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# ASSESSMENT OF SAFETY AND EFFICACY OF A SELF-EXPANDABLE METAL STENT FOR PALLIATION OF ESOPHAGEAL CANCER IN A TERTIARY CARE CENTER IN NORTHERN INDIA

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**ABSTRACT** **BACKGROUND AND AIMS:** Esophageal cancer is 8th common cancer worldwide with more than 50% patients non-resectable at presentation either due to distant metastasis, locally advanced disease or co-morbidity. Dysphagia is most common presentation of these, which requires palliation. The palliation by metallic stent is found effective. In view of high prevalence of esophageal cancer in India, the studies related to efficacy and safety of metallic stents is very less. The aim of this study was to study the safety and efficacy of metallic stents and to know the mortality after 6 months follow up period. **MATERIALS AND METHODS:** This prospective study of 103 patients of carcinoma esophagus with dysphagia fulfilling inclusion criteria was done in department of gastroenterology SMS Medical College, Jaipur from January 2020 to September 2020. Palliative metallic stenting was done fulfilling inclusion criteria and advised follow up in oncology/radiotherapy department. Patients were observed for complications and managed as per standard guidelines. Patients were followed up at 1st week, 4th week, 12th week and at 6 months. Data was statistically analyzed with SPSS version -22. **RESULT**: In this study of 103 patients of Ca esophagus with dysphagia, the mean age of diagnosis was 55.28 (SD +/-12.61) years. The mean age of presentation for male and female were 54.60 years (SD+/-12.70) and 56.49 years (SD+/-12.35) respectively. 64.08% (n-66) patients were male and 35.92%(n-37)were female. 66.02% (n-68) patients had squamous cell carcinoma and 33.98% (n-35) had adenocarcinoma. The most common clinical presentation was dysphagia in 97% patients. The mean dysphagia score Mellow and Pinkas before Esophageal SEMS placement was 3.1844 and post SEMS placement after 1 week was 1.5333 and during 6 month follow up period, the dysphagia improvement remained significant. During follow up minor complications were chest pain in 34.95%, gastroesophageal reflux in 33%, stent migration in 10.67% and stent obstruction in 21.36% patients. . In major complications, hematemesis was present in 6.79% and aspiration pneumonia in 8.74% of patients and after 6 month mortality was 75%. **CONCLUSION:** According to results from this study, it can be concluded that SEMS placement is appropriate for palliation of dysphagia as mean improvement in Mellow Pinkas score remained significant during 6 month follow up although mortality rates were high.

**KEYWORDS :** Dysphagia, Palliation, Esophageal SEMS

**INTRODUCTION:** Esophageal cancer is the 8th most common cancer among all cancers worldwide, with a substantially increasing prevalence. Significant regional variation exists in incidence and pathology of esophageal cancer. Countries with a higher human development index (HDI) have a lower incidence of esophageal cancer[1], but higher proportion of adenocarcinoma[2].Countries with a low HDI like India have a high incidence of esophageal cancer with higher proportion of squamous cancers[3]. India has an age standardized incidence rate (ASR) of 6.5 per 100,000 population for males and 4.2 per 100,000 population for females. This translates into approximately 47,000 new cases each year and 42,000 deaths[4]. The standard treatment of operable esophageal cancer in the absence of medical contraindications is surgery.

More than 50% of patients present with either locally advanced disease or metastasis at the time of diagnosis. Majority of patients with carcinoma of the esophagus present at an advanced stage of the disease, and have morbidity and mortality either due to absolute dysphagia or due to aspiration[5]. Despite advances in diagnostic methods, surgical techniques, radiotherapy and chemotherapy, survival rates for this disease have remained unchanged over the last four decades [6,7]. Thus, emphasis has now shifted towards achieving an acceptable quality of life (QOL) during the limited survival period by palliation of dysphagia.

Among palliative treatment modalities, surgery is not favoured due to its associated morbidity and mortality. Radiation therapy, either as external beam radiation or brachytherapy continues to be the procedure of choice in patients unsuitable for curative treatment.[8,9] Other methods used to alleviate dysphagia include blind or wire-guided dilatation of malignant stricture, laser therapy, photodynamic therapy, and chemical ablation; these, however, need repeated treatment sessions [10,11,12]. The predominant symptom of advanced esophageal cancer is dysphagia with 80–90% of all patients having some difficulty in swallowing. Relief of dysphagia is, therefore, a priority for any palliative treatment of patients suffering from esophageal cancer. In patients with inoperable esophageal cancers, palliative stenting with self-expandable metal stents (SEMSs) is effective in improving dysphagia and nutrition and also associated with improvement in the quality of life.[13] However, the use of SEMS in India is limited due to high cost. Like every palliative procedures, the placement of SEMS can cause complications, both minor (stent migration, obstruction, and thoracic pain) and major (hemorrhage, esophageal perforation, fistula formation and airway compression), which can be life threatening. Since the quality of life and to some extent the survival period in these patients depends on their ability to swallow, thus the improvement in dysphagia plays a significant role in patient's relief and the increase in their quality of life[14]. Based on the higher prevalence of esophageal cancer in India and according to the idea that a study featuring an appropriate study sample volume in this regard are very less, this study was planned.

**MATERIALS AND METHODS :**

This prospective and descriptive study of 103 patients of carcinoma esophagus with Mellow and Pinkas score 3 or more who were inoperable due to locally advanced disease or distant metastasis or other inclusion criteria was carried out in Department of Gastroenterology SMS Medical College, Jaipur, Rajasthan from January 2020 to September 2020. Data was 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. For tumor resectability, contrast enhanced CT scan of chest and abdomen was done. 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 their

willingness and assessment by a radiotherapist/oncologist.

**Assessment of Dysphagia**
**(Mellow and Pinkas)**[15] score :
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 Self-Expandable Metal Stent:**
Fully covered and partially covered nitinol metal stents were used. The delivery catheter was made up of polytetrafluoroethylene and stainless steel tubes. The markings were with gold wires. There is a nylon thread (lasso) at the proximal end.

**Procedure for Stent Placement:**
An upper GI endoscope (Olympus Inc., India) with use of sedation [midazolam] was carried out fluoroscopically. When it was not possible to pass the endoscope through the malignant esophageal stenosis, a metallic wire guided dilatation, with Savary-Gilliard thermoplastic bougies, up to a maximum of 13 mm (39 French) in diameter was performed. The length and position of malignant stenosis was measured endoscopically, if feasible with or without dilatation, if not then with the help of CT scan. The ends of stenosis were assessed under fluoroscopy with help of metallic markers placed on back of patients. Once the endoscope passed beyond the lesion, maintaining the metallic guide wire in the stomach, the stent insertion device was placed in the esophagus, guided by means of fluoroscopy. 4cm longer than the length of the tumor stent was used with final position documentation on a plain X-ray.

**Post-procedure Care:**
Patients were observed for at least 24 hrs 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 fluid 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 those that were considered 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 at 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 in-growth or migration of the previous SEMS.

Consecutive patients with esophageal cancer and dysphagia satisfying one of the following inclusion criteria were included.

**Inclusion criteria:**
1. Locally advanced unresectable esophageal cancer (as defined by involvement of tracheobronchial tree, aorta, or pulmonary vasculature) and metastatic disease.

2. Surgically resectable esophageal cancer with poor risk during surgery (extreme age >70yrs, poor cardio-respiratory reserve and poor performance status).

3. Patients with post-surgery tumor recurrence and dysphagia ≥ 3

4. Dysphagia during or post-chemo-radiotherapy and dysphagia ≥ 3

5. Tracheoesophageal fistula irrespective of dysphagia score and respectability.

**Exclusion criteria:**
1. Patients with operable esophageal cancer.
2. Patients not given consent.

**RESULTS:**
**TABLE 1. Baseline Demographic Characteristics and Clinical Presentation of Patients**

| | |
|---|---|
| **Age(years mean+/- SD)** | 55.28+/-12.61 years |
| Male | 54.60+/-12.71 years |
| Female | 56.49+/-12.35 years |
| **Gender** | |
| Male | 64.08% |
| Female | 35.92% |
| **Age group distribution** | |
| 20-30 years | 4.85% |
| 31-40 years | 9.71% |
| 41-50 years | 15.53% |
| 51-60 years | 37.86% |
| 61-70 years | 21.36% |
| 71-80 years | 10.68% |
| **Risk factors** | |
| Smoking | 62.14% |
| Alcohol | 25.25% |
| Smoking with alcohol | 21.36% |
| **Pre-stent treatment** | |
| Radio/chemotherapy | 32.04% |
| Surgery | 3.89% |
| **Pathology** | |
| Squamous cell carcinoma | 66.02% |
| Adenocarcinoma | 33.98% |
| **Reason for stent insertion** | |
| Locally advanced unresectable tumor | 44.65% |
| Surgically resectable with poor risk | 4.86% |
| Post radio/chemotherapy recurrence | 32.04% |
| Post surgery recurrence | 3.89% |
| Tracheoesophageal fistula | 14.56% |
| **Stent type %** | |
| Partially covered | 85.44% |
| Fully covered | 14.56% |
| **Distant metastasis at presentation** | 33.98% |
| **Clinical presentation** | |
| Dysphagia | 97.09% |
| Weight loss | 47.57% |
| Anorexia | 52.43% |
| Vomiting | 24.27% |
| Cough | 20.39% |
| Chest pain | 11.65% |
| Odynophagia | 7.77% |

In this study, total 103 patients fulfilling inclusion criteria were taken, out of which 64.08%(n-66) were male and 35.92%(n-37) were female. The mean age of carcinoma detection was 55.28 (SD+/-12.61) years. The mean age for male and female were 54.60 years(SD+/-12.70) and 56.49 years(SD+/-12.35) respectively. Most of the patients (59.22%) were between age group 51-70 years. The histology of 66.02%(n-68) patients were squamous cell carcinoma and 33.98%(n-35) had adenocarcinoma.

In this study, 62.14%(n-64) patients were smoker, 25.24%(n-26) were alcoholic, 21.36%(n-22) were both alcoholic and smoker while 10.68% (n-11) patients had co-morbid conditions excluding them from surgery. 32.04%(n-33) patients in this present study had dysphagia recurrence before SEMS placement either post radiotherapy or chemotherapy or combined therapy, while 3.89%(n-4) patients had post surgery dysphagia recurrence for Ca esophagus.

**Clinical Presentation:**
In this study, 97.09%(n-100) patients presented with dysphagia followed by 24.27% with vomiting, 20.39% (n-21) with cough, 14.56% with trachea-esophageal fistula, 11.65% with chest pain and 7.77%(n-8) with odynophagia. 47.57% patients had significant weight loss.

**Stent Type:**
In this study, 85.44% patients were inserted with Partially covered SEMS, 14.56% with Fully covered SEMS. Fully covered SEMS were deployed in trachea-esophageal fistula.

**TABLE 2. Dysphagia Score Following Stenting**

| | Baseline (before stent insertion)( n-103) | After 1 week SEMS insertion( n-103) | After 1month SEMS insertion( n-73) | After 3 month of SEMS insertion( n-48) | After 6 month of SEMS 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). |

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%CI1.8300to1.4728),at 1month 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). At all follow ups, the improvement in dysphagia score were significant.

**TABLE 3. Complications After Stent Placement**

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|---|---|---|---|
| **Major** | | | |
| Hematemesis | 0.97% | 5.82% | 6.79% |
| Aspiration pneumonia | 1.94% | 6.80% | 8.74% |
| **Minor** | | | |
| Chest pain | 27.18% | 7.77% | 34.95% |
| Gastro-esophageal reflux | 18.45% | 14.56% | 33.01% |
| Stent obstruction | 0.0% | 21.35% | 21.35% |
| Stent migration | 1.94% | 8.73% | 10.67% |

During follow up after SEMS placement, minor complications were chest pain in 34.95%, gastro-esophageal reflux in 33%, stent migration in 10.67% and stent obstruction in 21.36% either due to stenosis or tumour re-growth or food impaction. In major complications, hematemesis was present in 6.79% and aspiration pneumonia in 8.74% of patients.

**Mortality:** At 1 month of follow up, it was 29.12% and at 6 months, mortality was 74.76%.

## Discussion:

### Demographic Characteristics:

In this prospective observational study of 103 patients, 66 patients(64.08%) were male and 37(35.92%) were female with male to female ratio 1.78 which was comparable to other studies [16,17,18] and in contrast to studies done by RK Pradhan[19] et al (male 80.5% and female 19.5%) and Masaya uesato[20] et al (90.8% male and 9.2%female) in which male to female ratio was very high. In a study done by Mojgan Forootan et al, esophageal carcinoma was more common in female (60% female and 40% male).

In this study, most of the cases (59.22%) were in the age group of 51-70 years, which were consistent with study done by B Sharma et al (60.7% patients were in age group of 51-70 yrs).

In this study, the mean age of carcinoma detection was 55.28+/- SD 12.61 years. The mean age for male and female were 54.60+/-SD 12.70 years and 56.49 years+/-SD 12.35 respectively which was consistent with study done by RK pradhan et al[19] (57.71 ± 13.14 years) and in contrast to other studies in which mean age was in seventh decade.[16,17,18,20,21]

In this study, 66.02% cases had squamous cell carcinoma and 33.98% had adenocarcinoma which was consistent with most of the other studies.[18,21] while the studies done by Parminder et al[16]and B Sharma[17] et al, it was mostly squamous cell carcinoma (94% and 85.7% respectively) while in a study done by Jarvinen T[22] et al, adenocarcinoma was more common (54.7%) than squamous cell carcinoma (40.8%).

### Clinical Presentation:

In this study, 97.09%(n-100) patients presented with dysphagia, 47.57%weight loss, 24.27% vomiting, 20.39%(n-21) with cough, 14.56% with trachea-esophageal fistula,11.65% with chest pain and 7.77%(n-8) with odynophagia. In a study done by Parminder et al[16], dysphagia was found in 84%, vomiting 16%, odynophagia in 13.2%, cough and dyspnea in 8.3%, and trachea-esophageal fistula in 4% patients at presentation. In other studies, dysphagia presentation varied from 87.3% to 94.2%[23,22] and trachea-esophageal fistula from 2.1% and 5.8%.[22,23]

### Reason for Stent Insertion:

In this study, the cause for palliative stenting was locally advanced unresectable cancer in 44.65%, post radio/chemo therapy recurrence 32.04%, trachea-esophageal fistula in 14.56%, surgically resectable but poor risk for surgery in 4.86% and post surgery recurrence in 3.89%.

Distant metastasis was present in 33.98% patients. Consistent with this, a study done by Perminder et al[16] in which cause of palliation was locally advanced cancer in 52%, co-morbid condition in 8% cases and distant metastasis in 35% case.

In a study done by Kim et al[23], cause of SEMS palliation was post radio-chemotherapy recurrence in 39.9%, post surgery recurrence in 15.5% and poor surgical risk in 9.1% patients. The disease was locally advanced in 19.3% and distant metastasis was present in 72 % patients.

In contrast, locally advanced disease was present in 76% and 69% and distant metastasis in 24% and 18% in studies done by Forootan[21] and masaya[20] et al respectively.

### Dysphagia:

The improvement in Millow Pinkas dysphagia score (baseline score-post SEMS score) was clinically significant from 1 week after SEMS placement to 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 of3.18, which was comparable to other studies varing from 1.43 to 2.92 in post SEMS improvement in comparision to baseline.[16-23]

### Complications:

In this study, after SEMS placement minor complications were chest pain in 34.95%, gastro-esophageal reflux in 33%, stent migration in 10.67% and stent obstruction in 21.36% either due to stenosis or tumour re-growth or food impaction.

In early complications in various studies, chest pain varied from 30% to 94.8%. In this study, chest pain was present in 35% of cases, out of which 77.70% complained within 1st week, severity of pain was mild to moderate in most cases requiring either no treatment or to oral medications without need for hospitalization.

Gastro-esophageal reflux was present in this study in 33%patients, and 56% of them have early presentation. Symptoms were usually controlled by posture and diet modification. Gastro-esophageal reflux varied from 3.4% to 23.8% in various other studies.[16-23]

Stent obstruction post SEMS developed from 11.9% to 23% in various studies[16-22] mostly from tumor growth and less commonly by post RT/CT stenosis or food impaction. In this study, stent obstruction was present in 21.36% cases and 59% of them obstruction was due to tumor growth, stenosis in 27.25% beyond stent ends and 13.75% due to food impaction. Patients with stenosis and food impaction did well with serial dilations, patients with tumor growth either underwent repeat SEMS deployment or feeding jejunostomy.

Stent migration was present in this study in 10.67% and recurrence of dysphagia in 32% cases and mostly migrated after 1st week (82%) and mostly within esophagus which were repositioned with foreign body forceps and in some cases by another stent deployment. In 1 patient out of 11 patients, stent was migrated into stomach which could not be retrieved endoscopically and another stent was placed in esophagus and patients did well with stent in-situ in stomach without any complications in follow up. Stent migration in various other studies ranged from 2% to 32% with recurrence of dysphagia from 23.9% to 40%.[16-23]

In major complications, hematemesis was present in 6.79%(n-7) cases mostly as a late complication after 1st week (85%) requiring hospitalization and management including from IV fluids to blood transfusion and half of the patients succumbed to death. The haemorrhage occurs due to tumor growth, pressure stress on

esophageal wall by stent or direct trauma caused by stent ends. Hematemesis varied from 2% to 10% in other studies.

In this study, aspiration pneumonia was present in 8.74%(n-9) patients post SEMS deployment mostly after 1st week as a late complication (78%). Aspiration pneumonia usually occur if stents are placed beyond gastro-esophageal junction and these patients gives history of gastro-esophageal reflux most of the times. In this study, 7 out of 9 patients who had aspiration pneumonia had SEMS placement beyond GE junction. All patients were hospitalized and around 55% of the patients succumbed to death.

The variations between this study and other studies may be due to differences in sample size, geographical factors, technical factors like type of prosthesis and alike others.

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 trachea-esophageal fistula from 1.1 to 6.2% and tracheal compression from 1.7% to 2.1%.[16-23]

**Survival:**

In the present study, out of 103 patients only 26 patients survived (25.25%) 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. This was in contrast to studies done by Foortran et al[21], in which the 6 months survival was 64% .

## CONCLUSION:

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

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