

Double layered self-expanding metal stents for malignant esophageal obstruction, especially across the gastroesophageal junction

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(SEMS across GEJ, 18 patients) and non-GEJ group (SEMS above GEJ, 30 patients) according to SEMS position. Double layered (outer uncovered and inner covered stent) esophageal stents were placed.

RESULTS: The SEMS insertion and the clinical improvement were achieved in all patients in both groups. Stent malfunction occurred in seven patients in the GEJ group and nine patients in the non-GEJ group. Tumor overgrowth occurred in five and eight patients, respectively, food impaction occurred in one patient in each group, and stent migration occurred in one and no patient, respectively. There were no significant differences between the two groups. Reflux esophagitis occurred more frequently in the GEJ group (eight vs five patients, $P = 0.036$) and was controlled by proton pump inhibitor. Aspiration pneumonia occurred in zero and five patients, respectively, and tracheoesophageal fistula occurred in zero and two patients, respectively.

CONCLUSION: Double-layered SEMS are a feasible and effective treatment when placed across the GEJ for malignant esophageal obstruction. Double-layered SEMS provide acceptable complications, especially migration, although reflux esophagitis is more common in the GEJ group.

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Abstract

AIM: To evaluate the clinical outcomes of double-layered self-expanding metal stents (SEMS) for treatment of malignant esophageal obstruction according to whether SEMS crosses the gastroesophageal junction (GEJ).

METHODS: Forty eight patients who underwent the SEMS insertion for malignant esophageal obstruction were enrolled. Patients were classified as GEJ group

Key words: Metal stent; Gastroesophageal junction; Malignant esophageal obstruction

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INTRODUCTION

Despite recent developments in diagnosis and treatment, more than 50% of malignancies involving the esophagus are inoperable and the 5-year survival rates are < 10% at present^[1,2]. In advanced or metastatic patients, therapy is usually palliative in nature, with the major aims being relief of dysphagia, maintenance of nutrition, or closure of the tracheoesophageal fistula. Self-expanding metal stents (SEMS) are widely used for the relief of patients with dysphagia, providing rapid, safe, and effective symptomatic relief in most patients^[3-6]. However, placing a stent across the gastroesophageal junction (GEJ) face several limitations due to anatomic features leading to a higher migration rate and gastroesophageal reflux^[7-10].

Covered stents are now the most commonly used type in esophageal obstruction to prevent tumor ingrowth. But, covered stents are more likely to migrate than uncovered stents, especially in the region of the GEJ. Therefore, uncovered stents should be considered to prevent migration in those cases. However, considering the risk of stent obstruction owing to tumor in-growth and stent migration in GEJ tumors, a newly designed stent with advantages of uncovered (low migration) and covered (low tumor in-growth) stents should be considered^[11-13].

Although several studies have reported the efficacy of SEMS in malignant esophageal obstruction, there are only limited data about stenting across the GEJ^[14-16]. Because placement of SEMS across the GEJ has a tendency of higher migration, we evaluated the clinical outcomes of double-layered SEMS for treatment of malignant esophageal obstruction according to whether SEMS crossed the GEJ.

MATERIALS AND METHODS

Patients

Between February 2005 and June 2010, we enrolled a consecutive series of 48 patients with malignant esophageal obstruction who underwent SEMS placement. All patients had pathologically proven esophageal or gastric cardiac carcinoma. None were candidates for curative surgical treatment because of advanced or metastatic disease or poor functional status. Informed consent for stent placement was obtained from each patient before

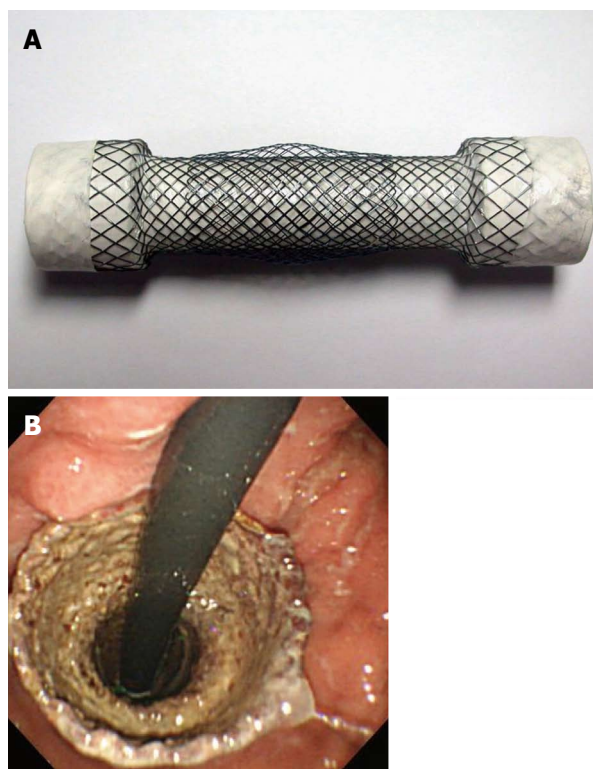


Figure 1 Niti-S double layered stent and endoscopic finding. A: Niti-S double layered esophageal stent, consisting of an inner polyurethane membrane layer and an outer uncovered nitinol wire; B: Endoscopic view of an expanding Niti-S stent, seen from the stomach.

SEMS placement.

SEMS construction and placement

Double-layered stent (Niti-S double layered esophageal stent; Taewoong, Seoul, South Korea) was used throughout the study. The double-layered stent was designed to have the advantages of both uncovered (low migration rate) and covered (low in-growth rate) stents to resolve some of the disadvantages of preexisting metal stents. The stents consist of an inner polyurethane membrane covered stent to prevent tumor ingrowth and an outer uncovered stent to reduce migration. The outer uncovered stent overlapped in the central portion of the covered stent (Figure 1). Because there is space between the covered and uncovered stent in the central portion, this space permits tissue and tumor growth throughout. Thus, the double-layered stent becomes anchored to the esophageal wall.

Patients were consciously sedated with intravenous midazolam during the procedure. Under fluoroscopic and endoscopic visualization, the length of the stricture was measured. A stent 2-4 cm longer than the length of the stricture was chosen to allow for a 1-2 cm extension above and below the proximal and distal tumor margin, respectively. After the guidewire was inserted through the stricture, the delivery system of the stent was gently introduced. After the stent placement, the positioning of the stent was assessed both radiographically and endoscopically.

Table 1 Patient baseline characteristics (*n* = 48) *n* (%)

| | Overall (<i>n</i> = 48) | GEJ obstruction (<i>n</i> = 18) | Non-GEJ obstruction (<i>n</i> = 30) | <i>P</i> value |
|---|-----------------------------|--|--|----------------|
| Age (yr, mean ± SD) | 68.4 ± 10.5 | 65.8 ± 10.3 | 69 ± 10.5 | 0.749 |
| Male | 39 (81.3) | 12 (25.0) | 27 (56.2) | 0.045 |
| Histological diagnosis | | | | |
| Squamous cell carcinoma | 32 (66.6) | 2 | 30 | 0.001 |
| Adenocarcinoma | 16 (33.4) | 16 | 0 | 0.001 |
| Type of treatment before SEMS placement | | | | |
| Supportive care | 29 (60.4) | 10 | 19 | 0.594 |
| Chemotherapy | 11 (22.9) | 7 | 4 | 0.041 |
| Radiation therapy | 7 (14.6) | 1 | 6 | 0.170 |
| Chemoradiation therapy | 1 (2.1) | 0 | 1 | 0.434 |

GEJ obstruction, distal esophageal and gastroesophageal junction obstruction; Non-GEJ obstruction, middle and upper esophageal obstruction. GEJ: Gastroesophageal junction; SEMS: Self-expanding metal stents.

Assessment of clinical outcomes and complications

The technical success of stent placement was defined as adequate positioning and deployment of the stent with complete bridging of the stricture. For the assessment of clinical improvement, we used a dysphagia score: score 0, ability to eat a normal diet; score 1, ability to eat some solid food; score 2, ability to eat some semisolids only; score 3, ability to swallow liquids only; score 4, complete inability to swallow^[17]. This was measured before and 1-2 weeks after the stent placement. We evaluated stent malfunction due to tumor overgrowth, stent migration, or food impaction and other complications including reflux esophagitis, aspiration pneumonia, or fistula.

Statistical analysis

Differences between categorical variables were examined statistically using the χ^2 test. Dysphagia scores before and after the stent placements were analyzed by the paired-*t* test. The incidence of complications was compared between two groups using the χ^2 test. All statistical analyses were performed with SPSS 12.0 (SPSS, Chicago, IL). A *P* value < 0.05 was considered statistically significant.

RESULTS

The clinical characteristics of the patients are shown in Table 1. Forty eight patients (39 men, mean age 68.4 years, range 45-86 years) with esophageal obstruction underwent SEMS placement. The histological types were squamous cell carcinoma in 32 patients (66.6%) and adenocarcinoma in 16 (33.4%). The location of obstruction was in the GEJ in 18 patients (37.5%) and non-GEJ in 30 patients (62.5%). In our study, GEJ obstruction meant that the location of obstruction was in the far distal esophagus and GEJ. Non-GEJ obstruction meant that the location of obstruction were in the upper, middle, and proximal distal esophagus. Before stent placement, 39.6% (19/48) of patients received anticancer treatments

Table 2 Clinical outcomes in 48 patients *n* (%)

| Outcomes | Overall (<i>n</i> = 48) | GEJ obstruction (<i>n</i> = 18) | Non-GEJ obstruction (<i>n</i> = 30) |
|--|-----------------------------|-------------------------------------|--|
| Technical success | 48 (100) | 18 (100) | 30 (100) |
| Clinical success | 48 (100) | 18 (100) | 30 (100) |
| Mean dysphagia score preprocedure (mean ± SD) | 3.20 ± 0.68 | 3.05 ± 0.63 | 3.30 ± 0.70 |
| Mean dysphagia score postprocedure (mean ± SD) | 1.77 ± 0.77 | 1.77 ± 0.73 | 1.76 ± 0.81 |
| Change dysphagia score (paired- <i>t</i> test) (<i>P</i> value) | < 0.001 | < 0.001 | < 0.001 |

GEJ obstruction, distal esophageal and gastroesophageal junction obstruction; Non-GEJ obstruction, middle and upper esophageal obstruction. GEJ: Gastroesophageal junction.

such as chemotherapy (*n* = 11, 22.9%), radiation therapy (*n* = 7, 14.6%) or chemoradiation therapy (*n* = 1, 2.1%). The remaining (*n* = 29, 60.4%) patients received supportive care. Patients were classified as GEJ (18 patients including distal esophageal cancer and GEJ cancer patients) and non-GEJ groups (30 patients) according to SEMS position. In GEJ group, SEMS placed across GEJ and distal flange portion of SEMS did not anchor to the esophageal wall but was free in the cardia portion. Baseline characteristics are similar except for histologic types.

The placement of esophageal stents was technically successful in all patients. Clinical success rates for malignant esophageal obstruction were 100%. The mean dysphagia score improved from 3.20 ± 0.68 to 1.77 ± 0.77 (*P* < 0.001) by stent placement. The mean dysphagia score improved from 3.05 ± 0.63 to 1.77 ± 0.73 (*P* < 0.001) and 3.30 ± 0.70 to 1.76 ± 0.81 (*P* < 0.001) in GEJ obstruction and in non-GEJ obstruction, respectively (Table 2). Most patients complained of mild foreign body sensation or pain immediately after the stent placement and were getting better and free of these symptoms after several days. There was no procedure-related mortality within 24 h of the intervention.

Stent malfunctions developed in 16 (33.3%) patients [seven (38.9%) for GEJ group and nine (30.0%) for non-GEJ group], the causes of which consisted of tumor overgrowth (13 patients, 27%), stent migration (one patient, 2.1%) and food impaction (two patients, 4.2%). Tumor overgrowth, stent migration, and food impaction occurred in five (27.8%) and eight (26.7%) patients, zero (5.6%) and zero patient, and one (5.6%) and one (3.3%) patient in the GEJ and non-GEJ obstruction, respectively (Table 3). There was no significant difference between GEJ and non-GEJ groups.

Twenty patients (41.6%) showed complications such as reflux esophagitis (13 patients, 27.1%), aspiration pneumonia (five patients, 10.4%), and tracheoesophageal fistula (two patients, 4.2%). Only reflux esophagitis occurred more frequently in GEJ group [eight (44.4%) *vs* five (16.7%), *P* = 0.036]. Aspiration pneumonia and tracheoesophageal fistula occurred in zero and five (16.7%) and zero and two (6.7%) patients in the GEJ and non-GEJ

Table 3 Complications and causes of stent malfunctions *n* (%)

| | Overall (<i>n</i> = 48) | GEJ obstruction (<i>n</i> = 18) | Non-GEJ obstruction (<i>n</i> = 30) | <i>P</i> value |
|------------------------------|-----------------------------|--|--|----------------|
| Causes of stent malfunctions | | | | |
| Overgrowth | 13 (27.1) | 5 (27.8) | 8 (26.7) | 0.933 |
| Migration | 1 (2.1) | 1 (5.6) | 0 (0.0) | 0.192 |
| Food impaction | 2 (4.2) | 1 (5.6) | 1 (3.3) | 0.709 |
| Other complications | | | | |
| Reflux esophagitis | 13 (27.1) | 8 (44.4) | 5 (16.7) | 0.036 |
| Aspiration pneumonia | 5 (10.4) | 0 (0.0) | 5 (16.7) | 0.067 |
| Fistula | 2 (4.2) | 0 (0.0) | 2 (6.7) | 0.263 |

GEJ obstruction, distal esophageal and gastroesophageal junction obstruction; Non-GEJ obstruction, middle and upper esophageal obstruction. GEJ: Gastroesophageal junction.

group, respectively. These complications were managed successfully with administration of proton pump inhibitors, antibiotics, or another covered stent, respectively.

DISCUSSION

Given the increased incidence of carcinoma involving the distal esophagus and gastric cardia, SEMS are increasingly being deployed across the gastroesophageal junction. Although endoscopic placement of SEMS has become an easy and safe palliative treatment for malignant esophageal obstructions, placing a stent across the GEJ still has several problems associated with anatomic location, such as stent migration and reflux esophagitis^[10]. However, little data has been published focusing on esophageal stenting across the GEJ.

In the present study, SEMS were shown to be a safe and effective treatment for malignant GEJ obstruction, providing a technical and clinical success rate of 100% and no procedure-related major complications. In comparison to another study^[18], our technical and clinical success rate was similar.

Stent placement in GEJ is especially vulnerable to migration, because the distal portion of the stent projects freely into the gastric fundus without fixation to the esophageal or gastric wall^[9]. In other studies, migration rates for covered stents have varied considerable, from 7% to as high as 50%^[18-22]. Especially, migration rates for covered stent placement in GEJ was reported as 20%^[18]. But, another study of migration rates for double layered stent placement in GEJ was reported as 4.7%^[11]. In our study, stent migration developed in one (5.6%) patient in the GEJ group. It has been recognized that stent design may play a role in reducing migration. The double layered stent was designed to reduce stent migration (Figure 1). This device combines two specific characteristics. First, it flares to 24-28 mm at both ends; this size was chosen to minimize the risk of stent-related esophageal complications. Second, it has a double-layered configuration, consisting of an inner silicone membrane layer and an outer uncovered nitinol wire to allow the mesh of the stent to embed itself in esophageal wall. So, our low migration

seems to be associated with outer uncovered stent portion. A central uncovered stent makes space between the uncovered and covered stent in the central portion of double layered SEMS. Adjacent tumor or normal tissue invades through mesh and anchor SEMS firmly to the esophageal wall. Furthermore, inner covered stent resists to tumor in-growth. So, double layered SEMS placement in GEJ is effective for prevention of stent migration with advantage of covered stent.

Overall 27% of patients experienced a symptomatic reflux esophagitis, which is similar to incidence of other studies (27%)^[10,19]. Placement of the stent across the GEJ eliminates the sphincter function of esophagus and permits free reflux of gastric contents into esophagus. Patients experience reflux from an increase in intraabdominal pressure and also passive reflux when gravity is eliminated^[23]. Thus, stenting across the GEJ seems to lead gastroesophageal reflux and even aspiration pneumonia. Weston *et al*^[24] reported gastroesophageal reflux disease, including cases of aspiration and death, in 27% of patients who had SEMS placed across the GEJ. Valbuena also reported cases of heartburn and coughing spells in 27% of patients in whom a standard open stent was used for palliative treatment of GEJ cancer^[25]. It is widely known that reflux esophagitis is more common westerners than asians. But, in our study, reflux esophagitis (44.4%) was more frequent developed by SEMS insertion in GEJ obstruction, compared to other studies (27%). Because our study was retrospective in nature, reflux esophagitis might be overestimated and multiple post-procedure symptoms could be considered as reflux esophagitis symptoms. For example, not only heartburn and regurgitation, but also chest pain and epigastric pain could be regarded as reflux esophagitis symptoms. Asians complain of atypical reflux esophagitis symptoms more frequently than westerners^[26] and 30% of atypical reflux esophagitis symptoms are related chest pain and epigastric pain^[27].

As reported on another study^[28], proton pump inhibitors were effective for controlling gastroesophageal reflux disease symptoms in most cases. Although several anti-reflux stents have been developed to prevent reflux, the results are conflicting^[29-31]. These stents also have demerits of higher rates of migration and gas bloating after meals^[32]. As our and Sabharwal *et al*^[33] results, conventional SEMS placement with a proton pump inhibitor seems to be useful alternative to manage reflux in patients with stenting across GEJ.

Our study has several limitations. First, since our study was a retrospective study, bias in evaluation of reflux esophagitis might be involved. Second, we did not take into consideration of anticancer treatment including chemotherapy and/or radiation therapy before SEMS placement. It is possible that these may cause different clinical outcomes in stent patency according to the oncologic outcomes of anticancer treatments. Consequently, such differences might have affected results of our study.

In conclusion, double-layered SEMS are feasible and

effective treatment when placing SEMS across GEJ for malignant esophageal obstruction. Double-layered SEMS provide acceptable complications, especially migration, although reflux esophagitis is more common in GEJ group.

COMMENTS

Background

There is not yet few data focusing esophageal stenting across gastroesophageal junction (GEJ). Because placement of self-expanding metal stents (SEMS) across the GEJ has a tendency of higher migration, the authors evaluated the clinical outcomes of double-layered SEMS for treatment of malignant esophageal obstruction according to whether SEMS across gastroesophageal junction.

Research frontiers

Placing a stent across the GEJ have several limitations due to anatomic features leading to a higher migration rate and gastroesophageal reflux. Double-layered SEMS provide acceptable complications, especially migration, although reflux esophagitis is more common in GEJ group.

Innovations and breakthroughs

The double-layered stent has the advantages of both uncovered (low migration rate) and covered (low in-growth rate) stents. The authors demonstrated the effectiveness of double-layered SEMS for treatment of malignant esophageal obstruction.

Applications

Double-layered SEMS are feasible and effective treatment when placing SEMS across GEJ for malignant esophageal obstruction.

Terminology

Double layered SEMS means that the stent consists of an outer uncovered and an inner covered stent. Dysphagia score is defined as follows: score 0, ability to eat a normal diet; 1, ability to eat some solid food; 2, ability to eat some semisolids only; 3, ability to swallow liquids only; and 4, complete inability to swallow.

Peer review

The paper is well structured and the results are presented and discussed in a good way.

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