



Enteral stent placement for benign and malignant disease

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The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (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 ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the ASGE. 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 from August 2010 to July 2024 for articles related to enteral, esophageal, duodenal, and colonic stents.

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Stents are devices to assist in maintaining the patency of a natural lumen in the GI tract, vessels, and ducts. Stents have been increasingly used in the GI tract to maintain the patency of an artificial lumen or fistulous tract created during endoscopy. In the United States, current stents available for use in the GI tract include self-expandable metal stents (SEMSs) for esophageal, gastroduodenal, and colonic obstruction. This report provides an update of the prior American Society for Gastrointestinal Endoscopy (ASGE) Technology Status Evaluation Report on enteral stents in 2011 that discussed the technical specifications, efficacy, safety, and financial considerations for stents used in the alimentary tract.

TECHNICAL CONSIDERATIONS

SEMSs consist of braided or laser-cut metal mesh cylinders that exert radial force as they expand to a maximum diameter. They are generally constrained in a compressed form within a delivery catheter. SEMSs are made of metals or metal alloys. They were previously made of stainless steel (eg, Z-stent [Cook Medical, Bloomington, Ind, USA] and Elgiloy (nickel, cobalt, and chromium; eg, Wallstent

[Boston Scientific, Marlborough, Mass, USA]) but have been replaced by nitinol (nickel and titanium) because of its magnetic resonance imaging compatibility (up to 3 Tesla), biocompatibility, and corrosion resistance. The various stent materials exhibit differences in expansile force, stent flexibility, and stent visibility under fluoroscopy. Although nitinol stents are notable for their improved flexibility in comparison with other materials, they are less visible on fluoroscopy and require the placement of radiopaque markers.^{1,2} There may be significant differences in the radial force (expansile strength) and axial force (recovery force with bending) depending on stent materials and construction, which clinically may translate to short-term expansion and symptom resolution and long-term resistance to compression. For example, Elgiloy stents have a higher radial force when compared with nitinol stents.³

All stents are available in a variety of lengths and diameters. Various stents are available in the United States, and their unique specifications and features are outlined in [Table 1](#). The main differences between delivery systems are in the handle design, how the constraining mechanism is removed, introducer diameter, and whether the deployment system can be advanced through the working channel of the scope. Most deployment systems release the stent from the distal to proximal end of the catheter.

SEMSs can be generally divided into uncovered, partially covered (PCSEMS), or fully covered (FCSEMS). Covered SEMSs consist of a metal meshwork coated with a polymer or silicone membrane to prevent tissue ingrowth and potentially seal leaks or fistulas. This covering comes at a cost of increased migration risk,²⁻⁴ which may be mitigated in part by proximal and/or distal flared ends and antimigration features (eg, antimigration fins).^{3,4} Although these stents are covered, prolonged placement has been associated with partial or complete delamination of the coatings, resulting in the exposure of bare metal struts that become completely embedded.^{5,6} Although this situation may be salvaged using a variety of techniques, including stent-in-stent placement of an additional FCSEMS to promote necrosis of tissue ingrowth before attempting endoscopic stent removal, surgical resection and reconstruction may ultimately be required.^{7,8}

Currently, in the United States, the available duodenal and colonic stents are uncovered with an indication to treat malignant obstruction and therefore are not removable. Outside of the United States, there are several partially and fully covered enteral and colonic stents with varying designs, including unique stents that integrate drainage sponges for anastomotic leaks (VacStent GI [MICRO-TECH Europe GmbH (Düsseldorf, Germany)]). To allow for fluoroscopic visualization, some SEMSs have radiopaque markers on each of the ends and center of the stent as well as their deployment devices. The introducer of some SEMSs have been downsized to fit through the scope (TTS) for deployment under direct

endoscopic and fluoroscopic visualization. For removal or repositioning of esophageal FCSEMSs, suture or braided metal wire is woven through the stent flanges to allow purse-stringing, which facilitates stent withdrawal off the mucosa and manipulation using a variety of grasping forceps.

TECHNIQUE

Often, a luminal stricture is first characterized with cross-sectional imaging (ideally contrast-enhanced CT). Regardless of the etiology of the stricture, multidisciplinary consultation should be considered. In the case of malignant strictures where radiation may be planned, placement of an enteral stent may increase the possibility of fistula, perforation, or migration⁹; thus, an alternative therapy (eg, brachytherapy) may be preferred.¹⁰ Surgical backup is recommended because of the risk of perforation and ultimate need for definitive management if stent placement fails to resolve the obstruction or is only used as a bridge to surgery. If there is any concern for luminal obstruction, the patient should have a nasogastric tube placed for decompression before stent placement to reduce the risk of aspiration and potential periprocedural adverse events. Judicious use of insufflation during endoscopy, ideally with carbon dioxide, is also generally recommended.

The stricture should be identified on endoscopy and characterized (diameter, length, angulation, proximal or distal aspect). Fluoroscopy is usually not required for esophageal stent placement as long as the stricture is traversable. If the stricture is not traversable, downsizing of the endoscope and/or use of fluoroscopic guidance alone with a guidewire and contrast injection may be required. For colonic stents, fluoroscopy is generally required, because the stricture is usually not traversable. Guidewire choice will likely be based on endoscopist preference; a recent ASGE Technology Status Evaluation Report details guidewire use in endoscopy.¹¹ Placement of external radiopaque markers (eg, paperclips) or internal radiopaque clips (eg, hemostatic clips) at the proximal and distal ends of the stricture may be helpful to ensure accurate placement. Technical details on the approach to luminal stent placement have previously been published extensively,^{3,12-14} and the ASGE Training Committee has developed a core curriculum for their deployment.¹⁵

The choice of SEMS (ie, stent design, size, etc) remains at the discretion of the endoscopist based on the clinical situation, available devices, characteristics of the stricture, and his or her personal experience and expertise. An important factor to consider during SEMS deployment is the variable degree of foreshortening that occurs in most SEMSs as they transition from a compressed to fully expanded state. The endoscopist must anticipate this foreshortening and choose the appropriate SEMS length to ensure appropriate placement and effective decompression. The labeled stent length indicates the length at full

TABLE 1. Specifications and features of stents commercially available in the United States

Esophageal stents	Composition, design	Delivery system diameter/length	Unconstrained outer diameter (mm)	Unconstrained length (covered length, cm)	Foreshortening (%)	Release point	Features
Boston Scientific							
Agile (covered, partially covered)	Nitinol, silicone covering, braided	3.5-mm TTS 6.2-mm over the wire	14, 18 TTS 23 over the wire (+5-mm flares both ends)	6, 10, 12, 15	Yes (specific data on foreshortening is not available)	Distal	Lower radial and axial force compared to WallFlex TTS, minimum 3.7-mm working channel Recapturable up to 75% up to 2 times Retrieval loop on both ends 5 radiopaque markers
Ultraflex (partially covered)	Nitinol, polyurethane covering	5.3 mm (7.3 at undeployed stent portion)/ 90-95 cm	18, 23 (+5-mm proximal flare)	18 mm: 10, 12, 15 23 mm: 10, 12	Yes	Distal and proximal	Suture deployment Delivery catheter metric ruler Not recapturable 4 radiopaque markers
Ultraflex (uncovered)	Nitinol	5.3 mm (7.3 at undeployed stent portion)/ 90-95 cm	18 (+5-mm proximal flare)	7, 10, 15	Yes	Distal and proximal	Suture deployment Delivery catheter metric ruler Not recapturable Loop on proximal end 4 radiopaque markers
WallFlex (covered)	Nitinol, silicone covering, braided	6.2 mm/78 cm	18, 23 (+5-mm proximal and distal flares)	18 mm: 10.3, 12.3, 15.3 23 mm: 10.5, 12.5, 15.5	Yes	Distal	Recapturable up to 75% Loop on proximal end 4 radiopaque markers
WallFlex (partially covered)	Nitinol, silicone covering, braided	6.2 mm/78 cm	18, 23 (+5-mm proximal and distal flares)	18 mm: 10.3, 12.3, 15.3 23 mm: 10.5, 12.5, 15.5	Yes	Distal	Not recapturable Loop on proximal end 4 radiopaque markers
Cook Medical							
Evolution controlled-release (covered, partially covered)	Nitinol, silicone covering, woven	8 mm/78 cm	20, (+5-mm flares both ends) (partially covered), 18, 20, (+5-mm flares both ends) (fully covered)	8, 10, 12.5, 15 (partially covered) 8, 10, 12 (covered)	Yes (fully covered, 28-33; partially covered, 30-40)	Distal	Controlled-release trigger deployment, recapturable up to 50% Partially covered: proximal loop Fully covered: loops at both ends made of 1 single string 4 radiopaque markers at each end
Merit Medical							
ALIMAXX-ES (fully covered)	Nitinol/polyurethane outer cover, silicone inner cover, laser cut	7.3 mm/ 62-67 cm	12, 14, 16, 18, 22 (+5-mm proximal flare and +3-mm distal flare)	7, 10, 12	No	Distal	One-handed delivery system Antimigration struts Not reconstrainable Nylon suture at proximal end

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TABLE 1. Continued

Esophageal stents	Composition, design	Delivery system diameter/length	Unconstrained outer diameter (mm)	Unconstrained length (covered length, cm)	Foreshortening (%)	Release point	Features
EndoMAXX (fully covered)	Nitinol /silicone cover, laser cut	8.2 mm/90 cm	19, 23 (+5-mm flares)	7, 10, 12, 15	No	Distal	One-handed delivery system More pronounced antimigration struts Not reconstrainable Metal sutures at both ends (distal suture can be grasped to invaginate stent for removal)
TaeWoong Medical USA							
Niti-S TTS Stent (fully and partially covered)	Nitinol, silicone covering, woven	3.5 mm/180 cm-220 cm	18, 20 (26-mm flare) 22 (28-mm flare)	6, 8, 10, 12, 14, 15	Yes (40)	Distal	TTS: minimum 3.7-mm working channel Not recapturable Proximal loop, 4 radiopaque markers at both ends and 2 in the middle
Niti-S over the wire (fully and partially covered)	Nitinol, silicone covering, woven	5.3 mm (16-mm, 18-mm stent), 6.6-mm (20-mm stent)/70 cm	18, 20 (+8-mm flares both ends)	6, 8, 10, 12, 14, 15	Yes (40)	Distal	Not recapturable Green loop on proximal end 4 radiopaque markers at both ends and 2 in the middle
Olympus							
M.I.Tech HANAROSTENT (fully covered) (over the wire)	Nitinol, silicone covering, hook-cross design	6 mm (18-mm stent)/8 mm (22-mm stent)/70 cm	18, 22 (+6-mm flares both ends)	8, 10, 12, 15	Yes (20-35)	Distal	Not recapturable 12 total radiopaque markers, 4 at the center and each of the ends Blue loop on both ends
M.I.Tech HANAROSTENT TTS (fully and partially covered)	Nitinol, silicone covering, hook-cross design	3.5 mm/180 cm, 230 cm	18 (+8-mm flare), 20 (+6-mm flare)	6, 8, 10, 12, 15	Yes (fully covered, 39-45; partially covered, 38-44)	Distal	45%-75% recapturable 12 total radiopaque markers, 4 at the center and each of the ends Loop at the proximal end
Gastroduodenal stents	Composition	Delivery system diameter/length	Unconstrained diameter (mm)	Unconstrained length (mm)	Foreshortening (%)	Release point	Features
Boston Scientific							
WallFlex (uncovered)	Nitinol, braided	3.3 mm/230 cm	22 (+5-mm proximal flare)	6, 9, 12	Yes	Distal	3 radioopaque markers
WallFlex Soft (uncovered)	Nitinol, braided	3 mm/230 cm	22 (+5-mm proximal flare)	6, 9, 12	Yes	Distal	Minimum accessory channel 3.2 mm Thinner gauge wire results in lower radial and axial forces compared to WallFlex 3 radioopaque markers

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TABLE 1. Continued

Gastroduodenal stents	Composition	Delivery system diameter/length	Unconstrained diameter (mm)	Unconstrained length (mm)	Foreshortening (%)	Release point	Features
Cook Medical							
Evolution controlled-release (uncovered)	Nitinol, woven	3.3 mm/230 cm	22 (+5-mm proximal and distal flares)	6, 9, 12	Yes (45)	Distal	Controlled-release trigger deployment Up to 50% recapturable marked by "point of no return" on handle 4 markers at both ends of stent
Olympus							
M.I.Tech HANAROSTENT LowAx uncovered stent	Nitinol, hook-cross design	3.4 mm/230 cm	22 (+5-mm flare)	6, 9, 12	Yes (37-43)	Distal	40%-65% recapturable marked by red "point of no return" on device handle 12 total radiopaque markers, 4 at the center and each of the ends
TaeWoong Medical USA							
NitiS Duodenal Comfort (uncovered)	Nitinol, woven	3.3 mm/220 cm	22 (27 flare)	6, 8, 10, 12	Yes (30-36%)	Distal	Not recapturable 11 radiopaque markers-4 in each end and 3 in the center
Colonic Stents	Composition	Delivery system diameter/length	Unconstrained diameter (mm)	Unconstrained length (cm)	Foreshortening (%)	Release point	Features
Boston Scientific							
WallFlex (uncovered)	Nitinol, braided	3.3 mm/135 cm, 230 cm	22,25 (+5-mm distal flare)	6, 9, 12	Yes	Distal	3 radiopaque markers
WallFlex Soft (uncovered)	Nitinol, braided	3 mm/230 cm	22 (+5-mm distal flare)	6, 9, 12	Yes	Distal	Minimum accessory channel 3.2 mm Thinner gauge wire results in lower radial and axial forces compared to WallFlex, 3 radiopaque markers
Cook Medical							
Evolution controlled-release (uncovered)	Nitinol, woven	3.3 mm/230 cm	25 (+5-mm proximal and distal flares)	6, 8, 10	Yes (45)	Distal	Controlled-release trigger deployment Up to 50% recapturable marked by "point of no return" on handle 4 markers at both ends of stent
Olympus							
M.I.Tech HANAROSTENT LowAx uncovered	Nitinol, hook-cross design	3.4 mm/230 cm	22, 25 (+5-mm flare)	6, 9, 12	Yes (36)	Distal	65%-80% recapturable marked by red "point of no return" on device handle 12 total radiopaque markers, 4 at the center and each of the ends

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TABLE 1. Continued

Colonic Stents	Composition	Delivery system diameter/length	Unconstrained diameter (mm)	Unconstrained length (cm)	Foreshortening (%)	Release point	Features
TaeWoong Medical USA							
Niti-S Colonic Comfort (uncovered)	Nitinol, woven	3.3 mm/220 cm	22, 24 (+5 mm flare)	6, 8, 10, 12	Yes 22 mm (30-36%) 24 mm (31-37%)	Distal	Not recapturable 11 radiopaque markers-4 in each end and 3 in the center

TTS, Through-the-scope.

expansion. As a general rule, FCSEMSs and PCSEMSs are used in esophageal strictures, because these limit the risk of tissue ingrowth causing recurrent obstruction, whereas uncovered SEMs are used in the small bowel and colon to limit the substantial risk of stent migration. Specific considerations may emerge for placement of esophageal stents proximally because of the proximity to the cricopharyngeal sphincter, risk of tracheal compression, risk of tracheoesophageal fistula (TEF) formation, and aspiration pneumonia. It is advisable to ensure that stents are deployed at least 2 cm from the cricopharyngeal muscle with continuous endoscopic assessment.¹⁶ Similarly, caution is warranted in stent placement in the low rectum, which may cause urgency, tenesmus, pain, and fecal leakage.^{17,18} Manufacturers recommend placing the distal end of the stent 2 cm above the anal canal or 6 cm from the anus. It is also advisable to avoid placement of SEMs flanges at luminal angulations and bends such as the C-loop of the duodenum or colonic flexures. Finally, in cases of concomitant biliary obstruction, ERCP with stent placement in the common bile duct should be performed before enteral stent placement, if possible, to prevent subsequent biliary obstruction.

After deployment, FCSEMSs can be repositioned or removed. Traversing the stent with the endoscope should generally be avoided immediately after deployment to reduce the risk of iatrogenic migration. Complete SEMs expansion is generally believed to take 48 to 72 hours. Subsequent removal of PCSEMSs can be challenging because of tissue ingrowth at the uncovered ends but may be feasible within 1 to 3 weeks of placement. The use of the stent-in-stent technique allows for removal of up to 91% of embedded PCSEMSs.^{8,19} This technique involves placing a FCSEMS of the same diameter into the lumen of the pre-existing PCSEMS to induce pressure necrosis of the ingrown tissue between the stents, thus allowing removal of both stents approximately 5 to 10 days later. Uncovered SEMs cannot be easily repositioned or removed after deployment and are not indicated by the U.S. Food and Drug Administration (FDA) for benign disease given their permanency. Colonic stent placement generally requires the use of an adult colonoscope or therapeutic upper endoscope to allow the delivery system to fit through the channel. This presents a problem when a stricture is

too tight to allow scope passage, hence the need to rely on fluoroscopic guidance for stent deployment. This may become a more significant issue when attempting to traverse an angulated sigmoid to reach a more proximal stricture. Newer stents are now available with smaller-diameter introducers to allow use with pediatric colonoscopes.

EFFICACY AND COMPARATIVE ANALYSIS

Esophageal stents

The primary indications for esophageal SEMs placement remain the palliation of malignant strictures and treatment of malignant perforation or tracheoesophageal fistula (TEF). SEMs consistently demonstrate efficacy in managing dysphagia for patients with malignant obstruction who are not surgical candidates. Among patients with dysphagia due to obstructing esophageal cancer, technical success is high (>98%) with clinical success observed in 80% to 90% of cases with rapid relief of dysphagia.²⁰⁻²³ Randomized trials have suggested that patients also have lower mortality and earlier transition to oral intake when compared with surgical interventions.²⁴ Esophageal stent placement in combination with adjuvant chemotherapy or radiation therapy may result in longer dysphagia-free survival, particularly among patients who live longer than 3 months. However, these studies noted significant rates of pain, migration, and fistula formation.^{25,26} SEMs placement as a bridge to surgical resection is not recommended because of a combination of stent migration, studies demonstrating higher morbidity and mortality, and lower R0 resection rates and overall survival.²⁷⁻³⁰ Alternatives to SEMs placement for management of malignant dysphagia include argon plasma coagulation,³¹ spray cryotherapy,^{32,33} and intraluminal brachytherapy.³⁴ In fact, a large randomized controlled trial comparing patients undergoing SEMs placement (n = 108) and single-dose brachytherapy (n = 101) demonstrated equivalent (73% vs 76%) dysphagia relief at 30 days after treatment with significantly better long-term dysphagia control and fewer adverse events with brachytherapy (33% vs 21%, $P = .02$).¹⁰ The breadth of these data underscores the need to manage patients with malignant dysphagia in a multidisciplinary setting and

based on institutional and individual expertise and practice patterns.

In patients where malignant dysphagia is complicated by the presence of a malignant perforation or a concomitant TEF, esophageal SEMSs are generally required for the palliation of both conditions. Although 5% to 15% of patients with esophageal adenocarcinoma may develop a TEF, <1% of patients with primary airway malignancies will present with a TEF.³⁵⁻³⁷ SEMS-associated TEF may develop in up to 4% of patients.³⁸ The main objectives in palliation of this condition are to improve the quality of life of the patient and reduce aspiration and airway compromise. Esophageal SEMSs have been reported to successfully palliate TEF in large case series.³⁶ These complex cases must be managed in combination with thoracic surgery, medical and radiation oncology, and interventional pulmonology because of frequent concern about airway compromise with esophageal stent placement. Proximal TEF may be better managed with a bronchoscopic stent rather than an esophageal stent.^{39,40} There are also reports of concomitant placement of bronchoscopic and esophageal stents for patients where there is concern for airway compromise.^{41,42} However, significant adverse events (45%) have been reported with this technique, particularly in patients with prior radiation therapy.⁴²

Although rigorous randomized trials do not exist for the off-label use of esophageal SEMSs for benign indications, retrospective and prospective series have suggested a reasonable safety profile and efficacy of SEMSs when used judiciously for refractory strictures. Retrospective series of SEMSs for benign esophageal strictures have reported improved dysphagia scores in patients undergoing SEMS placement, but long-term clinical success is seen in less than one-third of patients.^{43,44} Although rigorous studies have not been completed on optimal timing of stent placement and removal for this indication, generally, stents dwell for 6 to 8 weeks and no more than 12 weeks based on available safety data.^{45,46} A number of prospective case series on acute esophageal perforations have suggested a high technical success rate and low risk of subsequent surgery, although extreme care and multidisciplinary cooperation with surgical services must be taken to consider potential stent candidates and need for source control.^{47,48} Similarly, case series have suggested clinical success in the management of postoperative esophageal anastomotic leaks.^{49,50} Oral contrast CT and/or oral contrast esophagram after initial SEMS placement and SEMS removal is generally advocated to exclude the possibility of a persistent leak. Endoscopic vacuum therapy has also been shown to be a potentially effective alternative in the management of many perforations that may not be technically amenable to SEMS placement or that did not respond to initial treatment with a SEMS.⁵¹ Other reported off-label benign uses of SEMSs include the prophylaxis of stenosis of the esophagus after endoscopic submucosal dissection^{52,53} and in refractory variceal bleeding and bridging to definitive therapy.^{54,55}

Oral diet advancement after esophageal SEMS placement is not standardized and may be dictated by a variety of factors, including the time for full stent expansion, concomitant opioid use and underlying dysmotility, and other factors affecting a patient's digestion in the setting of advanced malignancy. Generally, manufacturers recommend starting with fluids and then progressing to smooth or pureed foods such as smooth soups, yogurt, and ice cream before finally advancing to a more varied soft diet. Avoiding foods that are difficult to break down with chewing is recommended to minimize stent obstruction (eg, bread, tough meats, fish with bones, pithy fruits, stringy vegetables, potato skins, salads, and raw vegetables). Encouraging patients to eat multiple smaller meals, slowly, in an upright position and using fluids, sauces, and gravies concurrently is also helpful. Formal consultation with nutrition and dietitian services can help patients adapt and ensure adequate caloric intake.

Gastroduodenal stents

Establishing luminal patency in patients with gastric outlet obstruction (GOO) is clinically significant for both quality of life and the ability to undergo subsequent treatments. Patients with malignant GOO usually present with advanced or unresectable disease with limited life expectancy. The most common malignant causes of GOO are gastric, duodenal, and pancreatic cancers, with GOO occurring in up to 20% of advanced pancreatic cancers.⁵⁶ SEMSs are FDA-approved for the palliative treatment of pyloric or duodenal obstructions caused by malignant neoplasms. Further details regarding the role of endoscopy in the management of benign and malignant GOO can be found in the 2021 ASGE guideline.⁵⁷

A comprehensive review of 19 prospective studies including 1281 patients demonstrated a pooled technical success rate of 97% and clinical success rate of 86%.⁵⁸ The etiology of technical failure included an inability to pass the guidewire across the stricture (1.0%), stent migration during deployment (0.3%), and insufficient deployment (0.3%). Stent dysfunction occurred in 20% of patients, mainly because of stent occlusion from tumor ingrowth or overgrowth (13%) and migration (4%). The median stent patency ranged from 68 to 307 days in 5 studies including 549 patients.⁵⁹⁻⁶³

Overall, stent placement in malignant GOO is associated with better short-term outcomes including faster resumption of an oral diet and shorter mean hospitalization, whereas surgery is associated with better long-term outcomes including lower rates of recurrent obstruction. A systematic review and meta-analysis, which included 3 randomized trials,⁶⁴⁻⁶⁶ analyzed 2354 patients with malignant GOO who underwent SEMS placement versus surgical gastrojejunostomy.⁶⁷ Although the mean time to oral intake and length of hospital stay were shorter in the SEMS group (mean difference, 5 days [$P < .001$] and 10 days [$P < .001$], respectively), the frequency of reinterventions was higher

in the SEMS group versus surgical bypass (26% vs 11%). The most common reason for reintervention is SEMS obstruction from tumor ingrowth or overgrowth. In this scenario, SEMS obstruction can be managed with a placement of another SEMS, shown to be up to 100% technically and 82.4% clinically successful.⁶⁸ Predictive factors for SEMS failure include poor baseline functional status and presence of peritoneal disease.⁶⁹⁻⁷³ A retrospective study involving 160 patients undergoing palliative SEMS placement also found peritoneal carcinomatosis as a risk factor for perforation ($P = .039$) and a higher rate of SEMS migration with shorter 6-cm stents ($P = .044$).⁷⁰ Poor nutritional and functional status and ascites have also been found to be independent predictors of clinical failure of a surgical gastrojejunostomy.⁷⁴ On the basis of these studies, patients with longer life expectancy who are surgical candidates should undergo surgical gastrojejunostomy, whereas those with shorter anticipated life expectancy should undergo SEMS placement. It is important to note, however, that the practice of performing surgical gastrojejunostomy in those with longer life expectancy has not been confirmed in larger prospective studies.

Beyond palliation, SEMSs may also be an option to re-establish luminal patency and maintain nutrition in patients with obstructed but potentially resectable gastric cancer. A retrospective study of 161 patients with GOO due to gastric cancer underwent successful pyloric stent placement with clinical improvement of obstructive symptoms in 159 (99%) and 156 (97%) patients at 1 and 12 weeks of stent placement, respectively. In a subgroup analysis of resectable cases (24.8%), 35 of 40 patients (87.5%) underwent neoadjuvant chemotherapy followed by curative surgery. SEMS placement helped to reduce vomiting and improve nutrition over a 4-week period after stent placement to allow follow-up systemic therapy.⁷⁵ More data are needed to assess the feasibility of SEMS placement to bridge patients with obstructing resectable gastric cancer.

EUS-guided gastroenterostomy (EUS-GE) has emerged as an off-label alternative to SEMS placement and surgical gastrojejunostomy in the management of GOO.⁷⁶⁻⁷⁸ Details of the technique are described in the ASGE technology document on lumen-apposing metal stents (LAMSs).⁷⁹ A systemic review and meta-analysis of 5 studies with 199 patients who underwent EUS-GE for both benign and malignant GOO reported a technical success rate of 93% and serious adverse event rate of 6%, including stent maldeployment, peritonitis, surgical intervention, and hemoperitoneum, with a reintervention rate of 11%.⁷⁷

A recently completed, multicenter, international, randomized trial comparing EUS-guided balloon-occluded gastrojejunostomy bypass (EPASS) technique with SEMS placement in 97 patients with unresectable malignant GOO demonstrated less reintervention within 6 months in the EUS-GE group (2 patients [4%]) versus the SEMS group (14 patients [29%], $P = .002$).⁸⁰ The GOO score at 1 month

was significantly better in the EUS-GE group (mean, 2.4) than in the SEMS group (mean, 1.91; $P = .012$). There were no statistically significant differences between the 2 groups in terms of technical success, clinical success, time to resumption of oral diet, quality-of-life scores, or mortality at 30 days. The rate of adverse events also did not differ, at 23% in the EUS-GE group and 24% in the SEMS group within 1 month ($P = 1.00$).¹ Median procedural time was significantly longer in the EUS-GE group (35 minutes) than in the SEMS group (20 minutes, $P < .0001$). Another randomized trial is ongoing, evaluating similar primary outcomes of reintervention rates and recurrent GOO (clinicaltrials.gov number NCT03259763). In summary, SEMSs are a less-invasive alternative to surgical gastrojejunostomy and likely best suited for patients with limited life expectancy. Surgical or EUS-guided bypass are good options for patients with reasonable life expectancy, given lower rates of reintervention.

SEMSs have a limited role in the management of benign gastroduodenal strictures, because all enteral stents in the United States are uncovered and not removable. The use of fully covered esophageal stents in benign gastroduodenal disease is off-label. FCSEMSs do provide another option in refractory benign strictures when endoscopic dilation fails. FCSEMSs are usually removed several weeks after insertion. Small retrospective studies have reported clinical success rates of 82% to 100% with an increased GOO score by at least 1 degree within 3 days of FCSEMS placement; however, durability of response after 6 weeks of FCSEMS placement was wide, ranging from 67% to 90%.^{81,82} Not surprisingly, the risk for migration of FCSEMSs in benign disorders in the upper GI tract ranged from 20% to 63%, and therefore stent fixation is recommended but does not completely mitigate the risk of migration.⁸³ Off-label use of LAMSs has been performed as a novel alternative treatment option in benign strictures to combat the risk of migration. The short length and wide double-flange stent design of LAMSs allows placement across focal strictures, including anastomoses. Successful LAMS management of short benign strictures has been described in numerous case series and within systematic reviews as discussed in the ASGE technology document for LAMSs.⁷⁹

Similarly, SEMSs have been used in the management of postoperative anastomotic leaks after foregut and bariatric surgery. GI leaks occur in 3% to 12% of cases after total gastrectomy for gastric cancer.⁸⁴ Studies have shown clinical success with SEMSs that ranges from 65% to 98% with migration rates of 26%.^{84,85} On the other hand, leaks occur in up to 8% of bariatric surgeries with higher rates after Roux-en-Y gastric bypass compared with sleeve gastrectomy.^{86,87} Leaks most commonly occur at the proximal end of the sleeve near the gastroesophageal junction, as opposed to the gastrojejunal anastomosis in Roux-en-Y gastric bypass. A meta-analysis of 488 patients with bariatric leak after SEMS placement found successful leak closure of

86% with a median stent duration of 6 weeks.⁸⁷ Reoperation was needed in 14%.² SEMS treatment in this scenario is also plagued by migration issues seen in up to 40% of patients, which improved to 15% with stent suture fixation in 1 study.⁸⁸

Colonic stents

Colonic SEMSs are FDA-approved for use in palliation of malignant colonic obstruction (typically colorectal adenocarcinoma) or in select patients as a bridge to surgical intervention. Stents designed for this purpose are uncovered to limit otherwise high rates of migration, although covered esophageal stents are occasionally used off-label to manage difficult to reach or angulated strictures. Most evidence for these practices is based on left-sided colonic obstruction. The use of SEMSs in benign colonic obstruction is off-label and generally reserved for refractory strictures to use as bridge to definitive surgery. This approach may allow for decompression of the dilated proximal segment to enable 1-step surgery as opposed to a 2-step diverting ostomy followed by take-down. Palliation of benign large-bowel obstruction in nonsurgical candidates has also been performed in patients with limited life expectancies.

Palliative SEMS placement in nonoperative candidates offers carefully selected patients benefits as an alternative to a diverting ostomy. In a 2015 meta-analysis of 10 primarily retrospective studies examining palliative SEMS placement in 375 patients, SEMSs were noted to be associated with a lower risk of early adverse events (odds ratio [OR], 0.34; $P < .01$) and also demonstrated lower mortality compared with surgery (OR, 0.31; $P < .01$). However, this was at the expense of an increased rate of perforation (OR, 5.25; $P < .01$) and late adverse events (OR, 1.94; $P = .03$).⁸⁹ A randomized trial also published in 2015 included 52 patients who were randomized to colonic stent placement versus surgical decompression for palliative management of a malignant colonic obstruction.⁹⁰ The study demonstrated a 73% technical success rate for SEMS placement and noted improved quality-of-life assessments compared with surgery. Patients were also noted to have improved 30-day mortality (8% vs 15%), shorter length of postprocedure hospital stay, and more rapid resumption of oral intake. An additional study of 73 patients comparing SEMS placement ($n = 73$) and palliative surgery ($n = 41$) found that patients with an Eastern Cooperative Oncology Group performance status of 0 or 1 had improved overall survival with surgical palliation versus SEMS placement, although no difference was seen in Eastern Cooperative Oncology Group performance status 2 or 3 patients.⁹¹

Colonic SEMS placement as a bridge to surgery may facilitate elective surgery and avoid a temporary ostomy, although published data appear to be mixed.³⁰ Two large registries including 182 patients undergoing colonic SEMS placement as a bridge to surgery noted a high technical success rate of 98% and clinical success rate of

94%, thus facilitating a 1-stage procedure in most patients, with only 6% of patients requiring a surgical stoma.⁹² Although 1 randomized trial demonstrated that 67% versus 38% of patients undergoing SEMS placement versus open surgery had 1-stage operations with a significantly reduced need for stoma creation,⁹³ 2 subsequent randomized trials were discontinued early because of high adverse event rates⁹⁴ and lack of efficacy.⁹⁵ One study demonstrated 53% technical failures in stent placement and a 7% stent perforation rate,⁹⁴ whereas the other study demonstrated a 30% technical failure rate in stent placement and a higher rate of leaks and perforations.⁹⁵ There remains concern that colonic SEMS placement may significantly increase the risk of systemic recurrence (relative risk, 1.63; 95% CI, 1.01-2.62)⁹⁶ with documented pathologic evidence of a “silent perforation” rate of up to 20% of patients undergoing resection.⁹⁵ However, several meta-analyses of randomized trials have demonstrated that patients who underwent colonic SEMS placement had significantly higher rates of primary surgical anastomosis, lower rates of permanent stoma, similar overall adverse events, and no difference in overall survival.⁹⁷⁻⁹⁹

Unlike the left side of the colon, retrospective data on the efficacy and technical success rate for colonic stent placement in the colon proximal to the splenic flexure are conflicting. Although some reports have indicated a similarly high technical success rate of $\geq 95\%$ in SEMS placement for proximal malignant obstruction,^{100,101} other reports have had lower success rates (75%-80%) with concern for increased rates of perforation in the right side of the colon.^{102,103} Surgical consultation should be obtained if considering endoscopic intervention in cases of proximal colonic obstruction in the event that primary ileocolonic anastomosis or temporary ileostomy is preferred or required.

Extracolonic malignancy may present with acute large-bowel obstruction because of extrinsic compression, infiltration of the mesentery, and/or underlying dysmotility. Many of these patients may have overt or subclinical peritoneal carcinomatosis that may promote multifocal obstruction, of which the colon may only be 1 site. In patients with underlying malignant bowel dysmotility, mechanical decompression is unlikely to provide relief. As such, the role of colonic stents in this context is controversial, with conflicting data in the literature. Initial reports in a small study (15 of 49 patients with extracolonic malignancy) demonstrated a poor clinical success rate (20%) with significantly more severe adverse events (33%), including 2 deaths.¹⁰⁴ Additional single-center reviews from Japan in 68 patients demonstrated a 67% technical success rate and a high rate (67%) of adverse events.¹⁰⁵ Two retrospective case series from South Korea reported a higher 93.2% to 100% technical success rate, with a 4.8% rate of perforation in 1 series.^{106,107} The most recent North American single-center study in 187 patients demonstrated a technical success rate in 76% of patients with a

clinical success rate of 55% and 6% adverse events.¹⁰⁸ Notably, the radiographic presence of multifocal disease and peritoneal carcinomatosis significantly predicted a lack of success, and the overall median survival of the cohort was only 3 months overall.

Although the use of colonic SEMSs for benign causes of colonic obstruction is off-label, clinical experience and evidence in the literature suggest potential benefits in carefully selected patients with refractory strictures. No prospective randomized trial data exist at this time. A retrospective series of 16 patients treated with FCSEMSs for benign anastomotic strictures demonstrated a technical success rate of 100% but a durable clinical success rate of only 56% with migration rates of 19%.¹⁰⁹ Another retrospective series of 23 patients with colonic obstruction due to benign colorectal strictures who underwent SEMS placement again noted high technical success (100%) and initial clinical success (95%). Etiologies of the obstruction included diverticular and inflammatory strictures (69.5%), surgical anastomosis (13%), radiation (13%), and Crohn's disease (4%). This procedure was used as a bridge to surgery in 16 patients who were able to undergo an elective rather than an emergent surgical intervention and an ostomy was avoided in 42% of patients.¹¹⁰ For focal benign colonic strictures, there have been small, promising case series of off-label LAMS application, with possibly fewer procedures required for successful remediation in comparison with balloon dilation.^{111,112} Given the larger overall luminal diameter and limited consequence to distal migration, LAMS placement may have advantages in this scenario.^{79,112} Use of a regular bowel regimen of osmotic laxatives (eg, polyethylene glycol) to target regular soft bowel movements is generally recommended after colonic stent placement.

SAFETY

Esophageal stents

Esophageal SEMSs are commonly associated with potential adverse events both immediately and after 30 days of placement, including postprocedure pain, perforation, hemorrhage, pneumonia, fistula formation, and airway compression.^{12,113,114} Proximal stent placement may be associated with a globus sensation. Prior radiation and chemotherapy may be associated with an increased risk, and studies have reported higher rates of pain, hemorrhage, and fistula formation.^{25,26} Additional adverse events include heartburn when SEMSs are placed across the gastroesophageal junction and retrosternal chest pain, which can occur in up to two-thirds of patients, frequently requiring opiate analgesia.¹¹⁵

There are considerable variations in the estimates of migration (5%-40%) and epithelial hyperplasia (11%-31%) in the literature.^{23,116-122} As indications for esophageal SEMSs have grown, covered stents have been increasingly used to prevent tumor ingrowth and reducing the need for

intervention,¹²³ sealing leaks and fistulas,¹²⁴⁻¹²⁶ and allowing for removability. The bare metal flanges of PCSEMSs promote tissue ingrowth, which may reduce the likelihood of migration at the potential cost of epithelial hyperplasia with resultant recurrent obstruction. As such, PCSEMS removal may be challenging.^{127,128} FCSEMSs, however, are associated with a higher rate of migration because of the stent coating surrounding the entirety of the stent.^{120,121} Some FCSEMSs have also integrated antimigration anchoring fins that aim to mitigate migration risk while maintaining flexibility for stent removal.^{4,119} Head-to-head studies of stent performance are lacking, but a large, multicenter, retrospective study of 357 patients demonstrated 15% overall rate of stent migration, ranging from 11% in PCSEMSs to 19% in FCSEMSs with antimigration fins and 25.3% in FCSEMSs.⁴ This study found that FCSEMSs and FCSEMSs with antimigration fins were significantly associated with migration when compared with PCSEMSs, with similar rates of clinically significant epithelial hyperplasia among stent types.

Although migration is common, SEMSs can be successfully retrieved without adverse events. Signs of migration include immediate recurrence of dysphagia, abdominal pain, nausea, and vomiting. An x-ray can be done for confirmation. The larger stent diameter, as compared with the pylorus, prevents further migration into the small bowel and subsequent potential obstruction. Therefore, emergent removal is usually not needed; however, retrieval should be considered soon given the risk of gastric ulceration, perforation, or obstruction. A large retrospective multicenter series of 214 patients with benign disease found a major adverse event rate of 2%.¹²⁹ In patients with malignant obstruction, the approach to stent removal after migration depends on the degree of esophageal stricture, technical ability in reaching the stomach to remove the stent, and overall prognosis of the patient.

Gastroduodenal stents

SEMS placement in the duodenum is associated with several known adverse events. Perforation is relatively rare, occurring in 1% of cases.⁵⁸ One retrospective study identified deployment of 2 SEMSs in the same session as a predictor of perforation.⁷¹ Bleeding can occur in 4% of cases, with around 1% being major bleeding requiring an intervention.⁵⁸

Gastroduodenal SEMS dysfunction may occur as frequently as in 25% of cases, primarily because of tumor progression but also related, less commonly, to stent migration.^{130,131} One unique adverse event associated with the placement of an enteral stent in this area is the possibility of precipitating biliary obstruction and/or cholangitis from both the compression of the ampulla itself or from backpressure on the intraduodenal segment of the common bile duct. Therefore, it is paramount to be aware of the proximal and distal ends of the SEMS in relation to the ampulla. Compounding this issue is the fact that biliary access can be

technically challenging if a SEMS is placed across the ampulla before sphincterotomy. Placing a biliary SEMS before a duodenal SEMS is advised when biliary obstruction is present or appears to be impending. Retrospective multicenter studies at high-volume centers demonstrate a wide range of successful biliary cannulation from 34% to 85% in patients with indwelling duodenal stents.^{132,133} Alternatively, trans-hepatic or transmural biliary stent placement may be required if the papilla is not accessible.

Colonic stents

Adverse events of colonic SEMS placement have been well reported. Median stent patency ranges considerably in the literature, with 1 meta-analysis reporting a median patency of 106 days (range, 68-288) in patients undergoing palliative placement.¹³⁴ Additional early adverse events include stent failure despite successful deployment (up to 12%), stent migration (up to 5%), reobstruction (up to 5%), pain (up to 7%), and bleeding (up to 4%).^{95,103,135} The most common and most feared adverse event is perforation, occurring at a rate of 7% in a large meta-analysis.¹³⁶ A meta-analysis of 4086 patients (with 207 perforations) identified Hanarostent (Olympus, Tokyo, Japan) and Niti-S covered stents (TaeWoong Medical, Gimpo, South Korea; not available in the United States) as having a lower perforation rate (<5%) compared with other commonly used stents.¹³⁶ Additionally, post-stent placement dilation had a significantly increased perforation risk (20%). Bevacizumab use was identified in this meta-analysis to be a risk factor for perforation with a rate of 13% compared with other chemotherapeutic agents with a rate of 7%. Additional reports have similarly raised this concern, with a perforation rate of up to 17% in retrospective data with the concomitant use of bevacizumab with median time to perforation of 21 days after bevacizumab initiation.¹³⁷

Perforation has been proposed to occur either because of guidewire or catheter malposition, dilation before or after the stricture placement, stent-induced perforation (tumor or nontumor local perforation), or proximal colonic distention from air insufflation or inadequate decompression.¹³⁸ Clinical outcomes after perforation are variable, with some reports of significant morbidity and mortality depending on the patient's comorbidities and extent of underlying malignancy.¹³⁹⁻¹⁴¹ A concern for silent perforation was identified on pathology specimens from 20% of stent patients (9/47) in 1 study, raising concern for potential peritoneal contamination and seeding with stent placement. A retrospective study from South Korea comparing patients who underwent SEMS placement ($n = 27$) versus emergency surgery ($n = 29$) found an OR of 46 to subsequently develop metastasis in patients who developed a perforation in the immediate postprocedure window after SEMS placement (3/27).¹⁴²

STENT FIXATION

SEMS migration rates are substantial, resulting in repeat procedures, reduced clinical efficacy, and potential adverse events. To mitigate this issue, extensive reports have highlighted the use of endoscopic fixation of covered SEMSs after placement. Through-the-scope hemostatic clips with or without bridling have reportedly reduced migration rates significantly; however, because of the propensity for these clips to be displaced and the cumbersome nature of bridles, over-the-scope clips (OTSCs) and endoscopic suturing have been the primary modality investigated for this purpose.¹⁴³⁻¹⁴⁵

OTSCs may be used to fixate a stent by capturing tissue near the proximal edge of the SEMS as well as the edge of the stent lattice within the clip. Care should be taken to avoid nearby vascular structures and also to avoid placement of OTSCs in or near the upper esophageal sphincter. Two OTSC products are available in the United States: the Ovesco OTSC system and the Padlock Clip Defect Closure System (Steris, Mentor, Ohio, USA). Ovesco offers an OTSC Stentfix system that received 510k clearance with the FDA in October 2019 and is designed specifically for stent fixation with key features including a slotted cap to allow easier positioning of the stent edge and an outward rounded hinge. In a meta-analysis of 9 studies, the pooled migration rate of SEMSs after OTSC fixation was 0.10 (95% CI, 0.04-0.20) and the pooled risk ratio of SEMS migration after OTSC Stentfix compared with no fixation was 0.24 (95% CI, 0.13-0.43).¹⁴⁶

However, removal of these clips remains a significant clinical challenge because frequently, epithelial hyperplasia is noted around the clip, and endoscopic visualization in the context of the indwelling stent may be limited. A wide array of methods has been reported for the removal of OTSCs including grasping forceps, Nd:YAG laser, argon plasma coagulation, EMR and endoscopic submucosal dissection, and ice-cold saline solution, with minor bleeding (7%) and superficial mucosal tears (1.4%-9.1%) the most common related adverse events.¹⁴⁷ A dedicated removal device, called the remOVE DC Cutter (Ovesco), is available that allows the application of direct current using a bipolar endoscopic cutting instrument introduced through the working channel.^{148,149} In the cases where the OTSC must be disrupted (either with Nd:YAG laser, argon plasma coagulation, or DC Cutter), the OTSC is cut into 2 pieces at the hinge on either side, which is the thinnest part of the clip. The fragments are then removed using an endoscopic grasper, taking care to avoid injury to the esophagus (eg, using a silicon foreign body hood).

Endoscopic suturing may fixate stents by using the needle-suture system to capture the proximal wire loops of the SEMS and anchor it through the underlying mucosa,

placing a cinch to lock the suture into place.¹⁵⁰ This is often performed in an interrupted fashion, allowing the placement of 1 to 3 anchors around the proximal edge of the stent. One retrospective review of 51 patients undergoing 62 FCSEMS placements at a single center used the OverStitch endoscopic suturing device (Boston Scientific) for stent fixation with 100% technical success, low risk of adverse events (9.2%), and an 87% reduction in risk of stent migration (OR, 0.13; 95% CI, 0.03-0.47).¹⁵¹ Notably, a single-center retrospective study compared sutured FCSEMSs (n = 25) to PCSEMSs (n = 30) and found similar rates of stent migration, suggesting that PCSEMSs may be considered especially in patients with malignant dysphagia where retrieval is not required.¹⁵² In a large meta-analysis of 14 studies in 212 patients, the technical success rate for suturing was 96.7% with a migration rate of 15.9% (95% CI, 11.4-21.6) with infrequent suture-related adverse events (3.7%; 95% CI, 1.6-8.2).¹⁵³ Removal of sutured SEMSSs is significantly more straightforward than OTSC removal and readily achieved by cutting the interrupted suture with an endoscopic loop cutter or endoscopic scissors.¹⁵⁴

A single-center retrospective study compared stent migration rates between no fixation, suturing, and OTSCs for SEMSSs placed for both benign and malignant diseases primarily for the upper GI tract and found OTSCs to have significantly lower migration rates (35%) compared with no fixation (62%) and suturing (57%; $P = .013$). Furthermore, the median time to stent migration was 3 weeks without fixation, 5 weeks with suturing, and 6 weeks with OTSCs ($P = .023$).¹⁵⁵ A recent systemic review and meta-analysis of 1014 patients demonstrated esophageal stent fixation was associated with significantly lower migration rates compared with nonfixation of stents, regardless of fixation technique (through-the-scope clips, OTSCs, or suturing) and stent placement indication.¹⁵⁶

FINANCIAL CONSIDERATIONS

Multiple factors must be considered in the cost-to-benefit analysis of endoscopic stent placement compared with alternative therapies. This includes the cost of the stent, procedure, and follow-up care (readmissions, elective stent removal). Although studies have compared initial interventional costs, most do not account for total costs after long-term follow-up.

Prior studies have shown a cost-to-benefit favoring SEMSSs for the treatment of malignant esophageal obstructions. Although upfront costs are higher with SEMS treatment in inoperable esophageal cancer, total cost was lower compared with non-SEMS treatments.¹⁵⁷ In acute esophageal perforations, SEMS treatment was significantly less expensive than surgical repair (\$91,000 vs \$142,000; $P < .0001$) with a shorter mean length of stay (6 vs 11 days, $P = .0007$) and with less time to oral intake (3 vs 8 days, $P = .0004$).¹⁵⁸

In the only cost analysis conducted together with a randomized controlled trial comparing enteral SEMS placement with surgical gastrojejunostomy, mean total costs for surgical gastrojejunostomy were higher compared with SEMS placement (\$16,535 vs \$11,720, respectively; $P = .049$ [comparing medians]).⁶³ A decision-analysis model comparing the cost-effectiveness of SEMS placement versus surgical gastrojejunostomy concluded that endoscopic stent placement (\$8213) was less costly than open (\$12,191) and laparoscopic gastrojejunostomy (\$10,340) within a 1-month follow-up period.¹⁵⁹ A retrospective claims analysis of the Medicare (MedPAR) database found the median length of stay (8 vs 16 days, $P = .0001$) and median cost (\$15,366 vs \$27,391, $P = .0001$) per claim were both significantly lower for SEMS placement versus surgical gastrojejunostomy in malignant GOO.¹⁶⁰ This was also confirmed in a retrospective review of a claims database for employer-provided insurance and Medicare supplemental insurance plans, which demonstrated median 90-day costs of SEMS placement and associated readmissions were \$18,500 (range, \$4100-\$49,500) compared with \$37,200 (range, \$12,200-\$67,800) for surgery in the management of malignant GOO.¹⁶¹ In assessing total cost in SEMS placement versus EUS-GE, initial data from a retrospective study demonstrated higher mean hospital charges in the SEMS placement group (U.S.\$34,250 vs U.S.\$27,599, $P = .03$) due to reinterventions, despite a shorter mean length of hospital stay.¹⁶²

Similar favorable cost-effective findings are seen with colonic SEMS placement versus surgery in the treatment of acute malignant obstruction.¹⁶³ A decision-tree analysis of costs, quality-adjusted life-years, and survival in patients with unresectable or metastatic colorectal cancer who presented with acute colonic obstruction found that emergency surgery cost \$5865.30 more without improved quality-adjusted life-years over SEMS placement.¹⁶⁴ In the scenario of SEMS placement as a bridge to surgery, stent placement has been shown to be a less-expensive treatment choice with shorter length of stay and faster time to oral intake.¹⁶⁵

In regard to benign stricture management with LAMSS, the cost-to-benefit ratio includes a balance between the high short-term clinical success with the high cost of LAMSS and high reintervention rate. However, LAMS placement may potentially have an economic advantage over repeated dilation treatments for strictures. A single-center, retrospective, case-control study comparing non-stented patients who underwent 3 endoscopic dilations with those who underwent LAMS placement for benign foregut strictures found that LAMS placement may have an economic advantage over serial dilations after the third dilation.¹⁶⁶ Cost-effectiveness data are expected to change with time, as dictated by the price of the LAMS itself.

As we await more comparative prospective data in the management of bariatric leaks, this should also include cost analyses. There are no studies evaluating cost-effectiveness of endoscopic treatments in this scenario,

TABLE 2. Current Procedural Terminology codes for stent placement in the GI tract

Current Procedural	
Terminology code	Procedure
<i>Esophageal, gastroduodenal, and colonic stent placement</i>	
43212	Esophagoscopy, flexible, transoral; with placement of endoscopic stent (includes pre- and postdilation and guidewire passage, when performed)
43266	EGD, flexible, transoral; with placement of endoscopic stent (includes pre- and postdilation and guidewire passage, when performed)
44370	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with transendoscopic stent placement (includes predilation)
44379	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with transendoscopic stent placement (includes predilation)
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and postdilation and guidewire passage, when performed)
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and postdilation and guidewire passage, when performed)
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and postdilation and guidewire passage, when performed)
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and postdilation and guidewire passage, when performed)
76000	Fluoroscopy (separate procedure), up to 1 h of physician time
<i>Foreign body removal (stent removal)</i>	
43215	Esophagoscopy, flexible, transoral; with removal of foreign body(s)
43247	EGD, flexible, transoral; with removal of foreign body(s)
44363	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with removal of foreign body(s)
44390	Colonoscopy through stoma; with removal of foreign body(s)
45332	Sigmoidoscopy, flexible; with removal of foreign body(s)
45379	Colonoscopy, flexible; with removal of foreign body(s)

although 1 French study demonstrated double-pigtail stents were more cost-effective than covered stents in the treatment of leaks after laparoscopic sleeve gastrectomy.¹⁶⁷

Strategies to decrease overall medical costs of SEMS treatment include decreasing the need for repeat interventions. One study looked at stent fixation with endoscopic suturing to potentially reduce migration and subsequent costs of repeat stent procedures. A decision-analytic model was constructed from a payer perspective evaluating SEMS placement for benign esophageal diseases (fistula, leak, perforation, or stricture) in a hospital outpatient setting. The model compared endoscopic suturing to anchor the stent with no suturing and calculated an average cost savings of U.S.\$866.92 per patient with suturing.¹⁶⁸

The Current Procedural Terminology codes for endoscopic stent placement and removal in the GI tract are listed in Table 2. Dilation of the stricture, if performed, before stent placement is included in the stent procedure code. If fluoroscopy is used, the Current Procedural Terminology code 76000 is separately reported. Facilities must also include a separate code for the stent itself to permit cost-tracking for future rate determinations by the Centers

for Medicare & Medicaid Services. These requirements change frequently, and therefore each facility should check with its local payers.

AREAS OF FUTURE RESEARCH

Improvements in stent design to mitigate migration, which is the most common adverse event, are warranted. We have made progress with LAMs and stent fixation options but require more solutions given the broad use of SEMSs both in clinical indication and anatomic location. Future prospective comparative trials of stent fixation should address which approach is most efficacious and cost- and time efficient, including identifying ideal clip and suture patterns. In terms of efficacy in malignancy, further prospective randomized controlled trials comparing EUS-GE with both surgical gastrojejunostomy and endoscopic SEMS placement will help tailor future management of malignant GOO. Standardization of the EUS-GE technique (direct vs balloon-assisted) with goals to improve safety and broaden applicability outside specialized centers will also be important moving forward. Ideal management of

benign refractory strictures remains uncertain. LAMSs represent an important alternative to traditional endoscopic options in short-segment strictures. The optimal duration of leaving the stent in is unknown, with balancing concerns about degradation and tissue ingrowth with prolonged duration versus concern for recurrent stricture with early removal. This is especially important in the elderly, where repeat procedures may not be feasible because of age and comorbidity. Prospective trials with standardized protocols are warranted to determine their long-term safety, efficacy, and cost-effectiveness as well as studies to compare LAMSs as first-line therapy for not only refractory strictures but potentially as upfront treatment for benign strictures (compared with multiple dilation sessions). At present, data are insufficient to elucidate the clinical applicability of biodegradable stents, which are currently not available in the United States.^{169,170} Promising data are emerging on the novel uses of stents beyond their capability in maintaining GI luminal patency, including local delivery of chemotherapy and radiation.¹⁷¹⁻¹⁷⁵ With the increasing applicability of SEMSs in the treatment of both benign and malignant diseases, advancements in stent design to address ease of use and durability are needed. Finally, cost-analysis data with long-term follow-up are paramount in this age of medical cost responsibility and containment.

SUMMARY

Enteral stents continue to offer the exciting opportunity to make an impact on the lives of patients with obstruction, leaks, and fistulas in the GI tract. In malignant obstruction, the SEMS offers a clear opportunity to palliate obstruction and provides a pathway to further oncologic treatments and bridge to curative surgery. In benign disease, SEMSs may be used to help manage fistulas, leaks, and perforations, and experience continues to develop in their use for benign strictures. The decision on how best to use these technologies should occur in a multidisciplinary setting with consideration of patient characteristics such as performance status, patient preference, and projected clinical course, available expertise, and plans for subsequent therapies.

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Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; EUS-GE, EUS-guided gastroenterostomy; FCSEMS, fully covered self-expandable metal stent; FDA, U.S. Food and Drug Administration; GOO, gastric outlet obstruction; LAMS, lumen-apposing metal stent; OR, odds ratio; OTSC, over-the-scope clip; PCSEMS, partially covered self-expandable metal stent; SEMS, self-expandable metal stent; TEF, tracheoesophageal fistula.



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