

“HOW I DO IT”

Expandable esophageal stents



AUTHORSHIP

How I do it: Expandable Esophageal Stents

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“HOW I DO IT”

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Introduction

Esophageal cancer is frequently unresectable at the time of diagnosis because of local invasion or metastatic disease. Therapy is therefore usually palliative in nature, with the major aims being relief of dysphagia, maintenance of nutrition, and occlusion of tracheoesophageal fistulas. Palliative surgery ultimately offers the best alleviation for esophageal obstruction symptoms and signs such as dysphagia and vomiting. However because of the poor prognosis, the short median survival time and the considerable morbidity and mortality rate for surgery, this approach cannot be justified in preference to less invasive nonsurgical techniques.

Recently various esophageal self-expanding metal stents (SEMSs) have been developed for palliation of malignant obstruction of the gastrointestinal tracts. The major impact of these stents relates to the ease of insertion and the potential for fewer complications compared with plastic stents. The physician's perception of ease of stent placement is an important factor in choosing a SEMS. Because of the small-caliber delivery system, a SEMS requires less dilation of the esophagus prior to placement.

This article mainly focuses on the technical aspects of esophageal SEMS placement, as well as considering what kind of patients are candidates, and what the physician needs to know before and after the procedure.

Specific indications and contraindications for esophageal SEMS placement

Indications The most common indication for placement of an esophageal self-expanding metal stent (SEMS) is palliation of malignant dysphagia in patients with tumors of the esophagus and gastric cardia, that are judged to be inoperable because of extensive local or regional disease or poor functional status because of advanced age, comorbidity, or both. Dysphagia due to extraesophageal tumors such



OMED “How I Do It”

Expandable esophageal stents

as lung cancer and malignant lymphadenopathy is also an indication. Another indication for placement of an esophageal SEMS is in the context of tracheoesophageal fistulas, which develop in patients with advanced esophageal and lung cancer and lead to continuous aspiration of saliva. Tracheoesophageal fistula is the only condition in which covered expandable metal stents may increase survival as compared with other therapies.

Contraindications Only a few years ago several clinical situations were considered to be contraindications for stent insertion, such as severe angulation of strictures, location of lesions at less than 2 cm from the upper esophageal sphincter (cervical esophagus), tumors lacking a proximal shelf to prevent migration, lesions having the risk of airway compression by the stent, luminal obstruction that could not be dilated, and horizontal orientation of a stricture at the gastroesophageal junction that would not allow good flow through a stent. However, this is a field of rapid technological and functional advances, and SEMSs have made a significant contribution to the management and palliation of dysphagia in a group of patients in whom treatment has traditionally proved extremely difficult. Currently, there is no consensus on absolute contraindications for esophageal SEMS placement, but careful patient selection is of utmost importance. Patients with a short life expectancy (less than 4 weeks), multiple metastatic disease, or peritoneal seeding should probably not be considered as candidates.

Benefits, risks and complications of esophageal SEMS placement

Informed consent should be obtained with all patients who undergo esophageal SEMS placement. Information should be given to the patient as well as the family on the expected benefits and risks, as well as on the short term and long term complications related to the procedure.

Benefits Improvement of quality of life is the most important objective of esophageal SEMS placement. Dysphagia has been shown to be effectively and reliably relieved after insertion of a SEMS. In recently published data the overall immediate success rate for palliation of dysphagia approached 90%. The ability of the patient to continue peroral nutrition is another benefit, which not only improves quality of life but possibly also the overall nutritional status of the patient. Though increased survival is not considered to be a general benefit of SEMS treatment, in the



OMED "How I Do It"

Expandable esophageal stents

context of tracheoesophageal fistulas the use of a covered SEMS may increase survival compared with other therapies. However, despite these benefits, it is important to consider the patient's life expectancy. Though SEMS may be more appropriate than chemotherapy or radiation therapy in patients with a life expectancy of more than 6 months, if a patient is not expected to live more than 1 month the merits of placing a SEMS are questionable.

Risks and complications Placement of an esophageal expandable metal stent can lead to several complications. Intraprocedural complications include those associated with conscious sedation, aspiration, malpositioning of the stent, and esophageal perforation. Early post-procedural complications may include chest pain, bleeding, and tracheal compression, with resultant airway compromise and respiratory arrest. Late complications include distal stent migration, formation of an esophageal fistula, bleeding, perforation, and stent occlusion. Although most migrated stents can be retrieved endoscopically or will simply pass through the gastrointestinal tract, small-bowel obstruction develops in some patients.

Technique

Patient preparation Before stent placement, it may be helpful to obtain a barium esophagogram to define stricture location, length, angulations, and presence of tracheoesophageal fistulas. Sedation can be achieved by administering a sedative and analgesic (3–5 mg midazolam and 50 mg meperidine intravenously). It is imperative to have a gastrointestinal nursing assistant who is experienced in complex therapeutic endoscopic procedures with metal stent placement under fluoroscopy.

Stent selection The choice of stent for an individual is influenced by a variety of factors, including tumor length and position, and presence of a fistula, potential airway compromise, and personal preference of the individual inserting the stent. The diameter and length of the stent should be determined after measuring and monitoring the length of the stricture using fluoroscopy or endoscopy. The length of the stent chosen should be at least 3 to 4 cm longer than the obstruction, to allow an adequate margin of stent on either side of the obstruction.

Many different types of stents are available, each with slightly different characteristics (Table I). Commercially available esophageal stents include the Ultraflex (Microvasive, Boston Scientific, USA), the Z-stent (Wilson-Cook Medical, USA), the Polyflex (Boston Scientific), the Bonastent (Standard Sci-Tech, Korea), the



OMED “How I Do It”

Expandable esophageal stents

Choo stent (M.I.Tech, Korea), and the Niti-S stent (TaeWoong Medical, Korea) (**Figure 1**). All stents appear to be equally effective in palliating obstructive symptoms.

Placement of metal stents for tumors of the distal esophagus and gastric cardia is associated with specific problems, because the distal part of the stent projects freely into the fundus of the stomach and thus cannot fix itself to the wall. Uncovered stents are preferred for tumors at the cardia, as they are less likely to migrate [1]. However, covered stents are advocated for tumors with a high risk of fistula formation or when a fistula already exists. These are also used to avoid ingrowth of tumor through the metal mesh; this occurs in 20%–30% of patients who receive uncovered metal stents.

A SEMS deployed across the gastroesophageal junction leads to gastroesophageal reflux in most patients, causing significant morbidity [2]. Stents with an antireflux valve should be considered in this situation. Several stents with an antireflux function have been developed, including the Dua stent (Wilson-Cook Medical), which is a modified Z-stent with a polyurethane "windsock"-type valve; a modified Choo stent (M.I.Tech) with a long inner antireflux valve; and the Bonastent (Standard Sci-Tech) that has an S-type valve with "Shim's modification" (**Figure 2**). Though the Dua stent effectively prevents reflux without disrupting antegrade flow, this stent has some limitations. First, stent insertion is more difficult than with conventional stents. In addition the antireflux valve can be inverted under high pressure gradients, for instance with belching and vomiting [3]. Recently we compared the dysphagia score and 24-hour ambulatory pH monitoring results for conventional SEMSs, the Dostent (M.I.Tech), and a newly developed S-type valve SEMS. The S-type antireflux valve was found to be best at preventing acid reflux according to 24-hour pH monitoring results [4].

Stents have also been developed that have an antimigration feature. The Flamingo Wallstent has a shift in the braiding angle, between the proximal and the distal part of the stent, which allows the distal part of the stent to stretch in response to peristalsis. The Ultraflex is available with proximal and distal uncovered segments which allow the normal mucosa above and below the tumor to project into the stent lumen. A newly developed covered esophageal SEMS with an uncovered proximal flange may be helpful in the prevention of migration. This stent can be held in place by means of a silk thread attached from the edge of the proximal end of the stent to the patient's ear via the nares. During a follow-up period of 7.5 months no stent



migration was reported among 61 patients when this stent was used [5]. This design appears to prevent stent migration and to improve dysphagia in patients with malignant tumor stenosis at the esophagogastric junction, a short tumor stricture less than 5 cm in length, a soft tumor stenosis, or tracheoesophageal fistulas.

Procedure The patient should be placed in a semi-oblique left lateral decubitus position with both arms placed in front of the body. This position is advisable, on the one hand to provide good vantage points for marking the tumor position, and on the other hand to minimize the risk of aspiration. Stents should be inserted under endoscopic guidance with the aid of fluoroscopy.

Before stent insertion, the stenosis is pretreated by bougienage with a Savary-Gillard bougie dilator (Wilson-Cook Medical) until an endoscope with a minimum diameter of 9–10 mm can pass the stricture without resistance. This pre-dilation may increase the risk of perforation; however there is currently no consensus on how many sessions of pre-dilation can be performed before the risk of perforation increases. If the endoscope can be passed with minimal difficulty through the obstruction, this can be attempted without pre-dilation. If the stricture is so tight enough or growth of the tumor is so tortuous that the stiff guide wire for bougie dilation cannot be passed easily through the lesion, a hydrophilic biliary guide wire preloaded through a standard biliary catheter can be used to cannulate or traverse the stricture. Once the guide wire has been passed through the stricture with fluoroscopic monitoring, bougie dilation can be performed.

After the endoscope has been passed through the stricture, the distance of the tumor from the incisors and the tumor length are measured. Once the length of the stricture has been determined, the length of the stent can be chosen. The proximal and distal margins of the stricture can be shown by marking the skin, or endoscopically by tissue clips, or by the intramucosal injection of a radiopaque contrast agent. Of the various marking methods, injection with a 1 ml syringe of the lipid-soluble contrast agent lipiodol is preferable because it allows easy, accurate, and persistent marking. This allows radiopaque markers in the stent to be accurately positioned and deployed between the injected marks.

Once the upper and lower tumor borders are marked, the endoscope is withdrawn, with the guide wire, preferably a superstiff 0.038 Savary wire (or a 0.035 stiff Savary wire; Wilson-Cook Medical) being left across the stricture in the stomach.

In the case of most stents that are used at our institution (Choo stent, Bonastent, NITI-S stent), a premounted delivery device is then carefully advanced over the



OMED “How I Do It”

Expandable esophageal stents

guide wire (**Figure 3A**) until the distal end of the stent is at least 2 cm below the distal margin of the tumor (**Figure 3B**). The stent is positioned under fluoroscopic control and then deployed by slowly retracting the outer sheath of the delivery device while maintaining the location of the inner shaft (**Figure 3C**). Once the stent is fully deployed, the delivery device and the guide wire are removed (**Figure 3D**). It is important that the inner shaft is held securely and not allowed to move, as pushing it will cause a misalignment of the stent. If retraction of the outer sheath is interrupted, the stent should be reloaded back into the outer sheath and the whole delivery device should be removed to perform the procedure from the beginning. If the 'olive' tip of the delivery device catches the distal part of the stent or the inside of the stent lumen due to the tight stricture, wait for the stent to expand to some extent or gently move the whole delivery device back over the 'olive tip' and gently remove the delivery device. If by mistake the stent is only partially deployed, along less than 50% of its length, from the delivery device, the stent can be repositioned by immobilizing the inner shaft and pushing the outer sheath gently until it reaches the distal marked end of the inner shaft. Thanks to their mechanical properties, most SEMS, whether fully or partially expanded, unexpanded, or migrated after release from the delivery device, are easy to reposition or remove endoscopically. Therefore, if a stent is completely deployed erroneously, deep down and far from the stricture, a forceps, inserted through the working channel of the endoscope can pull the lasso attached to the end proximal from the stricture (or in the case of stents with no lasso, the upper rim) for repositioning, causing the stent's radial diameter to decrease.

To facilitate accurate deployment of certain stents (Ultraflex), the endoscope can be re-inserted to the proximal end of the stricture alongside the mounted but undeployed stent to monitor the delivery process both endoscopically and fluoroscopically. After deployment, the endoscope is passed into the proximal portion of the stent, but not through the stent, to assess stent position relative to the tumor while avoiding dislodgement.

Special care should be taken when stenting in the cervical esophagus. A placement that is too proximal may result in choking and/or aspiration. The patient may also feel an intolerable foreign body sensation especially if encroachment on to the cricopharyngeus occurs. In these circumstances, positioning under fluoroscopic control has been advocated. Recently a modified SEMS with a proximal funnel of shorter length has been developed for cervical stenting (M.I.Tech. Korea). Though data are as yet preliminary, the results appear to be promising [6].



Post-procedure observation and care

Following stent insertion, chest radiography should be carried out to verify the position of the stent and to check for signs of perforation. Stent expansion can best be confirmed by chest radiography. The following day, endoscopy can be done to ascertain the location of the stent. To prevent dislodgment, the endoscope should not be passed through the length of the stent at this time.

Following stent placement, patients can experience varying degrees of chest pain and discomfort. This is usually controlled with simple analgesia, and occasionally opiates. It is important to ascertain whether or not the chest pain is related to acid reflux.

Patients with esophageal stents must modify their diet to prevent large boluses of food from becoming impacted within the stent. Most patients will not be able to tolerate a solid diet immediately following stent insertion. Diet should be advanced in a stepwise pattern. Leafy or raw vegetables, which could result in stent occlusion, should be avoided. Patients should be counseled regarding nutrition and choosing food of appropriate consistency for avoiding food impaction.

If a stent without an antireflux valve is positioned across the gastroesophageal junction, strict antireflux precautions and aggressive acid suppression are needed to prevent gastroesophageal reflux and aspiration. Patients with such a stent should be placed on high dose proton pump therapy indefinitely. Additional precautions should be taken, such as elevating the head of the bed and avoiding recumbency within 3 hours after a meal.

Stent occlusion may result from an impacted food bolus, which can be dislodged endoscopically. Tissue-related stent occlusion may be due to tumor ingrowth, tumor overgrowth, or tissue hyperplasia. Treatment options to restore luminal patency include placing a new stent through the previous stent, ablative techniques such as argon plasma coagulation, and mechanical debridement.

Conclusion

Esophageal SEMSs are now fully established as a management for palliation of esophageal obstruction. With appropriate selection and deployment they can effectively reduce obstructive symptoms and improve the patient's overall quality of life. However a multidisciplinary team approach must precede palliation. Patient



OMED "How I Do It"

Expandable esophageal stents

selection and choice of device that are appropriate, stricture characterization, and communication of expectations among the physician, the patient and the patient's family, are critical to successful endoscopic palliative therapy.

Over the past several years as innovative techniques and devices have been developed, esophageal metal stenting has become simpler and more convenient for the endoscopist, as well as more comfortable for the patient. I hope that this article may provide concise and useful information to physicians in this field.



Table 1 Commercially available covered esophageal stents, including stents available with antireflux valves.

	Stent (Manufacturer)					
	Ultraflex™ (Boston Scientific, USA)	Z-stent® (Wilson-Cook Medical, USA)	Polyflex® (Boston Scientific, USA)	Bonastent™ (Standard Sci- Tech, Korea)	Choo stent™ (M.I.Tech, Korea)	NITI-S stent™ (TaeWoong, Korea)
<i>Specifications</i>						
Stent material	Nitinol	Stainless steel	Polyester mesh	Nitinol	Nitinol	Nitinol
Covering material	Polyurethane	Polyurethane	Silicone	Silicone	Silicone	Polyurethane
Stent diameter, mm	18 23	18	16 18 21	18	18	16 18
Stent length, mm	100–150	80–140	90–150	60–160	60–170	60–120
Delivery diameter, mm	6	10	12 14	5	6	6.7
Remarks	Not intended to be repositioned or removed once deployed Proximal and distal release available Large proximal flares	Non-shortening stent Preloaded on a Z-speed introduction system	CT/MRI can be performed with it in situ Can be used in benign disease	Repositionable if misplaced less than 50% of its length Small delivery diameter (5 mm) Proximal and distal lasso	Retrievable if misplaced Antimigration stent available Proximal and distal lasso	Retrievable if misplaced Proximal lasso
<i>Antireflux valve</i>						
Stent diameter, mm	NA	18	NA	20 22	18	NA
Stent length, mm	NA	80–140	NA	90–150	90–160	NA
Delivery diameter, mm	NA	10	NA	7	8	NA
Remarks		Dua ‘Z’ antireflux stent Long windsock-type antireflux valve		Fixed flexible and stable inner antireflux valve (Shim’s modification)	Long S-shaped inner antireflux valve (Shim’s modification)	

CT/MRI, computed tomography/magnetic resonance imaging; NA, Not applicable



Figures

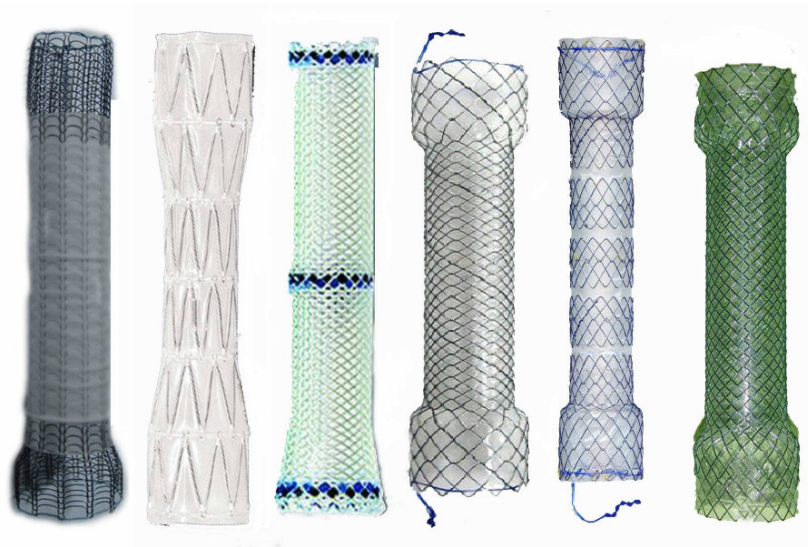


Figure 1 Various esophageal stents. Left to right: Ultraflex, Z-stent, Polyflex, Niti-S stent, Choo stent, and Bonastent.

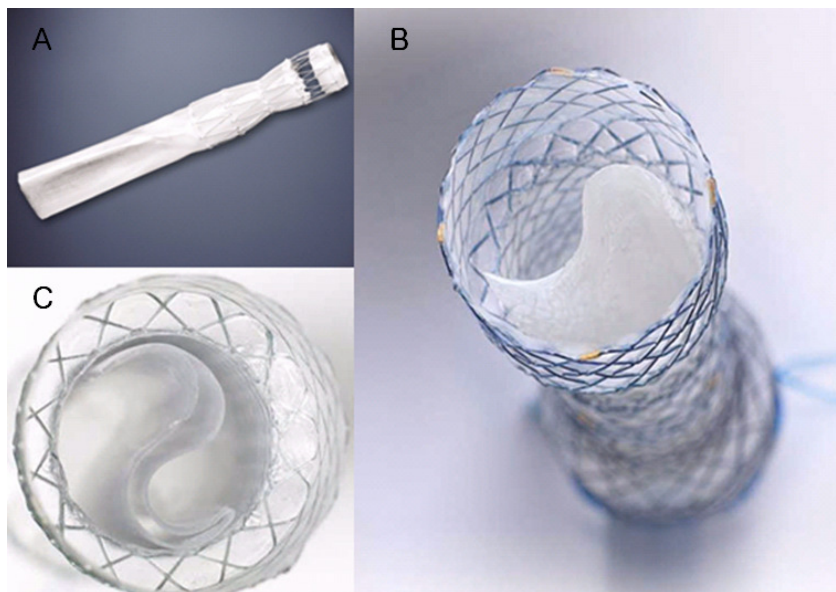


Figure 2 Stents with anti-reflux valves. **A** The Dua Z stent with a long ‘windsock’ type valve, **B** the anti-reflux Choo stent with a S-type anti-reflux valve, **C** the BONASTENT with a long flexible and stable S-type anti-reflux valve.

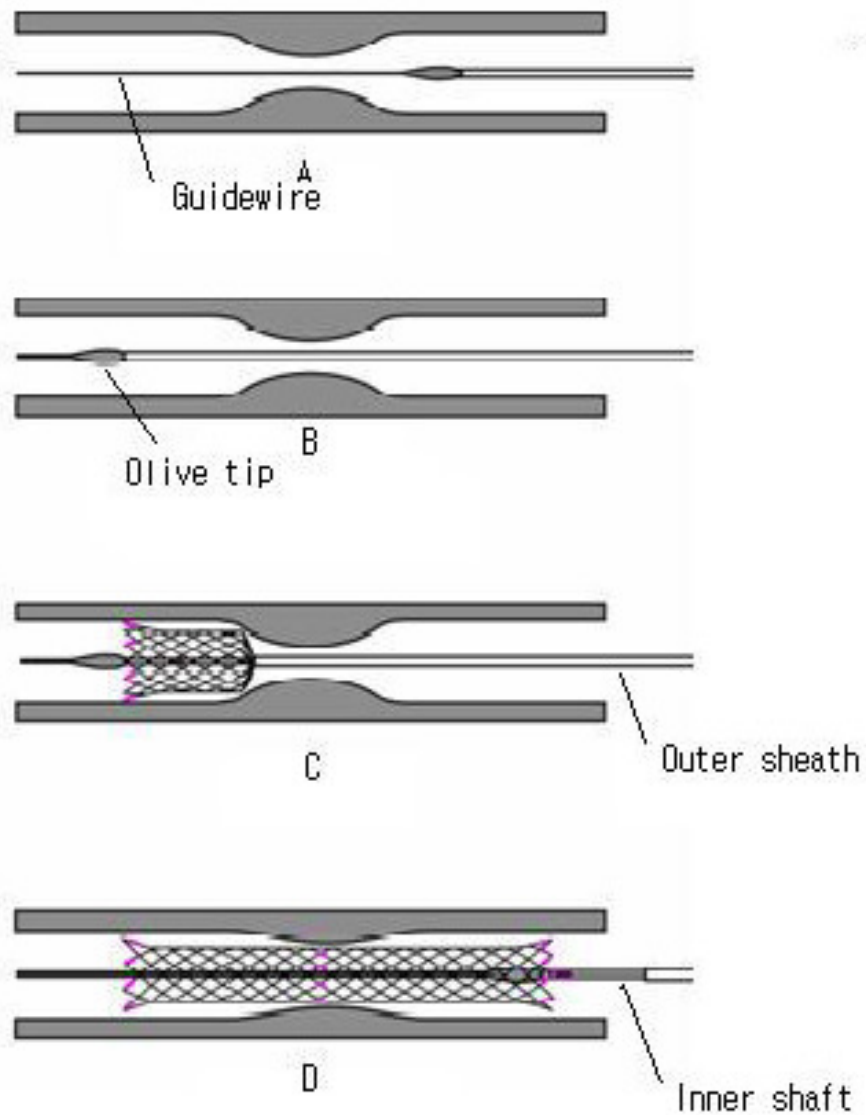


Figure 3 Stent deployment. **A** The delivery device is pre-mounted over the guide wire. **B** The end of the stent is placed at least 2 cm below the distal margin of the tumor. **C** As the outer sheath is retracted, the stent slowly expands. **D** Once the stent is fully deployed, the guide wire and delivery device are removed,.



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OMED “How I Do It”

Expandable esophageal stents

“HOW I DO IT”

Expandable Esophageal Stents

Comment

Jean-Francois Rey

Self-expanding metal stents (SEMSs) are a major step in esophageal stenting. We have come a long way from the Celestin tube which, although very useful, is rather difficult to insert (having a 10% complication rate in the 1970s). Professor Shim's contribution is an excellent reminder of the new possibilities.

Our practice in Europe is somewhat similar to the Korean experience except that it has been delayed by the slower development of fully covered metallic stents; for many years only partially covered metallic stents were available. Today we have a choice between completely covered metallic stents and Ultraflex devices where the last 2 cm at both ends are not covered. For most malignancies we are still using Ultraflex stents, as we think they embed more firmly and the risk of migration is lower.

We mostly use the fully covered Korean stent in the case of indications arising from benign stricture or fistula after gastric bypass. This latter indication will become more common with the development of this surgery. Thanks to the improvement in technique, there is now no real contraindication and we are able to stent even when only a limited space from the upper esophageal margin is available.

From the technical point of view, we rely only on endoscopic esophageal examination and the use of propofol sedation. In our own practice we have never used pre-stenting dilation in order to decrease migration, and we mark distal and proximal margins of the tumor with clips. Delivery of the stent is monitored fluoroscopically with direct endoscopic confirmation of the upper limit.

Patients are monitored the following day with endoscopy in order to verify correct positioning and the full deployment of the stent. In the case of benign fistula or benign stricture, the stent is removed after 3 months.

In summary, the use of SEMSs improves the endoscopic possibilities for esophageal treatment.



OMED “How I Do It”

Expandable esophageal stents

“HOW I DO IT”

Expandable Esophageal Stents

Summary

Douglas O. Faigel

Expandable esophageal stents provide the quickest and most reliable nonsurgical palliation of dysphagia from malignancy. Dr. Shim in his article does an excellent job of describing the current technology and the technique for stent insertion. He also gives us a glimpse of the future in his description of several new stents that are not yet widely available.

Dr. Rey provides additional insight in his comments. Similarly to Dr. Rey, it has been my practice not to perform a pre-dilation, to mark the stricture with metallic clips, and to use primarily the Ultraflex stent (Boston Scientific, USA).

While most authors use fluoroscopy, nonfluoroscopic monitoring during stent placement has been described by Dr. Todd Baron at the Mayo Clinic. In this technique, the proximal release Ultraflex stent is used and an endoscope is passed next to the insertion catheter. Using only endoscopic visualization, the proximal end of the stent is positioned above the stricture and continuously observed during deployment of the proximal release Ultraflex stent. Since only the proximal edge of the stent can be monitored, precise tumor measurements are required to select a stent of proper length and thus ensure adequate coverage of the stricture.

While palliation of malignant strictures accounts for the vast majority of stent placements, their use in benign strictures, previously considered a contraindication, has gained increasing acceptance. This has largely been due to the availability of an expandable plastic stent, the Polyflex stent (Boston Scientific), which has enhanced removability. This stent is approved by the US Food and Drug Administration for treatment of benign and malignant strictures as well as for its removability. The long-term efficacy of this stent for treatment of benign strictures has not been determined.

I thank Drs. Shim and Rey for their excellent articles and for their contributions to the field.



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Expandable esophageal stents