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Review Article

Enteral stents in the management of gastrointestinal leaks, perforations and fistulae

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ABSTRACT

Gastrointestinal leaks and fistulae are grave conditions associated with substantial morbidity and mortality. Expandable stents have shown significant success in the management of leaks and fistulae, providing an efficacious minimally invasive approach in patients who are frequently poor surgical candidates. Most reports, however, are limited by their small size or the pooling of different stents, techniques and locations of leaks and fistulae. Despite the numerous alterations in stent design, migration remains the pivotal drawback of this technique. In this article, we review the current status of expandable stents in the management of gastrointestinal leaks and fistulae, available anti-migration techniques and evolving innovations in stent design.

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Keywords: Anastomotic leak; Esophageal fistula; Expandable metallic stents; Gastric fistula; Stents

Introduction

Leakage from the gastrointestinal (GI) tract is a grave condition associated with substantial morbidity and mortality.^{1,2} The spillage of alimentary or ingested contents beyond the lumen leads to the formation of collections, which become infected rapidly leading to local and systemic sepsis. The conventional approaches to GI leakage were limited to surgical, medical or percutaneous management. Surgical approaches are usually complex, entail resections or diversions and are associated with high perioperative morbidity and mortality.^{3,4} Medical management includes prolonged administration of total parenteral nutrition and antibiotics.⁵ Medical management is also far from optimal as it is associated with prolonged hospitalization, suboptimal nutritional status, potential infectious complications, and often delayed and/or failed closure.^{5,6}

To provide a minimally invasive approach, several endoscopic techniques have been proposed to directly close luminal defects, analogous to surgical closure. Various types of endoscopic clips, tissue sealants and suturing devices have been used with variable success.⁷ However, surgical history has shown that simple closure of a defect often does not heal a GI leak or fistula.^{8,9} The presence

of infection and tissue friability combined with continued secretions and per oral intake hampers the healing process. As a basic surgical principle, providing a dry, clean environment for any wound accelerates the healing process. Thus, the concept of using GI stents to treat GI leakages is an attractive one. Stents isolate the leakage site while simultaneously allowing enteral feeding to resume so as to restore adequate nutritional status, an essential prerequisite for proper wound healing.

Self-expandable stents were initially introduced for the management of malignant esophageal obstruction.¹⁰ However, over the last three decades, especially with the introduction of fully covered retrievable stents, there have been numerous reports supporting the use of stents in the management of GI leaks and fistulae. In this article we review the current status of stenting for GI leaks and fistulae and possible future trends in this evolving field.

Types of Stents

A plethora of stents are currently available and the endoscopist must be aware of the different characteristics of each. Currently available stents are made of different materials, but are widely classified as metallic or plastic. The most commonly used

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metal alloy is nitinol, a mixture of nickel and titanium. Its main advantage over stainless steel and other metals are its high flexibility and ability to retain its shape. This comes at the expense of a slight disadvantage, which is a lower radial force. Plastic stents (Polyflex; Boston Scientific, Marlborough, MA, USA) are made of a woven polyester skeleton covered by a silicon membrane, and have high radial and axial forces. A few in vitro experiments have compared the physical properties of expandable stents.¹¹ Hirdes et al¹¹ compared 12 different stents and concluded that the stent mesh design significantly affects stent characteristics. Knitted stents (e.g., Ultraflex; Boston Scientific) and the laser-cut Alimaax stent (Merit Endotek, South Jordan, UT, USA) had the lowest axial forces as compared to braided stents. The metal Ultraflex and Alimaax, and plastic Polyflex stents had the highest radial forces. It is assumed that the "optimal" stent has lower axial force (thus conforming better to the lumen shape) and higher radial force (to maintain pressure on the surrounding walls, thus reducing migration).¹¹ No studies to date, however, have proved these assumptions or shown significant superiority of one stent material over the other for any indication.

More important than stent material when choosing a stent is the extent of stent covering. Uncovered (bare) stents rapidly become embedded within the surrounding wall and promote hyperplastic mucosa; this prevents migration, but sometimes at the expense of making stent extraction difficult, if not impossible. The concept of adding a coating to the stent mesh has revolutionized the use of stents for benign conditions.¹² Fully covered self-expandable metallic stents (FCSEMS) have a silicon or polyurethane coating that prevents embedding and tissue ingrowth, thus rendering the stents easily extractable (Fig. 1). The main drawback is a higher rate of stent migration. Partially covered self-expandable metallic stents (PCSEMS) have a small segment at each end which is uncovered, while the majority of the stent length is covered.

Available self-expandable plastic stents (SEPS) are not fenestrated and act as fully covered stents. Disadvantages of plastic stents are a large caliber insertion system and need for preloading the stent before insertion. The latter is because the constrained system loses expansile force over time. It is also believed that SEPS have a higher rate of migration due to their high axial force.¹³

A new emerging concept in stent design is the use of stents made of biodegradable material, referred to as biodegradable stents (BDS). The material safely disintegrates within the human body, obviating the need for stent extraction. There are limited studies using one type of BDS, the SX-ELLA-BD stent (ELLA-CS Ltd., Hradec Kralove, Czech Republic), which is made of polydioxanone.¹⁴⁻¹⁸ Unpublished in vitro studies performed by the manufacturer show that these stents maintain their initial radial force for 4 weeks, and begin to disintegrate at 9 weeks, enough time for leak closure or stricture resolution. In one study of 5 patients with esophageal anastomotic leaks, a modified SX-ELLA-BD stent with a non-absorbable polyurethane covering was placed.¹⁹ Early migration (within the first week after placement) occurred in 3 patients, while in one patient acute total dysphagia occurred due to collapse of the non-absorbable covering.¹⁹ In addition, it appears that currently available BDS induce significant tissue hyperplasia and are frequently associated with severe pain and intolerance.¹⁴⁻¹⁸ Despite these setbacks BDS are expected to improve and have a major role in the management of leaks and fistulae.

Stenting Technique

Due to the often severe acute and chronic underlying medical disease in patients with GI leaks, many of whom have no other options, the endoscopist and his/her team must be well prepared prior to undertaking stent placement. It is difficult to almost impossible to predict the exact endoscopic technique that will be

Fig. 1. Patient with recent complete gastrectomy and esophagojejunal anastomotic leak. (A) Endoscopic view of drain at leak site. (B) Endoscopic view of fully covered self-expandable metal stent across leak site. (C) Radiographic image of stent from esophagus to jejunum across leak site. (D) Endoscopic appearance after stent removal one month later.

used prior to performing the endoscopic procedure. All endoscopic therapeutic modalities within a given endoscopic unit should be accessible, including stents of different sizes, clips (through-the-scope [TTS] and over-the-scope clip [OTSC]), argon plasma, tissue sealants and adhesives. Strictures are frequently found concomitantly in patients with leaks, especially in the postoperative setting and are a major contributor to continued leakage. Thus, dilating balloons should also be available. Although these procedures can theoretically be performed solely under endoscopic vision, we believe that fluoroscopy is an integral part of the procedure to allow adequate assessment of leak extent and confirm proper stent positioning.

Knowledge of the type of stent and other devices (e.g., clips) used is also critical. Although all expandable stents share the same basic principles, there are differences such as distal vs proximal release systems, number of endoscopic and radiopaque markers and their position and degree of foreshortening. Representatives of the stent-producing companies are always willing to provide support and it is worth inviting one of them to be present during the procedure, especially if it is the first time to use a certain stent/device.

After identifying the site of leakage endoscopically, radiopaque contrast injection helps confirm the luminal defect and delineates the extent of leakage or length and diameter of the fistulous tract. The use of contrast also helps exclude the presence of other sites of leakage, often present at anastomotic sites. Before attempting to seal the leak, the endoscopist should clean the leak site under direct endoscopic visualization. If the luminal defect is wide enough, the endoscopist can cautiously explore the fistula tract and pass the endoscope into the surrounding cavity. Synonymous to endoscopic pancreatic necrosectomy, the leak cavity can be debrided under direct vision through aspiration, saline irrigation, and use of instruments such as Dormia baskets or snares to remove necrotic debris and foreign material (such as sutures). However, such cavities may be fragile, especially newly formed cavities that are surrounded by thin granulation tissue. Thus, care should be taken to avoid rupture of these cavities by using minimal insufflation, preferably with CO₂.

The standard technique for stent deployment is fluoroscopically guided. Once the decision is made to insert a stent, a guidewire is passed across the leak site, extending well beyond it, up to 30 cm if possible. Rigid metal wires are preferred especially in the presence of acute angulations (e.g., after sleeve gastrectomy) and when non-TTS stents are used. Metal markers (e.g., clips) may be placed on the skin surface coinciding with site of leakage to allow precise stent placement. The stent is then deployed under fluoroscopic guidance confirming that at least 5 cm of deployed stent is present on both sides of the leak site. Minor adjustments to stent position in a proximal direction can be made after deployment by grasping the stent edge or, if present, a lasso at the proximal end of the stent with a forceps. Advancing the stent distally is usually not feasible.

Variations in the technique exist including simultaneous endoscopic and fluoroscopic views during deployment and deployment solely under endoscopic vision. However, fluoroscopy offers a significant advantage by confirming the position of the distal edge of the stent. By using solely an endoscopic view it is often difficult to predict the actual length of the stent due to foreshortening, especially in the presence of concomitant strictures. TTS stents are more convenient and shorten the procedure time. However, currently available fully covered TTS stents (e.g., Niti-S [Taewoong Medical, Seoul, Korea] and Hanaro stents [M.I.Tech, Seoul, Korea]) are limited by smaller deployed shaft diameters

(18–20 mm).

Oral feeding is usually allowed after 24 to 48 hours once the stent has fully expanded. A contrast study is recommended before resuming oral feeding to confirm stent position and absence of leakage. A liquid or soft diet is recommended throughout the period of stent dwell. Pain and vomiting are common after placement of esophageal stents, especially those of larger calibre; antiemetics and analgesics are given as required. In our experience, paradoxically, some patients tolerate a solid diet better than a liquid one. Additional contrast studies are not routinely obtained during the period of stenting, but should be performed, if there are signs suggestive of stent migration (e.g., high drain output, fever, recurring pain or change in the site of pain).

No consensus exists on the duration of stent placement, but 6 to 8 weeks seems to be sufficient in most patients. A few authors suggest routine stent exchanges every 2 weeks, the rationale being that it prevents unnecessary prolongation of stent dwell time for leaks that have already closed, and also renders stent extraction technically easier.^{20,21} Extraction of fully-covered stents (FCSEMS and SEPS) is usually straightforward. If an attached lasso is present, it is grasped by a large forceps (rat-toothed) to withdraw the stent. When a lasso is present, care should be taken to pull the stent against the tip of the endoscope until the flared end collapses before withdrawing the endoscope and stent together. If a lasso is not present, the upper edge of the stent is grasped. Extraction of PCSEMS is more complex as the uncovered portion is usually deeply embedded within the walls and covered by thick hyperplastic mucosa. In such situations the “stent-in-stent” technique can be performed.^{22–25} This involves inserting a fully-covered stent within and across the entire PCSEMS. The fully-covered stent induces compression necrosis on the hyperplastic and embedded tissue, freeing the uncovered portion of the partially covered stent. Both stents are then removed simultaneously 2 or more weeks after FCSEMS placement.

Leaks close to the upper esophageal sphincter (UES) present a technical challenge to endoscopic stent placement since there is very little space to maneuver the endoscope. In addition, stents placed close to the esophageal sphincter cause globus sensation, pain, promote pulmonary aspiration, and may cause airway compromise. Care should be taken, if possible, to leave at least 2 cm between the upper edge of the stent and the UES. In such patients endotracheal intubation is preferable and close monitoring in the immediate post-procedure period is essential to confirm patency of the airway. The modified Choo stent (M.I.Tech) and Conio stent (Taewoong Medical) were specifically designed for use in the upper esophagus. These stents have smaller post-deployment diameters and shorter upper flared ends, and have been shown to be useful for management of cervical strictures.^{26,27} They are yet to be tested in the setting of cervical leaks or fistulae.

Outcomes of Stent Therapy

Over the last 2 decades, several studies have reported encouraging results for the use of stents in the management of GI leaks and fistulae, suggesting they can be a primary therapeutic modality in such conditions. However, when assessing the efficacy of any technique in the management of GI leaks it must be acknowledged that not all leaks are the same. Leaks behave differently according to many factors including site, size and chronicity of the luminal defect. Even more importantly, they differ according to the inciting factor i.e., postsurgical vs postendoscopic vs malignancy vs radiation, etc. Most of the reported studies are small, retrospective case series pooling different types of leaks and fistu-

lae together, resulting in heterogeneous patient populations that make it difficult to assess outcomes objectively. In the following section we try to further analyze the reported results according to the cause and site of leaks and fistulae.

Postsurgical leaks

One of the larger early reports by Langer et al²⁸ included 22 patients with post-esophagectomy and gastrectomy leaks. SEPS were used in all patients (Polyflex). The median time to endoscopic intervention was 19 days. Of 18 patients available for follow-up, 16 patients (89%) had complete closure. In 2 patients, however, stent placement resulted in an increase in the size of the luminal defect, necessitating surgical intervention. Migration occurred in 9 patients (38%).²⁸ Recently Dai et al²⁹ reported their experience with SEPS in 30 patients with postsurgical esophageal leaks. The median time to stenting was 2.7 days with technical success in all patients. Despite a migration rate of 34%, complete healing occurred in 27 patients (90%).²⁹

More recent studies involved the use of SEMS. Feith et al³⁰ reported the largest series to date assessing FCSEMS in the management of postesophagectomy leaks. Stents were inserted successfully in all 115 patients at a median of 8 days after the inciting surgery. After a stent dwell period of 4 to 6 weeks, successful leak closure occurred in 80 patients (70%). A further 9 patients (8%) had complete healing by additional endoscopic procedures such as clip placement and fibrin glue injection. Stent migration occurred in 53% of patients and 49% required 2 or more stents.³⁰ In a recent study by Gubler and Bauerfeind,²¹ 31 patients with postoperative leaks were treated by SEMS (fully and partially covered); the majority were postesophagectomy or bariatric surgery leaks. Stents were implanted after a median of 17 days from the time of diagnosis. Twenty-seven patients (74%) achieved complete leak healing. Notably, routine stent removal/exchange was

performed every 2 weeks. In the series by Orive-Calzada et al,³¹ 49 patients with leaks after different upper GI surgeries treated with FCSEMS, despite a very high rate of migration (67%), success was achieved in 36/46 patients (74%).

Post-bariatric surgery leaks seem to respond particularly well to endoscopic stenting. This may be attributed to the more favorable general condition of the patients in comparison to patients undergoing esophagectomies for malignant tumors, and the abdominal rather than mediastinal location. A meta-analysis by Puli et al³² included 7 studies with a total of 67 patients with post-bariatric surgery leaks. Complete healing was observed in 88%, with a stent migration rate of 17%. The relatively low migration rate is probably attributed to the use partially covered stents in several of the involved studies, but at the expense of unsuccessful stent removal in 9% of cases. Recently, bariatric-specific stents have been introduced outside of the U.S. in an attempt to reduce migration and allow better conformability to the post-surgical anatomy (Mega Stent & Beta Stent [Taewoong Medical] and Bariatric Stent [M.I.Tech]). The only published formal assessment of such stents involved the Mega Stents which are characterized by their high flexibility and very large post-deployment diameters (28 mm shaft diameter, 36 mm flares) and lengths (up to 23 cm).³³ Twenty-two patients with post-bariatric surgery leaks were treated by placement of Mega Stents with or without OTSC clips (Fig. 2). Radiologically-confirmed leak closure occurred in 18 patients (82%) while clinical success was achieved in 20 patients (91%). The rate of migration was relatively low (15%) but severe pain and vomiting were encountered in 91% of patients, with 2 (9%) requiring narcotic analgesics.

A recent pooled analysis of the literature included 20 studies with a total of 653 patients with benign esophageal leaks and fistulae treated by SEMS and SEPS.³⁴ Subgroup analysis according to etiology was possible in 358 patients; 247 were post-surgical leaks. Success was achieved in 201/247 post-surgical patients

Fig. 2. Patient with recent complete sleeve gastrectomy leak. An over-the-scope clip (OTSC) was placed with fully covered self-expandable metallic stents (SEMS) over the clip. (A) Endoscopic view with gastric fistula and drain. (B) Endoscopic view of follow-up endoscopy with OTSC wing protruding through SEMS. (C, D) Remaining OTSC at leak site after SEMS removal. No leak was seen endoscopically.

(81.4%) compared to 86% in patients with perforations (spontaneous and endoscopic), and 64.7% in fistulae.

There is a paucity of data on the use of stents for colonic leaks. The use of stents in the colon is hampered by the nearly uniform migration due to the large luminal diameter and the high motility of the colon. Stents placed in the rectum cause significant pain and tenesmus. A few case reports and small case series reported the success of SEPS in the management of post-colorectal surgery leaks, yet migration was almost universal.^{35–37} FCSEMS were used in a small case series including 5 patients with leaks after anterior rectal resection. Stents were left in place for a median of 20 days and success was reported in 4 patients (80%) without the need for surgical diversion. Migration occurred in 2 patients, while the main problem was severe rectal pain and tenesmus in 3 patients requiring narcotic analgesics.³⁸ The largest series to date was reported by Lamazza et al,³⁹ in 22 patients a FCSEMS was used to treat colorectal anastomotic leaks. Closure occurred without evidence of residual stricture or major incontinence in 19 patients (86%). It is to be noted, however, that 15 patients had a protective ileostomy. In two of the 3 failures, a diminution in leak size occurred, allowing further successful repair by flap interposition.³⁹

Post-endoscopic perforations

Endoscopic perforations can occur after therapeutic procedures (e.g., dilation, resection), or during diagnostic procedures caused by forceful pushing of the endoscope. The main advantage in treating endoscopic perforations is the ability to immediately diagnose and provide endoscopic treatment, allowing prompt sealing of the luminal defect before spillage of luminal contents, which then prevents the development of local or systemic infection. Stent placement can allow successful closure of endoscopic perforations, yet appears to be used much less frequently for this indication than for postsurgical leaks. In a recent pooled analysis of the literature, 466 endoscopic perforations were treated endoscopically, but only 2 (0.4%) were treated using stents.⁴⁰ The less frequent use of stents is attributed to the significant success of TTS and OTSC clips in this setting. In the same analysis clips were successful in over 90% of patients. The success of clips is attributed to the absence of infection and the presence of healthy perforation edges. Clips have the advantage of avoiding the problems of stents such as migration, intolerance, delayed healing and the necessity of additional procedures for stent extraction. Nevertheless, there remains a role for stenting in this setting, especially if defects are not amenable to clip closure, e.g., large or in endoscopically difficult positions. A particular situation is perforation occurring after endoscopic dilation of strictures. The presence of strictures makes clip application technically difficult, the fibrotic tissues may be difficult to grasp by clips, and more importantly, any stenosis will impair healing of the defect through the accumulation of secretions proximal to the stenosis. Stents have the advantage of sealing the perforation while simultaneously dilating the underlying stricture.

Stents have been used to successfully close endoscopic perforations.^{12,41–46} The study by Gubler and Bauerfeind²¹ clearly differentiates post-endoscopic perforations from other etiologies. This series included 85 patients treated by stent placement (32 endoscopic perforations, 31 postsurgical leaks, 15 spontaneous perforations, and 7 fistulae). Success occurred in 94%, 74%, 75%, and 43%, respectively. It is to be noted that the only 2 failures in the endoscopic perforation group were those induced by trans-esophageal echocardiography.

Boerhaave syndrome

Spontaneous rupture of the lower esophagus is caused by a sudden rise in the intraluminal pressure mainly induced during emesis combined with failure of relaxation of the UES.⁴⁷ Less common causes include straining during defecation, blunt trauma or seizures. The result is a longitudinal full thickness tear usually affecting the left posterolateral aspect of the esophagus.⁴⁸ Due to the rapid mediastinal contamination by food and secretions the condition remains highly morbid with mortality rates in the range of 16% to 24%.^{49–52} Conventional management includes surgical interventions including primary repair, esophagectomy or diversion, all of which are complex procedures with substantial morbidity and mortality.^{49–52}

A few case reports have addressed the success of stents in treating Boerhaave's syndrome.^{53–56} In a report by Siersema et al⁵⁷ PCSEMS were inserted in 5 patients; in 4 patients stents were placed within the first 36 to 60 hours while in one patient the stent was inserted 9 days after the onset of symptoms. Successful healing occurred in 4 patients (80%) with a median intensive care unit stay of 4 days. The largest report came from Freeman et al⁵⁸ whose prospective assessment included 19 patients with Boerhaave's syndrome and who had SEPS placed as their primary treatment modality. SEPS were inserted at a mean of 22 hours after the onset of symptoms and were left in place for a mean of 20 days. Percutaneous gastrostomy tubes were inserted in all patients while video-assisted thoracoscopic decortication and tube thoracostomy were required in 9 patients (47%). Successful healing occurred in 17 patients (89%), the 2 failures had tears extending below the gastroesophageal (GE) junction.

Malignant fistulae

Malignant fistulae are most frequently encountered in esophageal malignancies connecting the esophageal lumen to the pleura, mediastinum or major vessels, but the most common form remains esophago-respiratory. The main presentation is pulmonary aspiration and pneumonia, the latter of which is a frequent cause of death. In addition to several case reports and small case series that suggest SEMS and SEPS are useful for the management of malignant fistulae,^{59–67} a large case series by Shin et al⁶⁸ included 61 patients with malignant esophago-respiratory fistulae treated with FCSEMS. Successful fistula closure (defined as an improvement in aspiration symptoms) was achieved in 49 patients (80%). It is to be noted that 10 patients required simultaneous airway prostheses. Recurrence occurred in 17 (33%) of the 49 patients who had achieved initial success, and almost half of those (8 patients) were successfully treated by additional stenting. Mean survival was only 13.4 weeks, but importantly, it was significantly longer in those who were successfully closed after initial stent placement (15.1 vs 6.2 weeks). Kim et al⁶⁹ reported their experience in a patient population consisting only of malignant esophago-respiratory fistulae. Of 14 patients, initial success in sealing the fistulae occurred in 12 patients (86%). Despite a fistula recurrence in only 2 of the 12 initial successes, 13 patients eventually died of aspiration pneumonia. The authors concluded that although stents can seal esophagopulmonary fistulae, they might not improve or may actually worsen pulmonary parenchymal infection sometimes. The rationale is that stent placement likely occludes the only natural drainage site of lung abscesses. The authors also recommended early diagnosis and intervention by stent insertion before the development of pneumonia and lung abscesses as essential to optimal patient outcome.⁶⁹

Factors Associated with Stent Success

In view of the low number of patients in most studies, it has been difficult to convincingly elucidate factors associated with stent therapy success. El Hajj et al⁷⁰ compared 40 patients in whom successful esophageal leak closure was achieved after stent placement to 14 patients who failed stent placement. Those with successful closure had significantly smaller leaks (< 15 mm, 85% vs 35%), and a shorter time from diagnosis to stent placement (9 ± 5.6 days vs 22.5 ± 14 days). Etiology and location of leaks, stent type and size, and duration of stenting were not associated with stent success. The notion favoring earlier endoscopic stenting was confirmed by Bège et al⁷¹ in a series of 27 patients with post-bariatric surgery leaks. In the group who underwent early stenting (< 30 days from the time of diagnosis, $n = 13$) healing occurred in a significantly shorter period (95 vs 210 days) than those with delayed interventions (> 30 days from the time of diagnosis, $n = 14$). In a recent retrospective analysis of 187 patients with esophageal leaks and perforations treated by stents, stent therapy failure occurred in only 15 patients (8%). Stent failure was significantly more frequent in patients with proximal cervical esophageal leaks, leaks traversing the GE junction, those greater than 6 cm in length and in anastomotic leaks associated with a more distal conduit leak.⁷²

Formal head-to-head comparisons using different types of stents are not currently available, but so far it seems that no particular type of stent is significantly superior to the others. In a pooled analysis of the literature by van Boeckel et al¹³ including 267 patients, successful leak closure did not differ between SEPS (84%), FCSEMS (85%), and PCSEMS (86%). Stent removal was uncomplicated in almost all SEPS and FCSEMS cases (99% and 100% respectively); however, stent removal was complicated in 8% of PCSEMS cases. A more recent pooled analysis assessed studies between 2011 and 2014 and highlighted a trend of shifting away from the use of SEPS.³⁴ Of 302 patients, successful leak closure was achieved in 73% (135/185) with FCSEMS and 78% (68/87) with PCSEMS, while only one study focused on the use of SEPS alone, reporting a success rate of 90% (27/30).^{29,34}

Adverse Events

The pivotal weakness of stents is the issue of stent migration, which necessitates additional procedures for repositioning or replacing the stents, and may rarely be associated with serious adverse events such as perforation or intestinal obstruction.^{29,30} Importantly, it also leads to failure of leak healing. Rates of migration have varied in the literature from 8% to 84%.^{13,21,29–32,70,72,73} The significant variation may be attributed to the small sample sizes, different types of stents used, different indications and leak locations. Also notable is the method of calculation, as some studies reported the rate of migration per stent rather than per patient, giving a misleadingly lower rate of migration. In a large study by Feith et al³⁰ which included 115 patients with esophageal leaks treated by FCSEMS placement the rate of migration was 53% (61/115). In the recent pooled analysis by van Halsema and van Hooft,³⁴ 320 patients with leaks or perforations had 468 stents inserted. The rate of migration was reported as per stent: overall 16.5% (77/468), FCSEMS 21.8% (53/243), and PCSEMS 10.6% (23/218); data were insufficient to analyze SEPS migration rates. An earlier pooled analysis by van Boeckel et al¹³ showed that migration was highest in SEPS (31%) in comparison to FCSEMS (26%) and PCSEMS (12%). PCSEMS obviously carry a lower risk of migration and some authors strongly advocate the

use of PCSEMS and confirm that the stent-in-stent technique for stent removal is safe and effective.^{24,25,74} However, concerns about this technique still exist. Apart from adding a third endoscopic procedure for stent removal, mucosal hyperplasia causing luminal obstruction and dysphagia is a frequent problem.⁷⁴ Mucosal hyperplasia necessitating further endoscopic stenting or balloon dilatation has been reported in 20% of cases in one series.⁷⁴ Failure of stent extraction has also been reported despite the use of the stent-in-stent technique.^{24,74} Thus it remains understandable why many endoscopists are still hesitant to use PCSEMS in benign conditions such as leaks.

Other stent modifications have been proposed to reduce the risk of migration. The Shim's technique entails the attachment of a long proximal lasso to the upper edge of the stent that is extracted through the nares and looped around the patient's ear.⁷⁵ This technique was shown to completely prevent migration in 61 patients with malignant esophageal strictures. However, partially covered stents were used and no attempts were made to extract the stents. Thus, these results cannot be extrapolated to fully covered stents and for use in benign indications. Use of large stents has been suggested to reduce migration, Mega Stents (previously mentioned above for bariatric surgery leaks) were used in a recent series of 22 patients with post-bariatric surgery leaks.³³ Migration occurred in 4 patients (15%), yet severe pain was reported in the majority of patients (91%).

Stent fixation to prevent migration has been attempted using TTS clips. In one study the use of clips was associated with a migration rate of 13% (3/23 patients) in comparison to 57% (12/21 patients) in those without clip fixation.⁷⁶ However, in another series TTS clips failed to prevent migration in any of the 12 included patients.⁷¹ OTSC clips are able to grasp more and deeper tissue, and thus are likely to remain in place for long periods. While OTSC can prevent stent migration there are concerns of inability to remove the clip, which may result in an irremovable stent. To our knowledge, this has not been reported. Recently, a dedicated OTSC removal device has been developed (DC clip cutter, future trade name: remOVE; OVESCO, Tubingen, Germany).⁷⁷ With the availability of this device endoscopists will likely use OTSC clips to fix stents with more confidence knowing that their removal and stent extraction are ensured. Fixation of the upper edge of stents by endoscopic sutures using the OverStitch system (Apollo endosurgery, Austin, TX, USA) also appears to be very effective.⁷⁸ In a recent study the OverStitch was successful in stent fixation in 43/47 patients (91.4%).⁷⁸ However, cost and relative procedural complexity remain obstacles to use of this technology for stent fixation.

Stent-induced major adverse events are rare but not negligible (3%–7.8%).^{30,34,71} The most common major adverse event (2.7%) is hyperplasia-induced stenosis which mainly occurs with PCSEMS. Other major adverse events occur in < 1% of patients each and include bleeding, perforation, intestinal obstruction, aspiration and stricture formation.^{30,34,71,79} Thus, close monitoring during the period of stenting is essential, and any symptoms reported such as a change in the site or nature of pain, or development of vomiting after a period of quiescence may herald the onset of a major adverse event such as impending perforation or intestinal obstruction, and should be investigated urgently. The duration of stenting is independently associated with the occurrence of major complications.⁸⁰ In a recent study it was demonstrated that stenting for less than 2 or 4 weeks is associated with a reduced risk of complications of 56% and 39%, respectively.⁸⁰

In conclusion, stents are an invaluable tool in the management of GI leaks, perforations and fistulae. It is essential to keep

stent therapy within the context of a multidisciplinary approach especially in patients with postoperative leaks. Stents are generally safe and provide a highly effective minimally invasive approach to the management of leaks and perforations. In the United States and elsewhere, however, the use of stents for benign indications is considered off-label. In addition, currently available stents remain suboptimal, mainly due to the risk of migration or difficulty in extraction. Innovations in stent design and the addition of ancillary fixation techniques may further improve the performance of stents, particularly for benign disease. A fully covered completely biodegradable stent remains to date a future target.

Conflicts of Interest

Dr. Hany Shehab is consultant for M.I.Tech.

Dr. Todd H. Baron is consultant and speaker for the following: Boston Scientific, Cook Endoscopy, Olympus, W.L. Gore.

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