Esophageal Stenting

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ABSTRACT

Malignant obstruction of the esophagus is a debilitating condition, with dysphagia as its main symptom. Many patients present with advanced disease and palliative treatment is the only possibility. Since their widespread introduction 10 years ago, self-expanding metal stents have become accepted as an extremely effective method of palliating malignant dysphagia. Early reports suggesting very low complications have been superseded by results from randomized trials. It is now evident that the complication rate is significant and the need for reintervention can be as high as 50%. Modifications in stent design should reduce this reintervention rate. There are a large number of stent designs now available and it is essential that the interventional radiologist understand the particular strengths and weaknesses of each design, so that the correct choice of stent can be made for a particular patient. The most recent designs include antireflux stents and removable stents. Both represent significant advances and should reduce stent-related complications.

KEYWORDS: Esophageal stents, metallic stents, esophageal cancer

Objectives: Upon completion of this article, the reader will be able to (1) outline the various methods for percutaneous placement of metallic stents in patients with esophageal carcinoma; (2) comprehend the evaluation of the potential early and late complications; and (3) compare plastic stents and other palliative methods versus metallic stents.

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Esophageal carcinoma is the seventh most common malignancy worldwide.¹ In the UK there are ~7000 new cases and over 6000 deaths each year.^{2,3} The incidence is increasing in the western world, mainly due to adenocarcinoma of the lower third of the esophagus and cardia.^{4,5} These tumors are thought to arise in areas of Barrett's metaplasia, which itself is secondary to gastroesophageal reflux disease. Unfortunately, despite recent advances, the prognosis remains poor and many of these patients have incurable disease at the time of presentation.⁶ Malignant obstruction of the esophagus may also arise as a result of extrinsic compres-

sion from adjacent lymph nodes or tumors arising in the mediastinal organs. Dysphagia is a common and debilitating symptom of esophageal obstruction and the major palliative requirement, therefore, is restoration of swallowing.

Several nonsurgical palliative techniques are available to relieve malignant obstruction.^{7,8} These include palliative chemotherapy⁹ and radiotherapy¹⁰ endoluminal laser therapy, argon beam and bipolar electrocoagulation, ethanol injection, photodynamic therapy, and intracavitary brachytherapy. These techniques are suitable only for patients with primary esophageal

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carcinoma and all methods require several treatment episodes to restore swallowing. Insertion of an esophageal endoprosthesis can be used for either intrinsic or extrinsic obstruction. The choice of which method to use depends on the nature of the obstruction and on local availability and expertise, with each modality offering both advantages and disadvantages. Insertion of a self-expanding metal stent (SEMS) has become a well-established technique over the past 10 years. The major advantage of stent insertion is that it offers rapid improvement in dysphagia, and SEMS have a relatively low procedure-related complication rate. Advances in SEMS design now means that there are many different stent designs available. Recent data are informing the decision process as to which may be the most suitable for a given clinical situation.

STENT INSERTION

SEMS can be inserted using endoscopic guidance, fluoroscopic guidance, or a combination of both. With any of the techniques it is helpful to have a contrast swallow (usually water-soluble contrast) to allow an assessment of the site and length of the tumor and whether or not there is any evidence of fistulation into the trachea or bronchi (Fig. 1). This information is essential in choosing the type of stent to place. The following description of the insertion technique is under fluoroscopic guidance alone, which is the authors' preferred method of stent insertion.

The procedure is performed under conscious sedation (midazolam 1 to 5 mg). In most cases the addition of analgesia is not required. Oxygen is delivered via a nasal cannula at a rate of 2 to 4 L/min (beginning before administration of sedation) and the patient's pulse and oxygen saturation are monitored throughout the procedure. The patient lies on the x-ray table in the prone position for tumors of the gastroesophageal junction (GOJ) and in the left lateral position for strictures of the more proximal esophagus. The prone position has the advantage of opening out the GOJ, which is foreshortened in the left lateral position, allowing accurate positioning of the stent.

Once the patient is sedated, a 5-F catheter and guide wire combination is passed over the back of the tongue and into the esophagus. A shaped catheter (5- to 7-F), such as a Headhunter (Cordis/Johnson & Johnson, South Ascot, England) and a 0.035-inch hydrophilic guide wire (Radiofocus, Terumo UK, Knowsley, England) provide the fastest and least traumatic intubation. The guide wire and catheter are passed down as far as the proximal end of the stricture, the guide wire is removed, and 10 to 15 mL of a water-soluble contrast material is injected to indicate the proximal extent of the stricture. The hydrophilic guide wire is reinserted into the catheter and used to negotiate the stricture. At the

Figure 1 Barium swallow shows a short stricture in the mid esophagus. Biopsy showed squamous cell carcinoma.

distal end of the stricture, a further injection of water-soluble contrast marks the distal extent of the stricture. At this point, radio-opaque markers can be fixed to the patient's skin as indicators of the stricture length and position (Fig. 2). In the case of tumors at the GOJ, once the stricture has been traversed, air is injected into the stomach via the catheter. In the prone position, air fills the fundus of the stomach and the soft tissue mass of the tumor can be readily seen. This avoids having to fill the stomach with contrast medium. The guide wire and catheter are placed as distally as possible, to provide sufficient anchorage for passage of the stent. The hydrophilic guide wire is exchanged for a 180-cm stiff guide wire (Amplatz Super-stiff; Cordis/Johnson & Johnson). The catheter is then removed and the stent deployment system is passed over the wire (Fig. 3). The stent is placed so that it extends beyond the stricture by at least 2 cm at both proximal and distal ends (apart from tumors at the GOJ and cervical esophagus). The stent is then deployed under fluoroscopic control and the catheter and guide wire are removed (Fig. 4).

Following recovery from sedation, the patient is allowed free fluids until the following day, when he or she may begin a semisolid diet. Patients who tolerate this without difficulty are advised to slowly increase their diet. A check contrast swallow is not routinely performed.

Figure 2 A guide wire and catheter combination has been passed down through the stricture and a small amount of contrast injected at the proximal and distal margins of the tumor. Paper clips have been taped to the patient's skin to indicate the stricture length.

Using this technique, or modifications of it, the success rate for stent deployment is reported as being between 90% and 100%.

COMPLICATIONS

In the initial reports, the complication rates for insertion of SEMS was extremely low.¹¹⁻¹⁴ It is now clear, however, that although early complications are indeed relatively uncommon, delayed complications occur in up to one third of patients and in some series the reintervention rate is as high as 50%.¹⁵ Much of this information came from the early experience with SEMS and it has become clear that inherent problems in design of the first-generation SEMS led to delayed complications. There have been several modifications of stent design in the past 10 years and now the appropriate choice of stent may result in a reduction in delayed complications (see below).

Early Complications

PAIN

Dull chest pain, lasting up to 48 hours, occurs in many patients following SEMS insertion.¹⁶⁻¹⁹ Severe pain,

Figure 3 The stent deployment system has been passed across the stricture. Note in this example the markers on the proximal and distal ends of the stent and also in the center of the stent. The stent should be placed so that the proximal and distal ends are 2 cm beyond the stricture.

requiring opiate analgesia, occurs in up to 6% and seems particularly to affect patients with upper-third tumors and those with severe postradiation strictures and where larger-diameter stents have been chosen. Patients with pre-existing odynophagia are also more likely to experience postprocedural pain.¹⁶ In some, the distress of constant pain is worse than the original dysphagia. In these patients other methods of palliation such as laser or alcohol injection should be considered. If other methods were unsuitable it would be appropriate now to insert a removable stent (see below).

BLEEDING

A small amount of hematemesis is common in the first 24 to 48 hours after SEMS insertion, due to the direct trauma.

STENT MIGRATION

Early stent migration was a relatively common complication of the original covered SEMS, particularly when placed across the GOJ.²⁰ This was because the cover was on the outside of the stent, which prevented the mesh embedding in the tumor and thus reduced stent anchorage. Changes in stent design have addressed this problem reducing the early migration incidence (see below).

Figure 4 The stent has been released. Note the immediate expansion of the proximal and distal ends, while the central area is still constrained by the tumor. The olive at the distal tip of the delivery device may be difficult to withdraw through the stricture if it remains very tight. Some stent designs now allow the olive to be detached after the stent has been deployed, so that the delivery system can be easily removed. The olive passes through the GI tract.

ASPIRATION PNEUMONIA

Aspiration can occur during stent placement and subsequent pneumonia can develop in ~6% of cases.²¹

AIRWAY OBSTRUCTION

This occurs in tumors of the proximal esophagus, where there is a large tumor mass. As the esophageal SEMS expands, the tumor compresses the airway. This can cause acute stridor, which can be managed by placing a tracheal stent. If this complication can be anticipated (through review of available cross-sectional imaging), some authors would advise placement of a stent to protect the airway before inserting the esophageal stent.²²

Delayed Complications

TUMOR INGROWTH OR OVERGROWTH

In uncovered stents the most common cause of delayed obstruction is tumor ingrowth through the mesh of the stent (Fig. 5). This occurs in 20 to 36%^{11,15,20,23} of patients. Tumor extension into the lumen of the stent can be managed by laser therapy or alcohol injection (if a short segment is involved) or by placing a second SEMS

Figure 5 The delivery system has been removed. The stent expanded fully over the next 48 hours without further dilatation.

inside the first (if more extensive). Tumor overgrowth can occur at either end of a covered or an uncovered stent.¹⁵⁻¹⁷ It is important, when choosing the initial stent, that it extend at least 2 cm beyond both the proximal and distal margins of the tumor. If overgrowth occurs, it can also be managed by endoscopic ablation or deployment of a second stent.

STENT MIGRATION

The advantage of the covered stents has been their resistance to tumor ingrowth, but this has been at the cost of a high incidence of stent migration. One of the commonly used first-generation covered stents, the Wallstent (Schneider Bulach, Switzerland) had a polyurethane cover applied to the outside of the stent. This produced a smooth outer surface and the stent mesh was unable to embed in the tumor. Although the proximal and distal ends were uncovered, migration still occurred in a large number of patients.¹⁴ The covered Gianturco-Z stent (Wilson Cook Medical, Letchworth, England) is a stainless steel stent covered by polyethylene. This stent had flared proximal and distal ends and central sharp barbs to anchor the stent in the tumor. Although migration rates were not as high as for the Wallstent, the central barbs have been associated with more serious complications such as perforation and hemorrhage.^{19,24} SEMS have undergone several design modifications since this first generation. The Wallstent has had the cover applied to the inside of the stent. In a further modification, the shape of the stent was altered from a straight tube, to a conical design, with a variable braiding

angle (Flamingo stent, Microvasive, Boston Scientific, Watertown, MA). With the latest stent designs, late migration rates of ~5% have been described.²⁵ See below for more detailed description of individual stent designs and properties.

If a stent has only partially migrated (proximally or distally), a second stent can be placed, overlapping the first one to anchor this original stent in position. If the stent has migrated completely into the stomach, it may pass through the alimentary tract and pass per rectum without causing any problems for the patient. Some, however, can cause obstruction of the pylorus or obstruct more distally. Those stents with sharp uncovered ends or barbs may cause perforation. If the stent is in the stomach it may be possible to remove it endoscopically (depending on the stent design). If the stent is fairly soft and pliable (such as the Ultraflex stent), it can be grasped with forceps and pulled up through the esophagus. The more rigid stents are particularly difficult to remove as they may not collapse down and will require surgical removal if the patient is symptomatic.^{18,20}

PERFORATION AND HEMORRHAGE

These complications are the most serious and are potentially fatal. They are considered together because the underlying causative mechanisms are similar. In several large series, late perforation or fistulation has been described in 4 to 7% of cases and late hemorrhage in 1 to 7%.^{17-19,24-27} The mechanism is thought to be pressure necrosis caused by the continuing radial force of the stent on the tumor. There have been cases reported where the barb or wire of a stent has directly perforated the esophageal wall, causing fistulation into the aorta or mediastinum.²⁸ In several cases, postmortem evidence has not been available and it is difficult to be sure if the fistulation is truly stent-related or whether, in some cases, it is actually due to progression of the underlying tumor.²⁹ There has been some concern that the both perforation and hemorrhage are more common in patients who have had prior treatment with radiotherapy and/or chemotherapy.^{23,26} This has not been borne out in other series, however.^{17,19}

REFLUX

When a SEMS is placed across the GOJ for tumors of the distal esophagus and cardia it is inevitable that reflux will occur. Reporting of symptomatic gastroesophageal reflux has been extremely variable but it has reported in up to 38% of such cases.^{16,18,19,23} There is no doubt that in some patients symptoms of reflux are severe, requiring medication with proton-pump inhibitors. SEMS with antireflux designs are now available and early experience³⁰⁻³² suggests that these are highly effective in reducing the incidence of symptomatic reflux (see below).

COMPARISON OF SEMS, PLASTIC STENTS, AND OTHER PALLIATIVE METHODS

The original stents were plastic and were placed either at laparotomy (Celestin) or endoscopically (Atkinson tube). Both have a significant procedure-related complication rate, including perforation (4.2 to 12.5%), hemorrhage (1.5 to 5%), pressure necrosis (1 to 4%), and aspiration.^{33,34} The major reason for this high serious complication rate is the size and rigidity of the deployment system, which requires balloon dilatation up to 22.5 mm. The internal diameter of these stents is relatively small (12 mm) however, so patients must be maintained on a modified diet or risk stent blockage. Függer and colleagues reported an overall complication rate of 36%, including a 16% mortality rate and a 20% dislodgement rate, in their series of 95 patients treated with plastic tubes.³⁵ Barr and associates reported a complication rate of 40%, with none of their patients able to swallow solid food.³⁶ SEMS have an internal diameter of at least 18 mm. The delivery system may be as narrow as 8 mm and can be extremely flexible (depending on the exact stent design). In all but the tightest of strictures, therefore, SEMS can be deployed without initial balloon dilatation. There have been five prospective randomized trials comparing the use of plastic or latex stents and SEMS,^{22,23,37-39} assessing the technical success rate, improvement in dysphagia, and complication rate. In all but one of these studies, the success rate for insertion of SEMS was slightly higher than for plastic stents. Interestingly, despite the larger internal lumen of the SEMS, in three of the five trials, there was no significant difference in the reduction in dysphagia score between the two groups. There was, however, a significant difference in procedure-related and short-term complications in four trials, with a much higher complication rate in the plastic stent group. Interestingly, there was no significant difference in the incidence of delayed complications and requirement for reintervention. One of the trials³⁹ also included a quality of life assessment. There was a trend in favor of SEMS, but this did not reach statistical significance. Despite their initial high capital cost, SEMS have been shown to be more cost-effective than plastic stents due to the low early complication rate.^{37,40,41}

A recent development is the use of self-expanding (Polyflex) plastic stents. These represent an improvement on rigid stents, as the diameter of the introduction device is only 12 to 14 mm. The postexpansion luminal diameter is 16 to 21 mm. Their appeal is a cost of only half that of metal stents. It is unclear, however whether they are suitable in all cases since technical success rates as low as 75% have been described, due to failure to pass the delivery catheter across the stricture.⁴² Other groups have reported technical success rates of 100%.⁴³ Further studies are needed with this stent to assess its place compared with other stent designs.

In two randomized controlled trials, SEMS have been compared with thermal ablative therapy. In the first,²⁰ Adam and coworkers demonstrated that both types of SEMS (first-generation covered and uncovered) were superior to laser therapy in palliating dysphagia. Although the high reintervention rate of 43% and 26% for covered and uncovered SEMS, respectively, was high, the patients in the laser group effectively had a 100% reintervention rate, since this procedure had to be performed every 4 weeks. In the second,⁴⁴ Dallal and colleagues compared Ultraflex stents with a variety of thermal ablative measures. They found that the relief of dysphagia was disappointing for both treatments, and that patients in the stent group complained more of pain. Quality of life was quite severely impaired for both groups, but deterioration was seen in the stent group. It is possible that the extremely poor outcome in this study was due to the very advanced nature of disease at the time of treatment.

Stent Types

There is a large range of different SEMS designs available on the market (Fig. 6). All have specific advantageous design features as well as specific drawbacks^{45,46} and manufacturers are modifying stent design frequently (making comparisons between studies extremely diffi-

Figure 6 Combined overgrowth and ingrowth through an uncovered stent. Endoscopic assessment is useful to establish tumor progression. Progressive food impaction can occasionally cause diagnostic difficulty on a contrast swallow alone!

cult). All are delivered in a compressed form, which allows the delivery system to be of small diameter compared with the final stent diameter. Many of the stents are preloaded onto the delivery system. Some though, require loading immediately prior to the procedure (e.g., the Polyflex and the Dua AR Cook stents). The delivery systems vary in size from ~6-mm diameter (Flamingo stent) to 10-mm diameter (Gainturco-Z stent, Ella stent, Dua stent, and Choo stent) and 12- to 14-mm diameter introducer for the new plastic expandable stent (Polyflex). Both the delivery system and the stent itself vary in their degree of flexibility. Some of the stents shorten on deployment, such as the Ultraflex and the Flamingo. All delivery devices have radio-opaque markers indicating the limits of the compressed stent and some also indicate the expected stent length when fully expanded. It is essential that operators fully understand the individual features of the SEMS that they are using to avoid misplacing the stent in an incorrect position or using an inappropriate stent for a particular clinical indication.

The features of some of the more commonly used stents and the new stent designs are discussed below.

- (1) Ultraflex (Boston Scientific Ltd, St. Alban, England) (Fig. 7A). This stent has a knitted Nitinol mesh construction and is available both in covered and uncovered forms. It is the most flexible stent but has the weakest radial force so may require postdeployment balloon dilatation to achieve sufficient expansion. If no dilatation is performed it may take several days for the stent to fully expand, so a gradual reintroduction of a normal diet is recommended. The proximal release version (which is deployed from above downwards) allows more accurate stent placement just below the cricopharyngeus.⁴⁹ Furthermore, because it is constructed from a single wire, the stent can be removed by unraveling the strand.
- (2) Flamingo Wallstent (Boston Scientific Ltd, St. Alban, England) (Fig. 7B). This stent has a conical shape and like the original Wallstent, it is constructed from a braided stainless steel alloy and is covered on its inner surface. The conical design and the variable braiding angle of the mesh provide resistance to antegrade peristalsis and help prevent dislodgment. It is now recommended only for tumors of the lower third of the esophagus.
- (3) FerX-Ella stent (Radiologic UK/Ella-CS, Czech Republic) (Fig. 7C). This stainless steel mesh stent is covered on the inner and outer surfaces with a layer of polyethylene, which also extends distally to act as an antireflux valve.
- (4) The Niti-S Double stent (Taewong Medical, Seoul, South Korea) (Fig. 7D). This stent is made from Nitinol and has an inner covering of polyurethane. On the central area of the stent there is a further

Figure 7 Commonly used stents now available. From left, (A) covered Ultraflex, (B) Flamingo, (C) Ella removable AR stent, (D) Niti-S Double, (E) Polyflex, (F) Dua AR-stent, (G) Choo, and (H) Do AR-stents.

uncovered mesh placed over the covered part. This combines the advantages of an uncovered stent (very low rate of migration) with the advantages of a covered stent (low ingrowth rate).

- (5) Polyflex (Rusch; Kernen, Germany) (Fig. 7E). This self-expanding plastic stent is removable. A drawback is that the stent is radiolucent.
- (6) Dua AR-stent (Cook, UK) (Fig. 7F). This stent is a polyurethane-covered stainless steel stent. A 7-cm polyurethane sleeve attached to the distal end of the stent acts as an antireflux valve.
- (7) Choo stent (MI-Tech; Seoul, South Korea) (Fig. 7G). This is a polyurethane-covered Nitinol stent, which has a wider-diameter collar at both ends to prevent stent migration. It is removable.
- (8) Do Mark 1AR-stent (MI-Tech/Diagmed) (Fig. 7H) is similar to the Choo stent but in addition has a semilunar valve at the distal end to prevent reflux.

Choice of Stent

No one SEMS design is suitable for all clinical situations. It is essential that the operator consider each case individually to make the most appropriate choice.

TUMORS OF THE GOJ

As discussed above, the incidence of adenocarcinoma of the distal third of the esophagus and the GOJ is increasing and now has a higher incidence than squamous carcinoma of the esophagus. There are two specific problems when placing SEMS across the GOJ. First, the distal end of the SEMS may have to be placed in the fundus of the stomach, resulting in the distal end lying

free with no anchorage. This accounts for the high rate of migration of the first-generation covered SEMS placed in this position. Second, gastroesophageal reflux will be inevitable, with symptomatic reflux in 5 to 38% of patients. The recent introduction of the antireflux stents look promising in reducing symptomatic reflux dramatically and keeping migration rates low.³² Further clinical studies of the antireflux SEMS are needed to verify this early optimism.

HIGH ESOPHAGEAL AND CERVICAL TUMORS

Palliation of high esophageal obstruction is particularly difficult. After SEMS insertion, patients may complain of pain or be constantly aware of a globus sensation. For this reason, it is advisable to use a narrow-diameter stent (18 mm), since both pain and globus sensation appear to be related to stent diameter.⁴⁷⁻⁴⁹ The placement of a SEMS in the cervical esophagus may interfere with the swallowing mechanism, particularly if the SEMS is close to the cricopharyngeus. A SEMS that can be removed should any of these complications occur would be advisable. At present, the Ultraflex stent is the softest and most pliable and can be removed. It is probably the best SEMS for this indication, although the Gianturco-Z stent has been used successfully in this location.⁴⁹

FISTULATION OR PERFORATION

Fistulation into the tracheobronchial tree occurs in 5 to 10% of patients with primary esophageal carcinoma. It is associated with a high mortality rate due to the concomitant respiratory involvement. It is a particularly distressing symptom for the patient, who will be unable even to swallow saliva without coughing, and who is likely to have chronic respiratory infection until death. In

several series, patients with either fistulation or perforation following an endoscopic procedure have been included.^{11–21,49–51} The reported success rate for sealing of the fistula is 66 to 100%, with most series reporting success in over 90% of cases. Those patients in whom a SEMS is placed immediately following perforation do particularly well in that they do not develop the usual pulmonary complications and can get back to eating a near-normal diet with 24 hours.

EXTRINSIC COMPRESSION

Esophageal obstruction due to extrinsic compression from adjacent mediastinal nodes or tumors can be successfully treated with SEMS. Several authors have noted, however, that low expansile force SEMS, such as the Ultraflex stent, may buckle or fail to fully expand.^{15,21} It has been suggested therefore that higher radial force SEMS, such as the Gianturco-Z stent, may be the better option in this situation.

BENIGN DISEASE

The majority of benign esophageal strictures are due to reflux esophagitis, and a smaller number are secondary to corrosive ingestion, radiotherapy, and inflammatory processes such as Crohn's disease. Most peptic strictures can be successfully treated with a combination of proton-pump inhibitors and dilatation with rigid dilators or balloon catheters. In most cases this is successful, but a small number of patients will require repeated treatments to maintain esophageal patency. SEMS is sometimes considered in these refractory cases; however, an unacceptably high complication rate with the early stent designs has been described.⁵² These include the development of further strictures above the stent and tracheoesophageal fistula. More recent experience with removable stents suggests that they may play a role in these patients.^{53,54} Song and colleagues described the use of retrievable Nitinol stents in 25 patients with benign strictures. Stents were left in place for between 1 and 8 weeks. Thirteen patients required further treatment, but 12 maintained their improved swallowing after stent removal. It is crucial to remove the stent, as development of granulation tissue at the top of a stent is a well-recognized complication.⁵⁵

CONCLUSION

SEMS are a rapid and effective way of relieving dysphagia in malignant esophageal obstruction. Their technical success rate is high, but the radiologist must be prepared for a high reintervention rate. A suitable choice of stent may reduce this rate. Further clinical work is needed to look at the antireflux stents and stents in benign disease as well as the future development and clinical place of SEMS impregnated with radioisotope.⁵⁶

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