

# Efficacy and Safety of Endoscopic Self-Expanding Metallic Stent for Esophageal Malignancy: A Two-Institute Experience

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## Abstract

**Background** Self-expandable metallic stents (SEMS) placement is the procedure of choice for palliation of dysphagia in inoperable esophageal malignancies.

**Aim** To evaluate the safety of placement of SEMS in esophageal cancer at two institutes using only endoscopic control without fluoroscopy and to determine efficacy of SEMS in palliation of dysphagia after deployment.

**Methods** Participants who underwent endoscopy and esophageal SEMS placement at two centers for inoperable esophageal malignancy between 2014 and 2017 were included retrospectively. The indication for the procedure and clinical outcome measures like adverse events and improvement in dysphagia score were recorded on uniform structured data forms.

**Results** Eighty-three esophageal SEMS placement was performed in 78 patients (mean age  $64 \pm 10.1$  years; 59 men). The indication of SEMS placement was stricture in 72 (92.3%) and in 6 cases SEMS was placed for closure of trachea–esophageal fistula. All the patients in dysphagia score of 3 have improved to lower dysphagia scores post stent deployment. Postprocedure retrosternal pain, respiratory distress, and aspiration pneumonia in 58, 9, and 2 patients, respectively. Five patients required repeat stenting due to tumor ingrowth/granulation tissue during follow-up. The median survival of patients who received SEMS was significantly different from controls who did not receive SEMS (141 [41–360] days versus 98 [30–165] days;  $p = 0.01$ ). In 2 cases stent repositioning was done due to distal migration at the time of placement. There was no SEMS migration or stent related complications at follow-up.

**Conclusions** SEMS can be placed effectively under endoscopic control without fluoroscopic control in palliation of esophageal malignancy. Early SEMS deployment for palliating dysphagia may lead to survival advantage.

## Keywords

- ▶ controlled radial expansile dilation
- ▶ esophageal malignancy
- ▶ self-expanding metallic stent

## Introduction

Esophageal malignancy is the eighth-most common cancer and the sixth-most common cause of cancer-related deaths

worldwide.<sup>1</sup> Esophageal cancer incidence and histological type are highly variable based on the geographic location and mostly reported from the “Asian esophageal cancer belt.”<sup>2</sup> Esophageal malignancies are usually diagnosed at an

advanced stage, leaving palliation as a more realistic option.<sup>3</sup> Dysphagia is the predominant symptom in >70% of patients with esophageal cancer, resulting in weight loss and malnutrition.<sup>4</sup> The primary goal of esophageal stent insertion in patients with advanced disease is to relieve dysphagia and to prevent malnutrition. Compared with parenteral nutrition, endoscopic stent placement significantly improves a patient's quality of life by restoring the ability to take in food and fluids orally. Despite many advances in diagnosis and treatment, the 5-year survival rate for all patients diagnosed with esophageal cancer ranges from 15 to 20%.<sup>5</sup>

The hazard of radiation exposure pertaining to fluoroscopic guidance can be avoided when self-expanding metallic stents (SEMS) is deployed under only endoscopic control.<sup>6</sup> The aim of the present study was to evaluate the safety of placement of SEMS in esophageal cancer at two teaching institutes using only endoscopic control without fluoroscopy and to determine the efficacy of SEMS in palliation of dysphagia after deployment.

## Materials and Methods

We screened the records of all the patients who underwent endoscopy and SEMS placement for esophageal malignancies at two tertiary care centers between January 2014 and December 2017 retrospectively.

All patients/cases underwent a thorough clinical examination, upper gastrointestinal (GI) endoscopy, and biopsy to confirm the diagnosis. Contrast-enhanced computed tomography (chest and abdomen) was used to assess the local tumor infiltration and metastasis.

The indications for SEMS insertion were as follows: (1) locally advanced unresectable esophageal cancer (involvement of tracheobronchial tree, aorta, or pulmonary vasculature), (2) metastatic disease, (3) complications due to cancer such as tracheoesophageal fistula and aspiration pneumonia, (4) extrinsic esophageal compression due to primary or secondary tumors, (5) refractory or recurrent esophageal strictures, (6) malignant esophageal perforation, and (7) gastroesophageal anastomotic leaks/tumor recurrence after surgery or chemoradiotherapy. The contraindications for SEMS insertion were in terminally ill patients with a life expectancy of <4 weeks, distal obstruction, perforation, bowel ischemia, sepsis, or uncorrectable coagulopathy. Palliative radiotherapy was offered to patients after stenting for palliation of pain due to extraesophageal spread. The exclusion criteria in five patients were either tumor located within 2 cm from the upper esophageal sphincter (UES) (decrease chance of aspiration and foreign-body sensation) or inability to pass dilator balloon.

Cases are the patients who underwent deployment of SEMS and the patients who declined the SEMS deployment were taken as the control group. They underwent placement of either Ryle's tube or gastrostomy tube feeding.

### Assessment of Dysphagia

The following dysphagia scoring system<sup>7</sup> as given in (►Table 1) was used before and after the placement of the stent to assess the response.

**Table 1** The scoring system used for dysphagia

| Severity of dysphagia | Episodes of swallowing difficulty |                             |
|-----------------------|-----------------------------------|-----------------------------|
|                       | Liquid                            | Solid                       |
| None                  | None                              | None                        |
| Mild                  | None                              | Rare                        |
| Moderate              | None or rare                      | Occasional (specific foods) |
| Severe                | Present                           | Frequent                    |

Written informed consent was obtained from all patients after explaining the disease and the need for SEMS and its complications. The study was performed conforming to the Helsinki declaration of 1975, as revised in 2000 and 2008 concerning human rights.

## Procedure for Dilation and Self-Expanding Metallic Stents Placement

### Stent and Scope Design

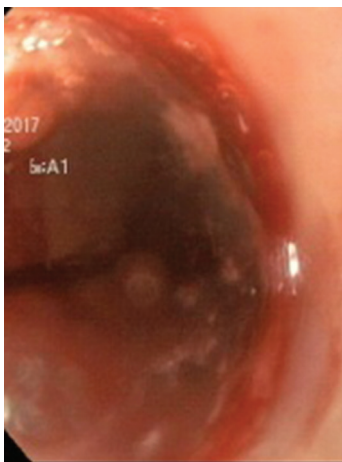
An upper GI endoscopy was performed using Exera II Evis 180 GIF180 (Olympus, Tokyo, Japan) video endoscope with high resolution (1080 dpi), 1.5-fold magnification, and narrow-band imaging technology was used. The stent used in all patients was partially polyurethane-covered proximal release stent (Ultraflex esophageal stent, Boston Scientific, Natick, Massachusetts, United States). The stents were made of knitted nitinol with 10, 12, and 15 cm in length and flange diameter being 23/28 mm. Only proximal release stents were deployed. Fluoroscopy was not used for the SEMS deployment.

### Technique of Self-Expanding Metallic Stents Insertion

The proximal end of the stricture is noted with endoscope (►Fig. 1), and a controlled radial expansion (CRE) balloon catheter (Microvasive, Boston Scientific Corporation, Natick, Massachusetts, United States) was used for dilation up to 11 mm for the passage of scope (►Fig. 2). All the patients undergoing balloon dilation had successful dilation up to 11 mm. The balloon was inflated with water to the recommended pressure for 60 seconds.<sup>8</sup> The stricture length was measured from distal end to proximal end while the withdrawal



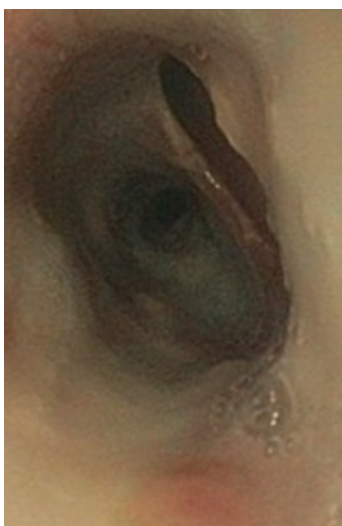
**Fig. 1** Endoscopic image of proximal end of stricture.



**Fig. 2** Controlled radial expansile balloon dilation of the esophageal stricture.

of the endoscope and a 0.035"/0.038" stiff guidewire was passed across the stricture. After dilation, in all the patients, the endoscope was passable throughout the length. In 10 patients who needed fluoroscopy for failed dilation were excluded from the study.

Four markings were recorded: level of UES, proximal and distal end of the growth, the gastroesophageal junction, and the presence or absence of tracheoesophageal fistulae (TOF) (► **Fig. 3**). The length of the stricture determined the length of the stent used. The SEMS length chosen was at least 3 cm longer than the growth with 1.5 cm extending beyond at either end. Stent deployment was begun by placing firmly on the inner catheter and using a finger ring with the other hand-suture unravels from the proximal end. Reintubation with the endoscope was performed immediately to confirm the accuracy of stent placement adjacent to the stent introducer (► **Fig. 4**). Proximal release stent has 1 cm distal migration during the deployment of the stent which can be corrected by counter traction.



**Fig. 3** Tracheoesophageal fistula proximal to the esophageal stricture.

Once deployed, if the stent diameter did not achieve nominal diameter, CRE balloon of appropriate size was used for dilation of the stent. Savary–Gilliard dilators were not used as axial force can dislodge the stent. The procedure was done as daycare surgery. Oral feeds with liquid diet were started 4 hours after the procedure. Patients were discharged if they tolerated oral food and a chest radiograph was done for documenting stent position.

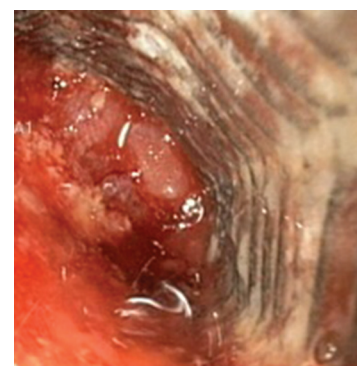
Patients who were planned for palliative radiation received 30 Gy/10 fractions/5 fractions in a week over 2 weeks with three-dimensional conformal radiotherapy technique.

### Clinical Follow-up

Patients were treated with antacids or proton-pump inhibitors for gastric acid suppression. Symptoms of dysphagia were recorded for each patient during the follow-up monthly thereafter till the death or lost to follow-up which is considered as death. Early complications (<2–4 weeks after SEMS placement) such as foreign-body sensation, pain, gastroesophageal reflux, migration, bleeding, and perforation were recorded. Delayed complications (>4 weeks after SEMS placement), including migration, tumor ingrowth and overgrowth, food impaction, and fistula development, were recorded. Follow-up endoscopy after SEMS placement was performed on demand whenever patients complained of dysphagia. Another SEMS was placed in the case of SEMS blockage due to tumor ingrowth or migration of the previous SEMS (► **Figs. 5 and 6**).



**Fig. 4** Self-expanding metallic stent deployment under endoscopic control.



**Fig. 5** Tumor ingrowth at the distal end of self-expanding metallic stent.



**Fig. 6** Esophageal self-expanding metallic stents in self-expanding metallic stents with resolution clip in situ.

### Statistical Analysis

Continuous variables are given by the mean and standard deviation. The continuous variables were analyzed using the Mann–Whitney U-test. Categorical variables were given in total and as percentages. They were analyzed using Fisher's exact test. Dysphagia scores before and after stenting were compared using paired student's *t*-test. Two-sided value of  $P < 0.05$  was considered statistically significant. Survival was assessed using Kaplan–Meier graph after comparing median survival time using Koch's regression model. The data were checked for normality by the Shapiro–Wilk test. All statistical operations were performed using SPSS WIN version 16.0 (SPSS Inc., Chicago, Illinois, United States).

### Results

A total of 78 patients underwent SEMS placement during the study. The mean age of the group was 64 years, and the rest of the demographic details are depicted in (► **Table 2**).

Following SEMS deployment, all 61 patients with dysphagia score of 3, improved to either (1) mild (52 patients [85.2%]) or (2) moderate (9 patients [14.8%]) as given in (► **Table 3**).

#### Control Group Without Self-Expanding Metallic Stents Placement

The location of the esophageal tumor was upper one-third in 9 (18%), middle-third in 35 (70%), and lower-third in 6 (12%). There was no difference in age and gender parameters.

#### Survival Difference

All patients died due to general debility and metastatic disease. No patient expired during the procedure of deployment of SEMS. The median difference in survival between 78 patients who underwent SEMS was compared with 50 patients who did not undergo SEMS deployment (141 [41–360] days vs. 98 [30–165] days;  $p = 0.01$ ). At 200 days, follow-up from the diagnosis or from SEMS deployment, 18 (24%) patients who underwent SEMS were alive, while none of the patients without SEMS survived (► **Fig. 7**).

The possible reason for the difference in survival between the cases and control groups might be due to improvement in nutrition and reduced aspiration rates.

The complications after dilation were respiratory distress in 9 (11.5%), aspiration pneumonia in 2, and perforation in 1

**Table 2** Characteristics of patients with esophageal or esophagogastric junction cancer who underwent self-expanding metal stents deployment in two centers

| Sl no. | Characteristics  | Number (n = 78)  |
|--------|--|--|
| 1      | Age in years (mean ± SD)   | 64 ± 10.1 years  |
| 2      | Sex—male: female   | 59 (75.6%): 19 (24.4%)                                       |
| 3      | Duration of dysphagia in months (mean ± SD)  | 2 months ± 1.6   |
| 4      | Dysphagia severity pre SEMS<br>None: mild: moderate: severe  | 0 (0%):6 (7.6%):11 (14.1%): 61 (78.2%)                       |
| 5      | Obstruction length in centimeters (mean ± SD)  | 5.94 ± 2.94  |
| 6      | Location of esophageal tumor:<br>Upper 3rd: mid 3rd: lower 3rd   | 7 (9.7%):46 (58.9%):25 (31.4%)                               |
| 7      | Tumor histopathology<br>Squamous: adenocarcinoma: undifferentiated   | 58 (74.3%):18 (23%):2 (2.7%)                                 |
| 8      | Previous treatment:<br>a. No treatment<br>b. Radiation<br>c. Chemotherapy (carboplatin and paclitaxel)<br>d. Chemo + radiation | a. 12 (15.3%)<br>b. 18 (23%)<br>c. 2 (2.5%)<br>d. 46 (58.9%) |
| 9      | Median patient survival time in days   | 220 (37–360 days)  |
| 10     | Complications:<br>a. Retrosternal pain<br>b. Respiratory distress<br>c. Aspiration pneumonia<br>d. Esophageal perforation      | a. 58 (74.3%)<br>b. 9 (11.5%)<br>c. 2 (2.5%)<br>d. 1 (1.2%)  |
| 11     | Dysphagia severity post SEMS<br>None:mild:moderate:severe  | 5 (6.4%):64 (82%):9 (11.5%):0                                |

**Table 3** Depicting dysphagia scores before and 30 days after deployment of self-expanding metal stents

|              | Post SEMS 0 | Post SEMS1 | Post SEMS2 | Post SEMS3 | Total |
|--------------|-------------|------------|------------|------------|-------|
| Pre SEMS 0   | 0           | 0          | 0          | 0          | 0     |
| Pre SEMS 1   | 3           | 3          | 0          | 0          | 6     |
| Pre SEMS 2   | 2           | 9          | 0          | 0          | 11    |
| Pre SEMS 3   | 0           | 52         | 9          | 0          | 61    |
| <b>Total</b> | 5           | 64         | 9          | 0          | 78    |

which were managed with noninvasive ventilation, antibiotics, and placement of SEMS, respectively.

### Discussion

The results suggest that endoscopic SEMS deployment in malignant esophageal stenosis as the palliative procedure is



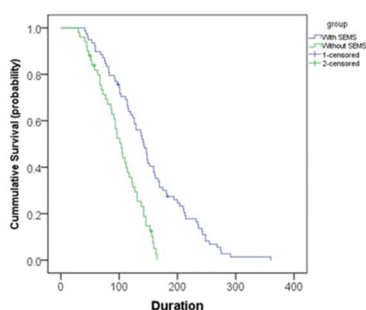


Fig. 7 Cumulative survival difference between cases and controls.

rapid, effective, and has low morbidity. All the patients in dysphagia score of 3 have improved to lower dysphagia scores.

Endoscopic modalities of palliation of malignant esophageal obstruction are the placement of feeding tubes and deployment of SEMS. Surgical modalities are the placement of either gastrostomy or jejunostomy feeding tubes. SEMS placement is useful for patients whose functional status is poor, cannot tolerate surgery or chemotherapy, or having advanced disease.<sup>9</sup> Compared with other palliative methods, the most significant and fastest improvement in swallowing is achieved in patients undergoing implantation of SEMS in ~90% of patients.<sup>10-12</sup>

Stents provide better oral intake and quality of life compared with surgical palliation techniques.<sup>13,14</sup> The majority of our participants were patients who were referred to our clinic for dysphagia palliation from different centers. The improvement in our patients following stenting is consistent with the literature.

Poststent placement and recurrence of dysphagia would be due to stent migration, tumoral or nontumoral tissue growth, and food impaction. Frequencies of recurrent dysphagia associated with overgrowth, ingrowth, and obstruction due to food impaction reported in the literature vary between 17% and 33%, somewhat higher than those observed in our study.<sup>15</sup> None of our patients had food impaction as they were strictly advised regarding consumption of semi-solid diet, antireflux measures as well as intake of carbonated water once a week.

The disadvantages of uncovered stents are tumor ingrowth, benign epithelial hyperplasia or granulation tissue, and recurrent obstruction. Ingrowth in uncovered stents has been reported in the literature to be in the range of 0 to 100%.<sup>16,17</sup>

In our study, recurrent dysphagia due to tumor ingrowth or by granulation tissue either at the proximal/distal end of SEMS occurred in 5/78 (6.4%). They presented with the recurrence of dysphagia and aspiration. They received another SEMS placement. The second SEMS was placed with an overlap of 3 cm on the earlier placed SEMS. If second SEMS was being deployed distally, the Resolution clip (Boston Scientific, Natick, Massachusetts, United States) was placed to prevent distal migration between the two stents. Placing second SEMS was avoided if the distance of the tumor overgrowth was <2 cm from UES in one patient.

SEMS is also used to treat malignant TOF. TOFs can develop either due to carcinoma esophagus invading the trachea or lung carcinoma invading esophagus. The major cause of mortality in carcinoma esophagus is the aspiration of saliva or food. Survival over 30 days is rare in these patients unless they undergo an occluding procedure using endoprosthesis.<sup>18-22</sup> Hybrid stents (ultra-flex) were deployed in six patients with the covered portion of the stent covering the fistulous area and with the proximal end of the SEMS at least 4 to 5 cm above the fistula to prevent the passage of esophageal contents through the mesh.

All the SEMS were deployed beyond 2 cm from UES. None of the patients complained of foreign-body sensation. Majority complained of retrosternal pain in 58 (74%), respiratory distress in 9 (11%), and aspiration pneumonia in 2 (2%). All the complications were managed medically. None required concurrent tracheal stenting or surgery. There were no immediate postprocedure complications. There was no mortality at the time of the SEMS deployment or immediately postprocedure. Approximately 0.5% to 2% of patients who undergo the procedure died as a direct result of the placement of an expandable metal stent.<sup>23</sup>

In one patient, after SEMS was in situ for 9 months; there was documentation of perforation of the esophageal wall at the proximal end of the SEMS. The stent deployed was of large flare—28 mm—and would have been due to stent-induced pressure necrosis within devitalized esophageal tissue.<sup>24</sup>

Two prospective, randomized, controlled trials have shown a significantly lower rate of procedural complications using expanding metal stents.<sup>25,26</sup>

In contrast to the conventional placement of SEMS using fluoroscopic control and use of bougie, the perforation risk is minimized by early referral for SEMS placement by radiotherapists. In our series, balloon dilatation was performed in all the patients before stenting. The frequency of dilatation has been reported to be in the range of 0 to 100% in the literature.<sup>27</sup>

Studies have reported the incidence of late migration from 0 to 58% for different types of covered stents. However, in our study, none of the placed stents migrated.<sup>28</sup>

Two patients had streaky hematemesis after SEMS deployment without any requirement of blood transfusion possibly due to balloon dilation or esophageal or gastric trauma.

Mean survival after stenting reported in the literature varies between 53 and 198 days.<sup>11,25</sup> In our study, the mean survival after stenting was 141 days. Overall survival time in our study was not significantly different from others in the literature but was significantly different from controls who did not receive SEMS (98 days).

## Conclusion

In our retrospective study, all the patients who underwent SEMS placement by endoscopic without fluoroscopic control were safe and rapid palliation of malignant dysphagia was achieved.

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Nil.

**Conflicts of Interest**

None.

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