Recent Advances in the Use of Stents for Esophageal Disease

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KEYWORDS

• Esophageal stent • Dysphagia • Esophageal cancer
• Esophageal stricture • Esophageal perforation
• Esophageal fistula

Esophageal cancer causes a unique type of misery. Beyond all the other disabilities and anxieties that come with a cancer diagnosis, patients with malignant dysphagia often feel like they are starving to death. Patients often report avoiding eating even though hungry, because of pain or choking sensations, and may present for treatment only after significant weight loss. Undernutrition itself is one of the strongest predictors of survival in patients with esophageal cancer anticipating treatment.[1] To make matters worse, esophageal cancer patients may suffer embarrassment and isolation when they cannot participate in the many social and family activities revolving around meals. Individuals with tight, benign strictures also share some of these handicaps. Although not facing the same grave prognosis, these individuals also experience weight loss, aspiration, and pain as well as frustration, anxiety, and decreased quality of life, especially if they have to undergo frequent endoscopic dilation.

Given the level of desperation caused by dysphagia, combined with the easy access of the esophagus, esophageal dilation was probably one of the earliest successful gastrointestinal interventions. It is easy to imagine some unfortunate prehistoric human using a stick or bone to dislodge a piece of meat in the first esophageal dilation. Through much of recorded history, wax candles and other tapered, rigid devices have been used for the same purpose. Because dilation alone provides only temporary relief in most cases of malignant dysphagia, early prostheses or stents were constructed out of smooth, rigid materials such as ivory, sandalwood,

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and bone. Esophageal stents evolved slowly over the first part of the twentieth century, with the use of rubber and plastics. Innovation has exploded over the last 20 years with the development of the self-expanding metal stent (SEMS). Constructed from surgical steel or, more commonly, a shape-retaining nickel and titanium alloy, nitinol, SEMS are easy to place and have quickly replaced rigid stents in the treatment of esophageal malignancies. Further modifications in stent materials, such as the construction of self-expanding plastic stents (SEPS) and even biodegradable materials, have spawned a rapid increase in the use of removable stents for benign conditions such as refractory strictures, perforations, and fistulas (**Fig. 1**).

This article describes the current experience with esophageal stenting for malignant and benign conditions, and examines new innovations in stent design and applications.

STENTS FOR MALIGNANCY

The primary application for esophageal stents remains the treatment of malignant dysphagia. While the incidence of new esophageal cancers has remained relatively stable over the past 10 years at about 4.5 new cases per 100,000 people, adenocarcinoma has rapidly replaced squamous cell cancer as the primary malignancy.[2,3] Squamous cell cancers remain a major source of mortality worldwide, with over 400,000 new cases each year, mostly in developing countries. Esophageal cancers internationally rank as the fourth most common cause of cancer mortality among men and the seventh most common cause among women.[4] Adenocarcinoma arising from Barrett's esophagus tends to develop more distally, but otherwise the complaints and complications associated with the 2 malignancies are similar. Most patients present with dysphagia and weight loss as their main complaints. Because tumor usually occupies over half of the esophageal lumen when dysphagia develops, most these cancers will be unresectable at the time of diagnosis. Treatment, therefore, often focuses on palliation of symptoms as well as attempts at improving nutrition, in the hope of at least marginally improving survival. Although esophagectomy may be performed to relieve dysphagia, undertaking a large operation in the setting of metastatic disease is discouraged because of associated morbidity and mortality, as well as a reduction in quality of life, without extending survival.[5,6] Even after esophagectomy for localized esophageal cancer, many patients will experience recurrence locally or at distant sites, with 5-year survival hovering around 20%.[7] Benign strictures of the esophagogastric anastomosis occur in at least 20% of those who undergo

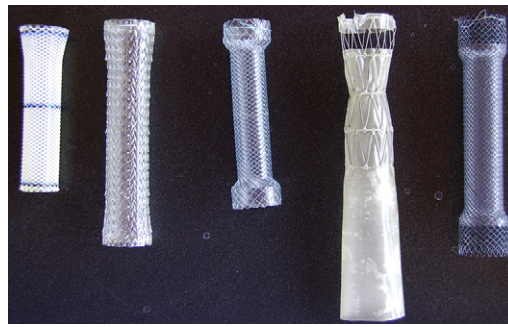

Fig. 1. A variety of partially and fully covered metal and plastic stents. From left Polyflex, Alimaxx, Niti-S, Dua Antireflux, Evolution.

surgery, although these rarely require stenting.[8] Chemotherapy and radiation therapy can often effectively improve swallowing in many patients; however, many of these patients will suffer from recurrent esophageal obstruction if tumor recurs locally. A portion of those who undergo esophagectomy for cure also experience local recurrence and require palliation. Several other cancers can cause dysphagia, including primary lung cancer, proximal gastric cancer, and a variety of cancers that metastasize to mediastinal lymph nodes.[9] Feeding tubes may be inserted below the obstruction to maintain adequate caloric intake; however, risks of aspiration persist and most people, even those with terminal diseases, simply want to eat.

RIGID STENTS

A discussion of new developments in esophageal stents merits a brief mention of older-style rigid stents. Although SEMS largely replaced rigid stents in the 1990s, in many developing countries rigid stents are still widely used. The low cost of rigid stents stands as the only real advantage of these devices. Commercially available rigid stents generally sell for as little as a few dollars, or can be fashioned out of rubber or polyethylene tubing for pennies. However, the cost of the stent is offset by numerous disadvantages. Rigid stents require stricture dilation up to 18 mm before placement, and heavy sedation is frequently necessary before driving them into position. Not surprisingly, perforations are common, with reported rates of 8% or higher.[10] Despite their generous exterior diameter, most rigid stents provide an internal lumen of only 12 mm or less, as several millimeters of wall thickness are needed to prevent collapse. Rigid plastic stents also seem to lead to more frequent interventions such as disimpaction of food, bleeding, and migration than SEMS, ultimately leading to higher cumulative costs.[11,12] Although rigid stents are technically removable, this is rarely performed.

SELF-EXPANDABLE METAL STENTS

The appeal of stenting with SEMS lies in their relative simplicity; as the stent expands, it pushes the tumor aside and allows food to pass almost immediately. The truth, of course, is that stenting with SEMS can be a complex undertaking with risks, discomfort, and limitations of effectiveness. Early enthusiasm for SEMS as a panacea for malignant dysphagia waned somewhat as reports of complications, stent migration, and reocclusion surfaced. Despite many modifications and overall stent evolution over the last 20 years, complication rates have not changed dramatically.[13]

Nonetheless stents remain tremendously appealing, in part because of limitations of other therapies. Unfortunately, only a few studies have looked at the relative effectiveness of different therapies for malignant dysphagia. There is broad recognition that endoscopic dilation of malignant strictures can alleviate dysphagia only for short periods. Complication rates—primarily for perforations—increase with larger, more sclerotic strictures, more aggressive dilation, and after radiotherapy.[14] There does not seem to be a difference in efficacy or complication rates between dilation with wire-guided Savary-type dilators or balloon devices.[15] Chemotherapy combined with radiation can improve survival in patients with both early and advanced-stage esophageal cancer, and can be very effective for controlling malignant dysphagia. In one large study, dysphagia resolved in 77% of patients with Stage III or IV disease after 5-fluorouracil, mitomycin C, and external beam radiation, and persisted until death in 60%. Median dysphagia-free duration was 5 months.[16] Single-dose brachytherapy seems to provide equal or better initial relief of malignant dysphagia

than stent placement,[17] except in patients with particularly advanced disease, multiple comorbidities, and short life expectancy.[18]

An abstract by Canto and colleagues[19] suggested that treatment of malignant dysphagia with SEMS cost about a third of treatment with photodynamic therapy, and a trial of thermal ablation using Nd:YAG laser or argon plasma coagulation versus SEMS suggested lower cost but reduced quality of life in the SEMS group.[20]

In general, the use of permanent stents should be reserved for patients with dysphagia secondary to advanced malignancy who are either not candidates for, or unwilling to undergo, surgery, chemotherapy, or radiotherapy, or who have experienced a recurrence after definitive treatment. Stents should extend about 2 cm proximal and distal to the tumor. Fortunately, most stents are sold in a variety of lengths to accommodate a broad spectrum of tumors. Partially covered stents have largely replaced uncovered stents for most indications, as they have been shown to delay tumor ingrowth longer without greater risk of migration. The main contraindication for esophageal stent placement is poor performance status, with life expectancy of less than 4 weeks. Relative contraindications include tumors within 2 cm of the upper esophageal sphincter, uncorrectable coagulopathy, or tumor invasion of the aorta or airways. Previous stent migration is not a contraindication, but does signal a need to try a larger or different type of stent or to use a securing device. Placement of standard stents within 2 cm of the upper esophageal sphincter has been associated with airway compromise, persistent discomfort, and osteomyelitis of the cervical vertebrae from pressure necrosis.[21,22] Smaller-diameter stents custom designed for the cervical esophagus are available in some countries, and stents sold for use in the upper airway or bile ducts have been used successfully in the hypopharynx (**Fig. 2**).[23] The caveat for placing these stents is that without flared ends, they are more likely to migrate, and the exposed tines of biliary stents may cause pain and irritation. Many experts now suggest that standard esophageal stents can also be used close to the upper esophageal sphincter, as long as these patients are followed closely and recognize the risk of complications.[24]

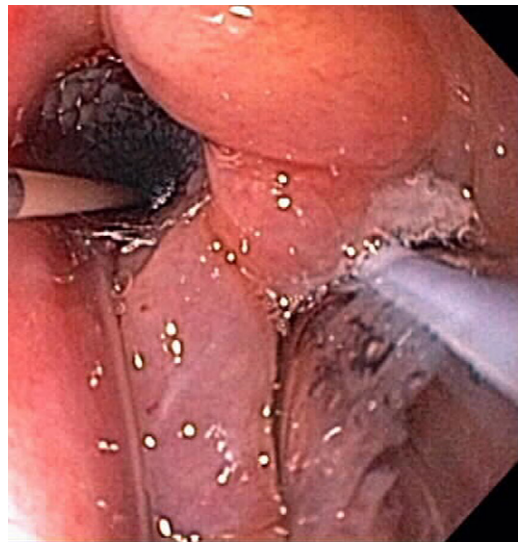

Fig. 2. Covered biliary stent deployed at the hypopharynx. Endotrachial tube seen in place at the level of the vocal cords.

Stenting across the lower esophageal sphincter poses its own challenges. Stents in this position may be more likely to migrate and can lead to free reflux of stomach contents. Attempts to incorporate antireflux mechanisms into SEMS have met with mixed reviews. The addition of a ''windsock'' to the distal end of a SEMS was intended to reduce free reflux from the stomach when a stent is placed across the esophagogastric junction by inverting and creating a partial barrier. Antegrade passage of food and liquids is generally unencumbered, and an inverted windsock can usually be straightened with a gulp of water.[25] The windsock and other variations of an antireflux stent probably do reduce exposure of the proximal esophagus and airways to regurgitated gastric and duodenal contents compared with standard stents[26]; however, no overall improvement in survival or reduction in severe complications has been demonstrated.[27]

Physicians have historically avoided placing stents in patients who anticipate chemo- or radiotherapy, as tumor response to treatment may lead to stent migration. In addition, scatter from metal stents may complicate radiation dosimetry. Further, pressure from an in-dwelling stent may increase the risk of fistula formation during chemo- or radiotherapy.[28] More recently, studies have shown that removable stents can be used during neoadjuvant chemo-radiotherapy to help patients avoid nutritional compromise as well as the need for a jejunal feeding tube during the several weeks of treatment leading up to esophagectomy.[29] In a recent series, Siddiqui and colleagues[30] retrospectively compared 12 patients who underwent placement of SEPS in 24 patients who had J-tube placement before neoadjuvant therapy and esophagectomy for locally advanced esophageal cancer. No difference was seen in complication rates, weight gain, or the ability to undergo successful surgery between the 2 groups; however all but one of the patients who had SEPS were able to resume oral alimentation.

SELF-EXPANDABLE METAL STENTS FOR MALIGNANT DISEASE

Placing SEMS has become standard therapy for palliation of malignant dysphagia. However, despite the seeming simplicity of placing an expandable tube in a luminal restriction, the complexity of tumor behavior and esophageal physiology has forced numerous stent design modifications. Original SEMS, such as the Esophacoil, produced a high level of radial force. Persistent discomfort was common, and reports emerged of pressure necrosis and fistula formation. SEMS woven from high-memory alloys such as nitinol allowed for production of a softer stent, which nonetheless opened the lumen with slow, constant radial force. Unfortunately, the tumor often grew through the open mesh and dysphagia recurred, sometimes within a few weeks. To combat this problem, stents were wrapped with a silicone or plastic cover. The ends of the stent were left uncovered to allow healthy mucosa to overgrow the exposed wire in order to prevent late migration. Migration within the first few days remained a problem, and designs were further modified to incorporate proximal and distal flares or ''dog bone'' shapes to combat this. Covered SEMS have virtually replaced uncovered stents for almost all esophageal applications. Covered stents also emerged as an excellent treatment for malignant fistulas, and have become the standard of care for treatment of malignant esophagobronchial leaks, sometimes with a second stent placed in the airway.[13] The ability to use partially covered stents to treat benign fistulas and perforations had been limited by difficulty in removing the devices once tissue has overgrown the open portion of the stent. Protruding wire ends of the original SEMS helped reduce migration; however, their tendency to project laterally into the esophageal wall immediately after deployment compromised the

ability to safely reposition or remove the stent if it were misdeployed. Rounded, continuous struts at the ends of stents allow them to move with traction via grasping forceps immediately after deployment. The incorporation of a purse-string suture at the proximal end of the stent is a welcome innovation. By pulling on the suture with forceps, the proximal end of the stent collapses, allowing the endoscopist to pull the entire stent higher in the esophagus or remove it completely. Displacing the stent distally can be more difficult, but can usually be accomplished by grasping distal tines with forceps, or inflating a dilating balloon within the stent and applying gentle pressure. However, once epithelium has grown over the uncovered portion of the stent, repositioning or removal becomes much more difficult. In fact, excessive growth of benign epithelium at the ends of SEMS remains the most common cause of recurrent dysphagia, with hypertrophic mucosa leading to at least partial occlusion of the lumen in up to one-half of patients at 2 months.[31] Fully covered metal stents and SEPS were designed in part to address this problem but also to facilitate repositioning and even late removal, thus opening up a broad array of new, benign applications. With these stents, occlusion by benign tissue overgrowth does seem to occur less frequently, or at least later, but at the cost of more frequent migration. In a recent study comparing partially covered metal stents to fully covered metal and plastic stents, SEPS migrated in 29% of patients compared with 17% for the partially covered Ultraflex stent and 12% for the double-layer Niti-S stent.[31] Further modifications have been made to the outer surface of some fully covered stents in an attempt to increase adhesion and decrease migration. The Alimaxx fully covered metal stent incorporates many small ''herringbone'' flanges on the outer surface of the stent, and the Tai-Woo double stent features a fully coated metal inner stent surrounded by an uncovered outer metal stent. Several new fully covered metal stents have either recently been introduced or will become available soon. The relative merits of differences in design will need to be studied. Further, the benefit of any of the fully covered stents over partially covered stents for malignant disease remains to be determined.

Many endoscopists use endoscopically placed clips at the proximal margin of newly placed stents over the exposed wire, or directly clipping the purse-string suture to the esophageal mucosa, to reduce the chance of early migration. Reliable data on the effectiveness of this technique is lacking; however, it is a relatively simple and safe intervention, and may help the endoscopist rest easier.

COMPLICATIONS

In addition to stent migration and benign tissue overgrowth, other complications have been associated with esophageal stents. Kozarek and colleagues[32] described the propensity for the development of late problems from SEMS in 1992, and numerous other articles since then have documented a broad array of potential complications including chest pain, perforation, fistula development, intestinal obstruction after migration, hemorrhage, epidural abscess, aspiration, and stent fracture.[33–35] Debate continues over the relative risks of complications after stenting in patients who have undergone prior chemo- or radiotherapy; however, because there are few good palliative options for these individuals, stenting remains the mainstay of treatment.[36,37]

STENTS FOR BENIGN DISEASE

As described earlier, uncovered and partially covered stents have not played a significant role in benign esophageal diseases because of their tendency to rapidly embed themselves in the esophageal wall, making removal difficult and dangerous. Left long

term, these stents may erode, occlude, fistulize, or cause other severe problems. However, with the introduction of a fully coated, removable plastic stent (Polyflex, Boston Scientific), a host of new applications has been attempted, with varying success. Fully coated metal stents have followed, and although they do not generally carry formal indications for temporary stenting in benign diseases, many of these devices have been placed to treat benign conditions with the expectation of eventual stent removal.

STRICTURES

Although most peptic inflammatory esophageal strictures respond to simple dilation, a subset of benign strictures recurs or even worsens despite aggressive treatment. These injuries may include strictures from caustic injury, radiation, complications from esophageal surgery or endoscopic therapies such as mucosal resection, submucosal dissection, or photodynamic therapy. Therapies have included repeated endoscopic or self-bougenage, dilation combined with steroid injection, hyperbaric therapy, or radial incision followed by dilation, with variable rates of sustained improvement. Because stents can successfully treat malignant strictures, the idea of using stents for benign disease has appeal. In theory, an expandable stent within a recalcitrant benign stricture would have an advantage over simple dilation by allowing the disrupted fibrous tissue to remodel over the fixed platform of the stent, rather than simply tearing scar tissue and allowing it to heal unsupported. Until recently, removing the stent once healing had occurred has been the major stumbling block. Nevertheless, some experts still advocate use of partially covered SEMS for up to 16 weeks for treating very proximal and distal strictures where migration with fully covered SEPS is more common.[24,38–41] Endoscopic inspection of these stents is suggested at 4-week intervals to detect the beginnings of tissue overgrowth of the open mesh, and to remove the stent—and place a new SEMS—if this occurs. Despite some limited enthusiasm for SEMS, SEPS have largely replaced partially covered SEMS for treating recalcitrant esophageal strictures. The Polyflex stent is constructed of polyester mesh completely covered with a silicone membrane, and has a flaring proximal end to reduce migration. Because the stent is fully covered, tissue ingrowth does not occur. Further, the use of plastic and silicone probably provokes less of a granulation reaction than metal, further reducing the amount of tissue buildup at the margins of the stent.[42] The Polyflex stent deforms into an ellipse with traction, decreasing the diameter of the proximal flared end, which enables removal by pulling slowly and continuously with grasping forceps. The inner surface is smooth, whereas a textured outer surface may help decrease migration. Three radiopaque bands facilitate visualization during deployment.

Placing a SEPS into a benign stricture can be somewhat more challenging than placing a SEMS. First, the SEPS must be loaded on the delivery system by pulling it into a plastic sleeve with a netlike grasping catheter. Care must be taken at this step to ensure the stent loads smoothly and does not fold on itself, as this can compromise uniform expansion on deployment. The delivery system is also stiffer and has a wider diameter than most SEMS, necessitating prior dilation of the stricture to at least 12 mm before placement. SEPS are less visible fluoroscopically, and have tendency to shorten and squirt out of the delivery catheter at the end of deployment as the device rapidly expands. This action may propel the stent beyond the stricture. It is important to carefully watch the position of the stent as it passes from the delivery device, often maintaining traction on the partially deployed stent. However, if the stent does misdeploy distally, it can often be repositioned endoscopically with grasping

forceps and traction. Repositioning a proximally displaced SEPS is more difficult, and it is usually better to simply remove the stent, wash it off, reload it into the delivery system, and try again. SEPS have greater radial force than SEMS but still may require several hours to fully expand. Care should be taken when removing the tapered tip of the delivery device, as this can dislodge the stent proximally. Advancing the delivery sheath distally to the proximal edge of the deployed stent to brace it as the tip is withdrawn through the narrowed portion of the stent may help prevent displacement.

Most series have reported high rates of technical success for SEPS delivery, and immediate improvement in dysphagia. In an early series, Radecke and colleagues[43] reported technical success in placing 50 SEPS in 39 patients with a variety of malignant and benign stenoses and fistulas, with 4 initial failures due to patient intolerance or maldeployment. Ultimately, 69% of these patients were able to resume eating while an additional 15% could handle their secretions but could not eat. Another 15% of placements were deemed unsuccessful. Many small, retrospective series have reported high levels of initial technical success, but long-term relief of dysphagia has been highly variable. Evrard and colleagues[44] reported that 17 of 21 patients (81%) achieved substantial improvement at 21 months after stent removal for a variety of benign strictures. Repici and colleagues[45] similarly noted that 12 of 15 (80%) patients with benign strictures in whom SEPS were placed were able to go without additional dilation for the almost 2 years after stent removal. However, most other series have reported lower long-term success. Holm and colleagues[46] reported only 17% durable response among 30 patients who had a variety of anastomotic, postradiation, and other strictures (including 9 with fistulas) after a total of 83 stents were placed. At the author's institution, reasonable relief of dysphagia was achieved among an initial group of 11 patients with a difficult collection of benign strictures after placement of 16 SEPS for an average of 52 days.[47] After removal of SEPS, 6 (55%) patients (2 with recalcitrant reflux strictures and 2 with stenotic anastomoses) required no further dilation. One patient with a radiation-induced stricture developed a fistula that required permanent stenting, and another required continued periodic dilation after stent removal. In another larger, retrospective series, 64 patients with benign anastomotic, radiation, or peptic strictures were treated with SEPS. Lasting success was achieved in only 17% of patients.[46] Although no severe complications were reported, SEPS migrated from 82% of peptic strictures and 75% of anastomotic strictures, but only 25% of radiation-induced strictures. Migration was more common among distal and proximal strictures compared with mid-esophageal locations.

In the only prospective trial of SEPS, Dua and colleagues[48] reported a modest 32% lasting improvement of dysphagia after stent removal among 40 patients with anastomotic, caustic, radiation, and other types of benign strictures after an average 4-week insertion. These patients had undergone a mean of 12 dilations each before stent placement. Stent placement was unsuccessful in 2 patients and complications were common, with 22% migration, 8% bleeding, 11% severe chest pain, 3% fistula, and 6% in whom the stent could not be safely removed. In reported series of SEPS for benign diseases, stent migration remains the most common complication, occurring in over half of the cases.[40,41,49] Although this problem can usually be treated easily, and at times results from a successful dilation of a stricture, it invariably requires repeat endoscopy, often with dilation, extraction, and placement of another stent. A variety of techniques has been attempted to reduce migration, including clipping the stent itself or sutures tied through the stent to the esophageal wall (**Fig. 3**).[50] In the author's experience, this may reduce the frequency of initial migration; however, the durability of traditional endoclipping to mucosa is limited, especially if a thick piece of covered stent is contained in the clip. These pieces tend to detach within a few hours to days, and

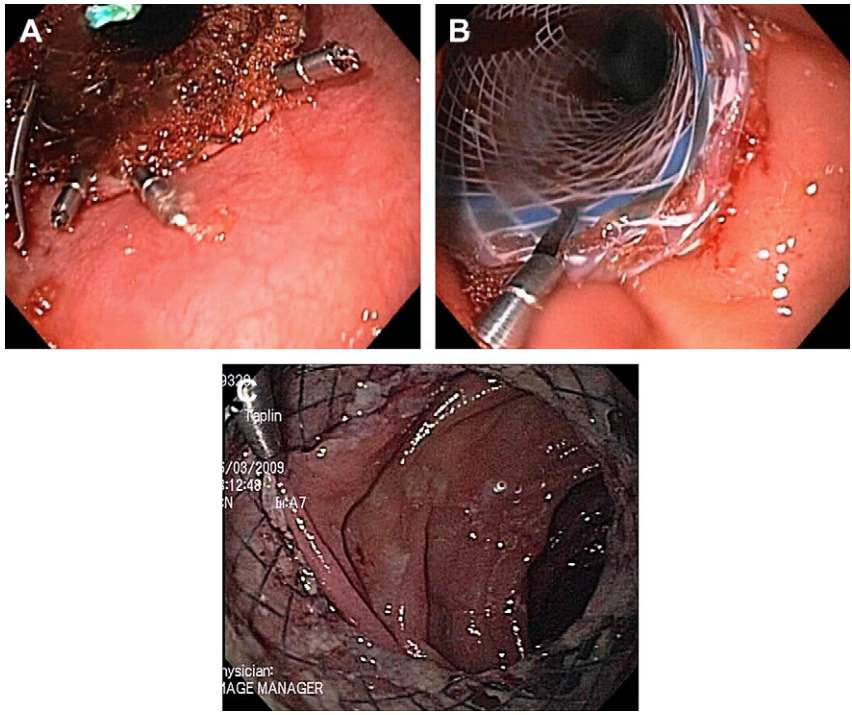

Fig. 3. (*A*) Multiple endoclips at the proximal margin of a Niti-S stent. (*B*) Single clip on a Polyflex stent. (*C*) Single clip at the distal end of a fully covered stent.

probably do not reduce the incidence of stent migration appreciably. Reports have surfaced of ways to modify these stents by cutting holes in the lining or sewing sutures into the proximal end to enhance the security of clips, although the overall effectiveness of these techniques remains uncertain.[51] One group of creative endoscopists tied a long suture to the proximal end of a fully covered stent, then after deployment passed it out of the patient's mouth and tied it around his ear.[52] Although possibly effective, it is doubtful that this technique will attract a wide following.

Other complications associated with SEPS have been more serious, including perforations, bleeding, fistulas, and an inability to remove stents.[53] These complications may be related to the relatively large diameter and stiffness of the insertion device. SEPS themselves produce more radial force than SEMS and may cause more discomfort as a result. This situation occasionally necessitates premature stent removal, although most patients can be controlled with oral pain medication.

An attempt to counter the shortcomings of SEPS inevitably led to the development of fully covered metal stents, or what has awkwardly been termed FCSEMS. Experience with these hybrid stents is limited. A recent report by Eloubeidi and Lopes[54] detailed 7 patients with refractory, benign esophageal strictures who underwent temporary stenting with an Alimaxx stent, an internally fully covered metal device. Stent placement and removal was successful in all patients; however, only 2 (29%) patients showed sustained improvement in dysphagia. Stent migration in the larger series of 31 patients with a mix of benign and malignant conditions occurred in 36% of patients. Migration was more common if the stent crossed the EG junction (59% vs 16%). Conio and colleagues[23] have reported using custom-made, 10- to 14-mm proximal flaring Niti-S

SEMS in either a fully covered or partially covered design for postradiation strictures of the hypopharynx. In this series, 6 of 7 patients experienced immediate and persistent improvement in profound dysphagia after placement of a modified Niti-S stent. These stents were well tolerated, easily removed, and led to lasting improvement in dysphagia at an average of 4 months after removal without additional intervention. One patient developed an esophagotracheal fistula that required permanent stenting, and 5 stents migrated at a median of 3 months. The author has used covered biliary SEMS with a diameter of 8 to 10 mm for the same indication, with good initial results in 5 cases of complete occlusion of the proximal esophagus (**Fig. 4**).[55] The author graduated to a 12- or 16-mm bronchial Polyflex stent in 2 cases. One patient developed cervical osteomyelitis requiring early stent removal and subsequent restenosis, and another developed an anterior neck abscess that resolved with simple drainage. Four of the 5 were able to maintain oral alimentation, albeit with periodic self- or endoscopic dilation. Tai-Woo has recently entered the United States market with a removable, fully covered Niti-S metal stent in a variety of lengths and diameters; however, published results are still forthcoming. In initial experience with this device in 10 patients, the author found it easy to deploy and remove from within benign strictures and fistulas. Stents migrated in 40% of patients, but no other serious complications occurred (**Fig. 5**). Among 2 patients with recalcitrant benign strictures, 1 has remained free of dysphagia after stent removal.[56] Fully covered metal stents from other manufacturers

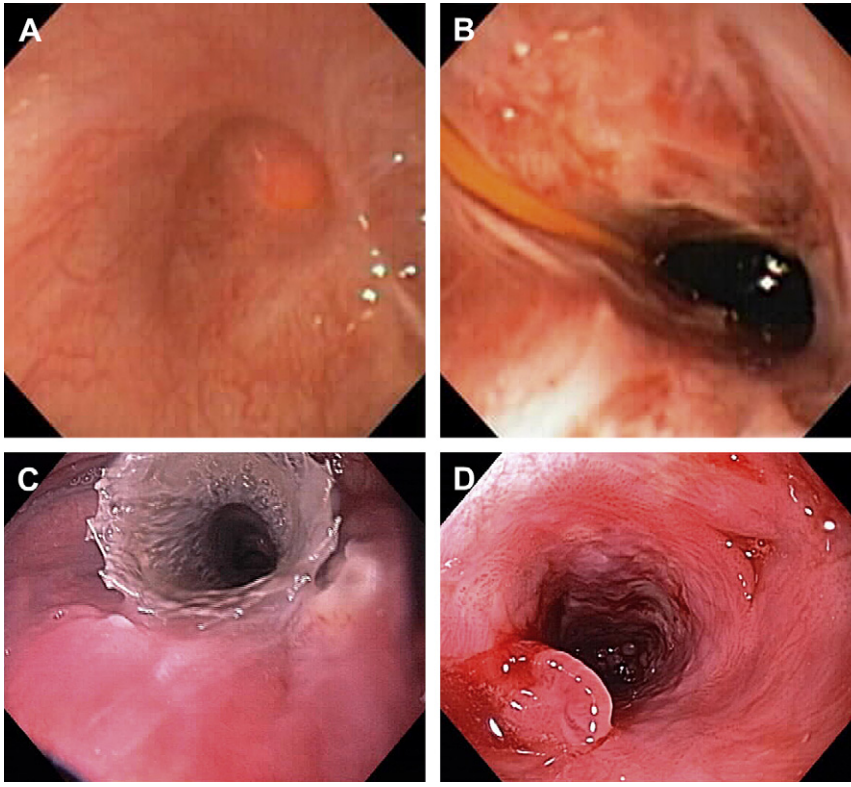

Fig. 4. (*A*) Complete obstruction of proximal esophagus after radiation therapy for laryngeal cancer. (*B*) Post dilation after blind puncture with an endoscopic ultrasound needle. (*C*) Covered biliary stent in place. (*D*) Post stent removal.

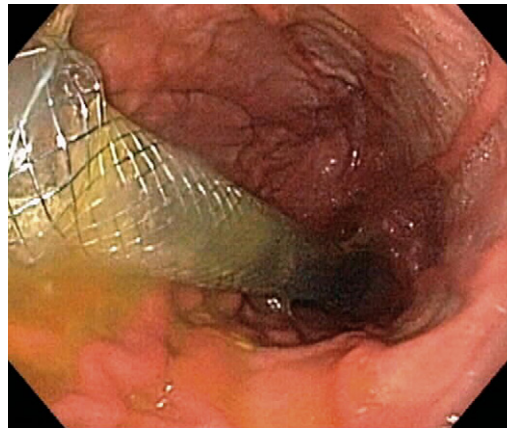

Fig. 5. Migrated Niti-S stent.

are expected in the near future. Ultimately, success with benign strictures probably has more to do with the degree of underlying tissue damage than any particular type of stent. Longer, denser, and more fibrotic strictures will probably recur after even prolonged stent dilation.

FISTULAS AND PERFORATIONS

Although results from the stenting of benign strictures have been disappointing, temporary stenting for perforations and fistulas has shown very favorable results. Palliative permanent metal stenting for malignant fistulas and perforations has been standard of care for the last 10 years, and numerous series have demonstrated the effectiveness of this strategy.[13] Because of these successes, stent placement for benign esophageal leaks has become more common. At present, placement of a potentially removable stent has become the first-line treatment for perforations and fistulas in many centers in the United States. This sea change has come in part due to the mortality associated with untreated perforations, which has been estimated at 20% to 45%.[57] Although aggressive surgical treatment may double or triple survival, some patients may not be ideal surgical candidates due to delayed diagnosis, age, recent anastomoses, and so forth.[58,59] Primary endoscopic repair of perforations of the esophagus using endoclips, tissue glues, and endoscopic suturing devices have been reported[60]; however, these techniques are usually reserved for acute perforations or fistulas limited to a few millimeters. Larger and more chronic defects usually require diversion, either surgically or by placement of an occlusive stent combined with mediastinal debridement and drainage. Virtually all currently available partially covered metal stents have been used to seal perforations and fistulas, and many have been successfully removed in the setting of benign diseases.[61–64] Just as with the treatment of benign strictures, problems arise when removing these stents, as tissue growth through the uncovered portion of the stent can adhere the stent to the esophageal wall. Complications such as bleeding,[65] fistula formation,[66] and even segmental amputation of the esophageal wall[67] have been reported with attempts at removing partially covered stents. Some SEMS may be easier to remove than others. Ultraflex stents can often be grasped distally and invaginated,[60] and Z-stents may be wedged free by grasping the proximal edge and advancing an overtube around it.[68] It has also been reported that SEMS with extensive granulation tissue overgrowth can be removed after placement of a second

SEPS within the SEMS, and waiting 2 to 3 weeks for the pressure of the internal SEPS to cause necrosis of the granulation tissue and allow simple withdrawal of both stents together.[69]

Introduction of SEPS has clearly increased the willingness of endoscopists to treat esophageal leaks. Placement is usually straightforward, and the stent can be removed easily once the defect has closed, or sooner if it is unsuccessful or complications arise. Several small series have documented the success of SEPS for this indication. In Germany Hünerbein and colleagues[70] reported an early series of 9 patients who developed leaks after esophagectomy. Stents were left in place for an average of 29 days and began oral intake around day 11. There was no mortality (compared with 20% mortality in a similar group treated conservatively without stenting), and at 12-month follow-up no structuring or leaks had occurred. Freeman and colleagues[71] described 17 patients who suffered iatrogenic perforations of the esophagus (8 during endoscopy and 9 from surgery) over 2 years, who underwent immediate stenting with a SEPS combined with mediastinal drainage where necessary. Initial sealing of the leak was achieved in 16 patients (94%) by esophagram, and 14 (82%) were able to initiate oral nutrition within 72 hours. Four stents required replacement or repositioning after migration, and all stents were removed at an average of 52 days with leak closure in all but 1 patient who was treated surgically. In the author's institution, 6 of 6 benign leaks resolved completely after SEPS placement for an average of 5 weeks.[47] Leaks do best with any therapy when they are treated immediately. Spontaneous esophageal perforation (Boerhaave syndrome) and other leaks associated with extensive soilage do less well but have shown reasonable rates of healing after placement of SEPS. An early case report of SEPS for a patient with delayed presentation of Boerhaave syndrome showed that this nonsurgical intervention could be effective even in the setting of extensive mediastinal involvement, as long as adequate drainage was provided.[72] A series of 32 patients with a mix of postsurgical and spontaneous perforations, over half of whom failed initial attempts at surgical closure, underwent treatment with SEPS, resulting in functional sealing of 78% of patients and successful closure in 70%.[73]

Limited experience has been generated with fully covered SEMS for treating esophageal leaks. Alimaxx stents were used to treat 8 patients with tracheoesophageal fistulas, with a 63% success rate. Two of 2 postoperative leaks treated with this device sealed completely, whereas only 1 of 2 perforations treated with the Alimaxx stent healed.[54] The author has successfully used the Alimaxx stent to treat leaks, but has occasionally found them difficult to remove after several weeks, with stents breaking apart and having to be removed piecemeal (**Fig. 6**). Fully covered Niti-S stents have also been used successfully for this indication, with 4 of 5 anastomotic and other benign fistulas remaining closed after stent removal.[56]

SEPS and fully covered SEMS are being placed in more severe disruptions. Amrani and colleagues[74] reported the use of SEPS to close a variety of large esophageal and colonic disruptions, some approaching complete disunion of the organ. The author has had similar success with patients with near complete separation of gastroesophageal anastomoses following bariatric and other types of surgery (**Fig. 7**). As long as the seal is complete and the surrounding area remains well drained complete healing may be the rule. Further studies will be necessary to define what stents are best for which problems, how to maximize the initial seal and, perhaps more important, how to reduce migration among fully covered stents.

Stenting for benign diseases has evolved from the difficult removal of permanent stents to easier removal of temporary stents (albeit with a tradeoff of higher migration rates) to, more recently, the development of biodegradable stents that require no removal at all. Although the idea of biodegradable stents has been around for over

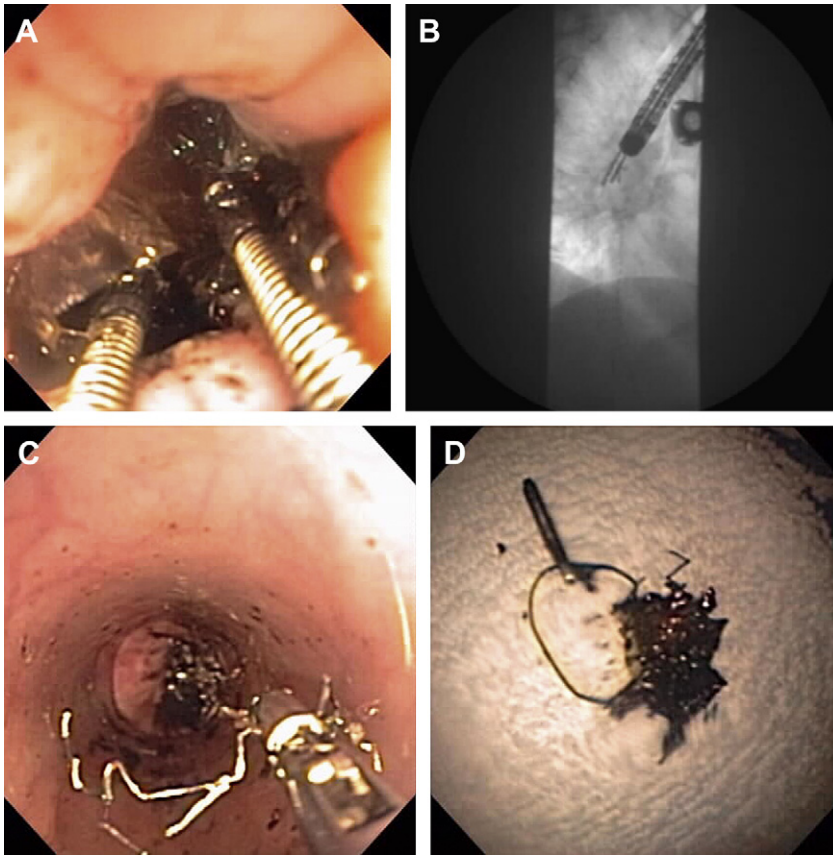

Fig. 6. (*A*) Removal of an Alimaxx stent with 2 grasping forceps. (*B*) Fluoroscopic view. (*C*) Fractured stent. (*D*) Stent fragment with endoclip still in place on purse-string suture.

10 years, newer designs and materials may finally allow more widespread use of the devices. Small series from Japan and Europe have shown utility of biodegradable stents. Saito and colleagues[75] used an "ultraflex-type" stent made of knitted poly-L-lactic acid monofilaments in 13 patients for a variety of indications. Six stenoses

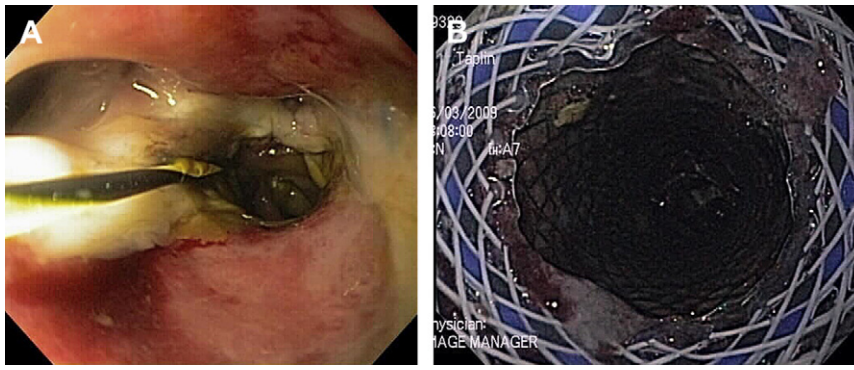

Fig. 7. (*A*) Large anastomotic leak. (*B*) Leak covered with Polyflex overlapping a Niti-S stent.

(2 caustic, 4 anastomotic) and 7 large-area mucosectomy had biodegradable stents placed without difficulty. Stents dissolved and migrated in most cases between 2 and 3 weeks; however, none of these patients developed a primary stricture or restenosis at up to 2 years of follow-up. Whereas it can be argued that the strictures treated may have responded to other measures, the idea of a prophylactic, dissolving stent after mucosectomy is intriguing. To date, the greatest obstacle to large-area mucosectomy in the esophagus, whether by endoscopic mucosal resection or endoscopic submucosal dissection, has been the high rate of stenosis once an area greater than about two-thirds the circumference of the esophagus has been removed, with stenosis occurring in 70% to 80% of patients in whom complete circumferential resection has taken place.[76] If a scaffold could be created that would reliably prevent stenosis, more aggressive resections would likely follow. Investigators have successfully used removable SEPS coated with an animal urinary bladder extracellular matrix (ECM) to encourage neoepithelialization without stenosis in animal models. More recently, these investigators dispensed with the stent entirely, and simply wrapped a glue-coated ECM around an inflatable balloon and deployed it over the mucosal defect, with good success.[77]

Other case reports and abstracts have described the use of biodegradable stents.[75,78] An English group reported the use of a polydioxanone stent (Ella-BD, ELLA-CS, Hradec Karlove, Czech Republic) in 4 patients with refractory benign esophageal strictures.[79] Despite some difficulty with deployment of early designs, all patients were dysphagia-free at short follow-up after insertion (4–17 weeks). In a larger series using the same type of stent, Repici and colleagues[80] described placing the Ella-BD stent in 12 patients with refractory benign strictures. Stents were successfully placed in all patients, with one episode of minor bleeding and a 17% early migration rate. Stents were still visible in half of the patients at 3 months. No long-term results were available; however, 2 of 12 patients had recurrent dysphagia at median follow-up of 22 weeks. These are clearly very early studies, and more information will need to be gathered concerning this type and other types of biodegradable esophageal stents.

Although drug-eluting stents are popular for endovascular applications, the concept has been slow to catch on for esophageal stenting. One recent animal study demonstrated that SEMS coated with the antiproliferative chemotherapy agent paclitaxel provoked very little local tissue reaction after 4 weeks in the esophagi of 7 dogs, and were easily separated from the esophageal tissue and removed.[81] No human trials have been reported, but are likely forthcoming.

It is important to briefly mention stent applications in the esophagus that have not been successful or widely adopted. Attempts at treating achalasia with permanent stents were unsuccessful due to high rates of complications.[82] A large-diameter (25 mm) fully covered SEMS with a deflatable balloon at the distal end for localization at the cardia was used to treat 15 patients with poorly controlled variceal bleeding.[83] Stents were left in place for 2 to 14 days, and removed after management of patients' portal hypertension was otherwise "optimized." Ultimately, all stents were successfully removed without complication, rebleeding, or mortality. Although this seems to have been a successful study, it remains unclear whether this would be more useful than other forms of endotherapy for bleeding varices, such as banding, sclerotherapy, or even temporary placement of a traction-type tamponade balloon.

In summary, while expandable stents remain highly useful for palliation of malignant dysphasia, evolution of stent materials and design have broadened the applications for the devices to encompass a host of benign conditions. Treatment of benign esophageal strictures and leaks has grown considerably over the last 10 years, largely due to

the creation of easily removable stents. Removable stents are also being used in malignant disease as a bridge to surgery or other therapies. Complication rates for malignant and benign applications remain significant, and careful patient selection and close monitoring are essential. New designs may help reduce these complication rates. Additional advances may enable stent placement as prophylaxis for large-area mucosal resection and dissection procedures. Newer applications will no doubt arise as technology improves.

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