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CIRSE GUIDELINES

Quality Improvement Guidelines for Placement of Esophageal Stents

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Esophageal 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 epidemiologic patterns associated with this disease [1]. Due to the distensible characteristics of the esophagus, patients may not recognize any symptoms until 50% of the luminal diameter is compromised, explaining why cancer of the esophagus is generally associated with late presentation and poor prognosis [3]. Esophageal 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 in this group of patients [3, 4]. The aims of palliation are maintenance of oral intake, minimizing 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 [7–9], photodynamic therapy [10–12], radiotherapy [13], chemotherapy [14, 15], chemical injection therapy [16–18], argon beam or bipolar electrocoagulation therapy [19], enteral feeding (nasogastric tube/percutaneous endoscopic gastrostomy) [20–22], and intubation (self-expanding metal stents (SEMS) or semi-rigid prosthetic tubes) [5, 6, 23–26] with different success and complications rates.

Endoluminal esophageal prostheses have been in use for over a 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 esophageal prosthesis [27]. Nowadays, esophageal 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 programs to assess fluoroscopy-guided placement of esophageal 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.

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Definition

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

Indications (Table 1)

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

Contraindications

There are no **absolute** contraindications for esophageal stent placement. **Relative** contraindications are:

- Because hemorrhage and perforation have to be considered, it is suggested the patient should have a normal coagulation profile in order to minimize these complications (INR > 1.5 and platelets <50,000).
- Recent high dose of chemotherapy/radiotherapy (3–6 weeks) because of the increased hemorrhage and perforation rates reported [39, 40].

Table 1. Indications for placement of esophageal stents

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

- 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 esophageal intubation.
- Extremely high stenoses, close to the vocal cords.

Current Stents and Stent Selection

There are several types of devices available such as: the esophageal Wallstent (Boston Scientific, Natick, MA) [7, 41–43], the Ultraflex stent (Boston Scientific) [7, 28, 44, 45], the Gianturco-Rösch Z-stent with or without an antireflux distal valve (William Cook Europe, Bjaeverskov, Denmark) [29, 46–48], the EsophaCoil (IntraTherapeutics, St. Paul, MN) [49, 50], the Flamingo stent (Boston Scientific) [49], the FerX-Ella stent with an antireflux distal valve (Radiologic) [51], the Choo stent (Diagmed) [52], the Memotherm (C.R. Bard) [43], the Song stent (Sooho Meditech, Korea) [53, 54], and the Polyflex esophageal 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 to avoiding the possibility of tumor ingrowth [29–31]. With the improved design of covered stents currently available, such as proximal flaring, partly uncovered portions and the covering material on the inside, covered stents should be the first choice in the palliation of esophageal strictures [57–59]. Covered esophageal stents should also be used in the palliation of tracheo-esophageal and broncho-esophageal fistulae and leaks secondary to esophageal perforation [60, 61]. Uncovered stents could be reserved for placement when there is extrinsic compression, a hugely dilated esophagus or with gastric pull-up and in refractory benign strictures. In a markedly dilated esophagus, the use of an uncovered stent firstly minimizes the entrapment of fluid/semi-solid food residue between the stent and the esophageal wall, and secondly reduces the risk of migration.

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

In the management of refractory benign strictures of the esophagus, 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 stent will offer more advantages.

Furthermore, in patients with esophageal cancer and significant dysphagia who are suitable for surgery but need nutrition and weight gain prior to this, or in whom down-staging of the tumor 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 esophagogram 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 anesthetized with lidocaine spray, and the catheter is passed perorally into the esophagus. The location of the tumor 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 guidewires. 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 enables 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 esophagus is covered by the stent above and below the stricture. Long strictures may require more than one stent with one third overlap between the stents. After stent deployment, contrast medium is injected to confirm the correct stent position and exclude complications such as perforation [5, 23]. A further esophagogram the next day is recommended in order to show that the stent has adequately expanded and is in a satisfactory position.

Aftercare

Following successful stent placement and in the absence of immediate complications, patients are allowed to start oral fluids and then progress to initiation of a low-residue diet followed gradually by more solid food. 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 antacid, preferably a proton pump inhibitor (Omeprazole), is recommended in all patients who develop reflux after the stent deployment. Antacids may also empirically be given whenever a non-valve stent is placed across the esophagogastric junction.

Table 2. Frequency of major complications associated with esophageal stents

Complication	Frequency
Hemorrhage	3–8%
Prolonged chest pain	14%
Migration: uncovered stent	0–6%
Migration: covered stent	25–32%
Tumor ingrowth: uncovered stent	17–36%
Tumor ingrowth: covered stent	Negligible
Fistula	Uncommon
Perforation	Uncommon
Death	0–1.4%

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, semi-solids 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 being noted in 92–98% of patients [5, 6, 26, 28–31]. Although most patients die in the 4 months after stent placement, their quality of life improves for a while [23].

In the palliation of malignant esophago-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, hemorrhage, stent migration, and pain.

Postprocedural

Postprocedural complications include: perforation, hemorrhage, stent migration, pain/sensation of a foreign body, tumor ingrowth/overgrowth, stent occlusion due to a bolus of food, reflux, esophagitis, mucous membrane ulceration, fever, fistula development, and sepsis.

However, procedure-related complications are lower in patients treated with metallic stents compared with those with a rigid plastic endoprosthesis. The major complications of stenting include hemorrhage, fistula, perforation, severe pain, migration, and ingrowth/overgrowth. Hemorrhage has been reported in between 3% and 8% of cases, although it is usually mild and self-limiting [26, 28–31, 35]. In rare cases of severe hemorrhage, angiography with embolization 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 stents is low (0–3%), increasing up to 6% for stents placed at the cardia [7, 26]. The migration rate for 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]. Tumor ingrowth with uncovered stents is reported in 17–36% of cases [28, 30], and is very rare with covered stents [7, 26, 44]. Recurrent dysphagia as a result of tumor overgrowth has been reported in up to 60% of the patients followed up for long enough [63]. However, many of the stents used in this study were uncovered. Tumor 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 by either laser coagulation, photodynamic therapy, argon beam treatment, alcohol injection or restenting. Finally, metallic stent insertion has a very low procedural mortality rate of between 0 and 1.4% [26, 28–31, 35].

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