Expandable wallstents for treatment of tracheoesophageal fistulas of malignant origin

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Summary

\textbf{Purpose:} To present our experience with endoscopic placement of esophageal endoprosthesis with self-expandable wallstents in patients with malignant tracheoesophageal fistulas.

\textbf{Patients and methods:} 16 patients were retrospectively evaluated, in whom 16 stents were positioned at the esophagus because of tracheoesophageal fistulas: 12 of them suffered of malignant tumors of the esophagus and 4 of malignant tumors of the lung. All stents were placed with a guidewire. We used self-expandable wallstents with internal silicon-based covering with flared ends, made of a stainless-steel alloy woven into a tubular mesh.

\textbf{Results:} Stents were successfully placed in all patients.

\textbf{Conclusion:} Self-expandable wallstents endoprosthesis in the esophagus for fistulas of malignant origin is an easy, well tolerated, safe and effective procedure without important complications or mortality.

Key words: esophageal carcinoma, esophageal endoprosthesis, lung cancer, self-expandable stents, tracheoesophageal fistula, wallstents

Introduction

Expandable metal stents are used increasingly as a non-surgical alternative for the palliation of luminal gastrointestinal neoplasms, particularly esophageal cancer. Esophageal cancer is often diagnosed at an advanced stage and stents can be useful for symptom palliation in patients with locally unresectable or advanced esophageal cancer, those with poor functional status who cannot tolerate surgery or chemoradiotherapy, or for those with locally recurrent disease after primary treatment. These patients generally have weight loss and dysphagia due to esophageal obstruction. Furthermore, cough and/or aspiration may be the result of a tracheoesophageal fistula, either as a complication of the tumor or its treatment [1].

About 5-13\% of patients with esophageal cancer develop fistulas [2,3]. It is a severe complication that can be associated with a dramatic course of illness and may be followed by respiratory infection, which may ultimately end up in sepsis and death [4].

Esophageal intubation for the palliation of dysphagia from malignant esophageal obstruction has been practised for over a hundred years. In 1959, Celestin [5] described the palliation of esophageal malignancy with a plastic endoprosthesis introduced at laparotomy. In the 1970s, Atkinson and Ferguson [6] introduced an endoscopically inserted plastic prosthesis, with a much
reduced complication rate. The internal diameter of these stents was small (10-12 mm), resulting in many patients having difficulty in resuming a normal diet. They had a relatively high complication rate (up to 36%), mainly due to esophageal perforation, with a procedure-related mortality rate of 2-16% [7]. Plastic stents have been superseded by the newer range of metallic self-expanding stents that are safer and easier to place [8-10]. Nevertheless, some series report little difference in the degree of palliation from dysphagia between plastic and metal stents [11], although the complication rates with metallic stents are significantly lower.

The first description of endoscopic placement of an expanding metallic spiral stent was made by Frimberger in 1983 [12]. There are currently at least 8 different types of metallic stents in the market, both covered and uncovered, some of which have anti-reflux valves [13,14].

The purpose of this study was to investigate the safety and clinical effectiveness of the self-expandable wallstent in patients with malignancy and tracheoesophageal fistula.

**Patients and methods**

From July 2002 to November 2005, 16 patients with tracheoesophageal fistulas associated with esophageal (n=12) and lung cancer (n=4) were treated with expandable wallstents. Each patient underwent barium contrast esophagography to allow visualization of the location and extent of the tumor and identification of the fistulous connection between esophagus and trachea. In all patients esophagography revealed a malignant fistula. Twelve patients had undergone radiation therapy and/or chemotherapy. All of them were men, aged 52-74 years (mean 58).

At presentation, patients could not swallow food or water because of aspiration.

All stents were placed over a guide wire and no fluoroscopy was used in any case. Patients were treated under diazepam-induced conscious sedation. The stent delivery catheter was passed over the pre-inserted guide wire and advanced so that the proximal end of the stent was at the estimated distance from the incisor teeth (Figure 1).

Generally, all stents were gradually deployed in such a position so that at least 2 cm of the prosthesis was over the fistula. The stent was thus deployed to achieve the maximum security regarding stent migration.

After the release of the wallstent, esophagography was performed to verify occlusion of the fistula and patency of the stent tube and to detect any complication of the procedure. The whole procedure lasted less than 35 min.

Follow-up esophagograms were obtained to evaluate occlusion of the fistula and patency or migration of the stent tube at 1 week.

To assess clinical improvement after placement of the stent tube, food intake capacity before and after the procedure was categorized by using the following method: no food, only liquids, soft food, most foods, all foods.

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**Figure 1.** A) Placement of the wallstent performed over a guide wire. B) After placement of the wallstent the guide wire was drawn. C) Plain chest x-ray showing wallstent in place.
Results

Immediately after insertion of the stent tube, esophagography was performed to make sure that all tracheoesophageal fistulas were occluded successfully, and clinical symptoms of aspiration were relieved.

One patient required 2 wallstents because, after the insertion, leakage in the barium contrast esophagography was confirmed (Figure 2). All patients had aspiration pneumonitis. Soon after wallstent insertion significant improvement was evident in 10 patients, while in 6 pneumonitis resolved completely.

Fourteen patients could eat all foods, but 2 patients could only eat soft foods because of chest discomfort caused by the stent. No technical failure or procedural complications occurred in any of the patients, and the stent tubes were placed accurately in all of them.

Twelve patients felt dull chest pain for 1-7 days after the procedure and 10 of them required analgesics to control the pain. There were no cases of esophageal perforation or migration of the wallstent. Eight patients were discharged from the hospital and died after a mean survival period of 14 weeks. Six patients died of diffuse metastatic disease, one patient died of pulmonary embolism and the cause of death was unknown in one.

Discussion

In the largest published series on patients with malignant tracheoesophageal fistula, Burt et al. [15] found that primary esophageal tumors accounted for the majority (77%) of the cases. The second most common tumor was primary lung cancer (16%), followed by less common etiologies such as primary tracheal cancers, metastatic mediastinal lymph nodes, Hodgkin’s lymphoma, laryngeal cancer and thyroid tumors.

It was noted that 4.5% of the patients with primary esophageal carcinomas developed tracheoesophageal fistulas, whereas the incidence of tracheoesophageal fistulas in patients with primary lung cancers was only 0.3%. The location of the primary esophageal tumor was usually in the upper thoracic esophagus, although lower thoracic and cervical locations were also found. The respiratory location of the tracheoesophageal fistula was in the trachea in over half of the cases. Other locations included either mainstem bronchus and, less frequently, the lung parenchyma or multiple sites.

Malignant tracheoesophageal fistula in patients with esophageal or pulmonary malignancies is a serious complication with ominous prognosis. Once the symptoms of the fistula develop, the natural history is that of continued contamination of the respiratory tract, sepsis, and ensuing death, with a median survival of 1 to 6 weeks.

These patients can only be offered palliative therapy directed at relieving dysphagia, maintaining nutrition, and preventing contamination of the respiratory tract. A variety of modalities have been utilized for managing such patients, including esophageal stenting, chemotherapy, radiation therapy and surgery. None of these interventions have been definitively proven to prolong survival [16].

Expandable metal stents are used increasingly as a non-surgical alternative for the palliation of tracheoesophageal fistulas. Self-expandable metallic stents are composed of a variety of metal alloys with varying shapes and sizes depending upon the individual manufacturer and the organ in which they are to be placed. Several self-expandable metallic stents are available, while new devices and refinements of existing stents continue to emerge.

Devices available today include:

Gianturco-Z stent. This is made from stainless steel and a polyethylene covering with barbs on the outside or uncoated flared ends to prevent migration [17].

Ultraflex. This stent is made from a knitted nitinol mesh and is available in both uncovered and covered forms [18].

Wallstent. This stent has an internal silicon-based covering with flared ends and is made of stainless-steel alloy woven into a tubular mesh [19].

Figure 2. One patient required insertion of two stents because of leakage in the barium contrast esophagography.
**Flamingo wallstent.** This is a tapered stent made from a braided stainless-steel alloy and is covered on the inside only [20].

**Esophacoil.** This stent is uncovered and made from a single nitinol filament [21].

**FerX-Ella stent.** This stent is made of stainless steel and is covered with polyethylene internally and externally [22].

**Choo stent.** This is a polyurethane-covered stent made from nitinol and has a retrievable attached thread [23].

**Memotherm.** This is a flared nitinol stent with an internal and external PTFE covering.

**Song stent.** This is a modified Gianturco Z-stent made of stainless steel with a polyurethane covering [24].

Closure of the fistula is successful in 70-100% of the patients undergoing stent placement for malignant tracheoesophageal fistula (Table 1) [25-49].

### Complications

Early chest pain occurs in up to 100% of the patients but prolonged chest pain occurs in less than 13% of them. Major complications such as bleeding, perforation, aspiration, fever and fistula occur in 10-20% of the patients [50]. Procedure-related mortality is uncommon. In our study no patient died because of the procedure. The incidence of stent migration for uncovered stents is low (0-3%), rising to 6% for stents placed at the cardia [51]. A higher rate of stent migration, between 25% and 32%, is reported for placement of covered stents. This may require multiple stent insertions [52]. In our study the incidence of migration was 6.25% (1 of 16 patients) and this patient required 2 stent insertions (Figure 2).

Re-intervention following stent placement is common. This is predominantly due to tumor in-growth with uncovered stents (8-35% of the cases). However, tumor in-growth is rare with covered stents. Recurrent dysphagia as a result of stent overgrowth has been reported in up to 60% of the patients when followed up for long periods of time. Overgrowth may not always be due to tumor spread but may result from benign epithelial hyperplasia, granulomatous tissue and fibrosis in up to half of these patients. Other late complications

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**Table 1.** Summary of 25 studies published from 1993 to 2005 reporting the clinical efficacy of covered self-expandable metallic stents for the palliation of malignant tracheoesophageal fistulas

<table>
<thead>
<tr>
<th>Study</th>
<th>Esophageal stent</th>
<th>Patients with TEF*</th>
<th>Sealed off, rate, n/n (%)</th>
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<tbody>
<tr>
<td>Do et al. [25]</td>
<td>SONG</td>
<td>8</td>
<td>8/8 (100)</td>
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<tr>
<td>Wu et al. [26]</td>
<td>G-Z</td>
<td>8</td>
<td>6/8 (75)</td>
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<td>Wiegert et al. [27]</td>
<td>SONG</td>
<td>8</td>
<td>7/8 (88)</td>
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<tr>
<td>Ell et al. [28]</td>
<td>G-Z</td>
<td>6</td>
<td>6/6 (100)</td>
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<tr>
<td>Bethge et al. [29]</td>
<td>Wall</td>
<td>6</td>
<td>6/6 (100)</td>
</tr>
<tr>
<td>Kozarek et al. [31]</td>
<td>SONG, G-Z, Wall, Ultra</td>
<td>14</td>
<td>13/14 (93)</td>
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<tr>
<td>Han et al. [32]</td>
<td>SONG</td>
<td>10</td>
<td>10/10 (100)</td>
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<tr>
<td>May et al. [33]</td>
<td>G-Z, Wall</td>
<td>7</td>
<td>7/7 (100)</td>
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<tr>
<td>Macken et al. [34]</td>
<td>Wall</td>
<td>11</td>
<td>8/11 (73)</td>
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<td>Nelson et al. [36]</td>
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<td>18/20 (90)</td>
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<td>Wall</td>
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<tr>
<td>Wengrower et al. [42]</td>
<td>ESOPH</td>
<td>5</td>
<td>5/5 (100)</td>
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<tr>
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<td>Tomaselli et al. [45]</td>
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<tr>
<td>Sumiyoshi et al. [48]</td>
<td>Wall, Ultra</td>
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ESOPH: esophacoil stent; G-Z: standard Gianturco-Z; SONG: modified Gianturco-Z; ULTRA: Ultraflex; Wall: wallstent

*TEF: tracheoesophageal fistula*
include haemorrhage (3-10%), oesophageal ulceration (7%), stent torsion (5%), stent migration (5%) and stent fracture (2%) [53]. Wang et al. found that life-threatening complications (massive haemorrhage, fistula, perforation and tracheal compression) were more common in patients with stent placement in the proximal third of the oesophagus [54].

Stenting of malignant tracheoesophageal fistulas continues to evolve with the introduction of newer anti-reflux, anti-migration stents with an internal plastic coating and with retrievable stents [55]. Most patients (75-90%) resume a near normal diet after stent placement. The initial cost of an expandable metal stent is high, but overall costs are favorable when compared with other forms of palliative therapy [56].

Larger comparative studies between the different metal stents may demonstrate which stent has the lowest complication rates. The placement of these stents should be performed following accurate tumor staging and patient evaluation in multi-disciplinary teams.

In the last years injection via endoscopy of either fibrin sealants or glue into the fistulous orifice and surrounding submucosa is an alternative therapeutic option for sealing tracheoesophageal fistulas [57]. This endoscopic therapy may be particularly applicable to patients with fistulas initially treated with a covered self-expandable metallic stents that do not completely close or recur after successful initial closure.

References


Palliation of patients with esophagogastric...Gastrointest Endosc 1994; 40: 22-33.


