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Efficacy and Safety of Esophageal SEMS in Advanced Esophageal Cancer

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Abstract: ***Background**: Esophageal cancer is the eighth most common cancer worldwide and constitutes the sixth leading cause of cancer deaths. Esophageal malignancies are advanced at the time of diagnosis in a large number of patients and they invariably require palliation for relief of dysphagia. Self - expandable metallic stent (SEMS) placement offers an excellent modality for palliation of dysphagia in inoperable esophageal malignancies, as well as in those whose disease recurred after different treatment modalities. It is a highly accepted method of treatment for palliation in cancer esophagus. **Objective**: To evaluate the safety and efficacy of esophageal stenting as a palliative therapy for dysphagia in esophageal cancer. **Methods**: Patients who underwent self - expandable metallic stent (SEMS) placement for relief of dysphagia in esophageal cancer were retrospectively recruited into the study in a consecutive manner. Stents from different manufacturers were used. Efficacy of the self - expandable metallic stent (SEMS) placement in terms of improvement in dysphagia score and adverse events were analyzed. **Results**: Esophageal SEMS placement was performed in 42 patients (median age 62 years; 48% men); 18 (43%) were diagnosed with adenocarcinoma and 24 (57%) with squamous cell carcinoma. Median dysphagia score improved from 3.45 ± 0.5 to 1.40 ± 0.58 after esophageal SEMS placement. Overall 12/42 (28.5%) of patients experienced complications. Most common complication was stent migration in 6 (14%) patients. **Conclusion**: SEMS is an effective therapy for relief of dysphagia in patients with esophageal carcinoma. Although certain complications like stent migration and tumor ingrowth are seen with SEMS placement, they can be easily managed.*

Keywords: Dysphagia, Radiation, Adenocarcinoma, Squamous Cell Carcinoma, Stent Migration

1. Introduction

Esophageal cancer is the eighth most common type of cancer overall and contributes significantly to cancer related mortality around the world. It accounts for 5 - 6% of all cancer related deaths[1].

Esophageal cancer is also one of the top five causes of cancer related mortality in India. It is prevalent in both men and women. Squamous cell carcinoma (SCC) is the predominantsubtype of esophageal cancer in India, although adenocarcinoma is on the rise due to changes in lifestyle pattern[2].

Esophageal cancer is often diagnosed at an advanced stage. It generally has a poor prognosis and a low five - year survival rate. Curative therapy is often not possible in most cases. Hence most patients of esophageal cancer end up requiring palliative care. Major cause of morbidity in advanced esophageal cancer is dysphagia due to luminal occlusion by the tumour. Most patients require some modality of palliation for dysphagia and the options include, brachytherapy, and external radiotherapy. A variety of esophageal stents have been developed and tested for relief of dysphagia in esophageal cancer and these include Self - expandable metallic stents (SEMS), Self - expandable plastic stents (SEPS), polyflex, and antireflux stents

Self - expandable metal stent (SEMS) placement is easy to perform and an affordable method to relieve dysphagia in patients with esophageal cancer in India. It can also be used in those patients with malignant tracheoesophageal fistulas (TEF) to allow oral feeding and prevent pulmonary complications. Major advantage of SEMS placement through endoscopy is that it is a minimally invasive procedure. However, in 30–50% of the patients undergoing SEMS placement, major or minor complications can develop. Most of these complications can be avoided by choosing appropriate SEMS correctly in terms of length and inherent characteristics. Complications can be managed in most patients with a few requiring repeat endoscopic procedure[3, 4].

The primary aim of this study is to evaluate the efficacy of self - expandable metal stents (SEMS) in relieving dysphagia in esophageal malignancy and to identify factors that can contribute to the adverse outcomes of SEMS placement.

2. Materials and methods

This is a retrospective study conducted at Yashoda Hospitals, Secunderabad which is a tertiary care centre in Hyderabad, India. Aim of the study was to evaluate the success and complication rate of esophageal stent placement for palliation of malignancy. All consecutive patients who underwent SEMS placement from January 2021 to December 2023 for palliation of dysphagia in esophageal cancer were enrolled in this study.

The exclusion criteria is: (1) follow - up period < 1 month; and (2) insufficient data on cancer characteristics or patient reported dysphagia scores.

All participants provided informed consent for the procedures. The retrospective study protocol was approved by the Institute Ethics Committee at Yashoda Hospitals.

Data Collection

Request for inclusion in the study and patient related data was collected from our health records and telecommunication with the patient or family members (if patient was deceased by the time of data collection): demographic parameters, location of tumour, histopathological subtype, length of stenosis, length of the SEMS placed, pre and post procedure dysphagia score. Mellow - Pinkas score was used to assess dysphagia ranging from 0 - 3; grade 0 has no dysphagia while grade 3 is able to swallow liquids only and grade 1, 2 suggest intermediate severity. Complications related to stent placement were recorded, which included perforation, bleeding, migration, tumour ingrowth, bolus obstruction, aspiration pneumonia or cardiac complications**.**

Stent - insertion protocol

All patients underwent a screening endoscopy prior to the day of SEMS placement and length of stenosis and involvement of GE junction was noted. The stents were placed over guidewires using the standard technique with the help of fluroscopy under propofol sedation. Majority of the SEMS used in our study were partially covered. These stents have a central covered portion and uncovered portion at both ends near the flanges. Self expandable metallic stents used were from different standard manufacturers. The location and size of the underlying pathology determined the lengths and diameter of the inserted stent. Dilatation was performed as an adjunct if deemed necessary. Stent position was confirmed endoscopically and radiologically (Fig 1&2).

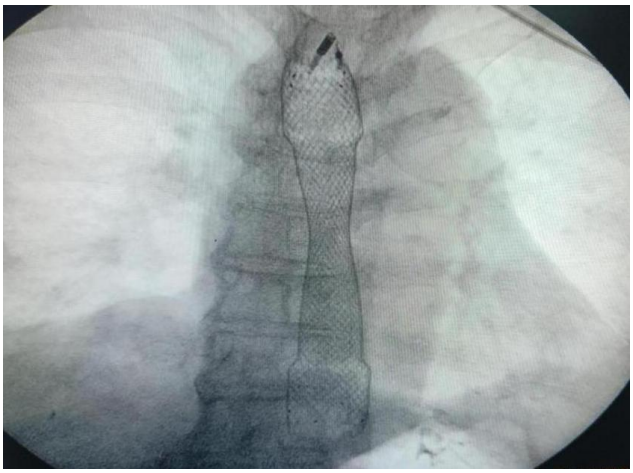

Figure 1: Fluoroscopy image - Post SEMS Deployment

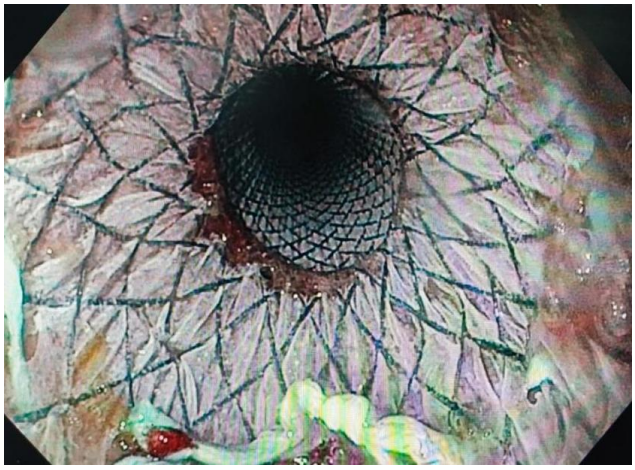

Figure 2: Endoscopic view - Post SEMS Deployment

Statistical Analysis

The study employed statistical analysis to compare the dysphagia score before and after esophageal stenting. Software used was SPSS version 2.4 and the statistical tests like Dependent t - test and chi square test were utilized. Statistical analysis was also performed for the complications of esophageal stenting in relation to the location of tumor. In view of smaller sample size, confidence interval was 95% and hence P value < 0.05 was considered as significant.

3. SEMS Results

Table 1: Characteristics of Patients (n=42)

Characteristic	Value
Age (years)	61.88±13.97
Sex	
Male	20 (48)
Female	22 (52)
Histology	
Adeno carcinoma	18 (43)
Squamous cell carcinoma	24 (57)
Location	
Upper third	08 (19)
Middle third	12 (29)
Lower third	22 (52)
Length of stenosis (cm)	
Short (≤3)	08 (19)
Long (>3)	34 (81)
Stent length (cm)	
<12	20 (48)
Dec-15	21 (50)
>15	01 (02)
Complications	
Stent migration	06 (14)
Tumor ingrowth/Overgrowth	03 (07)
Respiratory tract infection	03 (07)
Reinterventions	09 (21)
Median survival after stenting	162 (32 - 350 days)

Table 2: Comparison of Dysphagia Scores

Dysphagia Score		
Pre stenting score	Post stenting score	P value
3.45±0.50	1.40±0.58	<0.0001*

Statistically significant difference was found in dysphagia score before and after stenting.

Table 3: Complications Based on Location

Complications	Total	Upper third	Middle third	Lower third	P value
Stent migration	08	0	01	07	0.0780
Tumor in growth/Overgrowth	03	01	01	01	0.7425
Respiratory tract infection	03	01	02	0	0.1589

4. Results

From January 2021 to December 2023, a total of 42 patients underwent SEMS placement with palliative intent. Patient characteristics are depicted in (Table 1). The median age was 62 years. In this study, there were 20 (48%) men and 22 (52%) women.

Tumour Characteristics:
18 (43%) patients were diagnosed with adenocarcinoma and 24 (57%) were diagnosed with squamous cell carcinoma on histopathological analysis.

8 (15%) had upper third tumours, 12 (29%) had middle third tumours and 22 (52%) had lower third tumours. Short length stenosis was seen in 8 (19%) and long length stenosis was seen in 34 (81%).

Esophageal SEMS with stent length of < 12 cm were used in 20 (48%) of cases and SEMS with stent lengths of 12 - 15 cm were used in 21 (52%).

Overall median dysphagia score in our cohort prior to placement of esophageal SEMS was 3.45±0.50. After esophageal SEMS placement median dysphagia score improved to 1.40±0.58. Improvement in dysphagia score after placement of esophageal SEMS was statistically significant with p value <0.0001*. (Table 3)

Complications:
Overall 12/42 (28.5 %) of patients who underwent esophageal SEMS placement experienced complications. Most common complication was stent migration in 6 (14%) patients. Other complications noted were tumour ingrowth which was seen in 3 (7%) patient, respiratory tract infection in 3 (7%) patients.9 (21%) patients required re - intervention for stent migration and tumour in growth. (Table 4). All reinterventions were successful. (3/9) patients underwent SEMS in SEMS placement and the others (6/9) required SEMS repositioning.

Stent migration and re - intervention rate was seen in more patients with lower third tumours with or without GE junction involvement but did this not reach statistical significance. The overall median survival after stenting was 162 (32 - 350 days).

5. Discussion

Self expandable metal stents are a well established modality for palliation of dysphagia in inoperable esophageal cancer and has become a first line option for this purpose[5]. In comparison with other established methods, SEMS placement provides a rapid and effective means of providing relief from dysphagia in ~90% of patients[6 - 8]. The overall quality of life and ability to tolerate oral feeding is much better with SEMS placement compared with surgical palliation techniques for esophageal cancer[9, 10].

All patients in our study had some relief from dysphagia after SEMS placement to a varying extent. The improvement in dysphagia score over all was statistically significant after SEMS placement.

Multiple similar studies have supported the view that esophageal SEMS is highly effective in relieving dysphagia in patients with esophageal cancer[10 - 15]. Many prior published studies have reported an efficacy rate of more than 85% for dysphagia relief with SEMS placement in esophageal cancers[16, 17].

Histopathology of esophageal tumours in our study showed that squamous cell carcinoma was more common than adenocarcinoma. However the proportion of study population having adenocarcinoma (43%) is higher compared to prior published demographic trends in carcinoma esophagus from India[18, 19].

Most common tumor location in our series is lower third malignancy of esophagus with or without GE junction involvement. Majority of the patients had long segment stenosis (>3cm) due to tumour infiltration and hence longer esophageal stents > 12 cm were more used commonly in the study.

In our study 33% of subjects who underwent SEMS placement faced complications. Most common complication in this group was stent migration (14%). Other complications noted were tumour ingrowth, and lower respiratory tract infection.9 (21%) patients in the study required endoscopic reinterventions to overcome these complications. The rate of complications overall was similar in our study compared to previous literature (33% vs previously reported 23–56%) [20 - 23]. The rate of stent migration in our study (14%), is also in accordance to earlier accounts varying from 2% to 17%[22, 23].

Stent migration rate and re - intervention rate was numerically higher in lower third tumors with or without GE junction involvement compared to upper third and middle third tumors. However, this was not statistically significant.

Our study has a few limitations that needs to be acknowledged. Data was collected in a retrospective manner. Sample size was small and included a heterogeneous group of patients. In some cases information regarding dysphagia score and complications was obtained from patients relatives via telecommunication and these could be subjective to their recall.

Risk factors such as patient and tumour characteristics that may be associated with complications related to SEMS placement could not be assessed. Self expandable metal

stents from different manufacturers were used in the study. How the different characteristics of the various SEMS used affected the improvement in dysphagia score and development of complications was not analyzed.

6. Conclusion

Self- expandable metal stent placement is an effective method for palliation of dysphagia in esophageal cancer and. it can be considered the modality of choice as it is technically easy to perform and has a high efficacy. However, it can be associated with a significant complication rate. Patient selection and appropriate positioning of SEMS is important to reduce complication rate.

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Conflict of Interest: Authors declare no conflict of interest for this article.

Ethics Committee: Approval of the research protocol by an Institutional Ethics Committee, Yashoda Academy Of Medical Education and Research (RP/PP - 2/2024).

References

[1] Uhlenhopp, D. J., Then, E. O., Sunkara, T. *et al.* Epidemiology of esophageal cancer: update in global trends, etiology and risk factors. *Clin J Gastroenterol* **13**, 1010–1021 (2020).
[2] Samarasam I. Esophageal cancer in India: Current status and future perspectives. Int J Adv Med Health Res 2017; 4: 5 - 10
[3] Doosti - Irani A, Mansournia MA, Rahimi - Foroushani A, Haddad P, Holakouie - Naieni K (2017) Complications of stent placement in patients with esophageal cancer: A systematic review and network meta - analysis. PLoS ONE 12 (10): e0184784.
[4] Bor R, Fábián A, Bálint A, et al. Endoscopic management of complications of self - expandable metal stents for treatment of malignant esophageal stenosis and tracheoesophageal fistulas. *Therapeutic Advances in Gastroenterology*.2017; 10 (8): 599 - 607.
[5] Rustgi AK, El - Serag HB. Esophageal carcinoma. N Engl J Med 2014; 371: 2499 - 2509.
[6] Dobrucali A, Caglar E. Palliation of malignant esophageal obstruction and fistulas with self - expandable metallic stents. World J Gastroenterol 2010; 16 (45): 5739–5745
[7] Adam A, Ellul J, Watkinson AF, et al. Palliation of inoperable esophageal carcinoma: a prospective randomized trial of laser therapy and stent placement. Radiology 1997; 202 (2): 344–348
[8] White RE, Mungatana C, Topazian M. Esophageal stent placement without fluoroscopy. Gastrointest Endosc 2001; 53 (3): 348–351
[9] Raijman I, Siddique I, Ajani J, Lynch P. Palliation of malignant dysphagia and fistulae with coated expandable metal stents: experience with 101 patients. Gastrointest Endosc 1998; 48 (2): 172–179
[10] Ahmad NR, Goosenberg EB, Frucht H, Coia LR. Palliative treatment of esophageal cancer. Semin. Radiat Oncol 1994; 4 (3): 202–21417. Stewart DJ, Balamurugan R, Everitt NJ, Ravi K. Ten - year experience of esophageal self - expanding metal stent insertion at a single institution. Dis Esophagus.2013; 26: 276 - 81.
[11] Freeman RK, Ascioti AJ, Giannini T, Mahidhara RJ. Analysis of unsuccessful esophageal stent placements for esophageal perforation, fistula, or anastomotic leak. Ann Thorac Surg.2012; 94: 959 - 64.
[12] Irani S, Baron TH, Gluck M, Gan I, Ross AS, Kozarek RA. Preventing migration of fully covered esophageal stents with an over - the - scope clip device (with videos). Gastrointest Endosc.2014; 79: 844 - 51.
[13] Fujii LL, Bonin EA, Baron TH, Gostout CJ, Wong Kee Song LM. Utility of an endoscopic suturing system for prevention of covered luminal stent migration in theupper GI tract. Gastrointest Endosc.2013; 78: 787 - 93.
[14] Baron TH. Expandable metal stents for the treatment of cancerous obstruction of the gastrointestinal tract. N Engl J Med.2001; 344: 1681 - 7.
[15] Bethge N, Sommer A, Vakil N. Palliation of malignant esophageal obstruction due to intrinsic and extrinsic lesions with expandable metal stents. Am J Gastroenterol.1998; 93: 1829 - 32.
[16] Kozarek RA, Raltz S, Marcon N, Kortan P, Haber G, Lightdale C, et al. Use of the 25 mm flanged esophageal Z stent for malignant dysphagia: a prospective multicenter trial. Gastrointest Endosc.1997; 46: 156 - 60.
[17] Sharma P, Kozarek R; Practice Parameters Committee of American College of Gastroenterology. Role of esophageal stents in benign and malignant diseases. Am J Gastroenterol.2010; 105: 258 - 73.
[18] Choksi D, Kolhe KM, Ingle M, Rathi C, Khairnar H, Chauhan SG, Chaudhary V, Shukla A, Pandey V. Esophageal carcinoma: An epidemiological analysis and study of the time trends over the last 20 years from a single center in India. J Family Med Prim Care.2020 Mar 26; 9 (3): 1695 - 1699. doi: 10.4103/jfmpc.jfmpc_1111_19
[19] Krishnamurthy A, Behuria SS. Demographic Trends in Carcinoma Esophagus from India along with a Brief Comparative Review of the Global Trends. South Asian J Cancer.2020 Jul; 9 (3): 163 - 167. doi: 10.1055/s - 0041 - 1723103. Epub 2021 Apr 26. PMID: 33937139; PMCID: PMC8855215
[20] Burstow M, Kelly T, Panchani S, et al. Outcome of palliative esophageal stenting for malignant dysphagia: a retrospective analysis. Dis Esophagus 2009; 22: 519 - 25.
[21] Kim JY, Kim SG, Lim JH, et al. Clinical outcomes of esophageal stents in patients with malignant esophageal obstruction according to palliative additional treatment. J Dig Dis 2015; 16: 575 - 84.
[22] Verschuur EM, Steyerberg EW, Kuipers EJ, et al. Effect of stent size on complications and recurrent dysphagia in patients with esophageal or gastric cardia cancer. Gastrointest Endosc 2007; 65: 592 - 601.
[23] Stewart DJ, Balamurugan R, Everitt NJ, et al. Ten - year experience of esophageal self - expanding metal stent insertion at a single institution. Dis Esophagus 2013; 26: 276 - 81.