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QUALITY IMPROVEMENT GUIDELINES FOR PLACEMENT OF OESOPHAGEAL STENTS

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Introduction

Oesophageal cancer is now the sixth leading cause of death from cancer worldwide[1,2]. During the past three decades, important changes have occurred in the epidemiological patterns associated with this disease[1]. Due to the oesophagus distensible characteristics, patients may not recognise any symptoms until 50% of the luminal diameter is compromised, explaining why cancer of the oesophagus is generally associated with late presentation and poor prognosis[3]. Oesophageal cancer has a poor outcome, with an overall 5-year survival rate of less than 10%, and fewer than 50% of patients are suitable for resection at presentation. As a result, palliation is the best option for this group of patients[3,4]. The aims of palliation are maintenance of oral intake, minimising hospital stay, relief of pain, elimination of reflux and regurgitation, and prevention of aspiration[3,5,6]. For palliative care, current treatment options include thermal ablation[7,8,9], photodynamic therapy[10,11,12], radiotherapy[13], chemotherapy[14,15], chemical injection therapy[16,17,18], argon beam or bipolar electrocoagulation therapy[19], enteral feeding (nasogastric tube / percutaneous endoscopic gastrostomy) [20,21,22] and intubation (Self Expanding Metal Stents 'SEMS' or semi-rigid prosthetic tubes) [5,6,23-26] with different success and complications rates.

Endoluminal oesophageal prostheses have been in use for over one century. Different tubes of the pulsion and traction variety have been described. Leroy d'Etiolles made the earliest device in 1845 of decalcified ivory, followed by Charters J. Symonds in 1885 who introduce the first metal oesophageal prosthesis[27]. Nowadays, oesophageal stenting is the commonest means of palliation and can be achieved by insertion of either rigid plastic tubes or SEMS, the latter introduced in the 1990s, with high success rates and minimum complications.

These guidelines are written to be used in quality improvement programmes to assess fluoroscopy-guided placement of self-expanding metallic oesophageal stents (SEMS). The most important processes of care are selecting the patients, performing the procedure, and monitoring the patient. The outcome measures or indicators for these processes are indications, success rates and complication rates.

Definition

Oesophageal stenting or oesophageal intubation is defined as a placement of a stent into a diseased (stenotic) oesophagus[4,6]. All metallic stents used in the oesophagus are self-expanding. No balloon-expandable endoprostheses are dedicated for use in the oesophagus[5,6].

Indications (Table 1)

- Malignant oesophageal obstruction[5,26,28-31]
- Tracheo-oesophageal fistulae[32,33]
- Primary or secondary tumours within the mediastinum causing extrinsic oesophageal compression[34]
- Oesophageal perforation, usually iatrogenic, from direct endoscopic trauma or following stricture dilatation[26,28,35,36]
- Treatment of symptomatic malignant gastro-oesophageal anastomotic leaks[37]
- Anastomotic tumour recurrence following surgery[6]
- Benign oesophageal strictures refractory to balloon dilatation[38] and not suitable for surgery

Contraindications

There are no absolute contraindications for oesophageal stent placement.

Relative:

- Because haemorrhage and perforation have to be considered, it is suggested to have a normal coagulation profile in order to minimise them (INR > 1.5 and platelets <50.000).
- Recent high dose of Chemo / Radiotherapy (3 – 6 weeks) because of increased haemorrhage and perforation rates reported[39,40].
- Severely ill patients with limited life expectancy.
- Obstructive lesion of the stomach and/or of the small bowel due to peritoneal seeding.
- Severe tracheal compression that would be made worse by oesophageal intubation.
- Extremely high stenoses, close to the vocal cords.

Current Stents and Stent Selection

There are several types of devices available such as: the oesophageal Wallstent (Boston Scientific, Natick, Massachusetts)[7,41-43], the Ultraflex stent (Boston Scientific) [7,28,44,45], the Gianturco-Rösch Z stent with or without anti-reflux distal valve (William Cook Europe, Bjaeverskov, Denmark)[29,46-48], the EsophaCoil (IntraTherapeutics, St Paul, Minesota)[49,50], the Flamingo stent (Boston Scientific)[49], the FerX-Ella stent with anti-reflux distal valve (Radiologic Ltd)[51], the Choo stent (Diagmed)[52], the Memotherm (C.R. Bard)[43], the Song stent (Sooho Medi-tech, Korea)[53,54], and the Polyflex oesophageal stent (Rusch®)[55,56].

In the past, it was recommended to use an uncovered stent at the cardia to reduce the risk of distal migration[26,28]. However, covered stents should be used whenever possible, avoiding tumor ingrowth possibilities[29-31]. Now, with the improved design of covered stents like proximal flaring, partly uncovered portions and covering material on the inside, covered stents should be the first choice in the palliation of oesophageal strictures[57-59]. Covered oesophageal stents should also be used in the palliation of tracheo-oesophageal and broncho-oesophageal fistulae and leaks secondary to oesophageal perforation[60,61]. Uncovered stents could be reserved for placement when there is extrinsic compression, hugely dilated oesophagus or with gastric pull-up and in refractory benign strictures. In a markedly dilated oesophagus, the use of an uncovered stent minimises firstly, the entrapment of fluid/semi solid food residue between the stent and the oesophageal wall and secondly, reduces the risk of migration.

In the upper oesophagus, the covered Ultraflex stent (more flexible and less radial force) is recommended, reducing the risk of pain associated with the use of the stiffer devices[5].

In the management of refractory benign strictures of the oesophagus, stent usage should be carefully considered. The retrievable design stents (Choo, Song and Ella) would be more appropriate choices. However, with the recent availability of the new self-expanding retrievable plastic stent (Polyflex) and the promising early results[38], this plastic stent will offer more advantages.

Furthermore, in patients with oesophageal cancer and significant dysphagia, who are suitable for surgery, but need nutrition and weight gain prior to, or in whom downstaging the tumour by chemo / radiation therapy is required, the placement of this self expanding plastic stent would be greatly beneficial and least traumatic than the traditional methods.

Technique of Stent Insertion

Stents are inserted using radiological guidance with light sedation in the interventional suite. After an oesophagogram has been obtained to delineate the site and length of the stricture, the patient is placed in the left lateral position on a fluoroscopy table. The pharynx is anesthetised with lidocaine spray, and the catheter is passed perorally into the oesophagus. The location of the tumour is defined by contrast medium injected above and below the stricture and by anatomic landmarks. The stricture is crossed with a variety of angle-tip catheters and standard or hydrophilic guide-wires. A 180 or 260 cm long stiff guidewire is looped in the stomach or advanced into the proximal duodenum. The stricture may be predilated to 15 mm and although this is not uniformly done, the predilation helps to facilitate introduction of the delivery system, allows rapid expansion of the stent and enabled more accurate placement. A stent of appropriate size and length is advanced across the stricture on its delivery system, and to prevent migration, it is deployed in such a way that slightly more of the stent is above the stricture than below it. The length of the stent is chosen so that at least 2 cm of normal oesophagus is covered by the stent above and below the stricture. Long strictures may require more than one stent with 1/3 overlap between the stents. After stent deployment, contrast medium is injected to confirm correct stent position and exclude complications such as perforation[5,23]. A further oesophagogram the next day is recommended in order to show that the stent has adequately expanded and is in a satisfactory position.

After Care

Following successful stent placement and no immediate complications, patients are allowed to start oral fluids and then progress to initiate a low-residue diet and to progress to more solid food gradually. However, large lumps of food should be avoided and it is recommended to have free intake of liquid (particularly carbonated drinks) during the day and especially with each meal[5]. An anti acid, preferably proton pump inhibitors (Omeprazole), is recommended for all patients who develop reflux after the stent deployment. Anti acids may also empirically be given whenever a non-valve stent is placed across the oesophagogastric junction.

Success Rates

The technical success rates of stent placement under fluoroscopy guidance are close to 100%. The results of stenting are expressed by means of a dysphagia score with five grades: grade 0, normal diet; grade 1, some solid food; grade 2, semisolids only; grade 3, liquids only; grade 4, complete dysphagia. Dysphagia is relieved in most patients, with an improvement in the dysphagia score of at least one grade noted in 92 to 98% of patients[5,6,26,28-31]. Although most patients die in the next 4 months after stent placement, their quality of life improves for a while[23].

In the palliation of malignant oesophago-respiratory fistulae and perforations, covered metallic stents have a clinical success rate of 95-100%[60,61].

Initial clinical success in the use of metallic stents in the treatment of benign strictures resistant to balloon dilatation is close to 100%. However, there is also an approximate 100% rate of recurrent dysphagia in these patients due to occlusive tissue hyperplasia[5]. The rationale behind metallic stenting in this very minor group of patients is that stenting relieves the initial symptoms immediately and recurrent dysphagia is easily amenable to subsequent balloon dilatation or laser therapy. That is why stenting in these conditions should be reserved as a last resort.

Complications (Table 2)

Procedural
The procedural complications are: perforation, aspiration, haemorrhage, stent migration and pain.

Post-procedural
Post-procedural complications include: perforation, haemorrhage, stent migration, pain/sensation of a foreign body, tumour ingrowth/overgrowth, stent occlusion due to a bolus of food, reflux, oesophagitis, mucous membrane ulceration, fever, fistulae development and sepsis.

However, procedure-related complications are lower in patients treated with metallic stents compared with the rigid plastic endoprosthesis. The major complications of stenting include haemorrhage, fistula, perforation, severe pain, migration, and ingrowth/overgrowth. Haemorrhage has been reported in between 3 and 8%, although it is usually mild and self-limiting[26,28-31,35]. In rare cases of severe haemorrhage, angiography with embolisation of the bleeding vessel with gelfoam or coils can be undertaken. Fistulae and perforation attributable to stent insertion are uncommon[36]. Pain used to be more common with rigid stents. Early chest pain occurs in up to 100% of patients, but prolonged chest pain occurs in less than 13% of patients[28]. Furthermore, chest pain is more severe in patients with high strictures and when using large diameter stents[31]. The incidence of stent migration for uncovered stent is low (0 - 3%), increasing up to 6% for stents placed at the cardia[7,26]. The migration rate using covered stents, especially when positioned across the cardia, has been reported to be between 25% and 32%[26,28,59]. Partially migrated stents are treated by coaxially inserting another stent, which overlaps the upper half of the migrated stent. If there is complete migration of the stent, the lesion is treated by insertion of a new stent. The asymptomatic migrated stent in the stomach can be left as it is, but if symptomatic, it can be removed via a gastrostomy, surgical incision or endoscopy[62]. Tumour ingrowth with uncovered stents is reported from 17 to 36%[28,30], and very rare with covered stents[7,26,44]. Recurrent dysphagia as a result of tumour overgrowth has been reported in up to 60% of the patients followed up for long enough[63]. However, many of the stents used were uncovered in this study. Tumour ingrowth or overgrowth can be treated by coaxial stenting. In cases of recurrent dysphagia due to benign epithelial hyperplasia or granulation tissue, symptomatic relief can be obtained either by laser coagulation, photodynamic therapy, argon beam treatment, alcohol injection or restenting. Finally, metallic stent insertion has a very low procedural mortality rate, between 0 and 1.4%[26,28-31,35].

TABLES

TABLE 1 - Indications for placement of oesophageal stents

- Malignant oesophageal obstruction
- Tracheo-oesophageal fistulae
- Primary or secondary tumours within the mediastinum causing extrinsic oesophageal compression
- Oesophageal perforation
- Treatment of symptomatic malignant gastro-oesophageal anastomotic leaks
- Anastomotic tumour recurrence following surgery
- Benign oesophageal strictures refractory to balloon dilatation and not suitable for surgery

TABLE 2 - Frequency of major complications associated with oesophageal stents

Complication		Frequency
Haemorrhage		3 – 8 %
Prolonged chest pain		14 %
Migration	(uncovered stent)	0 – 6 %
	(covered stent)	25 – 32 %
Tumour ingrowth	(uncovered stent)	17 – 36 %
	(covered stent)	Negligible
Fistula		Uncommon
Perforation		Uncommon
Death		0 – 1.4 %

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