

Self-expandable Metallic Stents for the Palliation of Malignant Growth of Esophagus

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Cancer Esophagus; Dysphagia; Palliation; Stenting; Esophagus; Esophagus stenting; Self Expandable Metallic Stents

Abbreviations:

SEPS: Self-Expanding Plastic Stents; SEMS: Self-Expanding Metal Stents;

PCSEMSs: Partially Covered Self-Expandable Metal Stents; FCSEMSs: Fully Covered Self-Expandable Metal Stents; SEPSs: Fully Covered Self-Expandable Plastic Stents

1. Abstract

1.1. Background: Often patients with carcinomas of esophagus presents with dysphagia at a late stage where curative treatments are not a treatment option. To relieve dysphagia and its consequences palliative esophageal stentings are offered. Self-expanding metal stents (SEMS) and self-expanding plastic stents (SEPS) are available for relieving the dysphagia. Uncovered, partially covered, or fully covered are the commonly used SEMS.

1.2. Objectives: To study 30 days and 90 days hospital readmissions, and mortalities from uncovered, partially covered or fully covered SEMS when deployed for palliation of malignancy of the esophagus.

1.3. Methods: Patients who had malignant lesions in the esophagus and had palliative stenting from King Faisal Specialist Hospital Research Centre, Riyadh, (KFSHRC) between 2007 and 2019 were included. Stent related complications were recorded if they had stent migration, stricture formation, bleeding, or combination of them. Complications and death were recorded if the events were reported to KFSHRC within 90 days from the stent insertion. Patients who had self-expandable plastic stents were excluded.

1.4. Results: A total of 60 patients who had malignant tumors of

the esophagus and had palliative esophageal stenting were studied. The mean age of the population studied was 66 years. Dysphagia was the predominant symptom. Nineteen patients were treated with uncovered stent, 24 with fully covered stent, and the other 17 patients were treated with partially covered stents. A total of 14 patients died within 90 days of follow-up. Recurrence of stricture was observed in 7 cases, and stent migration occurred in 5. Five patients got readmitted within 30 days, and 13 were readmitted within 90 days. Univariate analysis showed no differences between three kinds of SEMS and different variables.

1.5. Conclusion: Thirty-day readmission, ninety-day readmission, and death were not different between the three kinds of SEMS for the palliative treatment of malignant lesions of the esophagus. Overall, 90 days mortality was 21.7%, stricture-recurrence 11.7%, and stent-migration 8.3 %.

2. Introduction

Esophageal malignancy is the eighth most frequent cancer worldwide, with an estimated 456 000 new cases and 400 000 deaths in 2012 [1]. More than 50% of individuals with esophageal cancer have metastatic disease at the time of diagnosis. Dysphagia is the most

frequent symptom of incurable obstructive esophageal malignancy, and esophageal stent placement is a treatment option for them.

Over the past few years, different designs of esophageal stents have emerged for improving dysphagia. Esophageal stent placement improves the quality of life in individuals with malignant esophageal tumors, malignant fistula, or extrinsic compression. [2, 3]. Esophageal stent placement in individuals with incurable esophageal cancer is aimed at preserving oral intake and enhancing the quality of life, but it carries a risk of adverse events such as bleeding, fistula, and pain [4]. The current commercially available stents for malignant disease comprise uncovered self-expandable metal stents (SEMSs); partially covered self-expandable metal stents (PCSEMSs), in which the distal and proximal ends of the stent are devoid of a covering; fully covered self-expandable metal stents (FCSEMSs), in which the entire length of the stent is covered; and fully covered self-expandable plastic stents (SEPSs).

The tubular-shaped esophagus is easily accessible and a very suitable organ for safe and simple stent insertion. For this reason, and owing to good results in dysphagia management, the use of self-expandable metal stents is widely accepted as one of the leading methods of palliative treatment of individuals with malignant esophageal tumors [5]. To date, several clinical reports have been published demonstrating good clinical results with multiple stent types. [6-9] However, literature comparing the clinical outcomes of the stents is limited. Therefore, we present this study comparing various types of esophageal stents in terms of complications and readmissions rates.

3. Methodology

Data was collected retrospectively from the medical records of King Faisal Specialist Hospital and Research Center (KFSH&RC), Riyadh. All patients with inoperable malignant esophageal stenosis and had SEMS inserted as palliative option between 2007 and 2019 were included. A total of 60 patients were identified for this study. We collected patient characteristics, causes of non-operability, early and long-term complications, re-interventions, re-admission, and mortality. The objective of the study was to follow 30 days and 90 days hospital readmissions, and mortalities from uncovered, partially covered or fully covered SEMS when deployed for palliation of malignancy of the esophagus.

4. Statistical Analysis

Computerized data entry was performed using Redcap website. The data was encrypted. Then the collected data was sent to a specialized biostatistician who analyzed the data using Jamovi. (<https://www.jamovi.org/jmv/>)

5. Results

A total of 60 patients who had malignant tumors of the esophagus and had palliative esophageal stenting were studied. Thirty-six of them were males and 24 were females. The mean age of the population studied was 66 years. Dysphagia was the predominant symptom. Baseline characteristics are given in table 1. Nineteen patients (31.7%) were treated with uncovered stent, 24 patients (40%) had fully covered stent, and the other 17 patients (28.3%) were treated with partially covered stents. Figure 1 The mean length of the stricture was 6.5 CM (median length 6 cm), and the mean length of the SEMS was 12 CM (median 12 CM).

Thirty-three patients had adenocarcinoma, 24 patients had squamous cell carcinoma, 2 had neuroendocrine tumor and one with cancer breast. The tumor location was in the lower part of the esophagus in 40 cases, in 17 cases its location was in the mid esophagus, and in two of them in the upper esophagus. Twelve patients had chemotherapy, 7 had radiotherapy and 14 had chemo and radiotherapy.

Recurrence of stricture was observed in 7 cases, and stent migration occurred in 5. Five persons got readmitted within 30 days, and 13 were readmitted within 90 days. A total of 14 patients died during three months of follow-up. Figure 2 shows outcomes from the palliative esophageal stenting. There was no statistical significance in death, readmission within 30 days and 90 days between three kinds of esophageal stents. Analysis showed death as outcome with a p value of 0.95; readmission within 30 days (p value 0.28); and readmission within 90 days (p value 0.41) respectively.

Univariate analysis showed no differences between three kinds of SEMS and different variables. Table 2: Cross Table showing differences between three kinds of esophageal stents and other variables. Odds ratio plot in Figure 3 shows that there is no significant risk of death between three kinds of SEMS.

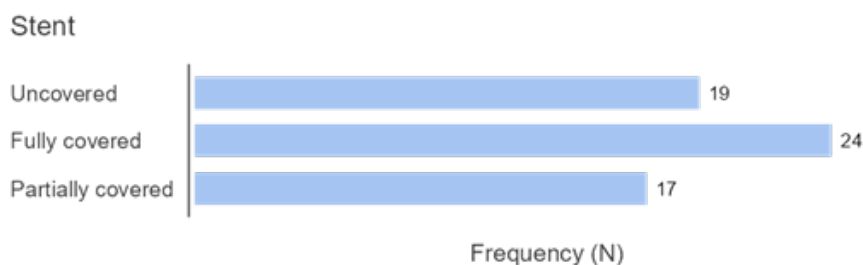


Figure 1: Shows the frequencies of three kinds of esophageal stent at KFSHRC. Total number of patients is 60.

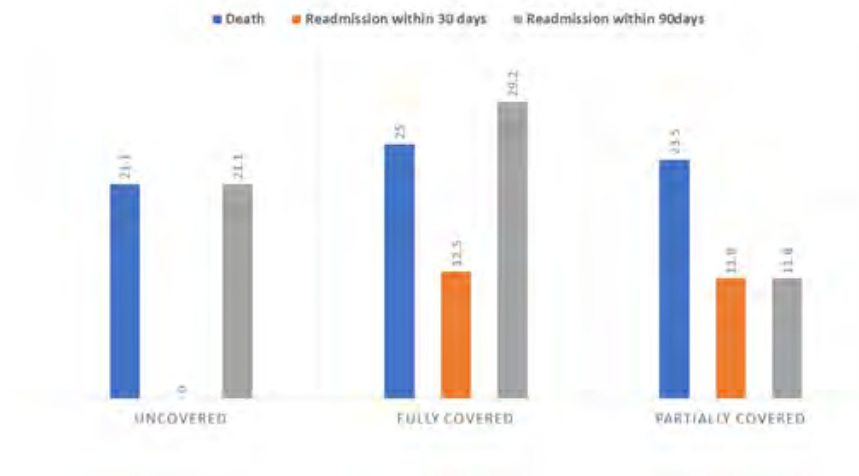


Figure 2: Outcomes of 60 patients who had esophageal stenting. Death within 90 days, 30 days and 90 days hospital readmission are given.

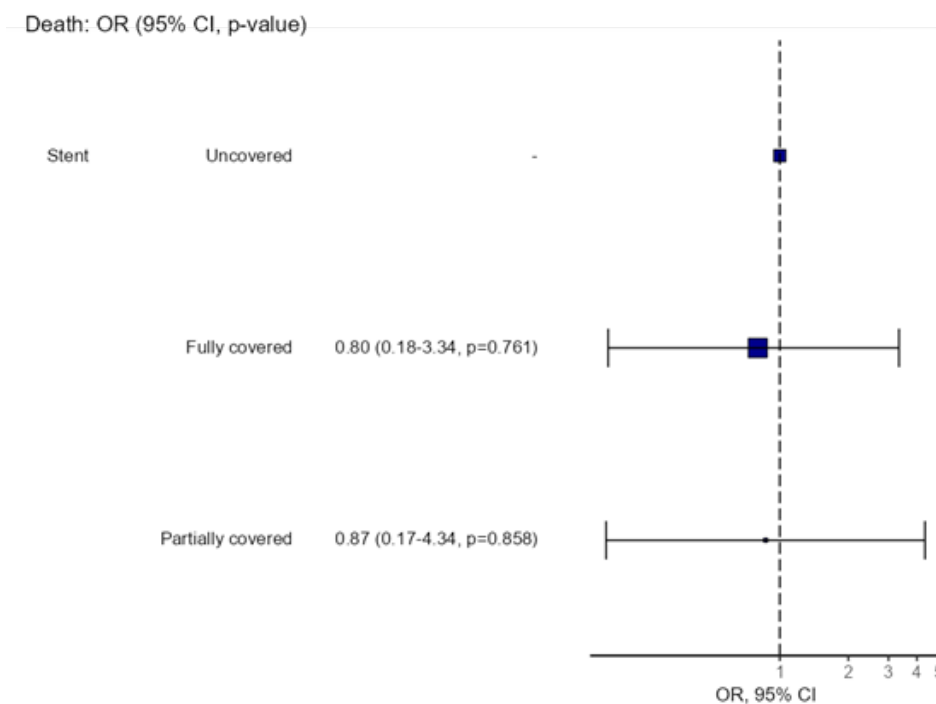


Figure 3: Odds ratio plot shows that there is no difference in risk of death within 90 days of three kinds of esophageal stents for the palliation of dysphagia in cancer esophagus.

Table 1: Showing baseline characteristics of the 60 patients with malignancy of esophagus who had palliative stenting.

	Overall (N=60)
Age	
Mean (SD)	66.0 (17.6)
Range	5.0 - 97.0
Gender	
Female	24 (40.0%)
Male	36 (60.0%)
Location of tumor	
N-Miss	1

Lower	40 (67.8%)
Mid	17 (28.8%)
Upper	2 (3.4%)
Symptoms	
N-Miss	2
Dysphagia	34 (58.6%)
Dysphagia+ wt loss	15 (25.9%)
Weight loss	2 (3.4%)
Dysphagia + GERD	2 (3.4%)
Hematemesis	2 (3.4%)
Dysphagia + vomiting	2 (3.4%)
Dysphagia +weight loss + vomiting	1 (1.7%)
Histology	
Adenocarcinoma	33 (55.0%)
Squamous cell carcinoma	24 (40.0%)
Ca breast	1 (1.7%)
Neuroendocrine tumor	2 (3.3%)
Stent	
Uncovered	19 (31.7%)
Fully covered	24 (40.0%)
Partially covered	17 (28.3%)
Etiology of stricture	
Malignant	60 (100.0%)
Length of stricture	
N-Miss	2
Mean (SD)	6.1 (2.7)
Range	0.0 - 13.0
Stent length	
N-Miss	1
Mean (SD)	12.1 (3.7)
Range	5.0 - 28.0
Complications	
No	48 (80.0%)
Stenosis	7 (11.7%)
Migration	5 (8.3%)
Chemoradiotherapy	
No chemo nor radiation	27 (45.0%)
Chemo radiation	14 (23.3%)
Chemo	12 (20.0%)
Radiation	7 (11.7%)
Death	
Yes	14 (23.3%)
No	46 (76.7%)
Readmission within 30 days	
Yes	5 (8.3%)
No	55 (91.7%)
Readmission within 90days	
Yes	13 (21.7%)
No	47 (78.3%)

Table 2: Differences between three types of palliative esophageal stents used.

	N	Uncovered	Fully covered	Partially covered	Test Statistic
Total number		(N=19)	(N=24)	(N=17)	
Age:					
Mean (SD) Median	60	69.9 (16.6) 74	61.8 (19.1) 65	67.5 (16.4) 69	F1,58=0.56, P=0.46
Length of stricture in CM.					
Mean (SD) median	58	6.48 (2.28) 6	5.44 (3.28) 5	6.81 (2.10) 6.5	F1,56=0.05, P=0.83
Stent length in CM.					
Mean (SD) median	59	12.6 (4.81) 10.5	12.1(3.41) 12	11.5 (2.32) 10	F1,57=0.22, P=0.64
		N (%)	N (%)	N (%)	
Gender: Male	60	13/19 (68.4%)	11/24 (45.8%)	12/17 (70.6)	X22=3.36, P=0.19
Location of the tumor	59				X24=4.44, P=0.35
Lower Esophagus		14/18 (77.8%)	13/24 (54.2%)	13/17 (76.5)	
Mid Esophagus		3/18 (16.7%)	10/24 (41.7%)	4/17 (23.5)	
Upper Esophagus		1/18 (5.6%)	1/24 (4.2%)	0/17 (0)	
Symptoms	58				X212=10.87, P=0.54
Dysphagia		10/18 (55.6)	16/24 (66.7)	8/16 (50)	
Dysphagia+ weight loss		5/18 (27.8)	4/24 (16.7)	6/16 (37.5)	
Weight loss		0/18 (0)	1/24 (4.2)	1/16 (6.3)	
Dysphagia + GERD		1/18 (5.6)	1/24 (4.2)	0/16 (0)	
Hematemesis		0/18 (0)	1/24 (4.2)	1/16 (6.3)	
Dysphagia + vomiting		2/18 (11.1)	0/24 (0)	0/16 (0)	
Dysphagia + weight loss + vomiting		0/18 (0)	1/24 (4.2)	0/16 (0)	
Histology	60				X26=3.84, P=0.70
Adenocarcinoma		12/19 (63.2)	13/24 (54.2)	8/17 (47.1)	
Squamous cell carcinoma		6/19 (31.6)	9/24 (37.5)	9/17 (52.9)	
Ca breast		0/19 (0)	1/24 (4.2)	0/17 (0)	
Neuroendocrine tumor		1/19 (5.3)	1/24 (4.2)	0/17 (0)	
Complications	60				X24=8.44, P=0.08
No complications		16/19 (84.2)	17/24 (70.8)	15/17 (88.2)	
Stenosis		3/19 (15.8)	2/24 (8.3)	2/17 (11.8)	
Migration		0/19 (0)	5/24 (20.8)	0/17 (0)	
Chemoradiotherapy	60				X26=6.44, P=0.382
No chemo nor radiation		6/19 (31.6)	11/24 (45.8)	10/17 (58.8)	
Chemo radiation		6/19 (31.6)	4/24 (16.7)	4/17 (23.5)	
Chemotherapy		3/19 (15.8)	6/24 (25)	3/17 (17.6)	
Radiation		4/19 (21.1)	3/24 (12.5)	0/17 (0)	
Death	60	4/19 (21.1)	6/24 (25)	4/17 (23.5)	X22=0.09, P=0.952
Readmission within 30 days	60	0/19 (0)	3/24 (12.5)	2/17 (11.8)	X22=2.53, P=0.282
Readmission within 90 days	60	4/19 (21.1)	7/24 (29.2)	2/17 (11.8)	X22=1.78, P=0.412

6. Discussion

In this study, when 60 patients with malignancies of esophagus who underwent palliative esophageal stents were studied, we found there were no significant differences between three kinds of esophageal stents and their outcomes.

The utilization of esophageal stents in managing esophageal malignant growth is grounded. Close to half of patients benefit from this line of treatment either as bridging or as a palliative measure to secure feeding and symptomatic relieve [10]. Our study showed that the complications when comparing uncovered, fully covered and partially covered stents were not statistically significant. However, having fully covered stent were associated with migration as a complication when compared to other stent types (20% vs 0% vs 0%) which is supported by **Saranovic et al.** (2005) [6] which seems to be contradicting metanalysis done by Wang et al 2020 [11] and [8]. The complication rate in terms of stenosis was showing no difference in our study which seems to be in alignment with the metanalysis done by Wang, [11] but contradicting the data mentioned by **Saranovic et al.** (2005) [6]. Regarding readmission rate post stent placement, our data support that there is no difference in readmission rate even though the results are statistically insignificant and considering that the complications of stents are proxies to readmission rates, we believe our data align with that statement, however low sample size and poor documentation contributed to the limited statistical significance. However, the findings might be useful for future research.

Our study showed that esophageal adenocarcinoma is more common than squamous cell carcinoma in Riyadh, Saudi Arabia which is consistent with worldwide esophageal cancer epidemiology [12]. Several Studies demonstrated that histologic type has no prognostic significance [13,14,15] however in our study adenocarcinoma is the prevalent type and considering the palliative use in our study, we can draw from our data that esophageal adenocarcinoma have worse prognosis when compared to squamous cell carcinoma. Nonetheless, these results must be interpreted with caution and several limitations should be borne in mind. One limitation of the study was the low sample size. Second limitation of the study was the access of the old data as the only way to access information is through the electronic medical record while paper-based files were not accessed which compromised some of the results leading to exclusion of number of patients.

7. Conclusion

Thirty-day readmission, ninety-day readmission, and death were not different between the three kinds of SEMS for the palliative treatment of malignant lesions of the esophagus. Overall, 90 days' mortality was 21.7%. recurrence of stricture has occurred in 11.7%, and stent migration in 8.3 % occurring mostly with fully Covered stents.

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