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Partially versus fully covered self-expanding metal stents for benign and malignant esophageal conditions: a single center experience

Gulseren Seven · Shayan Irani · Andrew S. Ross · S. Ian Gan · Michael Gluck · Donald Low · Richard A. Kozarek

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Abstract
Background Fully covered self-expanding metal stents (FCSEMS), unlike partially covered SEMS (PCSEMS), have been used to treat benign as well as malignant conditions. We aimed to evaluate the outcome of PCSEMS and FCSEMS in patients with both benign and malignant esophageal diseases.
Methods Data were reviewed of all patients who underwent SEMS placement for malignant or benign conditions between January 1995 and January 2012. Patients with cancer were followed for at least 3 months, until death or surgery. Patients with benign conditions had stents removed between 4 and 12 weeks. Patient demographics, location and type of lesion, stent placement and removal, clinical success, and adverse events were analyzed.
Results A total of 252 patients (mean ± standard deviation age 68.5 ± 14 years; 171 male) received 321 SEMS (209 PCSEMS, 112 FCSEMS) for malignant (78 %) and benign (22 %) conditions. Stent placement and removal was successful in 97.6 and 95.6 % procedures. Successful relief of malignant dysphagia was noted in 140 of 167 patients (83.8 %) and control of benign fistulas, leaks, and perforations was noted in 21 of 25 patients (84 %), but only 8 of 15 patients (53 %) with recalcitrant benign strictures had effective treatment. Fifty-six patients (22.2 %) experienced at least one stent-related adverse events. Migration was frequent, occurring in 61 of 321 stent placements (19 %), and more frequently with FCSEMS than PCSEMS (37.5 vs. 9.1 %, $p < 0.001$). FCSEMS, benign conditions, and distal location were the variables independently associated with migration ($p < 0.001$, $p = 0.022$, and $p = 0.008$). Patients with PCSEMS were more likely to have tissue in- or overgrowth than FCSEMS (53.4 vs. 29.1 %, $p = 0.004$).
Conclusions Both PCSEMS and FCSEMS can be used in benign and malignant conditions; they are both effective for relieving malignant dysphagia and for closing leaks and perforations, but they seem less effective for relieving benign recalcitrant strictures. Stent migration is more common with FCSEMS, which may limit its use for the palliation of malignant dysphagia.

Keywords Esophageal diseases · Fully covered SEMS · Partially covered SEMS

Self-expanding metal stents (SEMS) have dramatically changed the treatment of unresectable esophageal cancer. Incorporation of an impermeable covering for SEMS reduced tumor ingrowth and facilitated experimentation with temporary stent placement for benign conditions, such as recalcitrant strictures and leaks [1–4]. However, partially covered metal stents (PCSEMS) have exposed bare-metal mesh ends that promote tissue embedding. This effectively prevents stent removal except for a very short duration after deployment [5], but it can also result in restenosis in as little as 2 months [6]. Fully covered self-expanding plastic stents (SEPS) were introduced, in part, to prevent some of these undesirable effects. However, SEPS

G. Seven · S. Irani · A. S. Ross · S. Ian Gan · M. Gluck · R. A. Kozarek (✉)
The Digestive Disease Institute at Virginia Mason, Virginia Mason Medical Center, 1100 9th Ave., Mail Stop C3-GAS, PO Box 900, Seattle, WA 98101, USA
e-mail: richard.kozarek@vmmc.org; gasrak@vmmc.org

D. Low
Department of Thoracic and General Surgery, Virginia Mason Medical Center, 1100 9th Ave., Mail Stop C3-GAS, PO Box 900, Seattle, WA 98101, USA

have their own limitations. They must be loaded onto an introducer, which is stiff and wide, before insertion, often requiring a dilation before deployment. They exert a higher radial force than their metal counterparts, which can lead to patient discomfort, early migration, ulceration, and, rarely, fistulization [7]. Fully covered self-expanding metal stents (FCSEMS) were introduced to compensate for the shortcomings of SEPS and PCSEMS. The use of FCSEMS for various benign and malignant conditions has been previously described [8, 9]. We describe our experience with PCSEMS and FCSEMS at a single tertiary referral center for both benign and malignant conditions.

Patients and methods

Data were reviewed from all patients who underwent placement of a fully or partially covered SEMS for benign and malignant esophageal conditions from January 1995 to January 2012 at Virginia Mason Medical Center. The study was approved by our institutional review board. Patients without an electronic medical record and with stents placed distal to the gastroesophageal junction (GEJ) were excluded. Data included patient demographics, indication, stent type and size, lesion location, duration of stent placement, clinical outcomes, and adverse events (AEs) [10].

Stents were placed by one of six endoscopists usually under fluoroscopic control. The choice of a FCSEMS or PCSEMS was determined by the endoscopist. Intramural injection of contrast or an external paper clip was used to aid fluoroscopic stent placement. One or two endoscopically placed clips (Resolution, Boston Scientific Inc., Natick, MA; or QuickClip, Olympus America, Center Valley, PA) were usually placed at the proximal end of fully covered stents or in patients without a stricture in an attempt to prevent migration. Patients typically underwent an esophagram within 24 h of stent placement to evaluate for stent migration and function. For leaks and perforations, the size of the defect, output from the percutaneous drain, and other clinical parameters determined stent duration, which ranged from 3 to 6 weeks after drain removal. For bridge therapy in malignant strictures before esophagectomy, the intended duration of stenting was on average 4 weeks. The goal of treatment for benign conditions was subjective improvement in dysphagia or closure of a leak. Long-term success was defined as continued control without reintervention for at least 6 months after stent removal. The treatment goal for patients with malignant strictures was improvement in dysphagia or closure of fistula until death or definitive surgery. Stent migration was defined as radiographic or endoscopic visualization of the stent in a different position from the site of placement that necessitated an intervention. For patients with strictures, success was defined as improvement of dysphagia, along with radiologic and/or endoscopic evidence showing stricture improvement by at least 75 %. For patients with esophageal fistulae, leaks, or perforations, success was defined by an esophagram or endoscopic evidence of resolution. Duration of stenting was measured from the time of placement to removal or death. Over 80 % of procedures were performed using moderate sedation.

Statistical analysis

Data analysis was performed by SPSS for Windows, version 11.5 (IBM, Armonk, NY). Data are reported as mean ± standard deviation (SD) or as median (min–max), where appropriate. Comparisons of mean values between groups were compared by Student's t test and median values by the Mann–Whitney U test. Categorical data were evaluated by Pearson's Chi square test or Fisher's exact test, where applicable. Factors affecting stent migration were evaluated by multiple logistic regression analysis, backward linear regression method. Any factor whose univariate test had a p value of <0.25 was accepted as a candidate for the multivariable model. Odds ratios and a 95 % confidence interval for each independent variable were also calculated. A p value of <0.05 was considered statistically significant.

Patients

From January 1995 to January 2012, a total of 325 patients were identified who underwent endoscopic placement of a PCSEMS or FCSEMS for esophageal pathology. However, 73 of these patients (stent placement before 1998) were excluded as a result of the absence of an electronic medical record. Stents used in this study are listed in Table 1. A total of 321 SEMS were placed successfully in 252 patients (171 men, 81 women; mean ± SD age, 68.5 ± 14 years).

Fifty-five patients (22 %) had benign conditions and 197 patients (78 %) had malignant conditions (Table 2). There were 167 malignant strictures (including 16 extrinsic malignant compression) and 30 benign strictures. A fistula was noted in 27 malignancies and 4 patients with benign causes. Perforations were encountered in 3 patients at the time of dilation of malignant strictures and in 14 patients with underlying benign conditions. These included iatrogenic perforations at dilation in 7 patients (1 Schatzki ring, 2 peptic strictures, 1 eosinophilic esophagitis, 2 achalasia, and 1 normal esophagus dilated for patient dysphagia), at endoscopic mucosal resection for Barrett esophagus in 3 patients, and use of a rigid esophagoscope for removal of a food impaction in 1 patient. Other causes of perforations included Boerhaave syndrome in 3 patients. Stents were

Table 1 Types of SEMS used in the study

Type of SEMS and manufacturer	No. of stents
Partially covered	
Ultraflex, Boston Scientific Corp., Natick, MA	106
DuaStent, Cook Inc., Winston-Salem, NC	42
WallFlex, Boston Scientific Corp., Natick, MA	34
Evolution, Cook Inc., Winston-Salem, NC	12
Z stent, Cook Inc., Winston-Salem, NC	10
Biliary stent, Boston Scientific Corp., Natick, MA	3
Wallstent, Boston Scientific Corp., Natick, MA	2
Total	209
Fully covered	
WallFlex, Boston Scientific Corp., Natick, MA	53
Niti-S, Taewoong Medical, Seoul, Korea	25
Alimaxx-E, Alveolus Inc., Charlotte, NC	15
Biliary stent, Boston Scientific Corp., Natick, MA	8
Z stent, Cook Inc., Winston-Salem, NC	3
DuaStent, Cook Inc., Winston-Salem, NC	3
Endovation, Boston Scientific Corp., Natick, MA	1
Total	112

SEMS self-expandable metal stent

Table 2 Baseline patient characteristics and indications for self-expandable metal stent placement

Characteristic	Value
Patient characteristics	
Age (years), mean ± SD	68.5 ± 14
Gender (male/female)	171/81
Indication for stent placement	
Malignant condition, *n* (%)	197 (78 %)
Malignant stricture	165
Anastomotic recurrence	2
Fistula	27
Perforation	3
Benign condition, *n* (%)	55 (22 %)
Peptic stricture	7
Postradiation stricture	14
Postoperative anastomotic stricture	7
After EMR for Barrett esophagus	1
Achalasia	1
Anastomotic leak	7
Perforation	14
Fistula	4
Total	252

SD standard deviation, *EMR* endoscopic mucosal resection

placed for anastomotic leaks in 7 patients. Sixty-one percent (19 of 31) of the patients with fistulae had an associated stricture (17 malignant stricture and 2 radiation strictures).

Table 3 Baseline patient characteristics according to use of partially covered versus fully covered SEMS

Characteristic	Partially covered SEMS ($n = 209$)	Fully covered SEMS ($n = 112$)	*p*
Age (years), mean ± SD	69.5 ± 13.6	64.4 ± 13.8	0.002
Gender			0.848
Female	65 (31.1 %)	36 (32.1 %)	
Male	144 (68.9 %)	76 (67.9 %)	
Condition			<0.001
Benign	24 (11.5 %)	54 (48.2 %)	
Malignant	185 (88.5 %)	58 (51.8 %)	
Indication			<0.001
Leak/fistula/perforation	33 (15.8 %)	38 (33.9 %)	
Stricture	176 (84.2 %)	74 (66.1 %)	
Lesion length (cm), median (min–max)	6 (1–20)	5 (1–12)	0.087
Lesion location			0.051
Anastomotic	13 (6.3 %)	16 (14.3 %)	
Distal	118 (56.7 %)	59 (52.7 %)	
Middle	58 (27.9 %)	23 (20.5 %)	
Proximal	19 (9.1 %)	14 (12.5 %)	
Stent diameter (cm), median (min–max)	18 (8–25)	18 (6–28)	0.316
Stent length (cm), median (min–max)	10 (4–15)	10 (6–15)	0.374
Use of clips	42 (20.1 %)	30 (26.8 %)	0.171

SEMS self-expandable metal stent, *SD* standard deviation

One hundred ninety-seven patients underwent 250 SEMS for esophageal stenosis [PCSEMS 176 (84 %) and FCSEMS 74 (66 %)]. Fifty-five patients underwent 71 procedures for esophageal leaks, fistulae, and/or perforations [PCSEMS 33 (16 %) and FCSEMS 38 (34 %)]. PCSEMS were predominantly placed for malignant diseases and FCSEMS predominantly for benign disease ($p < 0.001$) (Table 3). There was no significant difference between groups in terms of gender, use of clips, stent diameter, or stent length. However, patients with PCSEMS were older (69.5 ± 13.6 vs. 64.4 ± 13.8 years, $p = 0.002$) and had a higher incidence of malignancy (88.5 vs. 51.8 %, $p < 0.001$) than patients with FCSEMS.

The location of the lesion was the proximal esophagus in 11 %, mid esophagus in 25 %, distal esophagus in 55 %, and anastomosis in 9 %. Median length of the stenosis was 6 (range, 1–20) cm. Esophageal dilation was performed before stent placement in 107 of 250 stents (43 %) (malignant stricture $n = 90$, benign stricture $n = 17$). Seventy-five percent of the dilations were performed with a Savary dilator, and 25 % were performed with controlled radial expansion (CRE) wire-guided balloon dilation

catheter (CRE Single-Use Wire Guided Balloon Dilator; Boston Scientific Microvasive, Natick, MA). The mean follow-up period was 150 (range, 1–3,782) days: 339 days for benign conditions (range, 1–3,782 days) and 98 days for malignant conditions (range, 1–4,370 days). Mean duration of stent placement was 51 ± 93 (range, 1–636) days, 49 ± 74 (range, 1–636) days for PCSEMS versus 78 ± 118 (range, 1–606) days for FCSEMS ($p = 0.002$).

Results

Stent placement was technically successful at first attempt in 321 of 329 procedures (97.6 %), with 8 patients requiring a second attempt. There was no significant difference between PCSEMS and FCSEMS in terms of initial technical success (209 of 215, 97 %, vs. 112 of 114, 98 %; $p = 0.504$) (Table 4). Of the 252 patients, 205 required only 1 stent; however, 30 required 2 stents, 14 required 3, 2 required 4, and 1 patient with a postoperative leak required 6 stent placements. Of the 47 patients undergoing multiple procedures, the indications were malignant strictures in 21 patients (45 %) and benign indications in the remainder.

In patients with malignant strictures presenting with dysphagia, there was significant improvement observed in 140 of 167 patients (83.8 %), allowing them to be maintained on oral nutrition alone. Patients with malignant leaks, fistulae, or perforations tolerated the stent well and were able to resume oral nutrition shortly after stent placement. Although stent migration occurred frequently, placement of a second or even third stent ultimately allowed permanent closure in 21 of 25 patients (84 %) with a variety of postsurgical, iatrogenic, or spontaneous esophageal leaks, fistulas, and/or perforations at a median of 47 days of stent dwell time. Two patients required surgery to allow complete closure, and 3 patients required a nasojejunal tube. Two patients underwent clips for residual fistula after stent removal. In the benign stricture group, out of the 30 patients who had SEMS placed, 12 still had an indwelling SEMS at the time of analysis, and 3 patients were intolerant due to pain or early migration and had their stents removed. Of the remaining 15 patients analyzed, 8 patients (53 %) had a successful durable response after stent removal during a median 121-day follow-up. Seven patients developed a restenosis shortly after stent removal and required periodic dilation with or without injection of corticosteroids.

Successful stent removal was possible in 88 of 92 patients (95.6 %) in whom it was attempted at a median of 38 (range, 1–244) days. In 9 of these 88 patients, SEMS removal (4 PCSEMS, 5 FCSEMS) was described as difficult (Fig. 1). There was no statistically significant difference between the 28 PCSEMS removed after a median of 32 (range, 1–236) days and the 64 FCSEMS after 37 (range, 1–244) days. Four stents (2 PCSEMS, 2 FCSEMS) could not be removed. Three patients had their stents fracture into multiple pieces at removal, with 1 patient (PCSEMS) developing a cervical esophageal perforation and the other 2 experiencing self-limiting bleeding. Stent removal was accomplished with a rat-toothed forceps in 62 patients, a snare in 23, and a CRE balloon dilator in 3. An overtube was used in 3 patients and a rigid laryngoscope in 1 patient. At the time of stent removal, 49 of 92 patients (53 %) had clinical improvement in their symptoms.

Eighty-six AEs (mild 8, moderate 78) were observed in 56 patients (22.2 %). Pain requiring stent removal was noted in 4 patients (1 PCSEMS, 3 FCSEMS). Symptomatic stent migration (Fig. 2) requiring replacement/repositioning of stent was seen in 39 patients. Tissue ingrowth or overgrowth resulting in dysphagia was observed in 17 patients and, as expected, was more frequently observed in patients with PCSEMS versus FCSEMS (53.4 vs. 29.1 %, $p = 0.004$). This was managed with an additional stent, or stent removal and dilation and/or injection of a corticosteroid in the case of benign strictures. Twelve patients presented with a food impaction, necessitating an endoscopy and removal. Severe acid reflux requiring brief hospitalization alone was seen in 6 patients and was managed

Table 4 Technical success and adverse events according to use of partially covered versus fully covered SEMS

Characteristic	Partially covered SEMS	Fully covered SEMS	*p*
Initial success	209/215 (97 %)	112/114 (98 %)	0.504
Stent duration (days), mean ± SD (range)	49 ± 74 (1–636)	78 ± 118 (1–606)	0.002
Stent removal	26 (12.4 %)	62 (55.4 %)	<0.001
Migration	19 (9.1 %)	42 (37.5 %)	<0.001
Migration (d), mean (range)	5 (1–76)	11 (1–205)	0.426
Adverse events	43 (20 %)	43 (37.7 %)	<0.001
Granulation tissue	29 (53.4 %)	21 (29.1 %)	0.004

SEMS self-expandable metal stent, *SD* standard deviation

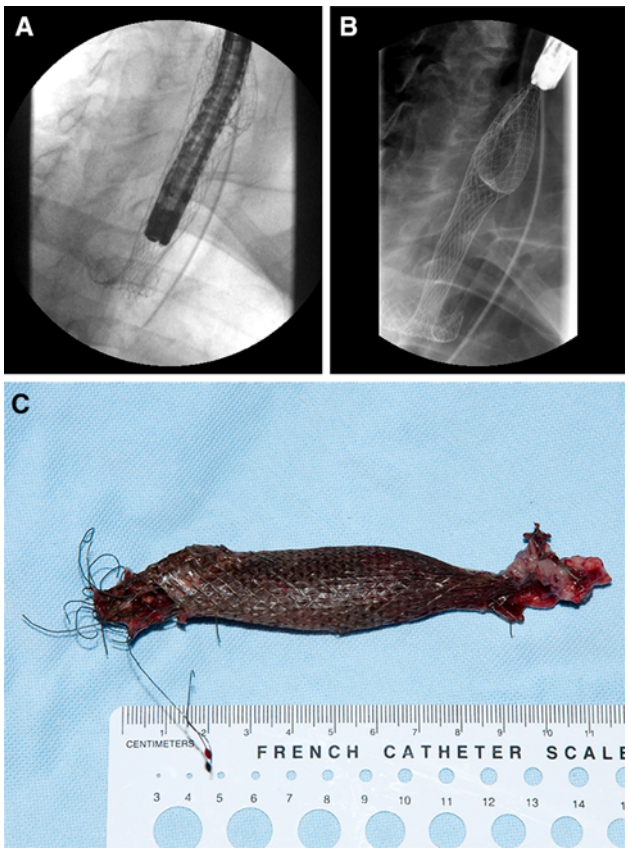

Fig. 1 Patient with benign esophageal stricture. **A** Endoscope advanced into the stent to grasp distal aspect. **B** Stent removal by inverting the prosthesis. **C** Partially covered stent extracted 6 months later. *Note* stent deformity and significant granulation tissue distally (*arrow*)

with high-dose proton pump inhibitors. Bleeding requiring a blood transfusion or endoscopy was seen in 3 patients, and a single perforation was encountered in a patient at stent removal, which was treated with the placement of a new FCSEMS. No deaths occurred as a result of any stent placement, repositioning, or removal.

Migration was common and occurred in 61 patients (distally 50, proximally 11) at a median of 10 days after placement (range, 1–103 days). Twenty-two patients were asymptomatic (noted at planned stent removal) and 39 patients were symptomatic (dysphagia 23, persistent leak 8, pain 3, vomiting 3, severe reflux 2).

Migration was noted in 38.5 % of the stents that were placed for benign indications and in 12.8 % of stents placed for malignant indications ($p < 0.001$). Table 5 shows factors associated with migration. FCSEMS were more likely to migrate than PCSEMS (37.5 vs. 9.1 %, $p < 0.001$) (Table 4). Stents that crossed the GEJ were more likely to migrate compared with those that were placed in the mid esophagus (24.3 vs. 7.4 %, $p = 0.016$). Migration was uncommon when placed across anastomotic strictures or leaks. Larger stent diameters were also associated with a higher risk of migration (30 % for stents with a diameter of >18 mm vs. 16.9 % for stents with a diameter of ≤18 mm) ($p = 0.012$). Stricture dilation before stent placement did not increase the rate of migration compared to stent placement without dilation (12 vs. 21 %, $p = 0.067$). The stricture length, use of clips, and stent placement into a previous stent (stent in stent) did not seem to affect the rate of migration either. There were also no statistically significant differences in migration rates between 3 FCSEMS (Alimaxx-E, Alveolus Inc., Charlotte, NC; Niti-S,

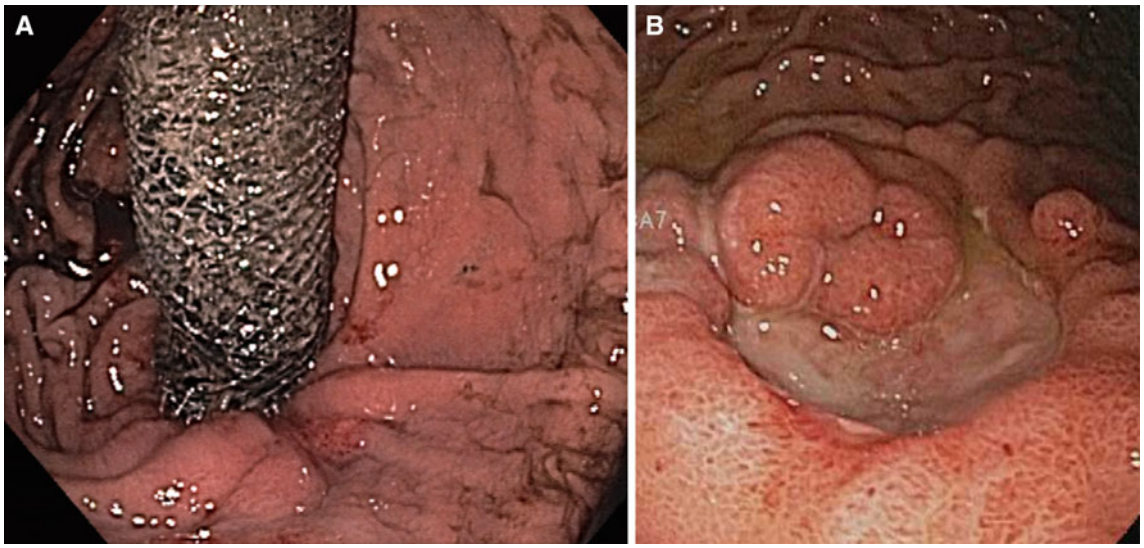

Fig. 2 **A** Endoscopic view of GEJ in retroflexion showing that both partially and fully covered SEMS have migrated. The FCSEMS was removed successfully, and a new stent was placed within the partially covered stent. **B** Ulceration at the great curvature of the stomach secondary to stent migration

Table 5 Assessment of factors associated with stent migration

Characteristic	No migration	Migration	*p*
Condition			<0.001
Benign	48 (61.5 %)	30 (38.5 %)	
Malignant	212 (87.2 %)	31 (12.8 %)	
Location of lesion			0.016
Anastomotic	23 (79.3 %)	6 (20.7 %)	
Distal	134 (75.7 %)[a]	43 (24.3 %)[a]	
Middle	75 (92.6 %)[a]	6 (7.4 %)[a]	
Proximal	27 (81.8 %)	6 (18.2 %)	
Type of lesion			0.122
Leak/fistula/perforation	53 (74.6 %)	18 (25.4 %)	
Stricture[a]	207 (82.8 %)	43 (17.2 %)	
Dilation of stricture before SEMS			0.067
Yes	94 (87.9 %)	13 (12.1 %)	
No	113 (79 %)	30 (21 %)	
Use of overlapping stents			0.498
Yes	34 (77.3 %)	10 (22.7 %)	
No	226 (81.6 %)	51 (18.4 %)	
Stent diameter			0.012
≤18 mm	123 (83.1 %)	25 (16.9 %)	
>18 mm	74 (69.8 %)	32 (30.2 %)	
Lesion length			0.839
≤10 cm	147 (80.8 %)	35 (19.2 %)	
>10 cm	107 (81.7 %)	24 (18.3 %)	
Use of clips			0.070
Yes	53 (73.6 %)	19 (26.4 %)	
No	207 (83.1 %)	42 (16.9 %)	

SEMS self-expandable metal stent

[a] The difference between middle and distally located strictures was statistically significant ($p < 0.001$)

Table 6 Multivariate logistic regression analysis of factors associated with migration

Factor	OR	95 % CI	*p*
Fully covered SEMS	3.92	1.91–8.00	<0.001
Benign condition	2.31	1.12–4.73	0.022
Distal location	4.07	1.45–11.44	0.008

OR odds ratio, *CI* confidence interval, *SEMS* self-expandable metal stent

Taewoong Medical, Seoul, Korea; and WallFlex, Boston Scientific Inc., Natick, MA) used in this study (53.3, 53.8, and 30.9 %, $p = 0.080$).

Fully covered SEMS, benign conditions, and distally located lesions were independently associated with higher rates of migration ($p < 0.001$, $p = 0.022$, and $p = 0.008$, respectively) (Table 6).

Discussion

This study has demonstrated that both FCSEMS and PCSEMS can be deployed easily and can be removed, when appropriate, even after several weeks of dwell time. Stent placement was successful in 97.6 % of procedures, and stent removal was complicated in only 4.5 % of procedures, albeit at a higher rate with PCSEMS. Adverse events occurred in 22.2 % of patients treated with either type of stent; this is comparable to previous studies, which have reported in 21–46 % of stented patients [9, 11, 12]. Stent migration was common in our patients, occurring in 61 of 321 stent placements (19 %), and as expected occurred more frequently with FCSEMS than with PCSEMS (37.5 vs. 9.1 %, $p < 0.001$). Previous studies using PCSEMS have demonstrated similar migration rates ranging 6–23 % [13–15]. Reported migration rates for SEPS have ranged widely from 20 to 82 % [15–18] but seem to be higher than for PCSEMS and FCSEMS [13]. The FCSEMS, Alimaxx-E, has been shown in 4 separate studies to have a fairly consistent migration rate, ranging from 35 to 39 % [9, 11, 19, 20]. In a more recent study, van Boeckel et al. [12], found a 20, 14, and 10 % migration rate with FCSEMS, SEPS, and PCSEMS in the treatment of benign esophageal ruptures and anastomotic leaks. The lower migration rate for PCSEMS compared to FCSEMS and SEPS is due to the ability of the bare metal portion of the PCSEMS to embed in tissue and anchor it [11, 15]. Although anchoring of the upper flare of the FCSEMS to esophageal wall with an endoscopic clip has been shown to reduce stent migration in one study [21], there is no consensus that this practice reduces migration [1]. We placed clips at the proximal margin of 72 of 321 deployed stents (22.4 %); however, we found no difference in migration rates between the stents that were clipped and those that were not. Bakken et al. [19] reported migration rates by stent size were 48 and 29 % for large and small stents, respectively. Similarly, in our series, stent diameter appeared to affect frequency of migration, which occurred in 16.9 % of stents with a diameter of 18 mm and 30.2 % of stents with a diameter larger than 18 mm ($p = 0.012$). This is in contrast to several previous studies [22, 23] that paradoxically found that larger stents were associated with lower migration rates. However, in these studies, larger-diameter stents were commonly used in patients who did not have a stricture shelf, a potential explanation for this difference.

We also found that placement of SEMS in benign conditions was associated with higher migration rates than malignant conditions (38.5 vs. 12.8 %, $p < 0.001$), as were stents that were placed across the GEJ compared to a mid esophageal location. Although not designed as a comparative study, the Niti-S, WallFlex, and Alimaxx-E stents

demonstrated similarly high migration rates. This is likely due to the lack of exposed wire or fenestrations in fully covered designs, which prevent granulation tissue from anchoring the stents. Even widely flaring ends are no guarantee that stents will not slide, especially in cases of benign leaks where a stricture may not exist. Ultimately, radial pressure on the esophagus appears to be an imperfect method of fixation. Migration does not preclude clinical success with stent placement and is dependant on the timing of migration.

A known drawback of both PCSEMS and FCSEMS is tissue in- or overgrowth, which may require reintervention. In particular, reactive nonmalignant tissue formation and embedding of the stent in the esophageal wall may be a problem, especially when stents are left in place for a long time. It has been suggested that the type of stent plays an important role in the formation of tissue growth, with metal or nitinol stents being more prone to tissue hyperplasia than plastic stents [14]. Another study reported higher tissue formation with PCSEMS (11 %), compared with FCSEMS [8]. In our series, tissue in- or overgrowth was seen in 17.4 % of patients and more often with PCSEMS. In a retrospective series of 110 patients with benign and malignant esophageal disease in whom SEMS removal was attempted, removal of both partially and fully covered SEMS was accomplished successfully at the initial attempt in the majority of cases [24]. A long stent dwell time was associated with an increased number of AEs during removal attempts. AEs were seen in 11 % of procedures, 93 % with partially covered and 7 % with fully covered SEMS, and almost three-quarters of these stents were placed for benign disease. SEMS were removed after a median 38 (range, 1–244) days after deployment in the current study. Despite this long time interval, we had only one AE during 88 SEMS removals (1.1 %), including one cervical esophageal perforation.

Pain is not uncommon after placement of SEMS and SEPS, as reported in several prior studies [1, 11, 18, 25]. Pain requiring long-term narcotics was seen in 2 patients and stent removal in 4 patients (all FCSEMS). This may have been due to the larger "dog bone" ends of these FCSEMS, which have diameters up to 28 mm. The large, flared ends were designed to help reduce migration, but the trade-off may be pain and local ulcer formation. In patients with benign disease, sealing of luminal leaks has been reported in 76–100 % of patients with the placement of a SEMS [9, 12, 26–29]. However, long-term clinical results of SEMS placement for benign strictures have been unsatisfactory [25, 30]. Eloubeidi and Lopes [9] reported higher rates of clinical success for patients with leaks than those with stenosis (44 vs. 21 %). In contrast, another study reported outcomes in 56 patients treated with SEMS for benign strictures and leaks and found a higher rate for stricture resolution than for fistula/leaks (71 vs. 32 %) [19]. In our series, we found that although stent migration was common, by being persistent with the placement of a second or even third (sometimes overlapping) stent, permanent closure was achieved in 21 of 25 patients (84 %) with a variety of benign fistulas, leaks, and perforations. In contrast, only 8 of 15 patients (53 %) with benign refractory strictures responded successfully to SEMS placement.

Multiple studies have reported the improvement of malignant dysphagia with SEMS. However, the application of metallic stents in patients who are considered candidates for definitive or neoadjuvant chemotherapy has been limited because of concerns of developing iatrogenic fistulas and perforations. Nevertheless, studies have shown that fully covered stents may help maintain weight and nutrition during chemotherapy and radiotherapy [21]. We have been similarly cautious with our use of SEMS in this group of patients (using SEMS as a bridge therapy to surgery) and included only 11 such patients. In this group, even when stent migration occurs, the stent has usually remained in position long enough to temporarily dilate the stricture. Alternatively, tumor shrinkage with chemotherapy and radiation has resulted in stent migration. The stent can be removed endoscopically before surgery or at the time of surgery. We demonstrated an improvement in dysphagia in 83.8 % of patients with malignant strictures, and we experienced successful closure of all malignant fistulas and perforations, which is comparable to prior studies [31].

This study has several limitations. It is a retrospective series of a heterogeneous population of patients with various benign and malignant diseases. We selected the type of stent on the basis of availability and endoscopist preferences. Most patients with malignant strictures during the study period received PCSEMS, and there may have been a bias toward treating less debilitated patients or those with less advanced disease with FCSEMS. Furthermore, some patients received a different type of prosthesis as their second or third stent. These factors, taken together, may allow some observations about the general behavior and application of SEMS; however, direct comparisons between PCSEMS and FCSEMS is limited. Larger, prospective studies will be needed to define the relative value of different stent designs in various malignant and benign esophageal diseases.

In conclusion, this study demonstrates that both PCSEMS and FCSEMS can be used safely in a variety of benign and malignant conditions. They are effective in relieving malignant dysphagia and in closing benign and malignant fistulas, leaks, and perforations, but they seem significantly less effective in the treatment of recalcitrant, benign esophageal strictures. In addition, stent migration remains a significant challenge in the use of partially and fully covered SEMS.

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