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ORIGINAL ARTICLE

Retrospective Study

Stent type used does not impact complication rate or placement time but can decrease treatment cost for benign and malignant esophageal lesions

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Abstract

AIM: To evaluate if differences exist between self-expanding esophageal metal stents (SEMS) and self-expanding esophageal plastic stents (SEPS) when used for benign or malignant esophageal disorders with regard to safety, efficacy, clinical outcomes, placement ease and cost.

METHODS: A retrospective analysis was performed to evaluate outcome in patients having SEPS/SEMS placed for malignant or benign esophageal conditions from January 2005 to April 2012. Inclusion criteria was completed SEMS/SEPS placement. Outcomes assessed included technical success of and time required for stent placement, procedure-related complications, need for repeat intervention, hospital stay, mortality and costs.

RESULTS: Forty-three patients underwent stent placement for either benign/malignant esophageal

disease during the study period. Thirty patients had SEMS (25 male, mean age 59.6 years old) and 13 patients had SEPS (10 male, mean age 61.7 years old). Placement outcome as well as complication rate (SEPS 23.1%, SEMS 25.2%) and in-hospital mortality (SEPS 7.7%, SEMS 6.7%) after placement did not differ between stent types. Migration was the most frequent complication reported occurring equally between types (SEPS 66.7%, SEMS 57.1%). SEPS was less costly than SEMS, decreasing institutional cost by $255/stent.

CONCLUSION: SEPS and SEMS have similar outcomes when used for benign or malignant esophageal conditions. However, SEPS use results in decreased costs without impacting care.

Key words: Esophageal; Stent; Benign; Malignant; Complication; Placement; Cost

Core tip: Self-expanding esophageal metal stents (SEMS) are preferable to self-expanding esophageal plastic stents (SEPS) for treatment of malignant or benign esophageal conditions, due to decreased technical difficulties. Comparative studies between stent types evaluating differences between SEMS and SEPS for these conditions with regard to safety, efficacy, clinical outcomes, placement ease and cost are lacking. Retrospective analysis indicated placement outcome, complication rate, most frequent complication and in-hospital mortality after placement was equivalent between stent types. SEPS was less costly than SEMS. SEPS and SEMS have similar outcomes when used for malignant/benign esophageal conditions but SEPS results in decreased costs without impacting care.

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INTRODUCTION

Placement of an esophageal stent is a minimally invasive procedure regularly used in both malignant and benign disease. Since the initial description in 1976, treatment using esophageal stents has advanced into a commonly accepted therapeutic technique for malignant esophageal strictures, fistulas and other complications[1-3]. The aim of esophageal stenting is to restore luminal patency and thereby nutritional intake, improving patient quality of life[2,4,5]. In addition, esophageal stent use has expanded to various inoperable malignancies localized in the esophagus, gastroesophageal junction and cardia as well as benign conditions including benign refractory strictures, anastomotic leaks, perforations, and trachea-esophageal fistulas[2-7].

Presently, the two most common types of self-expandable esophageal stents are the self-expandable esophageal plastic stent (SEPS), made from durable polymers and multiple self-expandable esophageal metal stent (SEMS), made from metal alloy compounds (Table 1)[3,7]. SEMS are considered preferable to SEPS for treatment of malignant or benign esophageal conditions, due to decreased technical difficulties at or following placement[8,9]. However, comparative studies of between stent types used for either benign or malignant esophageal conditions are limited with inconsistent results reported regarding technical outcome and migration[10-12]. The aim of the present investigation was to evaluate if differences exist between SEMS and SEPS placed for benign or malignant esophageal disorders with regard to safety, efficacy, clinical outcomes, placement ease and cost.

MATERIALS AND METHODS

A retrospective analysis was performed at the University of Florida Health Science Center-Jacksonville to evaluate the outcomes of patients undergoing endoscopic SEPS placement compared to endoscopic SEMS placement for malignant or benign esophageal conditions. Inclusion criteria were the following: Endoscopic esophageal stent placement between January 1, 2005 to April 30, 2012, presence of adenocarcinoma or squamous cell carcinoma of the esophagus, recurrent fistula caused by malignant tumor, benign esophageal strictures, and esophageal perforation or leak. Exclusion criteria were tumor above 2 cm from the upper esophageal sphincter. Clinical data obtained and assessed included technical success of stent placement, procedure-related complications, need for subsequent re-intervention, hospital stay, and mortality. Demographic and clinical data were collected from the local electronic medical record. Stent type selected for use was based on endoscopist and referring physician preference. Stent length was determined according to the size and localization of the tumor. All endoscopic treatments occurred under conscious sedation, monitored anesthesia, or general anesthesia. Initial evaluation occurred using standard esophagogastroduodenoscopy (EGD). If dilation was required, this was performed by means of fluoroscopic guidance prior to stent placement. Proximal and distal ends of the lesion to be stented was determined during EGD and hemoclips were used as markers to delineate both ends. A 0.35 mm tracer metro direct wire or Savary guide wire was used to assist placement. All stents used in the present investigation were from Boston Scientific, Marlborough, MA. The SEMS used was WallFlex fully covered with an institutional cost of $2650 and patient insurance cost of $4500. The SEPS used was Polyflex with an institutional cost of $2395 and patient insurance cost of $4090. All SEMS were placed under dual vision (fluoroscopy and endoscopy) while

Table 1 Currently available stents in the United States

Stent	Manufacturer	Material	Diameter body/flare (mm)	Length (cm)	Covering
Alimaxx-E	Alveolus	Nitinol	18/22	7/10/12	FC with antimigration struts
Esophageal Z-stent	Cook	Stainless steel	18/25	8/10/12/14	PC
Evolution	Cook	Nitinol	20/25	8/10/12.5/15	PC
Flamingo Wallstent	Boston Scientific	Stainless steel	20/30	12/14	PC
Gianturco-Z	Cook	Stainless steel	18/25	8/10/12/14	FC
Niti-S	Taewong Medical	Nitinol	16/20	8/10/12/14	FC
			18/23		
			20/25		
Niti-S; double layered	Taewong Medical	Nitinol	18/26	9/12/15	FC with additional uncovered outer nitinol wires
Niti-S; single layered	Taewong Medical	Nitinol	18/26	9/12/15	FC
Polyflex	Boston Scientific	Polyester	16/20	9/12/15	FC
			18/23		
			21/28		
SX-ELLA	Ella-CS	Nitinol	20/25	8.5/11/13.5/15	FC with antimigration ring
Ultraflex	Boston Scientific	Nitinol	18/23	10/12/15	PC
			23/28		
Wallflex	Boston Scientific	Nitinol	18/23	10/12/15	PC/FC
			23/28		

Adapted with permission from Curr Gastroenterol Rep 2013; 15: 319. PC: Partially covered; FC: Fully covered.

Table 2 Overall demographics in patients having self-expanding esophageal metal stents/self-expanding esophageal plastic stents placed for malignant or benign esophageal conditions from January 2005 to April 2012

	Overall (n = 43)	nHw (n = 25)	AA (n = 15)	Other (n = 3)
Mean age (yr)	60.2	57.7	60.4	80[1]
% male	85.1	80	80	100

[1]Compared to nHw (P < 0.01) and AA (P < 0.03). nHw: Non-Hispanic White; AA: African American.

SEPS were placed under fluoroscopy vision only due to the delivery system. Appropriate placement of the SEPS was confirmed by direct visualization using EGD to verify positioning. A contrast esophagogram was performed postoperatively at the discretion of the endoscopist. This study was approved by the University of Florida Health Science Center-Jacksonville Institutional Review Board.

Statistical analysis

Continuous data were described as mean ± SD and compared using two sided student t tests. Categorical data were presented as numbers or percentages and analyzed using appropriate χ^2 testing. Results were analyzed in relation to stent type placed (SEMS or SEPS). A P value of less than 0.05 was considered statistically significant. Data analysis was performed using the GraphPad Prism statistical analysis program (Kenneth J Vega, version 6, La Jolla, CA).

RESULTS

Patient characteristics

Forty-three patients underwent stent placement for either benign (8 patients) or malignant (35 patients) esophageal disease during the study period. Patients with benign esophageal disease had the following diagnosis: 3 with esophageal fistulas, 2 with extrinsic compression and 1 each with esophageal stricture, perforation or iatrogenic tear. Of the 35 patients with malignant esophageal disease, 14 patients had squamous cell carcinoma, 16 patients had adenocarcinoma and 5 patients had mixed malignant histology. Mean patient age of the overall group was 60.2 years (SD 13.5 years) and 81.4% were male (Table 2). Ethnicity was distributed as follows, 25 non-Hispanic Whites (nHw), 15 African Americans (AA) and 3 from other groups (2 Asian Americans and 1 Hispanic American). Compared to both nHw and AA, the other group was older [80 (other) *vs* 57.7 (nHw), P < 0.01 or 60.4 (AA) years, P < 0.03]. No significant difference was seen in the number of males in each ethnic group.

Stent groups

SEMS were placed in 30 patients and SEPS used in 13 patients. Patient characteristics of both stent groups are seen in Table 3. Mean age, percentage of male patients and ethnic distribution was equivalent in the SEMS and SEPS groups (Table 3). Both stent groups also were similar with regard to esophageal lesion location, percentage of malignant esophageal lesions and comorbid diseases (Table 3).

Stent placement, outcome and cost

Successful stent placement occurred in all SEMS and SEPS patients. No patient in either stent group required more than 1 stent initially. Table 4 illustrates placement and outcome comparisons between SEMS and SEPS. Dilation was more frequent in the SEPS group compared to SEMS (P = 0.023). No significant difference was seen between stent groups in initial placement time, complication rate, time to first complication, in hospital mortality, repeat intervention required frequency, length

Table 3 Patient characteristics based on stent type placed

	SEMS (n = 30)	SEPS (n = 13)	P value
Mean age (yr ± SD)	59.6 ± 14.87	61.7 ± 9.95	0.645
% male	83.3%	76.9%	0.681
Race/ethnicity, n (%)	AA: 9 (30%)	AA: 6 (46%)	0.704
	nHw: 18 (60%)	nHw: 7 (54%)	
	Other: 3 (10%)	Other: 0	
Malignant esophageal lesion, n (%)	25 (83.3%)	10 (76.9%)	0.681
Esophageal lesion location, n (%)	Upper third: 0	Upper third: 1 (7.7%)	0.15
	Middle third: 9 (30%)	Middle third: 6 (46.2%)	
	Lower third: 21 (70%)	Lower third: 6 (46.2%)	
Comorbid diseases, n (%)	HTN: 16 (53.3%)	HTN: 6 (46.2%)	0.747
	CAD: 7 (23.3%)	CAD: 2 (15.4%)	0.699
	COPD: 5 (16.7%)	COPD: 1 (7.7%)	0.649
	DM: 11 (36.7%)	DM: 3 (23.1%)	0.491

SEMS: Self-expanding esophageal metal stents; SEPS: Self-expanding esophageal plastic stents; nHw: Non-Hispanic White; AA: African American; HTN: Hypertension; CAD: Coronary artery disease; COPD: Chronic obstructive pulmonary disease; DM: Diabetes mellitus.

Table 4 Placement and outcome comparisons between self-expanding esophageal metal stents and self-expanding esophageal plastic stents

	SEMS (n = 30)	SEPS (n = 13)	P value
Initial placement procedure time (min, mean ± SD)	33.17 ± 16.88	35.85 ± 27.39	0.696
Dilation required prior to stent placement	0	23%	0.023
Complications, n (%)	7 (23%)	3 (23%)	1
Time to first complication (n)	< 30 d: 6	< 30 d: 2	1
	> 30 d: 1	> 30 d: 1	
In-hospital mortality (%)	7%	8%	1
Re-intervention required (%)	20%	23%	1
30 d survival after procedure (%)	95%	80%	0.251
Length of stay (d, mean ± SD)	11.47 ± 12.78	12.15 ± 16.21	0.883

SEMS: Self-expanding esophageal metal stents; SEPS: Self-expanding esophageal plastic stents.

of stay and 30 d survival (Table 4). Stent migration was the most frequent complication, occurring in 4 SEMS and 2 SEPS patients. Interestingly, SEMS resulted in increased costs than SEPS with an average cost savings of $255-410 for each SEPS used instead of SEMS for hospital and patient insurance cost, respectively.

DISCUSSION

SEMS are considered preferable to SEPS for treatment of malignant or benign esophageal conditions, due to decreased technical difficulties[8,9]. However, comparative studies between stent types are limited[10-12]. The present study was designed to assess whether if differences exist between SEMS and SEPS use for benign or malignant esophageal disorders with regard to safety, efficacy, clinical outcomes, placement ease and cost. The results indicate SEPS and SEMS are equivalent when used for benign or malignant esophageal conditions with regard to initial placement time, complication frequency, time to initial complication, in-hospital mortality, repeat intervention need, 30 d post procedure survival and length of hospital stay. In addition, SEPS use results in decreased costs without impacting care for either benign of malignant esophageal conditions.

The current investigation is the first to compare use of SEMS and SEPS on a combined population of benign and malignant conditions of the esophagus. All stents were placed successfully which is consistent with previous literature evaluating stent placement in exclusive subsets of either benign or malignant esophageal disease (98%-100%)[10-12]. Comparison of procedure time required for initial SEMS and SEPS placement was only performed by 1 group previously[10]. Conio *et al*[10] found initial SEPS placement was significantly longer than SEMS by a median of 12 min. However, no difference was seen between mean initial placement procedure time based on stent type in the present study. Moreover, no significant difference was present regarding lesion type stented in the SEMS and SEPS groups removing a potential confounder for initial placement time and suggesting equivalent placement ease in all cases in spite of different delivery systems used.

Complication rates following SEMS and SEPS were equal in both stent groups. Interestingly, the rate observed (23% for both SEMS and SEPS) was less than the reported in the literature (46%-48%)[10-12]. The main complication seen was stent migration in both stent groups which is consistent with the majority of studies

evaluating stent type for either benign or malignant esophageal lesions[11,12]. However, no difference was seen between SEMS and SEPS in frequency of migration. Of note, earlier data has been inconclusive with regard to migration rates with one study suggesting fully covered stents (either metal or plastic) are more likely to migrate while another indicated SEPS migrated more frequently[10,12]. Only one patient had recurrent dysphagia following stent placement (received SEMS) which was treated conservatively. Furthermore, no difference was observed in re-intervention requirement, in-hospital mortality, length of initial hospital stay and 30 d survival between SEMS and SEPS groups.

Health care costs remain a significant concern in the United States in spite of the Affordable Care Act of 2010[13]. In addition, placement of esophageal stents decrease costs for both benign and malignant esophageal conditions[14]. The present study indicated that if using SEPS in contrast to SEMS for either benign or malignant conditions reduced cost between $255-410 per SEPS used. Moreover, as outcome was not affected by stent type used in our investigation, significant cost savings could be achieved with SEPS use only for esophageal conditions requiring endoscopic intervention.

Of note, a third, less commonly used self-expandable esophageal stent, the biodegradable (BD) - stent, has been developed as an alternative to SEPS. Currently available BD stent designs are the ELLA-BD stent (ELLA-CS, Hradec Kralove, Czech Republic), which is composed of polydioxanone, a surgical suture material and the poly-L-lactic acid (PLLA)-BD stent (Marui Textile Machinery, Osaka, Japan), which consists of knitted PLLA monofilament. These stents can be degraded by hydrolysis, which is accelerated at low ambient pH. Generally, BD stents begin to degrade after 4 to 5 wk following placement and dissolve completely after a period of 2 to 3 mo. The major strength of BD stent over SEMS or SEPS is that it does not require removal, even after migration, as it is dissolved by gastric acid, thus avoiding further procedures and potential morbidity[15].

We are aware of the limitations of the present investigation. The primarily limitation is the retrospective design. In addition, our study had a small sample size for SEPS patients. Nevertheless, the majority of previously published studies have included small samples of SEPS patients as well. Furthermore, classification of stents used according to degree covered (fully or partially) may have had an impact in the results but given the small number of subjects, this was not performed. Finally, selection bias could impacted the results observed as stent type selected for insertion was dependent on the endoscopist performing the procedure.

In conclusion, SEPS should be considered as a treatment option for any esophageal indication, benign or malignant, with no increase in complications and equivalent efficacy to SEMS. In addition, SEPS use appears cost effective for management of esophageal lesions requiring restoration of luminal patency compared to SEMS. Performance of prospective clinical trials comparing SEMS and SEPS should be implemented to validate these findings. Furthermore, investigations comparing esophageal stents should occur and include biodegradable stents as well as longitudinal evaluations of biodegradable stents with an increased *in vivo* half-life, to assess longer term stent patency, mitigate stent-related complications, and whether the need for repeat interventions is required.

COMMENTS

Background

Self-expanding esophageal metal stents (SEMS) are preferable to self-expanding esophageal plastic stents (SEPS) for treatment of malignant or benign esophageal conditions, due to decreased technical difficulties. Comparative studies between stent types evaluating differences between SEMS and SEPS for these conditions with regard to safety, efficacy, clinical outcomes, placement ease and cost are lacking.

Research frontiers

To evaluate if differences exist between SEMS and SEPS placed for benign or malignant esophageal disorders with regard to safety, efficacy, clinical outcomes, placement ease and cost.

Innovations and breakthroughs

Stent placement outcome, complication rate, most frequent complication and in-hospital mortality after placement was equivalent between stent types. SEPS was less costly than SEMS. SEPS and SEMS have similar outcomes when used for malignant/benign esophageal conditions but SEPS results in decreased costs without impacting care.

Applications

SEPS should be considered as a treatment option for any esophageal indication, benign or malignant, with no increase in complications and equivalent efficacy to SEMS. In addition, SEPS use appears cost effective for management of esophageal lesions requiring restoration of luminal patency compared to SEMS.

Terminology

SEPS are made from durable polymers and SEMS are made from metal alloy compounds.

Peer-review

Both SEMS and SEPS are considered useful for treatment of malignant or benign esophageal conditions. However, few comparative studies between stent types have been reported. The study compared the safety, efficacy, clinical outcomes, placement ease and cost between SEMS and SEPS for benign or malignant esophageal disorders and found SEPS is cheaper. This may be helpful for clinical doctors in choosing stent types.

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