

## IMPACT ON QUALITY OF LIFE AFTER PALLIATIVE STENTING IN PATIENTS WITH INOPERABLE ESOPHAGEAL CANCER

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Received : 19/01/2023  
Received in revised form : 26/02/2023  
Accepted : 10/03/2023

**Keywords:**

Esophageal cancer, Dysphagia, Stents, Quality of Life, Palliative Esophageal, Radiotherapy.

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DOI: 10.47009/jamp.2023.5.4.96

Source of Support: Nil,

Conflict of Interest: None declared

*Int J Acad Med Pharm*  
2023; 5 (4); 476-480



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### Abstract

**Background:** Esophageal cancer has increased significantly, making palliative treatment preferable among inoperable patients. Dysphagia is the most common clinical symptom; however, advancements are being made in addressing it. This study aim to assess whether palliative therapy using Esophageal SEMS (Self Expanding Metal Stent) could improve the QOL (Quality of Life) in patients with inoperable cancer. **Materials and Methods:** After applying inclusion & exclusion criteria, patients were taken up for the study with informed consent. The Quality-of-life assessment was done using the FACT-E (Functional Assessment of Cancer Therapy -Esophagus) questionnaire Version 4. The evaluation was done before stenting and at the 1st, 4th-, and 12th weeks following placement of the stent. **Result:** Sixteen patients were included in the study & 13 were men. The mean age group was 61.4±12.5 years. Around 68.5% of patients presented with Grade II- III dysphagia. Squamous cell carcinoma (n=13) was the most common type & majority involved the lower esophagus (n=7). Fistula & metastasis were the commonest indications for stenting. After stenting, there was a significant improvement in the patient's functional, Emotional, Physical & Social well-being status of the patients during 1st week, 1st month & 3rd month compared to the pre-stenting status. 9 patients survived beyond three months. Regurgitation & Foreign body sensation were the most common complaints, nearly 50% & 37.5%, respectively, after Esophageal stenting. **Conclusion:** Palliative Esophageal SEMS improves the quality of life in patients with inoperable Esophageal cancer. Further randomized control trials are required to compare the quality of life after palliative radiotherapy.

## INTRODUCTION

Lately, the incidence of Esophageal cancer has increased tremendously in decades and ranks 7<sup>th</sup> in the world (high incidence rates in China). Moderate to high incidence rates have been reported from Central Asia, South Africa, South America, Northern France, and among African-Americans in the United States.<sup>[1,2]</sup> The diagnosis of ECs is mainly made at the advanced stage and within the comorbid patients. Most patients have locally advanced or disseminated cancer at the time of presentation, irrespective of histology & location. Thus, making palliative treatment preferable among inoperable patients. Palliative therapy aims to manage the disease's symptoms and improve the quality of life.<sup>[3-5]</sup>

Dysphagia is the most common clinical symptom in more than 80% of ECs patients. Lately, many palliative management options have been reported to cure malignant dysphagia. Other options to palliate malignant dysphagia include chemotherapy or radiotherapy, oesophageal dilation, endoluminal stents, laser ablation, brachytherapy, photodynamic therapy (PDT), and bypass surgery.<sup>[1,2]</sup> However, all these options possess some limitations, and the optimum management of dysphagia is not achieved to date. However, continuous progress has been recorded over the years. In recent times esophageal stent has become the option for palliative care with minimal morbidity. Self-expanding metal stents (SEMS) have been preferable over plastic or metal stents. They are successfully inserted in patients with good prognosis.<sup>[1,2,6]</sup>

In the present study, we assessed the change in the quality of life & survival rate of patients with inoperable esophageal cancer following endoscopic placement of SEMS using the FACT-E (Functional Assessment of Cancer Therapy- Esophagus) questionnaire.

## MATERIALS AND METHODS

After approval from the Institutional Ethics Committee, we prospectively collected data from March 2021 - March 2022 in the Department of Medical Gastroenterology, Tirunelveli Medical College, Tamil Nadu, India. Data regarding age, sex, complaints, Histological type, location of carcinoma, and ECOG (Eastern Cooperative Oncology Group) performance status were collected.

### Inclusion Criteria

Malignant fistula, locally advanced unresectable cancer, distant metastasis, comorbid illness precluding a major surgical procedure or chemoradiotherapy, and residual obstructive lesion were included.

### Exclusion Criteria

Eligible for radiotherapy and eligible for surgery or chemoradiotherapy were excluded.

### Procedure

All patients were hospitalized and received local anaesthetic lignocaine spray during the procedure. All endoscopic procedures were performed using Upper Gastrointestinal Endoscopy (Olympus Medical Systems Co., Ltd, Tokyo, Japan. Fujifilm Corporation, Japan).

The patients were kept on fasting for 8 hours before the procedure. The procedure was performed under the local anaesthetic spray, with intravenous sedation. A diagnostic endoscopy was done to assess the lesion location & to determine the appropriate SEMS. If an obstructive lesion does not allow the passage of an adult endoscope, a neonatal gastroscope was used to traverse the stenosis. The length of the stenotic lesion was measured & appropriate SEMS was chosen based on the lesion size. Ideally, SEMS should aim for a minimum of 2 cm coverage on both extents of the lesion.

After marking the lesion, the endoscope was advanced into the stomach & guidewire was placed in. Then the endoscope was withdrawn, leaving the guidewire in place. Further, the stent delivery system was railed over the guidewire. Furthermore, the stent was slowly deployed by distal release technique under continuous endoscopic guidance with the confirmation that the proximal end is 2 cm above the lesion. Once the stent was deployed, the delivery system & guidewire were removed.

After deployment, a chest X-ray was taken to check the expansion of the stent. The patient will be in an upright posture for 12 hrs. Oral liquids were allowed after 12 hrs, then gradually increased to semi-solids and then to solids over the next 48 hrs. The Quality-of-life assessment was done using FACT-E (version

4) questionnaire. The evaluation was done before stenting and at 1-, 4- & 12 weeks following placement of the stent.

### Statistical Method

The information collected regarding all the selected cases was recorded in a Master Chart. Data analysis was done with the help of a computer by using SPSS 16 software. By using this software, mean, SD, and percentage were calculated. P values were calculated through a One-way ANOVA test for raw data and a chi-square test for consolidated data to test the significance of the difference between variables. A p-value less than 0.05 is taken to denote a significant relationship.

## RESULTS

Out of 83 patients, 16 were included in the study after applying Inclusion & Exclusion criteria. Among 16 cases, 13 cases (81.25%) are male. The mean age group of patients was  $61.4 \pm 12.5$  years. All patients presented with complaints of dysphagia, 11 cases (68.7%) and 5 cases (31.2%) with Grade II-III & Grade IV dysphagia, respectively. The mean duration of symptoms is  $37.25 \pm 9.78$  days. Nearly eight patients (50%) had a cough, and three (19%) had breathlessness during the presentation. All 16 patients had significant weight loss; the mean weight at presentation was  $47.2 \pm 5.77$  kgs. Most patients had ECOG Performance status II-III (12 patients) [Table 1].

Our study's most common histology was squamous cell carcinoma with 13 (81%) patients. Only three patients (18.75%) were of adenocarcinoma type. The lower esophagus was the most commonly affected site, even among squamous cell carcinoma. Out of 10 lower oesophageal carcinomas (Squamous & adenocarcinoma), six patients had OG Junction involvement. The mean length of the tumor was  $8.87 \pm 1.927$  cm. A 15 cm stent was used in most cases due to long segment involvement of the esophagus by tumors. Tracheo-oesophageal fistula (7 patients) was the commonest indication for stenting. Two patients had residual lesions after radiotherapy, and one was intolerant to chemotherapy. Distant metastasis was the reason in 4 patients and severe cardiopulmonary disease in 2 Patients [Table 2].

Eight patients (50%) had regurgitation symptoms, and six patients (37.5%) had foreign body sensations in the chest after Esophageal stenting [Table 3]. Bleeding was a complication in 1 patient that occurred nearly one month after stenting, resulting in the patient's death. Stent migration was seen in 2 patients, and repositioning of the stent was done in one patient. Repositioning the stent was impossible in one patient, so re-stenting (stent in-stent technique) was performed on that patient.

Among 16 patients, two completed radiotherapies before stenting, and another 1 underwent ten cycles of radiotherapy. Further treatment was deferred due to the development of fistulous communication

between the trachea & esophagus. None of the patients were subjected to radiotherapy or chemotherapy after stenting.

After stenting, there was a drastic improvement in Physical, Functional, Social, and Emotional well-being scores using the FACT-E (Functional Assessment of Cancer Therapy- Esophagus)

questionnaire in the first week and first month. The Emotional well-being (15.625 vs 8.33; <0.001), Functional well-being (3.875 vs 13.56; <0.001), Physical well-being (17.688 vs 9.44; <0.001), Social well-being (11.688 vs 15.89; 0.005) scores had significant improvement after stenting when compared to baseline [Table 4].

**Table 1: Demographic and clinical characteristics of the study group**

Variables	Number
Male: Female	13:3
Age group	61.4±12.5 years
Dysphagia Grade II-III Grade IV	11 (68.7%) 5 (31.2%)
Duration of dysphagia (in days)	37.25 ± 9.78 days
Cough	8 (50%)
Breathlessness	3 (19%)
Weight loss	16 (100%)
Mean weight in kgs	47.2±5.77
Performance status ECOG 0-1 ECOG 2-3 ECOG 4	0 12 4

**Table 2: Histology, location, and indications for stenting of the study group.**

Variables	Number
Histology: Squamous cell carcinoma Adenocarcinoma	13 (81%) 3 (18.75%)
Location: Upper Oesophagus Middle Oesophagus Lower Oesophagus	0 6 (37.5%) 10 (62.5%)
Indication for stenting: Metastasis Fistula Intolerance to Chemotherapy Severe Cardiopulmonary disease Residual disease	4 (25%) 7 (43.7%) 1 (6.25%) 2 (12.5%) 2 (12.5%)
Stent size: 10 cm 12.5 cm 15 cm	3 3 10

**Table 3: Complications in the study group**

Variables	Number (n)
Foreign body sensation	6 (37.5%)
Respiratory Distress	2 (12.5%)
Regurgitation	8 (50%)
Bleeding	1 (6.25%)
Stent migration	2 (12.5%)

**Table 4: Comparison of symptoms score over the months**

Scale	Basal	One week	One month	Three months	P value	Inference
Emotional	15.625±1.708	11.5±1.592	10.25±1.571	8.33±4.377	<0.001	Significant
Functional	3.875±2.217	8.313±2.12	11.625±2.964	13.56±7.079	<0.001	Significant
Physical	17.688±3.459	13.938±3.395	12.0±3.286	9.44±5.363	<0.001	Significant
Social	11.688±1.922	12.75±0.931	14.438±1.209	15.89±8.185	0.005	Significant
Weight in kgs	47.25±5.768	47.125±5.807	47.188±6.145	48.88±25.346	0.884	Non- Significant

**Table 5: Survival percentage of patients in 3 months**

	Survival at three months	%
Yes	9	56.25
No	7	43.75

None was lost to follow-up, and seven patients died within three months. Only nine patients were considered for FACT-E assessment in the third month [Table 5]. There was no significant

improvement in the well-being status of the patient in the third month compared to the first month & no significant weight gain (47.25 vs 48.88; 0.884) was achieved after palliative stenting.

## DISCUSSION

Most esophageal cancer presents in the advanced stage & thus, curative therapy is limited.<sup>[7,8]</sup> Esophageal cancer is more common among males when compared to females in the ratio of 3:1.<sup>[9]</sup> The incidence of esophageal cancer increases as age increases & highest among >65. One retrospective data comprising 552 patients studied for 20 years has shown that the mean age group is 54.83 years.<sup>[10]</sup> Our study reveals that esophageal cancer has the highest peak of incidence in the 6<sup>th</sup> decade as correlated with most population-based data. An increasing incidence of adenocarcinoma was noted among several world countries, but no such changes were noted in India. Squamous cell carcinoma was the commonest type in India, irrespective of age, gender & site of the tumor.<sup>[1,2]</sup> One retrospective study from South India showed an increased incidence of squamous cell carcinoma in the lower esophagus.<sup>[11]</sup> In our study, the lower esophagus also appeared to have a greater propensity for Squamous cell carcinoma.

Most patients present with complaints of progressive dysphagia & weight loss. All patients included in our study had similar complaints. Nearly 50% of esophageal cancer shows at an inoperable stage either due to metastasis or poor general condition and needs palliative therapy. Among palliation for dysphagia in patients with inoperable carcinoma esophagus, Stents are the first choice due to rapid palliation & fewer complications.<sup>[1-3]</sup> Several studies have reported excellent results in relieving dysphagia using SEMs, with a technical success of 100% and improvement in dysphagia scores from 83% to 100%.<sup>[2]</sup> The chance of stent misplacement or deployment failure is less than 1%.<sup>[6]</sup> Technical successes in deploying the stent were 100% in our study. Even though it causes rapid palliation of dysphagia, few adverse events may occur with stents too. A retrospective study by Renáta Bor et al. showed 1.26% procedure-related deaths; complications like retrosternal pain & stent migration in 39.62% of cases.<sup>[12]</sup>

Migration is one of the common complications after stent placement, ranging from 4%-36%.<sup>[13]</sup> During follow-up, 12.5% had stent migration in our study. Stent migration can be prevented using large-diameter stents (25 – 28 mm). Still, it has a high chance of perforation & bleeding or by using external/Internal fixators like Through-the-scope or Over-the-scope clips. In 25.94% of repeat, endoscopic procedures were required. Re-stenting can be made if repositioning is impossible in case of stent migration.<sup>[14]</sup> Stent occlusion is another complication due to food impaction or tumor ingrowth. So, it's recommended to begin with liquids and gradually build up to a soft diet, as the stent can take up to 1–2 days to expand fully. To minimise tumour ingrowth, used stents are partially covered with synthetic materials such as polyurethane, silicone, or nitinol.<sup>[4]</sup> In case of tumor ingrowth, the stent-in-stent technique may also be applied to relieve dysphagia,

in which a second SEMs was placed through the first stent, adequately covering the site of tumor ingrowth.<sup>[2,4]</sup>

Bleeding is a complication in less than 1.5% - 5% of cases.<sup>[1,2,4]</sup> In our study, one patient had Upper Gastrointestinal bleeding after one month, which didn't require any interventions. Foreign body sensation was commonly seen after stenting. Chest pain is usually related to stent expansion, reported in 12-14%.<sup>[4]</sup> Regurgitation was more frequent among patients with carcinoma involving the Esophagogastric junction because SEMs will cross the Lower esophageal junction. Palliative stenting has an immediate effect in relieving dysphagia. A Study by Cwikiel et al. compared the results of radiotherapy, chemotherapy, and esophageal stent treatment. The palliative effects of chemotherapy and radiotherapy were evaluated retrospectively, whereas the impact of stent treatment was assessed prospectively. Finally concluded that chemotherapy may be less effective at relieving dysphagia than esophageal stent or radiotherapy.<sup>[15]</sup>

One another area where the stents need further improvement is their long-term efficacy in the palliation of dysphagia, tumor regression & improvement in survival. So, the hypothesis formulated for combination therapies: is to provide more durable management of dysphagia & improve survival.<sup>[15]</sup> Douglas Adamson et al. study showed that patients with advanced oesophageal cancer having SEMs insertion for the primary management of their dysphagia did not gain additional benefit from concurrent palliative radiotherapy and should not be routinely offered.<sup>[5]</sup> In their review article, Meena Sadaps et al. also stated that double palliation has no role. This would include manoeuvres such as esophageal stent placement followed by External beam radiotherapy/brachytherapy and External beam radiotherapy followed by brachytherapy.<sup>[16]</sup>

Previous studies assessing the quality of life after palliative stenting showed conflicting results. Helen J. Dallal et al. showed that Health-related quality of life deteriorated and no survival benefits in the stented group.<sup>[17]</sup> Marjolein YV Homs et al. showed that the Quality-of-life scores favoured brachytherapy compared with stent placement.<sup>[18]</sup> Giogia Diamantis et al. discussed that the SEMs insertion provides swift palliation of dysphagia compared to brachytherapy. However, this difference gradually diminishes over time, and, in the long run, brachytherapy appears to provide better dysphagia improvement and QOL.<sup>[1]</sup> A study by Cameron Schauer et al. showed significant improvement in overall QOL and dysphagia one-month post oesophageal stent insertion.<sup>[19]</sup> Another study by Yanet Ortega Dugrot et al. showed improvements in functional capacity (physical appearance, emotional factors) and symptoms.<sup>[20]</sup> In Madhusudhan et al. study, he concluded that stenting improves all quality of life scales.<sup>[3]</sup> In our study, significant improvement in quality of life was noted, but no improvement in survival following stenting.

## CONCLUSION

Patients with stage III (or) IV diseases who are inoperable can undergo Palliative Esophageal Self Expanding Metal Stent with less morbidity & mortality. There was a significant improvement in quality of life after SEMS during the initial period. Also, SEMS offers immediate relief of dysphagia compared to other care modalities. Further studies are required in combined modalities of therapy to improve the outcome.

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