Improvement in dysphagia and quality of life with self-expanding metallic stents in malignant esophageal strictures

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Background: Carcinoma of the esophagus often presents at an advanced stage, with absolute dysphagia or aspiration. Palliative procedures have an important role in improving the quality of life (QOL) of patients who are not candidates for curative therapy. We report on the efficacy and complications of self-expanding metallic stents (SEMS) in such patients.

Methods: Ultraflex nitinol SEMS were placed under endoscopic guidance in patients with malignant esophageal strictures. Dysphagia, pain and QOL were assessed before and after SEMS placement.

Results: Thirty patients were treated with SEMS. QOL score improved significantly from 62-94 before stenting to 80-133 after the procedure. There was improvement in dysphagia grades. Pain was the most common complaint noted on follow up. There was no major morbidity or mortality related to the procedure.

Conclusions: SEMS placement is a safe and effective treatment modality for palliation of dysphagia due to malignant esophageal strictures. It provides lasting relief in dysphagia and improvement in QOL, without major complications. [Indian J Gastroenterol 2006;25:62-65]

A majority of patients with carcinoma of the esophagus present at an advanced stage of the disease, and die due either to absolute dysphagia or to aspiration. Despite advances in diagnostic methods, and in surgical techniques, radiotherapy and chemotherapy, survival rates for this disease have remained unchanged over the last four decades. Thus, emphasis has now shifted towards achieving an acceptable quality of life (QOL) during the limited survival period by palliation of dysphagia.

Among palliative treatment modalities, surgery is not favored due to its associated morbidity and mortality. Radiation therapy, either as external beam radiation or brachytherapy, continues to be the procedure of choice in patients unsuitable for curative treatment. Other methods used to alleviate dysphagia include blind or wire-guided dilatation of malignant stricture, laser therapy, photodynamic therapy, BICAP and chemical ablation; these, however, need repeated treatment sessions.

Placement of self-expanding metallic stents (SEMS) made up of an alloy, usually nitinol or stainless steel, and deployed using endoscopic or fluoroscopic techniques, is a newer method for relief of dysphagia in these patients. In the current study, we looked at the efficacy of SEMS placement in palliation of dysphagia in patients with malignant esophageal strictures, particularly in improving the QOL, and the complications related to this procedure.

Methods

Between September 2001 and May 2003, forty-two patients with histologically-proven carcinoma of the esophagus and needing palliation of dysphagia were considered for SEMS placement. The indications for stenting were: inoperable malignant stricture due to extensive extraesophageal spread (n=16), post-radiotherapy stricture (n=12) or malignant tracheo-esophageal fistula (n=2).

Of these patients, 12 could not undergo SEMS placement either because the stricture could not be dilated (n=2), or because the lesion was located within 2 cm of the cricopharynx (n=2) or within 3 cm of the esophagogastric junction (n=8). (Anti-reflux stents were not used because of cost.) In the remaining 30 patients (mean age 57 years; 20 men), 32 stents were used, including 29 covered and 3 uncovered stents; the latter were used in 3 patients with post-radiotherapy strictures without evidence of residual disease.

The study was funded from the internal resources of our institution and had been approved by the Institute Research Council and Ethical Committee.

Procedure

All patients underwent clinical examination, abdominal ultrasonography, barium swallow and chest skigram. CT of the chest and abdomen was done, if required. Upper gastrointestinal endoscopy (UGIE) and biopsy was done for confirmation of diagnosis. In patients selected for SEMS placement, the site and length of the tumor and its distance from the cricopharynx and the gastroesophageal junction were...
recorded. Narrow strictures were predilated with Savary-Gilliard esophageal dilators (Wilson-Cook, Winston-Salem, USA) if necessary.

Ultraflex nitinol SEMS (Microvasive, Boston Scientific, Watertown, MA, USA) were placed using a distal release system, which can be deployed more accurately without distal migration in the absence of a C-arm facility. Each of these stents is knitted from a single nitinol wire, measures 18 mm in diameter on full expansion, and is provided with looped ends and a 23-mm proximal flare. The stents were available in two lengths, 10 cm and 15 cm, measuring 14 cm and 19 cm, respectively, when compressed in the delivery device.

At 24 hours after SEMS deployment, the position and expansion of the stent were confirmed using a check skiagram, and oral feeds were resumed. At 48 hours, repeat UGIE and barium swallow were done and the patients were discharged if there was no complication. The patients visited the hospital again 7 days after SEMS placement, followed by monthly visits thereafter. Complications occurring within one week of the SEMS placement were classified as early and the rest as late complications.

Thirteen patients had received radiotherapy before stenting and 12 patients received it after stenting. Five patients did not receive radiotherapy, either because of poor general condition (n=4) or multiple liver metastases (n=1).

Symptom evaluation

Dysphagia grade, pain score and quality of life (QOL) were assessed before and after stenting. The severity of dysphagia was assessed using the modified Takita’s dysphagia grading (grade I: able to eat normally, II: requires liquids with meals, III: able to take only semisolid food, IV: able to take only liquids, V: able to swallow saliva but not liquids, and VI: complete dysphagia). Severity of pain was assessed using a visual analogue scale, from 0 (absence of pain) to 100 (maximum pain). QOL was assessed using a questionnaire based on the European Organisation of Research and Treatment of Cancer (EORTC) QLQ C30; it consisted of 30 questions based on physical symptoms, emotional interactions, intellectual activity, economic independence and self-perception of wellness. Each question was scored on a scale of 1 (‘very poor’) to 5 (‘very good’).

Dysphagia and pain were scored one day before and one day, two days, one week and one month after stenting and at subsequent monthly visits. Since QOL questionnaire has several clauses pertaining to day-to-day activities after discharge, it was measured one month after stenting.

Statistical analysis was done using Mann Whitney U test. An alpha value of <0.05 was considered significant.

Results

The strictures were 3 cm to 10 cm (mean 6.3) in length. Two patients required two stents each, because of a long stricture and distal migration of the deployed stent, respectively. Two patients had tracheoesophageal fistula; in both, the stents successfully closed the fistula.
The dysphagia grade improved in all patients after stenting, from median (range) 4 (4-6) to 1 (1-3) (p<0.0001) (Fig. 1). Pain score increased from 48 (20-74) pre-stenting to 59 (30-90) following stenting (p=0.0112) (Fig. 2). QOL score, which was median 72 (62-94) before stenting, increased to 107 (80-133) after the procedure (p<0.0001) (Fig. 3). All patients had increase in food intake and increase in weight ranging from one to three kilograms.

Fifteen patients reported one or more early complications, chest pain being the commonest (Table). Pain was also the most common complaint on follow up. Two patients had partial block of the stent due to tumor overgrowth, one each at the distal and proximal ends; both these patients had relief of dysphagia with brachytherapy. One patient had distal migration of the stent. The other significant complications observed were respiratory infection and gastroesophageal reflux. No patient had esophageal perforation, bleeding or procedure-related death.

Twenty-two patients died within one year of stenting; median survival was 161 days.

**Discussion**

In our study all patients had significant relief of dysphagia and improvement in quality of life, though with increase in pain scores.

Following stent deployment, the relief of dysphagia is almost immediate.\(^\text{14}\) Lasting and excellent relief of dysphagia has been a consistent finding with the use of SEMS.\(^\text{14}\)

Randomized controlled trials have previously established the superiority of SEMS over plastic stents in improving overall QOL.\(^\text{15}\) Our study used the EORTC QLQ C30 questionnaire to measure the physical, emotional and social performance indices and to assess QOL. This method is superior to the Karnofsky functional score, which measures only physical performance status.

Complications are uncommon following SEMS placement, major ones being bleeding, perforation and aspiration pneumonia. In one study, the procedure had a 7% mortality rate.\(^\text{16}\) In our study, there was no procedure-related death, and pain, gastroesophageal reflux and respiratory infection were the commonest complications.

Stent obstruction due to tumor ingrowth or overgrowth is a known complication that occurs in up to 36% of patients.\(^\text{17}\) Overgrowth may not always be due to the tumor but may result from benign epithelial hyperplasia or granulation tissue. Two patients in our study had overgrowth; both responded to brachytherapy.

Distal migration of the stent is a common complication, with rates of up to 30%.\(^\text{18}\) Migration is more common with covered stents used to treat distal esophageal lesions near the gastroesophageal junction.\(^\text{19}\) Only one patient in our study had distal stent migration and was managed with placement of another stent proximally. Contrary to some previous studies,\(^\text{20}\) we did not observe any increase in device-related complications in patients who had received prior radiotherapy.

Our results are limited by the fact that these were obtained in a selected group of patients who had strictures that could be dilated, and were located neither too close to the cricopharynx nor to

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**Table: Complications following self-expandable metal stent placement in patients with carcinoma esophagus**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number (%)</th>
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<tbody>
<tr>
<td></td>
<td>(n=30)</td>
</tr>
<tr>
<td><strong>Early complications</strong></td>
<td></td>
</tr>
<tr>
<td>Chest pain</td>
<td>12 (40)</td>
</tr>
<tr>
<td>Gastroesophageal reflux</td>
<td>6 (20)</td>
</tr>
<tr>
<td>Respiratory infection</td>
<td>1 (3)</td>
</tr>
<tr>
<td><strong>Late complications</strong></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>8 (27)</td>
</tr>
<tr>
<td>Respiratory infection</td>
<td>6 (20)</td>
</tr>
<tr>
<td>Gastroesophageal reflux</td>
<td>6 (20)</td>
</tr>
<tr>
<td>Tumor growth at end</td>
<td>2 (7)</td>
</tr>
<tr>
<td>Tumor ingrowth at either end</td>
<td>2 (7)</td>
</tr>
<tr>
<td>Tumor ingrowth through stent</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Stent migration</td>
<td>1 (3)</td>
</tr>
</tbody>
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the esophagogastric junction. Thus, these may not be applicable to all patients with esophageal cancer.

In conclusion, SEMS placement is safe and effective in the palliation of dysphagia in selected patients with malignant esophageal strictures. It provides lasting relief of dysphagia and improves QOL significantly, without major complications.

References


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