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Predictors of adverse events and early mortality after esophageal stent placement in a low resource setting: a series of 3823 patients in Kenya

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ABSTRACT

Background and study aims Dysphagia from esophageal cancer may be palliated with self-expanding metallic stents (SEMS). Controversy exists about the use of dilation before SEMS deployment.

Patients and methods We performed a retrospective cohort study of patients who had SEMS placement without fluoroscopy for palliation at Tenwek Hospital in Bomet, Kenya between January 1999 and April 2019. The primary outcome was any serious adverse event (AE) (chest pain, stent migration, perforation, bleeding, or all-cause mortality) within 30 days of the procedure. Various demographic and clinical characteristics, and procedural details, were examined as risk factors. Technical success, defined as correct SEMS placement, and clinical success, defined as dysphagia score improvement without 30-day mortality, were examined.

Results A total of 3823 patients underwent SEMS placement, with 2844 (74.4%) placed in the second decade of the study. Technical and clinical success were achieved in 97.2% and 95.5%, respectively, with mean dysphagia scores improving from 3.4 (SD 0.6) to 0.9 (SD 1.3) post-stent placement. AEs occurred in 169 patients (4.4%). AEs, specifically perforations, were associated with dilation to greater than 36F in the first decade. Perforation rates decreased from the first (4.1%) to the second decade (0.2%). Only 30% had complete 30-day follow-up data.

Conclusions SEMS placement is a safe, effective method of palliating malignant dysphagia, with low rates of AEs and 30-day mortality and high rates of clinical and technical success. Dilation can facilitate placement of SEMS without fluoroscopy but should not be performed above 36F due to the risk of perforation.

Introduction

Esophageal cancer is the seventh most common cancer globally and the sixth most common cause of cancer death [1]. In most countries, the 5-year survival rate is less than 20%. Over 85% of esophageal cancers worldwide are esophageal squamous cell carcinoma (ESCC) [1]. Early cancer is often asymptomatic due to the nature of the disease, and by the time patients have dysphagia, the most common first symptom, the disease is usually advanced [2]. At this point, curative options are often limited.

Dysphagia is also often associated with negative psychosocial effects for a patient [3, 4].

Care for advanced ESCC involves palliating dysphagia [3], with various options [5]. SEMS are an excellent choice for palliation of unresectable esophageal tumors and are recommended over other possibilities [6–8]. SEMS placement is also beneficial in patients with poor functional status who cannot tolerate a surgical procedure or as a useful adjunct to maintain nutrition before surgery [9]. SEMS provide immediate relief [10] and have been shown to improve dysphagia scores by at least two units [11]. This relief of dysphagia has been closely tied to improved palliation and quality of life scores [12, 13], demonstrating effective palliation. The main adverse events (AEs) associated with placement of SEMS include bleeding, perforation, sternal chest pain, stent migration, and death [7, 10].

In many parts of the world, SEMS have traditionally been placed under fluoroscopy. However, there have also been multiple reports of SEMS stent placement under endoscopic visualization without fluoroscopy [14–16], and at our institution, we further refined this and now place stents using a modified technique that utilizes measurements without either fluoroscopy or direct endoscopic visualization during stent deployment [15].

Dilation is often required to assess tumor length before SEMS placement without fluoroscopy. In a meta-analysis concerning SEMS placement without fluoroscopy, numerous investigators reported on the use of esophageal dilation before deployment with either Savary or balloon dilators [16]. However, there is no consensus on the optimal size of dilation. In Egypt, Abdelshafy described dilating 41 % of patients up to 11 mm to allow passage of the endoscope [17]. Siddiqui et al. also dilated tumors up to 11 mm before SEMS deployment [18]. In a review of dilator types, Hernandez et al. found that Savary dilators were less likely to cause perforation than the blind passage of Maloney dilators [19]. Some authors argue that dilation does not provide any benefit and should be avoided due to the potential risk [20]. The European Society of Gastrointestinal Endoscopy (ESGE) also recommended against dilation in malignant strictures due to the increased risk of perforation [6]; however, their guidelines presume that fluoroscopy is available for the determination of the length and extent of the malignancy. In contrast, other authors argue that dilation can be safely performed up to 48 to 51F in a serial manner and that larger-diameter dilation makes SEMS placement easier and safer [21]. Thus, there are wide-ranging beliefs on the utility of dilation prior to SEMS placement, and the optimal strategy is not yet known, especially in settings without access to fluoroscopy.

In Kenya, ESCC is the third most common cancer in women and the second most common cancer in men and is the most common cause of cancer death in men [1]. Our institution, Tenwek Hospital, is a 360-bed faith-based teaching and referral hospital in rural western Kenya. For the past twenty years, the institution has served as a referral center for patients with esophageal cancer [22]. We hypothesized that there could be valuable lessons to be learned regarding the early AEs associated with SEMS placement at our institution over time.

Patients and methods

We conducted a retrospective cohort study of patients who had placement of SEMS for palliation of ESCC at Tenwek Hospital. The patients consisted of those presenting to our hospital between January 1999 through April 2019 with dysphagia from esophageal cancer.

The stent technique at our institution has been described previously [5, 15]. If an endoscope would not pass the tumor, dilation with wire-guided Savary-Gilliard Dilators (Cook Endoscopy, Winston-Salem, North Carolina, United States) was always performed to enable scope passage and endoscopic assessment of the entire tumor. In such cases, a guidewire was passed across the cancer into the stomach, avoiding guidewire advancement against resistance and passing at least 60 cm of wire beyond the tumor. At the endoscopist's discretion, dilation was performed even if the endoscope would pass across the tumor. In the second decade, dilation to >36F was rarely performed. After inserting an endoscope into the stomach, distances from the incisors to the tumor's proximal and distal margins and distances to the upper esophageal sphincter and the gastroesophageal junction were recorded. In the first decade of this cohort, the stents were primarily placed under direct endoscopic visualization, while in the second decade, they were placed primarily using only these tumor and esophageal measurements. After dilation, the stent was delivered over the guidewire with an 18-mm delivery system. Stents were deployed with a 2-cm margin of covered stent above and below the tumor when possible. SEMS were placed with a minimum of 0.5-cm margin from the upper esophageal sphincter [23]. Various SEMS were utilized throughout the study period, and their supply was variable; however, SEMS were mainly nitinol-covered stents with an uncovered proximal flange (Advanced Technology & Materials, Beijing, China). These were typically available in lengths of 10, 12, or 14 cm and had an internal shaft diameter of 20 mm and a flange of 27 mm. Ultraflex stents (Boston Scientific Corporation, MA) of either 18-mm or 23-mm shaft diameter were also used. In determining the optimal stent length, we also added 2 cm to compensate for stent shortening after deployment. Technical success was defined as correct placement at the desired distance from the upper incisors. Although assessment was typically made of whether the covered portion of the stent spanned the entire tumor or not, in 2007, the endoscopy team began recording this data point prospectively. For procedures done thereafter we defined technical success as the stent bridging the whole tumor at the end of the procedure, based on relook endoscopy after deployment. Clinical success for all time points was defined as improvement in dysphagia score after the stent placement, without 30-day all-cause mortality. Pre- and post-stent placement dysphagia was described using the following score: 0 = able to swallow a regular diet, 1 = able to swallow some solids, 2 = able to swallow semisolids only, 3 = able to swallow only liquids, and 4 = unable to swallow saliva [11]. The procedures were typically performed as an outpatient procedure with sedation, unless a patient was deemed to be too frail to withstand sedation. Benzodiazepines were commonly used in combination with fenta-

nyl. Patients were monitored in a recovery room until fully recovered and able to tolerate at least a liquid diet prior to discharge. Procedural and post-procedural AEs were recorded, as well as 30-day mortality. As part of the procedure's palliative intent, routine follow-up requiring patients to return for further visits was not performed to avoid the cost and difficulty of future travel for the patient. This is consistent with practice patterns in our region, where patients typically only present to the hospital when they are experiencing a problem. Patients and families were provided with careful instructions to return if they experienced any problems. They were also encouraged to return or call in after 2 weeks for their pathology report, and attempts were made to contact them for follow-up information 30 days after the procedure.

Patient data were extracted retrospectively from inpatient, outpatient, and endoscopy records to include patient age, sex, tumor characteristics, details of the stent procedure, and morbidity data. These data were extracted into an Excel file and de-identified for analysis.

The primary outcome was the occurrence of a serious AE within 30 days of the procedure, including chest pain, defined as severe pain after the procedure; stent migration; perforation; bleeding, defined as visible bleeding from the tumor during dilation or vomiting of blood after the stent placement; or all-cause mortality. A secondary analysis was performed for 30-day all-cause mortality on patients who had follow-up information through at least 30 days after the procedure. Due to the limitations of this retrospective review, we included any mortality within 30 days of the procedure as 30-day all-cause mortality and did not try to attribute the relationship of this mortality to the procedure.

Descriptive statistics were used. To examine changes over time, we divided the cohort into two periods from 1999 to 2009 and from 2010 to 2019. Comparisons of categorical data were performed with chi-squared analysis. Continuous variables were compared with *t*-tests. Multivariable logistic regression was performed for the outcomes of any AE and 30-day all-cause mortality, using a model with all variables that had a statistically significant association on univariate analysis. Missing data were accounted for with complete case analysis with an assumption that outcome data was missing completely at random. To avoid collinearity, the model included tumor location but did not include whether the tumor crossed the gastroesophageal junction, as these factors are not expected to be independent. $P<0.05$ was considered statistically significant and was two-sided. Data analysis was performed with Stata version 16 (StataCorp, Texas, United States).

The Tenwek Hospital Institutional Research and Ethics Committee granted ethical approval. Informed consent was waived because this was a retrospective analysis of de-identified patient data.

Results

A total of 3823 patients underwent SEMS placement over the 20-year period, 2844 (74.4%) of which were placed in the second decade (▶ **Table 1**, ▶ **Fig. 1**). Patient demographics, clinical findings, procedural details, and outcomes are listed in ▶ **Table 1**. The mean age of the patients was 60.7 years (SD 14.6), and the majority of the stents were placed in men (N = 2238 (59.3%)). The mean dysphagia score at presentation was 3.4 (SD 0.6), and the median score was 3 (IQR 3–4). The mean tumor length was 7.3 cm (SD 3.0), and most of the tumors were found in the middle (N = 1786 [47.9%]) or distal (N = 1543 [41.3%]) esophagus. Biopsies were obtained from 2823 patients (72.5%), and the rest presented with a pathology report of biopsies from a procedure done at another facility. Of those with histological confirmation at our hospital, 2522 (89.3%) were ESCC, 139 (4.9%) were adenocarcinoma, and 162 (5.7%) were different or uncertain diagnoses. 2527 (69.6%) of the tumors were entirely in the esophagus, and 1102 (30.4%) involved or crossed the gastroesophageal junction (GEJ). Esophageal dilation was carried out immediately before stent placement in 3328 (94.1%) of the patients. 1468 (40.1%) of the stents crossed the GEJ. Technical success was achieved in 97.2% of the SEMS placements. Mean dysphagia score was 0.9 (SD 1.3) post-stent placement, with a median score of 0 (IQR 0–2). The overall clinical success rate was 95.5%, improving from 93.5% in 1999–2019 to 96.4% in 2010–2019 ($P = 0.015$).

Procedural AEs were recorded in 169 patients (4.3%), and these included bleeding 21 (0.5%), migration 6 (0.2%), perforation 47 (1.2%), and chest pain 66 (1.7%). Perforations, which were typically less than 5 mm, were treated by overnight admission, intravenous antibiotics and covered stent placement. None of the patients who had a perforation required surgery and no further interventions were required. Repeat imaging with a chest x-ray was done at the time of discharge. Univariate risk factors for serious AEs are detailed in ▶ **Table 2**, which shows that earlier time period and endoscopic dilation to more than 36F were associated with increased risk of AEs; and longer tumor length, tumor crossing the GEJ, distal tumor location and stent crossing the GEJ were associated with decreased risk of AEs. Of note, longer tumor length was associated with decreased risk of total AEs but increased risk of 30-day mortality. On multivariable logistic regression, shorter tumor length, proximal or mid-esophageal tumor location, and endoscopic dilation to more than 36F before stent placement were each independently associated with increased risk of AEs, but the adjusted AEs rates were similar for the two time periods (▶ **Table 3**). There were fewer perforations in the second decade, 7 (0.2%) compared to the first decade 40 (4.1%) ($P<0.001$) (▶ **Table 1**).

Complete 30y-day follow-up information was available on 1161 (30.3%) of the 3823 patients. Death from all causes occurred within 30 days of the procedure in 33 patients (0.9% of the total cohort; 2.8% of those with 30-day follow-up information). ▶ **Table 2** shows the univariate associations between multiple clinical and endoscopic factors and 30-day mortality. In this analysis, 30-day mortality was significantly associated only with a longer tumor length ($P = 0.01$); however, in multivariable analysis, this association was no longer significant (▶ **Table 3**).

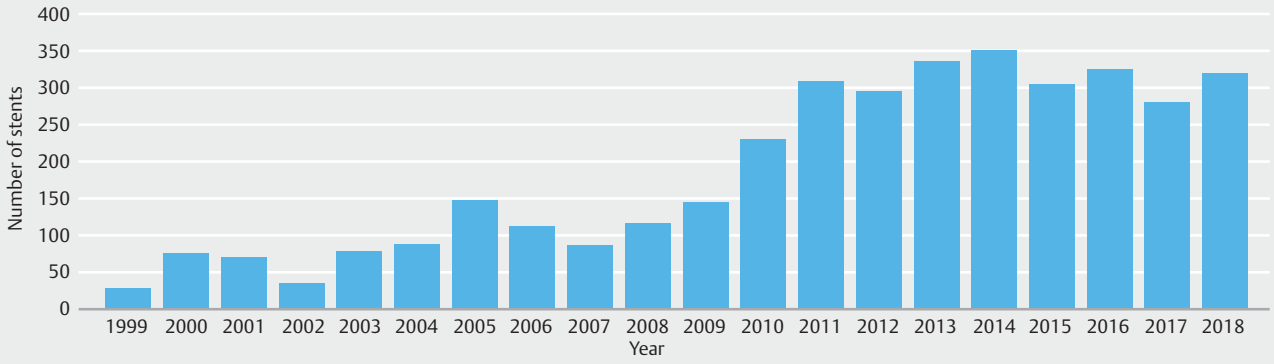
▶ **Table 1** Demographics, clinical characteristics, procedural details, and outcomes by time period.

Variable		All	1999–2009	2010–2019	*P* value
N		3823 (100.0 %)	973 (25.6 %)	2844 (74.4 %)	
Age (years), mean (SD)		60.7 (14.6)	61.1 (14.6)	60.6 (14.6)	0.31
Sex	Female	1539 (40.7 %)	392 (40.3 %)	1146 (41.0 %)	0.71
	Male	2238 (59.3 %)	581 (59.7 %)	1652 (59.0 %)	
Dysphagia score at presentation	0	1 (0 %)	1 (0.1 %)	0 (0 %)	< 0.001
	1	19 (0.5 %)	3 (0.3 %)	16 (0.6 %)	
	2	116 (3.1 %)	33 (3.6 %)	83 (3.0 %)	
	3	1751 (47.3 %)	494 (53.2 %)	1257 (45.3 %)	
	4	1816 (49.0 %)	397 (42.8 %)	1415 (51.0 %)	
Tumor histology	Squamous cell carcinoma	2522 (66.0 %)	474 (48.7 %)	2046 (71.9 %)	0.31[1]
	Adenocarcinoma	139 (3.6 %)	31 (3.2 %)	108 (3.8 %)	
	Other	162 (4.2 %)	62 (6.4 %)	100 (3.8 %)	
	No biopsy	1000 (26.2 %)	406 (41.7 %)	590 (20.8 %)	
Length of tumor (cm) on EGD, mean (SD)		7.3 (3.0)	7.1 (2.7)	7.4 (3.0)	0.003
Tumor length categorized	Tumor < 8 cm	2136 (57.5 %)	541 (60.1 %)	1594 (56.7 %)	0.075
	Tumor ≥ 8 cm	1576 (42.5 %)	359 (39.9 %)	1215 (43.3 %)	
Tumor Location	Proximal	403 (10.8 %)	133 (14.6 %)	270 (9.6 %)	< 0.001
	Middle	1786 (47.9 %)	467 (51.3 %)	1318 (46.8 %)	
	Distal	1543 (41.3 %)	310 (34.1 %)	1231 (43.7 %)	
Tumor crosses GEJ	No	2527 (69.6 %)	643 (73.3 %)	1882 (68.5 %)	0.006
	Yes	1102 (30.4 %)	234 (26.7 %)	867 (31.5 %)	
Dilation during procedure	No	209 (5.9 %)	52 (6.9 %)	157 (5.6 %)	0.20
	Yes	3328 (94.1 %)	703 (93.1 %)	2624 (94.4 %)	
Category of dilation	No dilation	209 (6.0 %)	52 (6.9 %)	157 (5.7 %)	< 0.001
	Dilated < 36F	167 (4.8 %)	5 (0.7 %)	162 (5.9 %)	
	Dilated 36F	2586 (73.9 %)	175 (23.3 %)	2411 (87.7 %)	
	Dilated > 36	539 (15.4 %)	519 (69.1 %)	19 (0.7 %)	
Endoscope passed beyond tumor before dilation	No	1599 (53.1 %)	132 (50.2 %)	1467 (53.3 %)	0.33
	Yes	1415 (46.9 %)	131 (49.8 %)	1284 (46.7 %)	
Stent position	Across entire tumor	2991 (97.2 %)	270 (98.5 %)	2720 (97.1 %)	0.72
	Stent too proximal	57 (1.9 %)	3 (1.1 %)	54 (1.9 %)	
	Stent too distal	27 (0.9 %)	1 (0.4 %)	26 (0.9 %)	
Stent crosses GEJ	No	2190 (59.9 %)	631 (69.5 %)	1558 (56.7 %)	< 0.001
	Yes	1468 (40.1 %)	277 (30.5 %)	1189 (43.3 %)	
Clinical success	No	66 (4.5 %)	30 (6.5 %)	36 (3.6 %)	0.015
	Yes	1395 (95.5 %)	435 (93.5 %)	959 (96.4 %)	
Any AE within 30 days	No	3654 (95.6 %)	893 (91.8 %)	2755 (96.9 %)	< 0.001
	Yes	169 (4.4 %)	80 (8.2 %)	89 (3.1 %)	
Perforation	No	3776 (98.8 %)	933 (95.9 %)	2837 (99.8 %)	< 0.001
	Yes	47 (1.2 %)	40 (4.1 %)	7 (0.2 %)	

▶ **Table 1** (Continuation)

Variable		All	1999–2009	2010–2019	*P* value
Bleeding	No	3802 (99.5 %)	965 (99.2 %)	2831 (99.5 %)	0.18
	Yes	21 (0.5 %)	8 (0.8 %)	13 (0.5 %)	
Chest pain after stent placement	No	3757 (98.3 %)	959 (98.6 %)	2792 (98.2 %)	0.42
	Yes	66 (1.7 %)	14 (1.4 %)	52 (1.8 %)	
Stent migration within 30 days	No	3817 (99.8 %)	972 (99.9 %)	2839 (99.8 %)	0.62
	Yes	6 (0.2 %)	1 (0.1 %)	5 (0.2 %)	

EGD, esaphogastroduodenoscopy; SD, standard deviation; GEJ, gastroesophageal junction.
[1] Comparison between squamous cell carcinoma and adenocarcinoma.



▶ **Fig. 1** Number of self-expanding metal stents placed for esophageal cancer at Tenwek Hospital over 20 years.

Discussion

SEMS placement is a safe and effective method of palliating malignant dysphagia, with a low rate of AEs and 30-day mortality and a high rate of technical and clinical success. To our knowledge, this represents the largest series of SEMS stents reported in the literature. We noted an association between dilations greater than 36F and the risk of perforation. During this two-decade experience, as SEMS placement increased, dilations beyond 36F were abandoned with a resultant decrease in the perforation rates. Despite AEs like perforation, the 30-day mortality rate was low, and this was also true in patients who suffered an AE.

Similar to other studies regarding SEMS placement [8, 24], both the technical and clinical success rates were high. A recent meta-analysis from Chandan et al. demonstrated the safety and efficacy of SEMS placement without fluoroscopy and reported rates of technical and clinical success of 94.7 % and 82.1 %, respectively [16]. Notably, our series has twice as many patients as the meta-analysis and further demonstrates the importance of high-volume centers in improving outcomes. There were improved clinical success rates in the second decade of our experience. In an audit of upper gastrointestinal endoscopy, Quine et al. observed that perforation rates decreased if the endoscopist had performed over 500 endoscopies. Given the high and increasing volume of upper gastrointestinal endoscopy at our institution [25], this probably contributed to the decrease in AEs and improved outcomes over time [26]. Our technical success remained high as the deployment procedure, without fluoroscopy throughout the study period, changed to be based upon measurements alone instead of endoscopic visualization during stent deployment.

Dilation is a vital component of the procedure in our institution in the absence of fluoroscopy to determine tumor measurements on advanced malignancies that the endoscope is unable to traverse. In this cohort, 94 % of patients underwent dilation of their tumors, with the majority being dilated to 36F. In contrast, very few of the series described in the meta-analysis by Chandan et al. involved pre-dilation. However, the vast majority of patients in our series presented very late in their disease with large, circumferential tumors, and an average pre-stent dysphagia score of 3.4. Other centers usually report lower presenting dysphagia scores, such as 2.3 [27], 2.5 [28, 29], or 2.8 [30]. Dilation is vital for patients presenting with advanced disease and luminal obstruction as very tight strictures will naturally make it harder for the stent to expand. In addition, dilation allows more rapid expansion of the SEMS upon deployment and immediately resolves dysphagia. In this series, dilation to greater than 36F was associated with the AE of perforation and was abandoned in the second decade, which likely accounts for a decrease in perforations and thus AEs. Because the goal was to have no perforations, the high number in the first

▶ **Table 2** Factors associated with adverse events[1] among all patients and 30-day mortality among patients with documented follow-up through 30 days post-procedure.

Variable		All patients			Patients with 30-day follow-up		
		No report of an adverse event	Report of an adverse event	*P* value	No mortality within 30 days	Mortality within 30 days	*P* value
N		3654	169		1128	33	
Time period	1999–2009	893 (91.8 %)	80 (8.2 %)	<0.001	428 (96.0 %)	18 (4.0 %)	0.32
	2010–2019	2755 (96.9 %)	89 (3.1 %)		700 (97.9 %)	15 (2.1 %)	
Age (years), mean (SD)		60.8 (14.6)	59.2 (15.0)	0.18	58.6 (14.5)	58.0 (16.1)	0.80
Sex	Female	1471 (95.6 %)	68 (4.4 %)	0.94	452 (97.6 %)	11 (2.4 %)	0.42
	Male	2138 (95.5 %)	100 (4.5 %)		668 (96.8 %)	22 (3.2 %)	
Dysphagia score at presentation	0	2 (66.7 %)	0 (0 %)	0.15			0.71
	1	18 (100 %)	0 (0 %)		3 (100 %)	0 (0 %)	
	2	112 (97.4 %)	4 (2.6 %)		35 (97.2 %)	1 (2.8 %)	
	3	1676 (95.7 %)	75 (4.3 %)		554 (97.7 %)	13 (2.3 %)	
	4	1731 (95.3 %)	85 (4.6 %)		507 (96.6 %)	18 (3.4 %)	
Length of tumor (cm) on EGD, mean (SD)		7.3 (3.0)	6.7 (2.6)	0.011	6.8 (2.6)	8.0 (2.5)	0.01
Tumor length categorized	< 8 cm	2036 (95.3 %)	100 (4.7 %)	0.25	717 (98.1 %)	14 (1.9 %)	0.019
	≥ 8 cm	1513 (96.0 %)	63 (4.0 %)		376 (95.7 %)	17 (4.3 %)	
Tumor crosses GEJ	No	2399 (94.9 %)	128 (5.1 %)	0.004	778 (96.9 %)	25 (3.1 %)	0.32
	Yes	1070 (97.1 %)	32 (2.9 %)		295 (98.0 %)	6 (2.0 %)	
Tumor location	Proximal	382 (94.8 %)	21 (5.2 %)	0.018	142 (96.6 %)	5 (3.4 %)	0.17
	Middle	1694 (94.8 %)	92 (5.2 %)		526 (96.5 %)	19 (3.5 %)	
	Distal	1493 (96.8 %)	50 (3.2 %)		430 (98.4 %)	7 (1.6 %)	
Dilation during procedure	No	201 (96.2 %)	8 (3.8 %)	0.66	56 (96.5 %)	2 (3.5 %)	0.76
	Yes	3179 (95.5 %)	149 (4.5 %)		948 (97.2 %)	27 (2.8 %)	
Dilation by size	No dilation	201 (96.2 %)	8 (3.8 %)	<0.001	56 (96.5 %)	2 (3.5 %)	0.37
	Dilated < 36F	158 (94.6 %)	9 (5.4 %)		53 (98.1 %)	1 (1.9 %)	
	Dilated to 36F	2513 (97.2 %)	73 (2.8 %)		621 (97.9 %)	13 (2.1 %)	
	Dilated > 36	475 (88.1 %)	64 (11.9)		262 (96.0 %)	11 (4.0 %)	
Stent position	Across entire tumor	2891 (96.7 %)	100 (3.3 %)	0.84	753 (97.7 %)	18 (2.3 %)	0.91
	Stent too proximal	56 (98.3 %)	1 (1.8 %)		2 (100 %)	0 (0 %)	
	Stent too distal	27 (100 %)	0 (0 %)		6 (100 %)	0 (0 %)	
Stent crosses GEJ	No	2075 (94.7 %)	115 (5.3 %)	0.002	686 (96.6 %)	24 (2.3 %)	0.10
	Yes	1422 (96.9 %)	46 (3.1 %)		400 (98.3 %)	7 (1.7 %)	
Any Adverse Event	No	–	–		1041 (97.0 %)	32 (3.0 %)	0.32
	Yes	–	–		87 (98.9 %)	1 (1.1 %)	
Bleeding	No	–	–		1113 (97.2 %)	32 (2.8 %)	0.41
	Yes	–	–		15 (93.8 %)	1 (6.3 %)	
Perforation	No	–	–		1101 (97.1)	33 (2.9 %)	0.37
	Yes	–	–		27 (100 %)	0 (0 %)	

▶ **Table 2** (Continuation)

Variable		All patients			Patients with 30-day follow-up		
		No report of an adverse event	Report of an adverse event	*P* value	No mortality within 30 days	Mortality within 30 days	*P* value
Chest pain	No	–	–		1082 (97.0 %)	33 (3.0 %)	0.24
	Yes	–	–		46 (100 %)	0 (0 %)	
Stent migration	No	–	–		1127 (97.2 %)	33 (2.8 %)	0.86
	Yes	–	–		1 (100 %)	0 (0 %)	

SD, standard deviation; EGD, esophagogastroduodenoscopy; GEJ, gastroesopheal junction.
[1] Adverse events included bleeding, perforation, chest pain, stent migration, and mortality within 30 days of the procedure.

▶ **Table 3** Multivariable logistic regression model for the outcomes of an adverse event after stent placement and 30-day mortality among patients with at least 30 days of follow-up post-procedure.[1]

Variable		Odds ratio for adverse event	Confidence interval	*P* value	Odds ratio for 30-day mortality	Confidence interval	*P* value
Time period	1999–2009	Reference			Reference		
	2010–2019	1.01	0.50–2.02	0.980	0.44	0.12–1.66	0.225
Tumor Length (continuous, per centimeter)		0.92	0.87–0.98	0.013	1.11	0.97–1.27	0.139
Dilation	No dilation	Reference			Reference		
	Dilated < 36F	1.49	0.53–4.14	0.447	0.73	0.06–9.00	0.808
	Dilated to 36F	0.77	0.34–1.70	0.515	0.74	0.15–3.57	0.707
	Dilated > 36F	3.63	1.42–9.31	0.007	0.69	0.12–3.84	0.671
Tumor location	Proximal or mid-esophagus	Reference			Reference		
	Distal esophagus	0.68	0.48–0.97	0.034	0.40	0.15–1.06	0.066

[1] The model included factors noted to have univariate association with adverse events: time period, tumor length, dilation, and tumor location.

decade necessitated the change. The overall treatment remained the same for both decades for perforation. The overall perforation rate was low (1.2 %) and comparable to other series' rates of 0 % to 4 % [7, 14, 24, 31]. From our prior experience, if a perforation occurred during dilation, then a SEMS was immediately placed [32]. Our practice to dilate to 36F is consistent with Wilkes et al., who in a series of 126 patients, dilated 34 % of patients to 12 mm without perforation [14]. While we perform serial dilation over a 0.035 flexible guidewire with progressively larger dilator sizes, we do not generally adhere to a "rule of three" for dilations [33], instead relying upon the feel of how tight the stricture is, based on the resistance to passing the dilator. Grooteman et al. did not see an increase in perforation with non-adherence to the arbitrary rule of three [31]. Thus, we believe that we can safely dilate patients to 36F prior to SEMS deployment, and the data from this series supports this practice.

Of the patients who experienced an AE and had follow-up contact 30 days or more after the stent placement, only one patient died within 30 days of the procedure (1.1 %). This patient had presented with hematemesis, and after therapeutic maneuvers to stop the bleeding were unsuccessful, a SEMS was placed to tamponade the tumor. However, the patient died the following day with rebleeding. All patients who experienced perforation and had 30-day follow-up were alive. The low mortality rate following AEs demonstrates that patients who experience AEs following SEMS placement can be successfully managed [34]. The only factor identified to be associated with 30-day mortality was longer tumor length. This finding is consistent with advanced disease.

Our experience reflects limited access to radiotherapy in our region. We do not have this treatment available with the closest radiotherapy facility 4 hours away. In addition, palliative radiotherapy usually requires multiple treatments, meaning multiple visits, over time, and radiotherapy machines are not always functional. In addition, stent-related AEs may be increased by the use of chemoradiotherapy in high-resource settings [35]. And finally, patients, who present with very advanced disease benefit from the immediate effect of SEMS placement, in con-

trast to the delay associated with external-beam radiotherapy or brachytherapy [29, 30].

Our study has several limitations. As a retrospective chart review spanning two decades, there were challenges in data collection, especially for the very early periods. There was a change to electronic records in 2012 and 2013 at our institution, which posed some challenges for tracking patient information during that period. Our clinical practice is designed to meet the needs of frail patients who often travel long distances at considerable cost to obtain care and may not return for routine follow-up visits. Because care for esophageal cancer patients is limited throughout the region, those who experienced severe AEs would return to our hospital for further evaluation. Nevertheless, we may have missed some early AEs and deaths in this review. We also could not obtain data on additional palliative chemotherapy or radiation therapy received, though access to these therapies has anecdotally increased in recent years. An ongoing prospective analysis of survival and outcomes of patients with esophageal cancer will address the lack of follow-up and determine AEs beyond 30 days. A strength of the study is the high volume of real-world experience in SEMS placement, with a focus on improving the palliative nature of the procedure, which is one of the largest series reported to date. Typically, reports describing large volumes of SEMS are in the hundreds of procedures [24] instead of the thousands. Another strength of this report is that we describe a technique with very low AE rates that is able to help patients in resource-limited settings, as there is no need for fluoroscopy.

Conclusions

In conclusion, SEMS placement is a useful palliative method for dysphagia in esophageal cancer with low rates of serious AEs. SEMS stent placement without fluoroscopy can be safely done. This two-decade experience shows that the technique is reproducible and is ideal for resource-limited areas. Dilation prior to SEMS stent placement does not adversely affect placement and helps achieve technical and clinical success.

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Competing interests

Michael Mwachiro is a consultant for Boston Scientific. All other authors have no conflicts to declare.

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