizer Inc, and Allergan Inc. A. Copland: Education compensation from Salix Pharmaceauticals, Ltd. K. Krisbnan: Consultant for Olympus Corporation of the Americas and Medtronic; has received travel compensation and food and beverage from Olympus Corporation of the Americas; has received food and beverage from Boston Scientific Corporation. N. Kumta: Consultant for Boston Scientific Corporation, Gyrus ACMI, Inc, Olympus Corporation of the Americas, and Apollo Endosurgery US Inc; travel compensation from Boston Scientific Corporation, Gyrus ACMI, Inc, Olympus Corporation of the Americas, and Apollo Endosurgery US Inc; food and beverage compensation from Boston Scientific Corporation, Gyrus ACMI, Inc, Olympus Corporation of the Americas, and Apollo Endosurgery US Inc, Fijufilm Medical Systems USA, Inc, Steris Corporation, ERBE USA Inc, Endogastric Solutions, and Conmed Corporation. R. Pannala: Consultant for HCL Technologies; travel compensation from Bos-Scientific Corporation; food and beverage ton compensation from Boston Scientific Corporation and Apollo Endosurgery US, Inc; scientific advisory board for Nestle Health Sciences. M. Parsi: Travel compensation from Olympus Corporation of the Americas; food and beverage compensation from Olympus Corporation of the Americas, Conmed Corporation, Salix Pharmaceuticals, AbbVie, Inc, Shionogi Inc, Shire North American Group Inc, and Boston Scientific Corporation. E. Rahimi: Food and beverage compensation from AbbVie, Inc, Boston Scientific Corporation, and Covidien LP. M. Saumoy: Food and beverage compensation from Boston Scientific Corporation, Ethicon US, LLC, Allergan Inc, and AbbVie, Inc. G. Trikudanathan: Consultant for Boston Scientific Corporation; travel compensation from Boston Scientific Corporation; food and beverage compensation from Boston Scientific Corporation and Cook Medical LLC. A. Trindade: Consultant for Olympus Corporation of the Americas, Pentax of America, Inc, and Gyrus ACMI, Inc; food and beverage compensation from Olympus Corporation of the Americas, Pentax of America, Inc, and Gyrus ACMI, Inc; travel compensation from Pentax of America, Inc, Gyrus ACMI, Inc, and Boston Scientific

Corporation; research grant from NinePoint Medical, Inc. J. Yang: Consultant for Olympus Corporation of the Americas and Cook Medical LLC; travel compensation from Olympus Corporation of the Americas; food and beverage compensation from Olympus Corporation of the Americas, Cook Medical LLC, US Endoscopy, Boston Scientific Corporation, Conmed Corporation, Salix Pharmaceuticals, and AbbVie, Inc. D. Lichtenstein: Consultant for Olympus Corporation of the Americas, Augmenix, Inc, and Boston Scientific Corporation; education compensation and travel compensation from Olympus Corporation of the Americas; food and beverage compensation from Olympus Corporation of the Americas and Boston Scientific Corporation.

ACKNOWLEDGMENT

We thank Ajaypal Singh, MD, Priya Jamidar, MD, Jenifer Lightdale, MD, and Glenn Littenberg, MD for their review of this document.

REFERENCES

- Binmoeller KF, DeSimio T, Donovan R. Design considerations of the AX-IOS stent and electrocautery enhanced delivery system. Techn Innovat Gastrointest Endosc 2020;22:3-8.
- Song TJ, Moon JH, Lee YN, et al. Design considerations of the novel lumen-apposing metal stents (Niti-S SPAXUS). Techn Innovat Gastrointest Endosc 2020;22:9-13.
- Shah RJ, Shah JN, Waxman I, et al. Safety and efficacy of endoscopic ultrasound-guided drainage of pancreatic fluid collections with lumen-apposing covered self-expanding metal stents. Clin Gastroenterol Hepatol 2015;13:747-52.
- Walter D, Will U, Sanchez-Yague A, et al. A novel lumen-apposing metal stent for endoscopic ultrasound-guided drainage of pancreatic fluid collections: a prospective cohort study. Endoscopy 2015;47:63-7.
- Siddiqui AA, Adler DG, Nieto J, et al. EUS-guided drainage of peripancreatic fluid collections and necrosis by using a novel lumenapposing stent: a large retrospective, multicenter U.S. experience (with videos). Gastrointest Endosc 2016;83:699-707.
- Lang GD, Fritz C, Bhat T, et al. EUS-guided drainage of peripancreatic fluid collections with lumen-apposing metal stents and plastic doublepigtail stents: comparison of efficacy and adverse event rates. Gastrointest Endosc 2018;87:150-7.
- Brimhall B, Han S, Tatman PD, et al. Increased incidence of pseudoaneurysm bleeding with lumen-apposing metal stents compared to double-pigtail plastic stents in patients with peripancreatic fluid collections. Clin Gastroenterol Hepatol 2018;16:1521-8.
- Teoh AYB, Bapaye A, Lakhtakia S, et al. Prospective multicenter international study on the outcomes of a newly developed selfapproximating lumen-apposing metallic stent for drainage of pancreatic fluid collections and endoscopic necrosectomy. Dig Endosc 2020;32:391-8.
- Wang Z, Zhao S, Meng Q, et al. Comparison of three different stents for endoscopic ultrasound-guided drainage of pancreatic fluid collection: a large retrospective study. J Gastroenterol Hepatol 2019;34:791-8.
- **10.** Fugazza A, Sethi A, Trindade AJ, et al. International multicenter comprehensive analysis of adverse events associated with lumenapposing metal stent placement for pancreatic fluid collection drainage. Gastrointest Endosc 2020;91:574-83.

- Puga M, Consiglieri CF, Busquets J, et al. Safety of lumen-apposing stent with or without coaxial plastic stent for endoscopic ultrasoundguided drainage of pancreatic fluid collections: a retrospective study. Endoscopy 2018;50:1022-6.
- 12. Aburajab M, Smith Z, Khan A, et al. Safety and efficacy of lumenapposing metal stents with and without simultaneous double-pigtail plastic stents for draining pancreatic pseudocyst. Gastrointest Endosc 2018;87:1248-55.
- Messallam AA, Adler DG, Shah RJ, et al. Direct endoscopic necrosectomy with and without hydrogen peroxide for walled-off pancreatic necrosis: a multicenter comparative study. Am J Gastroenterol 2021;116:700-9.
- 14. Bang JY, Varadarajulu S. Lumen-apposing metal stents for endoscopic ultrasound-guided drainage of pancreatic fluid collections. Techn Innovat Gastrointest Endosc 2020;22:14-8.
- **15.** Chandrasekhara V, Topazian M, Abu Dayyeh BK, et al. Re-deployment of a dislodged lumen-apposing metal stent (LAMS): avoiding the sacrificial LAMS. Endoscopy 2018;50:E233-4.
- **16.** Gulati R, Rustagi T. Endoscopic removal and replacement of the same lumen-apposing metal stent for multiple endoscopic necrosectomy sessions. Endoscopy 2021 Jan;53(1):71-4.
- 17. Sharaiha RZ, Tyberg A, Khashab MA, et al. Endoscopic therapy with lumen-apposing metal stents is safe and effective for patients with pancreatic walled-off necrosis. Clin Gastroenterol Hepatol 2016;14: 1797-803.
- 18. Siddiqui AA, Kowalski TE, Loren DE, et al. 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. Gastrointest Endosc 2017;85:758-65.
- **19.** Kayal A, Taghizadeh N, Ishikawa T, et al. Endosonography-guided transmural drainage of pancreatic fluid collections: comparative outcomes by stent type. Surg Endosc 2021;35:2698-708.
- Bang JY, Navaneethan U, Hasan MK, et al. Non-superiority of lumenapposing metal stents over plastic stents for drainage of walled-off necrosis in a randomised trial. Gut 2019;68:1200-9.
- Chandrasekhara V, Barthet M, Deviere J, et al. Safety and efficacy of lumen-apposing metal stents versus plastic stents to treat walled-off pancreatic necrosis: systematic review and meta-analysis. Endosc Int Open 2020;8:E1639-53.
- 22. Parsa N, Nieto JM, Powers P, et al. Endoscopic ultrasound-guided drainage of pancreatic walled-off necrosis using 20-mm versus 15-mm lumen-apposing metal stents: an international, multicenter, case-matched study. Endoscopy 2020;52:211-9.
- 23. Powers PC, Siddiqui A, Sharaiha RZ, et al. Discontinuation of proton pump inhibitor use reduces the number of endoscopic procedures required for resolution of walled-off pancreatic necrosis. Endosc Ultrasound 2019;8:194-8.
- 24. Law R, Grimm IS, Stavas JM, et al. Conversion of percutaneous cholecystostomy to internal transmural gallbladder drainage using an endoscopic ultrasound-guided, lumen-apposing metal stent. Clin Gastroenterol Hepatol 2016;14:476-80.
- Imai H, Kitano M, Omoto S, et al. EUS-guided gallbladder drainage for rescue treatment of malignant distal biliary obstruction after unsuccessful ERCP. Gastrointest Endosc 2016;84:147-51.
- 26. Walter D, Teoh AY, Itoi T, et al. EUS-guided gall bladder drainage with a lumen-apposing metal stent: a prospective long-term evaluation. Gut 2016;65:6-8.
- Irani S, Baron TH, Grimm IS, et al. EUS-guided gallbladder drainage with a lumen-apposing metal stent (with video). Gastrointest Endosc 2015;82:1110-5.
- 28. Dollhopf M, Larghi A, Will U, et al. EUS-guided gallbladder drainage in patients with acute cholecystitis and high surgical risk using an electrocautery-enhanced lumen-apposing metal stent device. Gastrointest Endosc 2017;86:636-43.
- 29. Mohan BP, Asokkumar R, Shakhatreh M, et al. Adverse events with lumen-apposing metal stents in endoscopic gallbladder drainage: a

systematic review and meta-analysis. Endosc Ultrasound 2019;8: 241-8.

- 30. Teoh AYB, Kitano M, Itoi T, et al. Endosonography-guided gallbladder drainage versus percutaneous cholecystostomy in very high-risk surgical patients with acute cholecystitis: an international randomised multicentre controlled superiority trial (DRAC 1). Gut 2020;69: 1085-91.
- **31.** Teoh AYB, Leung CH, Tam PTH, et al. EUS-guided gallbladder drainage versus laparoscopic cholecystectomy for acute cholecystitis: a propensity score analysis with 1-year follow-up data. Gastrointest Endosc 2021;93:577-83.
- **32.** Krishnamoorthi R, Dasari CS, Thoguluva Chandrasekar V, et al. Effectiveness and safety of EUS-guided choledochoduodenostomy using lumen-apposing metal stents (LAMS): a systematic review and metaanalysis. Surg Endosc 2020;34:2866-77.
- **33.** Amato A, Sinagra E, Celsa C, et al. Efficacy and safety of lumen apposing metal stents or self-expandable metal stents for endoscopic ultrasound-guided choledocho-duodenostomy: a systematic review and meta-analysis. Endoscopy Epub 2020 Nov 27.
- **34.** Jacques J, Privat J, Pinard F, et al. EUS-guided choledochoduodenostomy by use of electrocautery-enhanced lumen-apposing metal stents: a French multicenter study after implementation of the technique (with video). Gastrointest Endosc 2020;92:134-41.
- **35.** El Chafic AH, Shah JN, Hamerski C, et al. EUS-guided choledochoduodenostomy for distal malignant biliary obstruction using electrocautery-enhanced lumen-apposing metal stents: first US, multicenter experience. Dig Dis Sci 2019;64:3321-7.
- **36.** Chen YI, Callichurn K, Chatterjee A, et al. ELEMENT trial: study protocol for a randomized controlled trial on endoscopic ultrasoundguided biliary drainage of first intent with a lumen-apposing metal stent vs. endoscopic retrograde cholangio-pancreatography in the management of malignant distal biliary obstruction. Trials 2019;20: 696.
- 37. Kedia P, Sharaiha RZ, Kumta NA, et al. Internal EUS-directed transgastric ERCP (EDGE): game over. Gastroenterology 2014;147:566-8.
- Irani S, Yang J, Khashab MA. Mitigating lumen-apposing metal stent dislodgment and allowing safe, single-stage EUS-directed transgastric ERCP. VideoGIE 2018;3:322-4.
- **39.** Dhindsa BS, Dhaliwal A, Mohan BP, et al. EDGE in Roux-en-Y gastric bypass: How does it compare to laparoscopy-assisted and balloon enteroscopy ERCP: a systematic review and meta-analysis. Endosc Int Open 2020;8:E163-71.
- 40. lqbal U, Khara HS, Hu Y, et al. EUS-guided gastroenterostomy for the management of gastric outlet obstruction: a systematic review and meta-analysis. Endosc Ultrasound 2020;9:16-23.
- **41.** Kerdsirichairat T, Irani S, Yang J, et al. Durability and long-term outcomes of direct EUS-guided gastroenterostomy using lumenapposing metal stents for gastric outlet obstruction. Endosc Int Open 2019;7:E144-50.
- **42.** Ge PS, Young JY, Dong W, et al. EUS-guided gastroenterostomy versus enteral stent placement for palliation of malignant gastric outlet obstruction. Surg Endosc 2019;33:3404-11.
- 43. Khashab MA, Bukhari M, Baron TH, et al. International multicenter comparative trial of endoscopic ultrasonography-guided gastroenterostomy versus surgical gastrojejunostomy for the treatment of malignant gastric outlet obstruction. Endosc Int Open 2017;5: E275-81.
- Perez-Miranda M, Tyberg A, Poletto D, et al. EUS-guided gastrojejunostomy versus laparoscopic gastrojejunostomy: an international collaborative study. J Clin Gastroenterol 2017;51:896-9.
- **45.** Bronswijk M, Vanella G, van Malenstein H, et al. Laparoscopic versus EUS-guided gastroenterostomy for gastric outlet obstruction: an international multicenter propensity score-matched comparison (with video). Gastrointest Endosc Epub 2021 April 11.
- 46. Chen YI, James TW, Agarwal A, et al. EUS-guided gastroenterostomy in management of benign gastric outlet obstruction. Endosc Int Open 2018;6:E363-8.

- **47.** James TW, Greenberg S, Grimm IS, et al. EUS-guided gastroenteric anastomosis as a bridge to definitive treatment in benign gastric outlet obstruction. Gastrointest Endosc 2020;91:537-42.
- **48.** Rodrigues-Pinto E, Grimm IS, Baron TH. Efficacy of endoscopically created bypass anastomosis in treatment of afferent limb syndrome: a single-center study. Clin Gastroenterol Hepatol 2016;14:633-7.
- Irani S, Itoi T, Baron TH, et al. EUS-guided gastroenterostomy: techniques from East to West. VideoGIE 2020;5:48-50.
- 50. Tan S, Zhong C, Huang S, et al. Clinical outcomes of lumen-apposing metal stent in the management of benign gastrointestinal strictures: a systematic review and meta-analysis. Scand J Gastroenterol 2019;54:811-21.
- Santos-Fernandez J, Paiji C, Shakhatreh M, et al. Lumen-apposing metal stents for benign gastrointestinal tract strictures: an international multicenter experience. World J Gastrointest Endosc 2017;9:571-8.
- Trindade AJ, Hung CK, Zimmerman HM, et al. Placement of a lumenapposing metal stent for palliation of malignant pyloric stenosis. Endoscopy 2018;50:E210-1.
- Larson B, Adler DG. Lumen-apposing metal stents for gastrointestinal luminal strictures: current use and future directions. Ann Gastroenterol 2019;32:141-6.
- 54. Baron TH, DeSimio TM. New ex-vivo porcine model for endoscopic ultrasound-guided training in transmural puncture and drainage of pancreatic cysts and fluid collections (with videos). Endosc Ultrasound 2015;4:34-9.
- 55. Tyberg A, Jha K, Shah S, et al. EUS-guided gallbladder drainage: a learning curve modified by technical progress. Endosc Int Open 2020;8:E92-6.
- 56. Tyberg A, Kedia P, Tawadros A, et al. EUS-directed transgastric endoscopic retrograde cholangiopancreatography (EDGE): the first learning curve. J Clin Gastroenterol 2020;54:569-72.
- Tyberg A, Kats D, Choi A, et al. Endoscopic ultrasound guided gastroenterostomy: What is the learning curve? J Clin Gastroenterol Epub 2020 Jul 29.
- 58. Teoh AY, Perez-Miranda M, Kunda R, et al. Outcomes of an international multicenter registry on EUS-guided gallbladder drainage in patients at high risk for cholecystectomy. Endosc Int Open 2019;7: E964-73.
- Jovani M, Ichkhanian Y, Parsa N, et al. Assessment of the learning curve for EUS-guided gastroenterostomy for a single operator. Gastrointest Endosc 2021;93:1088-93.
- **60.** Chen YI, Khashab MA, Adam V, et al. Plastic stents are more costeffective than lumen-apposing metal stents in management of pancreatic pseudocysts. Endosc Int Open 2018;6:E780-8.
- Chen YI, Barkun AN, Adam V, et al. Cost-effectiveness analysis comparing lumen-apposing metal stents with plastic stents in the management of pancreatic walled-off necrosis. Gastrointest Endosc 2018;88:267-76.

- 62. Corral JE, Das A, Krner PT, et al. Cost effectiveness of endoscopic gallbladder drainage to treat acute cholecystitis in poor surgical candidates. Surg Endosc 2019;33:3567-77.
- 63. James HJ, James TW, Wheeler SB, et al. Cost-effectiveness of endoscopic ultrasound-directed transgastric ERCP compared with deviceassisted and laparoscopic-assisted ERCP in patients with Roux-en-Y anatomy. Endoscopy 2019;51:1051-8.
- Hallac A, Srikureja W, Liu E, et al. Economical effect of lumen apposing metal stents for treating benign foregut strictures. World J Gastrointest Endosc 2018;10:294-300.

Abbreviations: AE, adverse event; CBD, common bile duct; CPT, current procedural terminology; DPPS, double-pigtail plastic stent; EUS-CD, EUSguided choledocboduodenostomy; EUS-GBD, EUS-guided gallbladder drainage; EUS-GE, EUS-guided gastroenterostomy; GOO, gastric outlet obstruction; LAMS, lumen-apposing metal stent; PFC, pancreatic fluid collection; SEMS, self-expandable metallic stent.

*Drs. Law and Chandrasekhara contributed equally to this article.

Copyright \circledast 2021 by the American Society for Gastrointestinal Endoscopy 0016-5107/\$36.00

https://doi.org/10.1016/j.gie.2021.05.020

Received May 11, 2021. Accepted May 12, 2021.

Current affiliations: Department of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota, USA (1), Department of Gastroenterology, Hepatology & Nutrition, Cleveland Clinic, Cleveland, Ohio, USA (2), Division of Gastroenterology and Hepatology, Stony Brook Medicine, Stony Brook, New York, USA (3), Division of Gastroenterology and Hepatology, University of Virginia Health Systems, Charlottesville, Virginia, USA (4), Division of Gastroenterology, Department of Internal Medicine, Harvard Medical School and Massachusetts General Hospital, Boston, Massachusetts, USA (5), Division of Gastroenterology, Mount Sinai Hospital, New York, New York, USA (6), Department of Gastroenterology and Hepatology, Mayo Clinic, Scottsdale, Arizona, USA (7), Section for Gastroenterology and Hepatology, Tulane University Health Sciences Center, New Orleans, Louisiana, USA (8), Department of Gastroenterology, Baylor Scott & White Health, Lakeway, Texas, USA (9), Department of Gastroenterology, University of Pennsylvania, Philadelphia, Pennsylvania, USA (10), Division of Gastroenterology, Hepatology and Nutrition, University of Minnesota, Minneapolis, Minnesota, USA (11), Department of Gastroenterology, Zucker School of Medicine at Hofstra/Northwell, Long Island Jewish Medical Center, New Hyde Park, New York, USA (12), Division of Gastroenterology, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, New York, USA (13), Division of Gastroenterology, Boston Medical Center, Boston University School of Medicine, Boston, Massachusetts, USA (14).