SCIENTIFIC ARTICLE

Efficacy of Oesophageal self expandable metal stent placement for palliation of dysphagia in inoperable oesophageal cancer patients: A low-income country perspective

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Abstract

Introduction

This study assesses the efficacy of self-expandable metal stents (SEMS) in palliating dysphagia among patients with oesophageal cancer. Despite potential complications, SEMS emerges as a preferred option in palliative care world-wide.

Methods

A prospective cohort study over one year period among 80 patients with inoperable oesophageal carcinoma considered for palliative treatment and referred for SEMS to relieve the malignant dysphagia. All the stenting were performed by a single Gastro enterologist (ANR). Mellow-Pinkas scoring system was used to assess the efficacy.

Results

The mean age of the patients was 66 years with majority of them being male (60%, n=48). A substantial proportion of tumors were in the middle third of the esophagus (57.5%, n = 46). Notably, 53% of patients (n=42) reported exclusive liquid swallowing ability, while 27% (n=22) could swallow semi-solid foods, and 20% (n=16) experienced complete dysphagia. The technical success rate of the intervention was 100%, with a noteworthy 98.8% (n=79) of patients reporting an improvement. However, clinical success, defined by the achievement of improved swallowing function, was observed in only 63.7% (n=51) of cases. Despite a statistically significant average reduction of 1.7 points in the dysphagia scoring system (range 0-3) ($p<0.001$), tumor location did not emerge as a significant factor influencing clinical success ($p>0.05$). Procedure related complications were rare.

Conclusion

Fully covered self-expanding metal stent is a safe and an effective method of palliation of an intolerable symptom in oesophageal carcinoma patients. Life threatening complications were rare. Further improvements to the quality of stents may help reduce the number of complications and enhance the quality of life of patient.

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Introduction

Oesophageal carcinoma is considered as a virulent tumour with respect to prognosis and fatal outcome [1]. In 2020, oesophageal cancer ranked seventh in new cases (604,000) and sixth in mortality (544,000 deaths), making it responsible for one in every 18 cancer deaths in the world [2]. In Sri Lanka, it is the fourth and seventh most common cancer in males and females, respectively [3].

Symptoms of Oesophageal cancer includes - dysphagia, odynophagia, nausea, vomiting, regurgitation, and retrosternal pain. Dysphagia is the most common and favourable symptom of an advanced-stage disease [4]. Diagnosis of the tumour size, location, and the length need an upper gastrointestinal endoscopy, and further it helps to take biopsies for pathological conformation. Following the diagnosis, further assessment is performed to determine the clinical stage and the patient's fitness for further treatment [5]. Oesophageal cancer's poor prognosis has been attributed to late presentation. In the US, 40% were diagnosed with distant organ or lymph node spread, while 32% had regional spread to nearby organs and nodes [6]. Survival is mainly predicted by the stage of cancer. Localized disease expresses a survival rate of <50% at 5 years, whereas regional and distant metastasis demonstrate 5-year survival rates of 25.1% and 4.8%, respectively [7].

Surgery is the treatment of choice for oesophageal cancer if the tumour is in the operable stage. If the tumour is considered inoperable, therapeutic objectives are mainly palliative [5]. Palliative treatment includes surgery, radiotherapy, chemotherapy and endoscopic procedures or a combination of the these [8]. The symptoms that need palliation include, dysphagia, pain, and nausea. Compared to the other modalities of treatment, endo therapy provides simple and safe options for the palliation of dysphagia. Both the European Society of Gastrointestinal Endoscopy (ESGE) [8]

and the American Gastroenterological Association (AGA) [9] suggest endoscopically placed oesophageal self-expandable metal stents (SEMS) as a choice for dysphagia, which offer a high degree of palliation and improvement. However, SEMS can be associated with some potential complications, such as dislodging and stent obstruction, perforation, chest pain, and fistula formation [10]. Oesophageal SEMS can also be considered a relatively expensive treatment option, considering its cost. Although routinely recommended, there were no similar studies done in our country to assess the efficacy of SEMS in our hospital setting, where cost can play a major factor in determining treatment options.

Hence, this study was done to evaluate the efficacy of SEMS for palliation of dysphagia in patients with oesophageal cancer as part of their palliative treatment in a low-income setting.

Materials and Methods

Study design

A prospective cohort study in the Northern province including Cancer Hospital in Thellipalai over one year period.

Eligibility criteria

Patients with inoperable oesophageal carcinoma considered for palliative treatment and referred for SEMS to relieve the malignant dysphagia were included in our study. The diagnosis of oesophageal cancer was confirmed by histopathological assessment with the biopsy taken during endoscopy. Cancer staging was done using standard radiological imaging modalities.

Outcomes

In our study, the primary objective was to assess the efficacy of stent placement in improving malignant dysphagia. To evaluate the severity of dysphagia, we employed the Mellow-Pinkas scoring system, which assigns grades ranging from 0 to 4. This evaluation was conducted both before the stent procedure (pre-procedure, 24 hours prior) and four weeks following stent insertion (post-procedure). A score of 0 indicated the ability to consume a normal diet with no dysphagia, while a score of 1 signified the capacity to swallow some solid foods. A score of 2 indicated the ability to swallow only semi-solid foods, while a score of 3 meant the ability to swallow liquids exclusively. Finally, a score of 4 represented complete dysphagia, rendering the individual unable to swallow anything. This assessment system allowed us to precisely gauge the impact of stent placement on the improvement of malignant dysphagia.

At least a 2-point reduction was considered clinical success, while at least a 1-point reduction was considered a reported improvement in the Mellow-Pinkas scoring system. Successful placement of the stent through the stricture, ensuring clear visibility and patency confirmed through both endoscopic and fluoroscopic examinations, is considered a technical success.

SEMS placement technique

Fully covered self-expandable metal stents (Ultraflex™ Esophageal Stent System) were placed across the obstructing tumour in all patients. Standard endoscopic techniques were used during endoscopy – 6 hours fasting, topical anaesthesia with lignocaine to the throat, midazolam sedation according to patient body weight and left lateral position during the procedure. Prior to stent placement, the upper and lower margins of the tumour from the incisors and anatomical location in the oesophagus were evaluated endoscopically. Measurement of the tumour length is important because stent should extend at least 2cm beyond the tumour margins to reduce the chance of tumour overgrowth at the ends of the stent [12]. Balloon dilatation was used when there was a difficulty in passing the endoscope through the obstruction. The stents were from 10 – 15 cm of length and placed so that at least 2cm was tumour free at either end of the stent. Anti reflux stents were used when the tumour was involving the gastro oesophageal junction or within 2cm of it. After stent deployment correct placement of the stent was ensured endoscopically.

In all cases, the patient was kept nil by mouth for 24 hours after the procedure and discharged from the hospital after 48 hours if there were no complications. Proton pump inhibitors (PPI) were prescribed to all patients post procedure to reduce symptoms of reflux. A liquid diet was started initially followed by semi-solid and solids gradually over a 7-day period. After 48hrs patients were discharged or retransferred to their original units. Clinical improvement of their symptoms and complications were monitored and recorded by contacting them over the telephone and receiving data from their follow up units. Patient with complications after stent insertion were admitted again to the Jaffna Teaching Hospital for further management.

Statistical Analysis

Data analysis was done by SPSS (version 26) software and associations were determined using parametric tests. A p value of < 0.05 was considered statistically significant.

Results

Patients and demographic characteristics

Table 1. Location of tumour in the oesophagus

Tumour location	Number of Patients	Percentage of Patients
Lower	30	37.5%
Middle	46	57.5%
Upper	4	5.0%
Total	80	100%

A total of 80 patients with a diagnosis of oesophageal cancer who were referred for palliative stenting included in this study. The mean age of the patients was 66 years. Majority of them were male (n=48, 60%).

Endoscopic characteristics of the oesophageal cancer

Anatomical location of tumour in the oesophagus is divided into upper (up to 10cm from the upper oesophageal sphincter), middle and lower (within distal 10 cm). Table 1 shows the number and the percentage of patients according to their location of tumour in the oesophagus. Most tumours were in the middle third of the oesophagus (57.5%, n = 46), 37.5% (n = 30) affected the lower third and 5% (n = 4) affected the upper third.

Efficacy of SEMS

Dysphagia severity was assessed Pre and post SEMS placement in all 80 patients. Majority (n=42, 53%) of patients were only able to swallow liquid in our study group. And 27% (n=22) were able to swallow only semi solids whereas 20% (n=16) were unable to swallow anything (fig 1). The technical success rate was 100% in our study population. After SEMS placement 98.8% (n=79), reported an improvement while only 63.7% (n= 51) achieved the clinical success; the average reduction was 1.7 points (range 0-3). There was a significant reduction in the dysphagia grade after SEMS placement ($p<0.001$) noted in the patients (table 2).

SEMS improved the dysphagia 100% in both upper and middle esophageal tumors and 96.7% in lower esophageal tumors (table 3). The tumor location was not associated with

Table 1. Dysphagia before and after – SEMS placement

Variable	Before-SEMS placement	After-SEMS placement	Change from baseline	P Value
	Mean (SD)	Mean (SD)	Difference, 95% CI	
Mellow–Pinkas scoring system for dysphagia	2.9 (0.7)	1.3 (0.5)	- 1.6 (-1.8, -1.5)	<0.001
SD – standard deviation, CI - confidence interval				

Table 3. Improvement of esophageal score according to their tumor location

Site of tumour	Improvement in dysphagia N (percentage)		Significance
	No	Yes	p >0.05
Lower	1 (3.3%)	29 (96.7%)	
Middle	0	46 (100%)	
Upper	0	04 (100%)	

the clinical success of SEMS placement ($p > 0.05$).

Morbidity and mortality

There were no early complications observed, but late life-threatening complications were observed in 2.5% (n= 2) of the patients., which included oesophageal perforation (n=1) and massive haematemesis (n=1).

We managed to follow up with the patients for up to 6 months following the procedure. In the study group, 72.5% (n = 58) patients died during the follow-up period, the first three months (50%, n = 40), and between 3-6 months, 22.5% (n =18).

Discussion

Our study reiterates the usefulness of stent placement in palliative treatment of oesophageal tumour to relieve the symptoms of dysphagia because of its efficacy and safety [13,

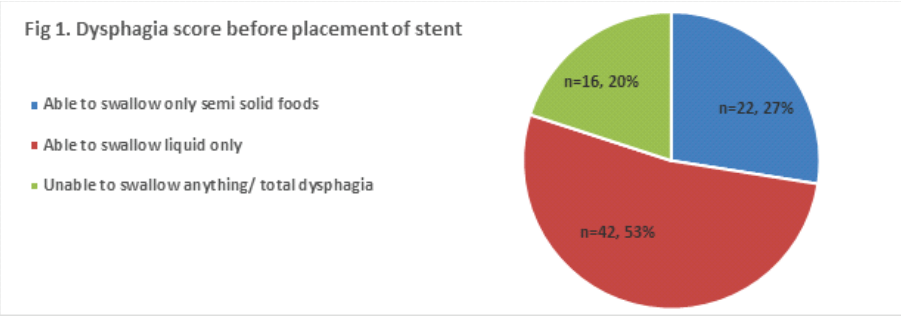

Figure 1. Dysphagia before placement of stent

14]. The study showed that most of our patients had at least reported improvement in their dysphagia degree, which is comparable to similar studies [10]. There were several objective assessments developed to evaluate dysphagia severity, in which most studies used reduction of at least 2 points as clinical success [15–17]. Jiménez-Gutiérrez JM et al. described 58.9% as meeting the definition of clinical success, whereas in our study, 63.7% (n= 51) patients met the definition of clinical success. Further similar efficacy of palliative oesophageal stent placement is noted in the literature [12, 18]. But this is the first study done in our country.

Although complications were uncommon in our patients, two life-threatening late complications were observed. Haematemesis, as seen in our patient, most often occurs as a late complication. Both stent placement and disease progression may equally contribute to its occurrence. Post-stent placement haematemesis was seen in 2-3% of patients in other studies as well [12, 18]. Perforation was seen in one of the patients. Prior radiation or chemotherapy is known to increase the risk of oesophageal perforation [19]. It was observed in 6.52% of another study [12]. Information regarding post SEMS radiotherapy and chemotherapy is not available in our study, which is a limitation.

Further limitations in our study included getting information regarding complications following stent insertion. Patients were referred from various centres in the northern region, and we had practical difficulties bringing them back to Jaffna Teaching Hospital for further follow-up.

Conclusion

In patient with oesophageal cancers with obstruction to food passage, stenting with partially covered self-expanding metal stent is a safe and an effective method of palliation of an intolerable symptom. Life threatening complications were reported only in 2.5%. Further improvements to the quality of stents may help reduce the number of complications and enhance the quality of life of patient.

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