Fixation of a Modified Covered Esophageal Stent: Its Clinical Usefulness for Preventing Stent Migration
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Background and Study Aims: Membrane-covered self-expandable metal stents are effective in preventing tumor ingrowth and stent obstruction in patients with inoperable esophageal cancer, but migration of stents continues to be a major problem. We therefore constructed a modified covered self-expandable esophageal metal stent capable of being fixed using a silk thread. The stent was studied prospectively to define its palliative characteristics and whether it is effective in preventing migration.

Patients and Methods: Modified covered self-expandable metal stents were placed in 17 patients with malignant gastric cardiac cancer involving the esophagogastric junction, 41 patients with esophageal cancer, and three patients with tracheoepiglottic fistulas. Clinical and radiographic follow-up examinations were carried out at regular intervals.

Results: Placement of the stent was successful in all patients, with good symptomatic relief and no serious stent-related complications such as esophageal perforation or hemorrhage. Acute stent placement problems, such as incomplete expansion or acute angulation of the stent were noted in four patients. However, during a mean follow-up period of 7.5 months (range 1 to 17 months), there was no stent migration.

Conclusions: Modified covered self-expandable esophageal metal stents of this type would be very effective in preventing stent migration, especially in patients with malignant gastric cardiac cancer extending to the lower esophagus, those with short-segment esophageal cancer, and those with tracheoepiglottic fistulas.

Introduction
Palliative treatment of malignant obstruction of the upper gastrointestinal tract, including tracheoepiglottic fistulas, mainly consists of symptomatic treatment of the dysphagia. There are numerous forms of nonsurgical palliative treatment, including radiation therapy, insertion of endoprostheses, endoscopic laser therapy, tumor ablation with electrocoagulation, and injection of necrotizing agents [1]. Endoscopic endoprostheses are well established as a fast and durable method of providing palliation for malignant dysphagia and tracheoepiglottic fistulas. An ideal
esophageal endoprosthesis should have the following characteristics: it should have an optimal internal diameter; it should be flexible and nontraumatic, but with sufficient radial force; it should have a compact and easy-to-use delivery system; it should be possible to reposition or remove it if necessary; and it should have long-term patency without ingrowth or migration [2].

Recently, various types of self-expandable metal stents (SEMS) have been increasingly used because of advantages that include easy placement and fewer acute complications than conventional plastic esophageal stent [3, 4]. However, the major disadvantage of these metal stents is tumor ingrowth through the wire mesh, leading to recurrent obstruction. To overcome this problem, membrane-covered SEMS were developed. Membrane-covered SEMS are effective in preventing tumor ingrowth and scent obstruction, but migration of the stent continues to be a problem. In addition, the risk of migration is increased in the case of stenoses at the esophagogastric junction (5-8). A recent prospective multicenter trial of covered SEMS reports a 27% rate of delayed migration (8). In an attempt to prevent scent migration, a variety of expandable metallic prostheses have been tested clinically (9,10). We report here on a prospective trial using external fixation of a modified covered SEMS leer preventing steno migration.

Patients and Methods

Patients

The selection criteria for patients liable to suffer stent migration were based on the published literature (5,8,10) and our experience (11). Patients with malignancies located at the esophagogastric junction, a short tumor stricture to a 5 cm in length, tracheoesophageal fistula, or very soft tumor stenosis capable of being passed with a relatively small-caliber endoscope without dilation, were included in the study.

Between 1 January 1998 and 1 June 2000, modified cover self-expandable metal stents were inserted in 17 patients with malignant gastric cardiac cancer involving the esophagogastric junction, 41 patients with esophageal cancer, and three patients with tracheoesophageal fistulas (two with lung cancer and one with esophageal cancer) (Table 1). The patients were followed up until the end point of patient death or data analysis (on 15 July 2000).

Table 1 Characteristics of 61 patients with malignant dysphagia or tracheoesophageal fistula

<table>
<thead>
<tr>
<th>n</th>
<th>%</th>
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<tbody>
<tr>
<td>sex of patients</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>36</td>
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Female 25 41.0
Mean age (range) 63.6 y (20-83 y)
Location and mean length of malignant obstruction
Proximal third of esophagus 2 3.3
(mean length of stricture 3.4 cm)
Middle third of esophagus 19 31.1
(including 3 cases of 71 fistula;
mean length of stricture 4.1 cm)
Distal third of esophagus 23 37.7
(including 4 cases of soft tumor
stenosis; mean length of stricture 5.4 cm)
Gastric Cardia involving EG junction 17 27.9
(mean length of stricture 3.5 cm)
Histology of tumor
esophageal squamous-cell carcinoma 42 68.9
Gastric adenocarcinoma 16 26.2
Pulmonary adenocarcinoma 2 3.3
Gastric lymphoma (B-cell type) 1 1.6

EG: esophagogastric; TE: transesophageal.

All patients had dysphagia at the initial evaluation. Dysphagia was graded on a scale of 0 to 4 (0, no dysphagia; 1, dysphagia for regular solids; 2, dysphagia for soft solids; 3, dysphagia for solids and liquids; 4, complete dysphagia including saliva). Nine patients (14.8%) had grade 4 dysphagia, 32 patients (52.5%) had grade 3, 16 patients (26.2%) had grade 2, and four patients (6.5%) had grade 0 (The mean dysphagia grade was 2.8.

Stent Design
Stent Design
The stent is a self-expanding tubular prosthesis designed to maintain the patency of esophageal strictures caused by malignant tumors (manufactured by M.I. Tech. Co., Inc.: Suwon, Korea). The stent is made from a strand of nitinol wire. Individual stent bodies have an internal diameter of 18 mm and a length of 20 mm. Multiple stent bodies were interconnected with a polyurethane membrane to produce stents of 4-14 cm in length. The unique structure, with the polyurethane membrane connecting several separate segments, increases the flexibility of the stent. The stent is flare-shaped, with flanges at the proximal and distal ends.
measuring 24 mm in diameter. There are four excellent radiopaque markers made of gold wire at each end of the stent.

The stent is completely covered with a polyurethane membrane (0.004 inch thickness), except for the proximal flange, to impede tumor ingrowth through the wire mesh. The uncovered proximal flange of the stent is buried and fixed in the esophageal mucosa. The stent introducer is 6mm in diameter and 56 cm long. There is a silk thread attached to the edge of the wire of proximal flange. This silk thread is connected to the patient's earlobe during complete fixation of the uncovered proximal flange of the stent to the esophageal mucosa. In addition, there is a retrieval lasso attached inside the proximal flange of stent to allow retrieval and repositioning of an inappropriately placed stunt (Figure 1).

Implantation Techniques

To allow free passage of the delivery apparatus and deploy mend of the stent, dilation to 11-13 mm in diameter was performed using a Savary-Gilliard bougie dilator or balloon dilator under fluoroscopic guidance. The proxima and distal borders of the strictures were indicated with Lipiodol. We chose scents that were 4 cm longer (upper an lower margins of 2 cm each) than the length of the tumor stricture, to prevent tumor overgrowth. The minimum and maximum lengths of the stent used in this study were 5 cm and 12 cm (mean 8 cm). After placement of a 0.038 inch stiff guide wire in the stomach, the stent introducing catheter was advanced over the guide wire into the esophagus under fluoroscopic control, and the stunt was then deployed by pulling back the introducer sheath (Figure 2).
If the scent expanded in an inappropriate location, it was repositioned correctly using the retrieval lasso under endoscopic guidance. Finally, with the same method of pulling out the nasobiliary drainage catheter, the silk tied at the edge of the wire of the flange was drawn out through the nose and connected to the patient’s earlobe during complete fixation of the proximal uncovered part of the stent into the esophageal mucosa. To protect the esophageal mucosa and nasal cavities against irritation from the silk, the silk was threaded through a 14-Fr rubber tube before being connected to the earlobe (Figure 3).

To evaluate the time required for the proximal uncovered part of the stunt to become fixed into the esophageal mucosa, endoscopic examinations were performed on the first day and every two days after insertion of the scent until fixation of the stent was confirmed. If the proximal uncovered flange part was completely buried in the esophageal mucosa and did not separate from the esophagus in spite of air insufflation or esophageal movement on endoscopic
observation, complete fixation of the stent to the esophageal wall was confirmed (Figure 4).

After confirmation of complete fixation of the stent to esophageal mucosa, the silk connected to the patient's earlobe was removed.

Clinical and radiographic follow-up examinations and a short medical history were subsequently scheduled every four weeks. Endoscopy and barium swallow examinations were repeated if there was recurrent dysphagia.

**Statistical Analysis**

Statistical comparisons were carried out using the paired t-test to compare the grades of dysphagia before and after insertion of the stent, with the significance level set at $P < 0.05$.

**Results**

**Technical Success**

The implantation of modified covered self-expandable metal stents was successful in all 61 patients. No technical problems or complications occurred during placement of the stent. In three cases, the stents were inadvertently placed lower than the desired location, but were easily repositioned by pulling the circumferentially threaded silk around the proximal flange. Follow-up chest radiography examinations, taken on the sixth day after stent insertion showed a completely expanded stent in all except flour patients (93.4%). The cause of insufficient expansion of the stent in three of these patients was rigidity of the tumor, and these patients were managed with one session of balloon dilation (Rigiflex, Microvasive, Boston Scientific Corporation, Watertown, Massachusetts, USA). In the other patient, a short stent (6 cm long) had collapsed due to an acute angular configuration of the stenotic area at the esophagogastric junction. In this case, the stent was removed using the snare under endoscopic guidance, and a longer stent (10 cm) was reinserted. After a mean of 4.2 days (range 3-7 days), the proximal uncovered flange section was completely buried in the esophageal mucosa.

**Clinical Response**

After insertion of the stent, 58 of the 61 patients with dysphagia (95.1%) showed improvement in the dysphagia by at least one grade. The dysphagia scores before stenting and one month after
stenting were 2.8 and 1.2 (P< 0.05). Three nonresponders never resumed oral intake due to severe debility.

In the radiological check-up examinations with water-soluble contrast medium, which were carried out in the three patients with tracheoesophageal fistulas, all fistulas proved to be completely sealed, and the patients were able to ingest regular solid and soft solid food again.

The mean survival time for all 61 patients was 6.4 months. At time of data analysis, 28 patients had died, 25 remained alive with the stent in place, and eight patients had been lost to follow-up.

**Complications**

Severe early complications such as bleeding and perforation did not occur. Immediate technical problems such as incomplete expansion or acute angulation of the stent were observed in four patients (6.6%). Patient-related early complications such as chest pain and erosion in the nostril were noted in six patients (9.8%) (Table 2). However, with the exception of two patients, most of these complications were mild, and resolved spontaneously within a few days without any further treatment. Two patients with severe chest pain after stent insertion were treated with intravenous medications.

During a mean follow-up period of 7.5 months (range 1-17 months), two patients had recurrent dysphagia, caused in one case by tumor overgrowth (time interval between stent deployment and recurrence of dysphagia two months) around the proximal margin of the stent and in the other case by epithelial hyperplasia in the esophageal mucosa due to chronic irritation around the uncovered proximal Table 2 Complications after placement of stent in 61 patients with malignant dysphagia or tracheoesophageal fistula

<table>
<thead>
<tr>
<th>Complications</th>
<th>Patients</th>
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<tbody>
<tr>
<td>Immediate technical</td>
<td>4 6.6</td>
</tr>
<tr>
<td>Incomplete expansion</td>
<td>3</td>
</tr>
<tr>
<td>Acute angulation</td>
<td>1</td>
</tr>
<tr>
<td>Migration</td>
<td>0</td>
</tr>
<tr>
<td>Early patient</td>
<td>6 9.8</td>
</tr>
<tr>
<td>Chest pain</td>
<td>5</td>
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flange (time interval between stent deployment and recurrence of dysphagia four months). These two patients were re-treated successfully, with another stent insertion into the stricture segment in the first case and balloon dilation in the other. Five patients who experienced heartburn due to the transcardial prosthesis were easily managed by administering with proton-pump inhibitors. No stent migrations occurred during the follow-up period.

Discussion

Migration of stunts is a major problem with both plastic and membrane-covered SEMS. The migration rate with uncovered metal stents is reportedly less than 5% [12], but the migration rate with membrane-covered metal stents is higher, presumably due to reduced friction between the membrane and the esophageal wall [13]. The migration rate with these stents ranges from 10% to 35% in reported series [8,14].

Kozarek et al. [8] reported a 27% migration rate with covered Z-stents Wilson-Cook, Inc., Winston-Salem, North Carolina, USA) at a mean of one month. Three patients required surgery for gastric or small-bowel obstruction, and one endoscopic stent retrieval was associated with small-bowel perforation that directly contributed to the patient's death. Some early migration incidents were attributed to over dilation prior to deployment. Others were related to the esophagogastric location of the tumor, and followed subsequent chemoradiotherapy for the primary malignancy.
Complete distal migration may be a more serious problem, due to difficulty in retrieving the stent. It should be noted that stent manufacturers (Wallstent, Microvasive, Boston Scientific Corporation, USA) recommend that stents should not be used in lower esophageal strictures, as they may be prone to migration [13]. Displacement or incorrect positioning may also result from miscalculating the stricture length or failure to control the movement of the SEMS during deployment [4,10,15].

Recently, various new types of stent and several methods of preventing stent migration have been tested [9,10]. In 1997, a North American multicenter trial prospectively studied a 25-mm flanged covered Z-stent to assess dysphagia palliation and whether the increased diameter of the flange affected placement or migration problems [10]. From the standpoint of migration, enlarging the end flanges from 21 mm to 25 mm decreased the migration rate from 27% to 8%, and appeared to do so without any increase in the frequency of subsequent stent erosion with hemorrhage. This result showed that enlarging the proximal flange of the stent might reduce the migration rate, but did not completely prevent stent migration.

Wu et al. [9] reported only four cases of stent migration in 32 patients treated for malignant dysphagia or fistula using modified covered self-expanding Gianturco-Rosch Z-stent with a 22-mm diameter flange. This group used a slightly different delivery system, and the stent itself contained metal barbs that locally penetrated the esophageal wall or the tumor itself, to preclude subsequent migration. Although the addition of barbs may minimize displacement at delivery and subsequent migration, use of this type of stent may also cause an increased incidence of erosion, with subsequent perforation or fatal hemorrhage [9].

To overcome stent migration, we constructed a modified covered self-expandable esophageal metal stent that could be fixed using a silk thread attached to the edge of proximal end of the stent and to the patient's ear via the nares. Symonds in 1885 [16] made the original proposal for using a silk thread passed via the nares to tie the proximal end of a stent to the patient's moustache, if available, to prevent stent migration. However, external fixation using a silk thread for repositioning has not received wide attention to date.

The structural and functional characteristics of this modified membrane-covered self-expandable esophageal stent are as follows. The uncovered proximal flange tends either to embed in tissue or to elicit growth of granulation tissue wherever exposed wires are in contact with the mucosa. If the uncovered proximal flange of the stent is completely embedded in the
esophageal mucosa after several days of stent insertion, it can prevent migration of the stent. During this period, a silk thread tethering the proximal end of the stent to the patient’s ear has a major role in preventing early migration of the stent, which may occur within seven days. The authors experienced two cases of stent migration (stent length 8 cm) in patients with gastric cardiac cancer invading the lower esophagus. In these patients, the same type of stent was inserted without a silk thread tethering the proximal end of the stent to the patient’s ear. The stent migrations occurred two and four days after insertion in these patients. We therefore consider that both of these structural changes are needed to prevent stent migration. In addition, the flared shape of this stent is intended to prevent proximal and distal migration without the use of barbs, thereby avoiding the mucosal trauma caused by hooks, as well as allowing repositioning or removal of the stent.

The main differences between the Wilson-Cook Z-stent and the stent described in this report are as follows. The Wilson-Cook Z-stent is made of stainless steel, whereas our modified stent is made of a strand of nitinol wire. The individual stent bodies of the Z-stent are interconnected with silk, while our stent bodies are interconnected with a polyurethane membrane. The proximal flange of the stent is partially uncovered in the Z-stent, while in our stent it is completely uncovered. There is no silk thread for fixation, removal, and repositioning of stent in the Z-stent.

The reason the repeated endoscopic examinations were carried out in this study was to evaluate the exact time needed for fixation of the uncovered proximal part of the stent into the esophageal mucosa. The data showed that almost all stents became fixed to the esophageal mucosa within five days after insertion of the stent. In accordance with this result, we usually remove the silk thread on the fifth day after insertion of the stent, without additional endoscopic evaluation of mucosal fixation. The method of removing the silk thread is very simple. After cutting one part of the looped silk thread fixed to the earlobe, the thread can be pulled and removed, with no need to cut the suture endoscopically.

In this study, no stent migration occurred in the 61 patients during a mean follow-up period of 7.5 months (range 1-17 months). This result is remarkable, and is an important point of the study. Distal migration of the stent is one of the most significant complications relating to stent insertion, and this modified stent effectively prevents distal migration. The disadvantage of the stent is nasopharyngeal discomfort due to insertion of nasopharyngeal rubber tube.

In conclusion, this modified covered esophageal stent appears to prevent stent migration and to
improve dysphagia in patients with malignant tumor stenosis at the esophago-gastric junction, a short tumor stricture less than 5 cm in length, a soft tumor stenosis, and tracheoesophageal fistula.

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