

Assessment of Safety and Efficacy of Self-Expandable Metal Stent (SEMS) For Palliation of Esophageal Cancer at a Tertiary Centre in Northern India

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Abstract:

Background and aims: Esophageal cancer is a common malignancy in Indian population with most patients presenting with advanced stage which is not amenable to definitive cure. Hence, palliation by esophageal self-expandable metallic stent (SEMS) is an important aspect of management. The studies related to efficacy and safety of SEMS is less despite high prevalence of esophageal cancer in India. This study aims to assess efficacy of esophageal SEMS and to determine the mortality after 6 months follow up period.

Methods: This is a prospective and descriptive study of 103 patients of esophageal carcinoma conducted at department of gastroenterology, SMS Medical College and Hospital; Jaipur (Rajasthan) from January 2019 to June 2020. Upper gastrointestinal (UGI) endoscopy was done to assess location, longitudinal extent of tumor, extent of luminal obstruction, feasibility of esophageal stent placement and esophageal tissue sampling. Contrast enhanced CT (CECT) of thorax and abdomen was done to assess loco-regional spread, lymph nodal and distant metastasis. Palliative metallic stenting was done in patients who fulfilled the inclusion criteria. The severity of dysphagia was assessed by mellow and pinkas dysphagia grading system before and after esophageal stenting. Patients were followed up after 1 week, 1, 3 and 6 months interval and in between in case of worsening of dysphagia or development of any complications.

Results: The result demonstrated mean Mellow and Pinkas dysphagia score was 3.184 at baseline, 1.533 at 1 week, 1.794 at 1 month, 1.812 at 3 months and 1.961 at 6 months after esophageal SEMS placement. The improvement in dysphagia score persisted during 6 month follow up period. The 6 month mortality rate was 75 %.

Conclusion: SEMS placement is a safe and effective modality for palliation of dysphagia in esophageal cancer patients with significant improvement in dysphagia after esophageal SEMS placement which persisted during follow up period of 6 months.

Keywords: UGI (upper gastro-intestinal), dysphagia, palliation, Mellow and Pinkas dysphagia score.

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Introduction

Esophageal cancer is the 8th most common cancer among all cancers worldwide, with a substantially increasing prevalence. The standard treatment of esophageal cancer in the absence of contraindications is surgery or chemo-radiotherapy with curative intent. However, more than 50% of patients present with either locally advanced disease or metastasis at the time of diagnosis with unrespectable disease or have high morbidity and mortality due to either absolute dysphagia or aspiration [1]. The acceptable quality of life (QOL) during the limited survival period by palliation of dysphagia is an important part of treatment. Among

palliative treatment modalities, esophageal stenting, radiotherapy and surgery are the most commonly used modalities. Surgery is not favoured due to high peri-operative morbidity and mortality. Radiation therapy continues to be the procedure of choice in patients unsuitable for curative surgery [2,3]. Other less commonly used methods to alleviate dysphagia include blind or wire-guided dilatation of malignant stricture, laser therapy, photodynamic therapy, and chemical ablation; however, these modalities need repeated treatment sessions [4-6]. In patients with inoperable esophageal cancers, palliative stenting with self-expandable metal stents (SEMSs) is

effective in improving dysphagia and nutrition and also is associated with improvement in the quality of life [7,8]. However, the use of SEMs in India is limited due to high cost. Despite higher prevalence of esophageal cancer in India, studies featuring an appropriate sample size in this regard are less. Hence this study aims to assess safety and efficacy of esophageal SEMs and to determine the mortality after 6 months follow up period.

Material and Method

This prospective and descriptive study included 103 patients of carcinoma esophagus with mellow and pinkas score 3 or more, who were inoperable due to locally advanced disease or distant metastasis was carried out in department of gastroenterology SMS Medical College, Jaipur, Rajasthan from January 2019 to June 2020.

The patients included in the study were locally advanced unresectable esophageal cancer (as defined by involvement of tracheobronchial tree, aorta, or pulmonary vasculature), metastatic disease, surgically resectable esophageal cancer with poor risk during surgery (extreme age >70 years, poor cardiorespiratory reserve and poor

performance status) ,patients with post-surgery tumor recurrence and dysphagia score ≥ 3 , dysphagia during or post-chemo-radiotherapy and dysphagia score ≥ 3 and tracheoesophageal fistula irrespective of dysphagia score and resectability.

The patients with operable esophageal cancer and patients who did not give consent were excluded from the study.

Data were collected regarding symptoms at presentation, age, sex, risk factors like smoking, alcohol or obesity. The diagnosis was done by UGI endoscopy with biopsy for tissue histology. Contrast enhanced CT scan of chest and abdomen was done for tumor respectability. Dysphagia was calculated as mellow and pinkas score before SEMs placement and after 1 week, 1 month, 3 months and 6 months of stent placement. The dysphagia was considered improved with decrement of at least 1 score of mellow and pinkas one week after the intervention. Palliative radiotherapy / chemotherapy was offered to patients after stenting as per willingness of patients and assessment by radiotherapist / oncologist.

Assessment of dysphagia

Mellow and Pinkas score [9]

Score	Degree of Dysphagia
0	Able to eat normal diet / No Dysphagia
1	Able to swallow some solid foods
2	Able to swallow only semi-solid foods
3	Able to swallow liquids only
4	Unable to swallow anything/ Total Dysphagia

Characteristics of the self-expandable metal stent: Fully covered and partially covered nitinol metal stents were used. The delivery catheter was made up of polytetrafluoroethylene. There is a nylon thread (lasso) at the proximal end.

Procedure for stent placement: An UGI endoscope (Olympus 150) was used. Sedation done with midazolam and fluoroscopy used. When it was not possible to pass the endoscope across the malignant esophageal stenosis or growth a metallic wire guided dilatation, with Savary-Gilliard thermoplastic bougies, up to a maximum of 11 mm (33 French) in diameter was performed.

The length and position of malignant growth was measured endoscopically and also correlated with CT scan findings. The ends of stenosis were marked under fluoroscopy with help of metallic markers placed on spine of the patients. Once the endoscope was passed beyond the lesion, the metallic guide wire was placed in the antrum of stomach, the stent insertion device was placed over the guide wire in the esophagus, guided by fluoroscopy. The stent used were 4 cm. longer than the length of tumor (2 cm. at each end).

Post procedure care: Patients were observed for at least 24 hours after the procedure. A routine chest X-ray was done for stent position and to rule out perforation. The deployment of stent was considered successful when there was no need for immediate intervention due to complications while carrying out this procedure. Oral fluids intake was allowed in the absence of complications such as pain or vomiting. The patients were discharged with advice regarding diet, anti-reflux measures and follow-up visits.

Assessment of complications: Both stent and procedure-related complications were assessed during and after the procedure. Minor complications included were chest pain, gastroesophageal reflux, stent migration, stent fracture and obstruction of the endoprosthesis by tissue hyperplasia, growth of the tumor or impaction by ingested food and major included life threatening complications such as haemorrhage, esophageal perforation, formation of a tracheo-esophageal fistula and airway compression. All complications were managed as per the standard guidelines. Patients were followed up at 1, 4, 12

and 24 weeks or as and when required and were assessed for dysphagia scores and complications.

A repeat endoscopy was performed in patients with recurrent dysphagia, GI bleeding, and persistent vomiting to assess the cause. Another SEMS was placed in the case of SEMS blockage due to tumor ingrowth or migration of the previous SEMS.

Result

A total 103 patients were taken, out of which 64.08% were male and 35.92% were female. The mean age of carcinoma detection was 55.28 (SD+/-12.61) years. The two major histological subtypes are squamous cell carcinoma (66.02%) and adenocarcinoma (33.98%). Dysphagia was the most common presenting complaint (97.09%) followed by vomiting (24.27%), with cough (20.39%), tracheoesophageal fistula (14.56%).

Table 1: Base line characteristics of Patients-

Age (years mean+/- SD)	55.28+/-12.61 years
Male	54.60+/-12.70 years
Female	56.49+/-12.35 years
Gender	
Male	66 (64.08%)
Female	37 (35.92%)
Age group distribution	
20-30 years	5 (4.85%)
31-40 years	10 (9.71%)
41-50 years	16(15.53%)
51-60 years	39(37.86%)
61-70 years	22(21.36%)
71-80 years	11(10.68%)
Risk factors	
Smoking	64(62.14%)
Alcohol	26(25.25%)
Smoking with alcohol	22(21.36%)
Prestent treatment	
Radio/chemotherapy	33(32.04%)
Surgery	4(3.89%)
Pathology	
Squamous cell carcinoma	68(66.02%)
Adenocarcinoma	35(33.98%)
Reason for stent insertion	
Locally advanced unresectable tumor	46(44.65%)
Surgically resectable with poor risk	5(4.86%)
Post radio/chemotherapy recurrence	33(32.04%)
Post-surgery recurrence	4(3.89%)
Tracheoesophageal fistula	15(14.56%)
Stent type %	
Partially covered	88(85.44%)
Fully covered	15(14.56%)
Distant metastasis at presentation	35(33.98%)
Clinical presentation	
Dysphagia	100(97.09%)
Weight loss	49(47.57%)
Anorexia	54(52.43%)
Vomiting	25(24.27%)
Cough	21(20.39%)
Chest pain	12(11.65%)
Odynophagia	8(7.77%)

In this study partially covered SEMS was inserted in 85.44% patients and fully covered SEMS in 14.56%. However in all cases of tracheoesophageal fistula fully covered SEMS was used. The mean dysphagia score Mellow and Pinkas before Esophageal SEMS placement was 3.1844 and post SEMS placement after 1 week was 1.5333+/-

0.6655 (p<0.001, 95% CI 1.8300 to 1.4728), at 1 month 1.7945+/-1.019 (p<0.0001, 95% CI -1.6362 to -1.1436), at 3 months 1.8125+/-0.8330 (p<0.0001, 95% CI -1.6146 to -1.292) and at 6 months 1.961+/-0.8978 (p<0.0001, 95% CI-1.5248 to -0.9220). The improvement in dysphagia score was significant in all follow up visits.

Table 2: Dysphagia score following stenting

	Baseline (before stent insertion) (n-103)	After 1 week of SEMS insertion (n-103)	After 1 month of SEMS insertion (n-73)	After 3 months of SEMS insertion (n-48)	After 6 month of stent insertion (n-26)
Mellow pinkas score (mean+/-SD)	3.184+/-0.634	1.533+/-0.665	1.794+/-1.019	1.812+/-0.833	1.961+/-0.898
P Value compared to baseline with 95% CI		<0.0001, 95% CI (-1.8300 to -1.4728)	<0.0001, 95%CI (-1.6362 to -1.1436)	<0.0001, 95%CI (-1.6146 to -1.292)	<0.0001, 95%CI (1.5248 to -0.9220).

Table 3: Complications after stent insertion

Adverse events	Early(<1week)	Late(>1week)	Total
Major			
Hemetmesis	1 (0.97%)	6 (5.82%)	7 (6.79%)
Aspiration pneumonia	2 (1.94%)	7 (6.80%)	9 (8.74%)
Minor			
Chest pain	28 (27.18%)	8 (7.77%)	36 (34.95%)
Gastroesophageal reflux	19 (18.45%)	15 (14.56%)	34 (33.01%)
Stent obstruction	0 (0.0%)	22 (21.35%)	22 (21.36%)
Stent migration	2 (1.94%)	9 (8.73%)	11 (10.67%)

Among major complications, most common were stent obstruction (21.36%) followed by stent migration (10.67%), hematemesis (6.79%) and aspiration pneumonia (8.74%) of patients. The minor complications observed were chest pain (34.95%) and gastroesophageal reflux (33%). The mortality-at 1 month of follow up 29.12% patients died and at 6 months mortality was 74.76%.

Discussion

The management of patients with esophageal carcinoma who are not candidates for definitive surgical cure mostly relies on esophageal stenting to improve nutritional status and alleviating symptoms of dysphagia to improve quality of life. In the present study, the demographic characteristics of patients were comparable to those presented in previous studies [10-16]. The present study mainly evaluated the safety and efficacy of esophageal SEMS placement in patients with esophageal carcinoma by assessing change in mellow and pinkas dysphagia score.

The improvement in mellow and pinkas dysphagia score (baseline score-post SEMS score) was clinically significant from 1 week after SEMS placement upto 6 months follow up study, varying from 1.53 at 1st week after stent insertion to 1.96 after 6 months from baseline score 3 which was comparable to other studies [10-16]. However, placement of esophageal SEMS did not give any survival benefit to the patient as depicted by high mortality at 6 months follow up period. The result built on existing evidence of role of esophageal SEMS in patients of esophageal carcinoma as shown in previous studies with improvement in dysphagia score comparable to previous studies.

The major complications encountered post SEMS insertion were hematemesis and aspiration pneumonia which were seen in approximately 15% patients, and half of these patients succumbed to death in same admission. This data was comparable to study conducted by Turkyilmaz et al which showed approximately 14% incidence rate of major complications.

The possible explanation for occurrence of aspiration pneumonia is placement of lower end of SEMS beyond gastro-esophageal junction causing incompetence of lower esophageal sphincter. Similarly, the occurrence of gastro-intestinal bleeding after procedure may be related to deeper invasion of esophageal wall by the tumor and causing erosion of surrounding vasculature.

The minor complications were seen in 36 % patients. In this study no case of post SEMS fistula, perforation or tracheal compression was seen although in other studies perforation ranged from 0.8% to 2.1% and tracheoesophageal fistula from 1.1 to 6.2% and tracheal compression from 1.7% to 2.1% [10-16]. The minor complications observed in the study were chest pain and gastroesophageal reflux which were observed within one week of stent placement while stent obstruction and stent migration were mainly observed after 1 week of procedure. The minor complications like chest pain and gastro-esophageal reflux responded well to conservative measures while stent obstruction and migration required re-interventions in form of dilatation and stent repositioning or repeat stent placement, respectively. The incidence of stent obstruction and stent migration is 11.9% to 23% and 2% to 32%, respectively in previously published studies [10-16] which is quiet comparable to results of this study. In the present

study 25.25% of patients survived at 6 months post SEMS and 39% of total death occurred within 1 month. The mean survival was 94 ± 14 days (95% confidence interval). This was less than the study done by B Sharma et al 147 ± 7.9 days [11]. This was in contrast to studies done by foortran et al in which the 6 months survival was 64% [8]. The main limitations of our study are observational study design, single centre study small sample size. We could not extend the follow up period beyond 6 months due to natural course of disease. Hence, further studies are required with larger sample size to evaluate the efficacy of esophageal SEMS and to also compare the different modalities of palliation of dysphagia.

Conclusion

According to the results obtained in the present study and considering the results obtained by the other researchers, it can be concluded that SEMS can be an appropriate and useful solution to the reduce dysphagia and improve quality of life in patients with inoperable esophageal cancer even though the 6 month survival is very less. However, further larger studies are needed to more clearly elaborate the outcomes of the SEMS placement.

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