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Review

Polyflex stents for malignant esophageal strictures: An overview

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SUMMARY

Self-expandable metallic stent (SEMS) placement has been widely accepted to be a safe and effective option for palliation of the symptoms caused by malignant esophageal strictures and for occlusion of malignant esophago-respiratory fistulae. Covered stents, preventing ingrowth of tumor through the metal mesh, are now the most commonly used metal stents in patients with esophageal cancer; however, they are more likely to migrate than bare metal stents. New devices with various modifications in size, flares and material have been designed to overcome the unwanted sequela of stent placement. Self-expandable plastic stents (SEPS) have been developed to overcome tissue ingrowth, there to offering lower costs, increased levels of radial expansion and the possibility of stent repositioning/removal. This article reviews current knowledge regarding the commercialised type of SEPS, the Polyflex stent (Boston Scientific, USA), including description, placement technique, and complications. Literature in the area of SEPS for malignant strictures, along with an overview of Polyflex series for malignant strictures is also discussed.

Key words: Malignant esophageal strictures, esophagus, malignant, stents, strictures, Polyflex

INTRODUCTION

Despite recent advances in the curative treatment of esophageal cancer, 50% to 60% of patients have incurable disease at presentation. Thus, emphasis has been given to offering an acceptable quality of life during the limited survival period by achieving palliation of dysphagia, maintenance of nutrition, and closure of tracheoesophageal fistulas[1]. Self-expandable metallic stent (SEMS) placement has been widely accepted to be a safe and effective option for palliation of the symptoms caused by malignant esophageal strictures, especially as an alternative to conventional plastic endoprostheses or endoscopic laser therapy.[1, 2]

The first devices used for esophageal stenting for malignant strictures have been rigid plastic tubes. These prostheses were placed fully deployed within specially designed introducers, which also allowed repositioning and removal in selected cases. SEMS, both uncovered and covered, offer a similar survival rate and are associated with fewer (procedure-related) complications, such as bleeding and perforation,[3] than the previously used nonexpanding stents. Currently, endoscopic placement of SEMS is the quickest method for palliation of dysphagia for patients with inoperable and/or unresectable malignant esophageal strictures, for occlusion of malignant esophago-respiratory fistulae and also for recurrent malignant strictures after esophago-gastric resection.[2,4,5]

Covered stents are now the most commonly used metal stents in patients with esophageal cancer. The cover prevents ingrowth of tumor through the metal mesh, which occurs in more than 25% of patients with an uncovered stent in the esophagus.[6] However, covered metal stents are more likely to migrate than bare metal stents. New devices with various modifications in size, flares and material have been designed to overcome the unwanted sequela of stent placement. While expert and ordinary practitioners have broad or specific preferences, there is insufficient evidence to allow one particular SEMS manufacturer, design, or configuration to claim superiority, being equally effective in relieving symptoms and having similar complication rates.[7] During the last decade, self-expandable plastic stents (SEPS) have been developed to overcome SEMS

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drawbacks such as tissue ingrowth and new stricture formation whereas offering lower costs. However, the problem of neoplastic or non-neoplastic tissue overgrowth in the stent edges remains.[8] SEPS offer increased levels of radial expansion that potentially decrease the need for dilation at the time of insertion, and the possibility of stent repositioning and elective removal.[9-12]

This article reviews current knowledge regarding SEPS, including placement technique, description of the commercialised Polyflex stent *(Boston Scientific, USA)* and complications. Literature in the area of SEPS for malignant strictures is also discussed.

The Polyflex stent (Boston Scientific, USA)

The Polyflex stent is a silicone device with an encapsulated monofilament braid made of polyester. The meshes are completely covered by a silicone layer with a smooth inner surface (protecting against incrustation) and a more structured outer surface (opposing migration). The edges of the monofilaments are protected with silicone to avoid impaction and/or tissue damage at the proximal and distal ends. The proximal end is slightly flared, whereas the middle and distal portions of the stent have the same diameter. Specifically, luminal diameters of 16, 18, and 21 mm are available with proximal flare diameters of 20, 23, and 25 mm, respectively. The stent is available in three stent lengths: 9, 12 and 15 cm, and each one is available in all three diameters (figure 1). Radiopaque markers are located at the proximal end, midpoint, and distal end of the stent to aid in positioning at the time of deployment. This stent has a high malleability permitting an easy and atraumatic repositioning or removal, but also a sufficient radial force to restore luminal patency and remain anchored firmly to the tumour. Furthermore, it has the advantage that, currently, its purchase cost is approximately 50% lower than that of metal stents.

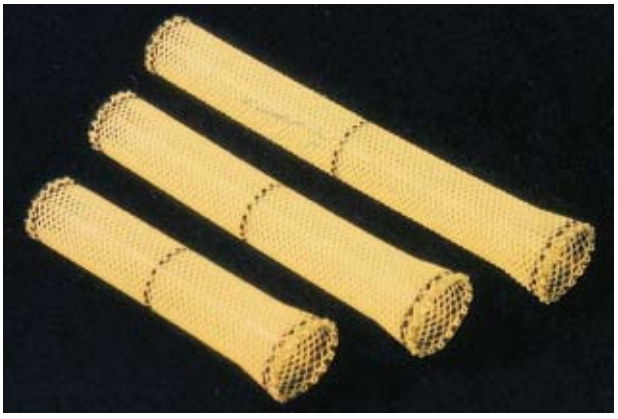

Figure 1. The Polyflex stent. The stent comes in 3 sizes: 9 cm, 12 cm, and 15 cm. Luminal diameters of 16, 18, and 21 mm are available with proximal flare diameters of 20, 23, and 25 mm, respectively. Radiopaque markers are located at the proximal end, midpoint, and distal end of the stent to aid in positioning at the time of deployment.

Polyflex Stent placement technique

Although some centres offer the possibility of general anaesthesia or deep sedation with the use of propofol iv, SEPS are usually placed under conscious sedation with midazolam iv. The pharynx is anesthetized with 2% viscous or a 15% spray lidocaine solution. Oxygen should be administered via a nasal cannula, and the patient's vital signs continuously monitored during the procedure. If it proves impossible to pass the tumor with an endoscope, the stricture could be dilated to a maximum of 12 mm by a Savary-Miller esophageal Dilator or a through-the-scope progressive dilation balloon. Then, the upper and lower tumor margins are marked with sclerotherapy needle–injected radiographic contrast material. The stents are advanced over a guidewire into the esophagus. Stents are usually deployed under fluoroscopic monitoring; however, in some instances, stent deployment under endoscopic view only has been reported.[13-15] The choice of the stent size depends on the length of the stricture. A stent 2 to 4 cm longer than the stricture should be chosen to allow for a 1- to 2-cm extension above and below the proximal and distal tumor shoulder. Depending on the radial force of the selected prothesis, the stent slowly expands to its full diameter over hours or days.[16]

Polyflex stents need to be loaded prior to insertion into a delivery device of a rather large diameter (36–42F vs. 16–28F of SEMS) and high rigidity, and a short nonflexible conic tip at the distal end. Assembling the delivery device can sometimes be difficult in less well trained centres with low volume of cases. These features increase the difficulty of SEPS placement. The rigidity of the system requires to hyperextend the patient's neck, to use stiff guidewires and may increase the risk of perforation, particularly in angulated strictures or tumour location in the proximal oesophagus (figure 2). This has been demonstrated in a recent prospective randomized trial; although dysphagia relief was achieved with all three types of stents (the Ultraflex, the Niti-S and the Polyflex), technical problems during stent placement were more frequently observed with Polyflex stents than with the other two stents.[17] The retraction rate is 18% of the stent length before deployment. In this series, Polyflex stents were positioned too proximally or too distally in seven patients. The authors considered that this was caused by uncontrollable stent deployment at its final stage, when the last 20–40% of the

Figure 2. The Polyflex stent ready for insertion. The diameter of the completed stent assembly is 12 mm, and it can be introduced over a guidewire into the stenosis. From: Bethge N, Vakil N. A prospective trial of a new self-expanding plastic stent for malignant esophageal obstruction. Am J Gastroenterol 2001;96:1350-4.

stent is released from the introduction catheter. At that stage, the stent tends to jump in an unpredictable way from the sheath.[18,19] However, repositioning was possible in 8/9 patients.[17] Indeed, stents can be repositioned with a ''rat tooth'' forceps if required.

Another technical issue with the Polyflex stents is the large calibre of the introduction catheter. The applicator, in which the stent is loaded prior to stent placement, has a diameter of 13 mm and, as already mentioned, is rather rigid. An aggressive preplacement stricture dilation, associated with a risk of oesophageal perforation in 8–13% of cases and bleeding or fistula formation in 5–10%, respectively,[9,20] may be required. In the series reported by Costamagna et al, the placement of SEPS was not possible in 25% of cases because of failure to pass the delivery device through the stricture despite a 14 mm mechanical dilation. In one case, a failure of the stent to open despite correct deployment was noted.[12] Szegedi et al[21] reported Polyflex placement in 69 patients with advanced oesophageal cancer. Mechanical dilation was necessary to pass the delivery catheter in 47% of the cases, but technically failed in three cases out of the seven proximal malignant strictures. Table 1 summarizes data from studies reporting safety, dysphagia relief, technical success and complication rates of Polyflex stents for malignant obstructing esophagogastric strictures published in the literature since Polyflex stents commercialization.

Complications

SEPS placement, similarly to all interventional endoscopic procedures and specifically to SEMS placement, has been related to minor and major complications. Some of the complications associated with SEMS are chest pain, bleeding, perforation, fistula formation, aspiration, and severe gastroesophageal reflux. Despite correct stent placement and achievement of palliation, dysphagia can recur as a result of tumor overgrowth or ingrowth, migration, food bolus impaction, and device malfunction/malposition. In a recent study, major complications were noted in 37% of patients, requiring a total of 46 repeat endoscopic procedures (10 additional stent placements for stent occlusion and persistent/new fistula).[22] Similar rates were reported by Siersema et al[7] in a prospective randomized study comparing 3 types of SEMS. In the 2004 report of ROST[23] on 415 patients, early complications were noted in 14% of patients with a 0.2% post-procedural mortality rate. Late complications were observed in 37.9% of patients, emphasizing the fact that these patients require close monitoring. In a previous study by Homs et al,[24] of the 216 patients with SEMS, 63 (29%) had 74 episodes of stent-related recurrent dysphagia resulting from overgrowth, migration, and food bolus obstruction. This occurred at median 129, 92, and 80 days after stent insertion, respectively. Therefore, complications and poor durability of palliation are significant drawbacks in stent placement.

Stent migration has been reported to occur in up to 28% of patients treated with a covered SEMS.[3,4,7,24-27] Migration is more likely to occur with stents placed across the gastroesophageal junction than with those placed for tumors more proximal in the esophagus. This is probably because the distal part of the stent projects freely into the fundus of the stomach and is thus unable to fix itself to the esophageal wall[6]. Fully covered SEMS do not incorporate into tissue[28] and may be removable, being also useful for benign disease; however, in these cases, migration remains an unsolved issue. Specifically for the Polyflex stent, some series reported migration as the second most common overall complication occurring in 30% of patients[29] raising serious concerns. In a recent randomized prospective trial, recurrent dysphagia due to stent migration was less frequently seen with the Niti-S stent (12%) compared to Ultraflex stents (17%) and Polyflex stents (29%)[17] (figure 3). In another study, a 15% migration rate was observed for SEPS at the oesophago-gastric junction, although the stent was routinely fixed to the mucosa with an endoclip. Stent migration is still a frequently occurring problem, particularly for distally located tumors.[6] This is an indication which is marginal with SEPS whose risk of migration is very high for the tumors involving the lower part of the oesophagus and which should be avoided for this specific indication. In a study by Dormann et al[18], migration was observed in only 6% (2/33) of patients with

Table 1. Published series reporting SEPS (Polyflex) safety, efficacy and complications in malignant obstruction of the esophagus/EGJ.

Study/ Journal/ Year	Type of study	No of patients	indication	Mean length of strictures ±SD (cm)	Technical success	Previous dilation N (%)	Dysphagia relief (%) Day 30	Dysphagia score Pre-	Dysphagia score Post-	Overall survival Mean ± SD (d)	Migration N (%)	Overgrowth and Ingrowth N (%)	Haemorrhage N (%)	Perforation N (%)	"Minor" Complications N (%)	General remarks
Verschuur AmJG 2008	Prospective Randomized Multicenter Vs Ultraflex Vs Niti-S	41	Dysphagia due to inoperable esophageal/gastric cancer Or recurrence of dysphagia	7.5 ± 2	34/41(83)	5/41(12)	-	Median 3(0)	Median (d30) 1(2)	102 (still 6 pts alive when the study completed)	12/41(29)	4/41(10)	0/34 (0)	2/34 (5.9)	Pain=2/34 (5.9) Reflux=1/34 (2.9)	
Conio AmJG 2007	Prospective Randomized Multicenter Vs SEMS(Ultraflex)	47	Dysphagia due to inoperable esophageal cancer	5 (range 3–11)	46/ 47 (98)	34 (72..3)	91	Mean ± SD 2.8±0.6	Mean ± SD (d30) 1.2 ± 1.0	134 (range 100–168)	6/46 (13.04)	14/46 (30.4)	2/46 (4.35)	1/46 (2.17)	Pain= 20/46 (43.5) Reflux= 2/46 (4.35)	Cancer of EGJ not included
Conigliaro EJGH 2007	Prospective case series	60	Dysphagia due to inoperable esophageal cancer	-	59/60 (98.3)	41 (69.5)	86	Mean ± SD 2.8± 0.8	Mean ± SD (d30) 1.0	Median 4.6 months	12/59 (20.4)	9/59 (15.3)	4/59 (6.8)	0/59 (0)	Pain= 11/59 (18.6) 0ther= 8/59 (13.6)	
Ott Surg End 2007	Retrospective case series	23	Malignant strictures	5.5±2.77	23/23 (100)	8/23 (34.8)	95.6(immediate post stenting)	Median (range) 3.0(1-4)	Median (range) (d30) 1.0(0-3)	Median 50 (range 11–264	9/23 (39.1%)	0/23 (0)	0/23 (0)	1/23 (4.34)	-	1/23 patients benign stricture due to lye ingestion
Szegedi EJGH 2006	Prospective case series	69	Dysphagia due to inoperable esophageal cancer	6.6 (range 4.0–11.5)	66/69 (95.6)	31/66 (46.7)	100	Mean (range) 3.5(3-4)	Mean (range) (d30) 1.3 (1–2)	129 (range 40–312)	3/66(4.5)	9/66 (13)	0/66 (0)	0/66 (0)	Pain= 27/66 (40.9)	EGJ tumors anchored by clipping.
Siddiqui Dig Dis Sci 2006	Prospective case series	6	Relief of dysphagia prior RCT/operation	6.67 (range1-17)	5/6 (83)	1/5 (20)	100	Mean (range) 3.4 (3-4)	Mean (d30) 1.4	Mean follow up 48d	1/5 (20)	0/5 (0)	0/5 (0)	0/5 (0)	-	
Dormann, Endoscopy 2003	Prospective case series	33	Dysphagia due to inoperable esophageal cancer	6.5 (range 2–14)	33/33 (100)	5/33 (15.16)	100	Mean (range) 3.4 (3–4)	Mean (range) D5= 1.3 (0–4) D30=0.9 (0–4)	149.5 (range 25–469)	2/33 (6.0)	4/33 (12.13)	0/33 (0)	0/33 (0)	-	Technical problems in 3 pts: 2 stent foldings, I incorrect loading
Costamagna Surg Endosc 2003	Prospective case series	16	Palliation of dysphagia due to malignant esophageal/EGJ strictures	4.6 ± 2.1 (range 1–9)	12/16 (75)	10/12 (83.3)	100 (data in 10 pts after 7d)	Mean ± SD 3.31 ± 0.6	Mean ± SD (7d) 1.1 ± 0.9	100.6 ± 71.2 (range 8–225)	3/12 (25)	1/12 (8.3)	1/12 (8.3)	0/12 (0)	Pain= 3/12 (25)	2 deaths in the first 15 d, 2 pts with benign strictures
Bethge & Vakil AmJG 2001	Prospective case series	8	Palliation of malignant esophageal obstruction	5.7 ± 0.7 (range 4–9)	8/8 (100)	Yes but rate not reported	87.5(immediate post stenting)	Mean ± SD 3± 0.5	Mean ± SD (immediate post stenting) 1.1± 0.12	87±28	1/8 (12.5)	0/8 (0)	0/8 (0)	0/8 (0)	-	1 pt with prior RT developed a esophagotracheal fistula
Decker Surg Endosc 2001	Prospective case series	14	Palliation of malignant esophageal obstruction	-	14/14 (100)	Yes but rate not reported	not reported	Mean 3.0	Mean (immediate post stenting) 0.5	6.2 months (range, 3 days–25 months)	1/14 (7.1%)	0/14 (0)	0/14 (0)	0/14 (0)	Not reported	

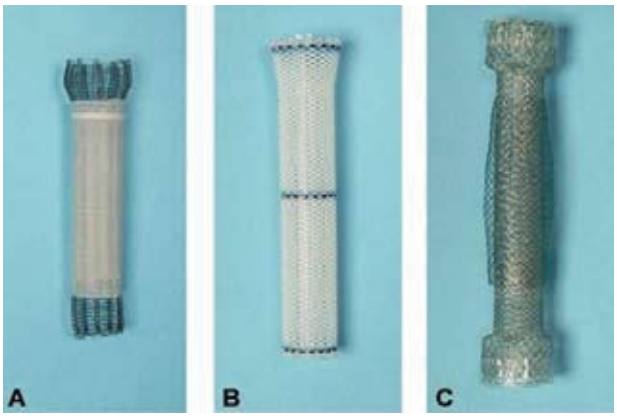

Figure 3. The 3 types of stents: Ultraflex stent (A), Polyflex stent (B), and Niti-S stent (C). From: Verschuur EM, Repici A, Kuipers EJ, Steyerberg EW, Siersema PD. New design esophageal stents for the palliation of dysphagia from esophageal or gastric cardia cancer: a randomized trial. Am J Gastroenterol 2008;103:304-12.

malignant dysphagia. In contrast, in a study from Rome and another one from Rotterdam, comparable migration rates of 25% and 29% were reported.[12,17] Even so, the relatively high migration rate of the Polyflex stent is not surprising, because the Polyflex stent is completely covered by a relatively smooth silicone membrane.[17]

However, Polyflex stents offer the advantage of withdrawal if necessary, although this is not commonly an option for malignant strictures. Stent removal can be accomplished by one of two methods. With the use of ''shark's tooth'' forceps, the edge of the proximal flange is grasped, which then becomes elliptical with traction. With additional gentle traction, the stent separates from the esophageal wall, allowing removal with the expectation of the greatest resistance being encountered at the upper esophageal sphincter. The other method involves pulling the stent over a dilator placed into the proximal esophagus with a ''shark's tooth'' forceps and simultaneously removing both.[29] Based on these advantages of repositioning and removability, Polyflex stents have been inserted before neoadjuvant chemoradiotherapy to maintain oral nutrition and avoid the need for gastrostomy[30, 31]. After neoadjuvant therapy completion, the Polyflex stents could be removed immediately prior to or at the time of esophagectomy. In these series, restoration of oral nutrition after stent placement occurred in 100 % patients. Migration of the stent into the stomach occurred in about half the patients without occurrence of gastric outlet obstruction; in this case, migration should probably be considered a result of tumor shrinkage due to neoadjuvant therapy. No proximal migration was reported. Stents were successfully removed endoscopically or at the time of esophagectomy. When these stents were used for refractory anastomotic strictures a 100% migration rate was documented[10]. In addition, these stents tend to migrate when positioned across the esophagogastric junction (EGJ).[29] SEPS have also been used to seal esophagotracheal fistulas but high rates of migration remained a drawback. On the other hand, SEMS have been demonstrated to effectively seal fistulas, but they cannot be removed. To overcome this problem, recently a new technique of SEPS through SEMS has been reported[32]. The SEPS causes necrosis in the hyperplastic tissue and makes removal of both SEMS and SEPS easier. Currently, there is no technique agreed upon to reduce Polyflex stent migration. However, precise placement and full initial deployment are important. The use of clips may be indicated when stents are placed in areas with an increased probability of movement, such as the EGJ and anastomotic strictures, although this has not been proved.[29]

Malfunction of stents is mainly related to ingrowth and overgrowth in 17–30 and 9%, respectively.[33] Tissue overgrowth may be caused by non-malignant hyperplastic tissue growth at the end of a stent or by tumor overgrowth. It has been demonstrated that tissue overgrowth from nonmalignant obstructive tissue is more likely to occur in patients with a prolonged survival. In patients with a prolonged survival, the use of covered SEMS permits to significantly reduce the incidence of ingrowth (3%) and the need for additional endoscopic intervention to restore patency. This is why uncovered SEMS should be avoided in cases of benign strictures, the most common cause of recurrent dysphagia in this group of patients being probably still overgrowth.[34] In this context, different kinds of stents were designed to prevent tumor overgrowth and in the same time minimize stent migration. The Polyflex stent has been expected to prevent tumor overgrowth since it does not integrate into the esophageal wall. However, this unexpectedly occurred in equal numbers for SEPS and SEMS patients in one study.[8]

CONCLUSIONS

In the modern era, SEMS have been proven an efficient minimally invasive method with acceptable complications to alleviate dysphagia. Although, most types of stents offer the same degree of dysphagia palliation, to make the optimal choice, it is important to remember that all strictures are not made alike and that one size or shape does not fit all. The more recently developed SEPS offer some advantages (i.e lower cost, allow repositioning, removable); however, they also present some drawbacks such as higher migration rates. Parameters like tumor location, stricture rigidity, possible airway obstruction, coexistence

of thacheoesophageal fistula and overall survival expectancy should be taken under consideration before the optimal stent for each patient is selected.

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