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Original Article

Predictors of esophageal self-expandable metal stent migration: An academic center study

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ABSTRACT

Background: Although safe and effective, a wide array of complications of esophageal stent placement continues to pose a significant challenge to clinicians in providing optimal care for their patients.

Methods: To identify factors associated with migration of self-expandable metal stent (SEMS) used in treating malignant and benign disease of esophagus, a retrospective study analyzing 105 cases (85 patients) of esophageal SEMS placement between January 2013 and June 2015 was conducted. All cases were performed in a single tertiary referral center. The key outcomes of interest were SEMS migration rates based on indication, stent type, design, and endoscopic findings prior to SEMS placement. Technical success rate, other major adverse outcomes and subgroup analysis of interest were also performed.

Results: Overall esophageal SEMS migration rate was 26.7%. Significantly higher rates of stent migration were associated with fully covered stent use (38.1% vs 9.5%, $P = 0.001$) and stent use in benign conditions (43.9% vs 15.6%, $P = 0.002$). Our multivariable analysis also showed statistically significant increased risk of migration for SEMS placement in distal esophagus ($P = 0.006$).

Conclusion: This study validated some of previously reported predictors of stent migration. In addition, stent use in benign esophageal disease was found to be a significant risk factor of SEMS migration. Large, prospective studies are necessary to further clarify modifiable risk factors to reduce the rate of SEMS migration.

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Keywords: Dysphagia; Migration; Stent; Stricture

Introduction

Since its introduction in early 1990s and subsequent seminal report in the New England Journal of Medicine,¹ the use of esophageal self-expandable metal stent (SEMS) has gained wide acceptance within the arena of therapeutic endoscopy. Initially constructed as little more than cylinder-shaped wire mesh, the material and design of SEMS have evolved and expanded over last two decades. In the beginning, the sole purpose of SEMS was to forcefully open the area of tumor obstruction, hence relieving the symptoms of dysphagia. Much has changed since then. What was initially conceived as adjunct tool of palliation, the SEMS is now considered as an integral part of definitive treatment of esophageal and gastroesophageal malignancy. The benefit of SEMS seems to reach beyond relief of dysphagia. Several surgical and oncologic literatures reported better nutritional support with the use of SEMS compared to enteral nutrition via tube feed in

those suffering from severe malnutrition due to their dysphagia and tumor burden.²

In addition to its utility in relief of dysphagia from malignancy, there has been increase in the use of esophageal SEMS in treating symptoms arising from non-malignant conditions.^{3,4} In addition to relieving dysphagia from benign stricture/stenosis, sealing of the compromised area of esophageal lumen has become another consideration of SEMS use. Ultimately, the end goal of stent placement in benign setting is the avoidance of surgical intervention.

Although esophageal stent placement is technically safe and well tolerated by the majority of the patients, it comes with a wide array of complications. Often divided into in early and late, these complications include, but not limited to, pain (from mild where adjustment of pain medication is often sufficient to severe where stent removal is required for symptom relief), aspiration, airway obstruction, perforation, fistulae formation, tissue ingrowth/over

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growth, bleeding and most commonly, the stent migration. This substantial list of complications can bring a pause to those who would consider SEMS use in settings beyond palliation of terminal illness. Many studies have endeavored to identify the risk factors that contribute to these adverse outcomes. Considering migration is the most common major adverse outcome of SEMS placement, it is no surprise there has been enormous amount of intellectual resources spent in attempts to identify predictors of stent migration. Unfortunately, some success in identifying predictors has not resulted in significant reduction in stent migration rate. And despite some reports of new and creative methods to reduce the risk, it remains as a formidable challenge.

The primary aim of this study is to identify factors that can contribute to the adverse outcome of stent migration. Since the publications of a practice guideline of esophageal stent and a technology evaluation of enteral stent in 2010 and 2011 by two gastrointestinal (GI) societies,^{5,6} there has been introduction of several new SEMS in the market. Thus, we consider now to be a good time to revisit this issue that will benefit from timely validation.

Methods

Study design and patient selection

This is retrospective registry based study which was approved by the Institutional Review Board (IRB) at the Cleveland Clinic Foundation (Cleveland, OH, USA). Esophageal stent registry was created to record multitudes of variables including demographic, clinical, and device related details for those who underwent esophageal stent placement in our center. Initially, by accessing SEMS inventory control manifest, we generated a list of patients linked with esophageal stent insertion. We then obtained desired variables from ProVation[®] MD (ProVation Medical, Minneapolis, MN, USA) endoscopy report system and EPIC[®] (Epic Systems Corporation, Verona, WI, USA) electronic medical record (EMR) system that are available in our institution. The list contained the patients (age ≥ 18 years) who underwent esophageal stent placement procedures between January of 2013 and June of 2015 at Cleveland Clinic Foundation. Both benign and malignant indications were included. Only those with stent placement for treating lesions in esophagus or gastroesophageal junction (GEJ) based were selected. Those who received esophageal stent for the management of bariatric surgery complications were excluded. Those without medical records (such as office/clinic visit, radiographic imaging, repeat endoscopy, hospital admission/discharge, or operative note) after stent placement procedure were also excluded. We extracted following variables from each patient's medical re-

cords: patient demographic, primary lesion size, location, etiology, stent characteristics (brand, type, and stent diameter), technical success rate, tolerability, adverse outcomes (migration and major complications including life threatening GI bleed, aspiration, airway obstruction, and perforation), and success rate of esophageal stent removal if attempted.

Endoscopic procedures

Endoscopic procedures for esophageal stent placement were performed by seven experienced endoscopists; six interventional endoscopy faculties and one surgical endoscopist from our institution. GI fellows and surgical residents assisted in majority of the procedures. All procedures were performed either with monitored anesthesia care or with general anesthesia. In majority of cases, a standard single channel upper endoscope (GIF-160, GIF-180, and GIF-190; Olympus America, Center Valley, PA, USA) or pediatric upper scope (XP scope; Olympus America) were used. The length and location of lesion, and endoscopic descriptions (malignant, benign) were identified (Fig. 1). For a thorough the scope type of SEMS (Niti-S[®] esophageal stent; Taewoong Medical, Gimpo, Korea), a large therapeutic channel upper endoscope was used. Fluoroscopy was used in all procedures. After initial inspection, target lesions were marked either internally with application of hemostatic endoclips (Boston Scientific, Natick, MA, USA), or externally using radio-opaque markers such as paper clips in corresponding integuments of the patients. The choice of stent type (fully covered vs partially covered), brand (WallFlex[®] [Boston Scientific], Evolution [Cook Medical, Bloomington, IN, USA], Hanaro[®] [M.I.Tech, Pyeongtaek, Korea], and Niti-S[®] [Taewoong Medical]), and size was determined by the performing endoscopist.

Study definition

Technical success was defined as successful deployment of SEMS at the target area in one endoscopic session without need for removal or use of another stent. Thus, failure of full deployment, and immediate dislodgment (either due to excessive foreshortening or spastic deployment resulting in "jumping" of the stent) during the endoscopic procedure were considered as technical failure. The tolerability was defined as patients' ability to undergo stent deployment procedure without any major intra-operative complication and to keep the stent within in-situ without need for removal due to onset of severe symptom(s).

Based on multiple previously published literatures addressing complications of esophageal stent,⁷⁻⁹ major adverse outcomes considered were perforation, fistula, aspiration with respiratory compromise, hemodynamically significant bleeding, stent migra-

Fig. 1. (A) A large defect is seen at the esophagectomy site with drainage of abscess into esophageal lumen. (B) Successful placement of fully covered 22 mm diameter Hanaro[®] esophageal CCC stent (M.I.Tech) covering the entire length of defect.

tion requiring surgical removal and death related to stent insertion. Efficacy was defined as the ability to produce desired or intended outcomes: relief of dysphagia, successful sealing of compromised area of esophageal lumen.

In regards to the length of the lesion, short lesion was defined as length less than 3 cm and long lesion as lesion/defect length greater than 3 cm. This arbitrary distinction is based on Barrett's esophagus classification where the short segment is defined as length less than 3 cm. Location of the lesion was categorized based on beginning and end point of lesion in relation to conventional anatomic division of cervical, middle and distal esophagus. Thus, proximal segment would be defined as < 26 cm from incisor, middle segment as 26 to 32 cm from incisors, and distal segment as > 32 cm from incisors. Understanding that long lesion can encompass more than one section of esophagus, categorizations of those circumstances were made based on where the most of lesion was confined. Thus for example, if the lesion begins at 30 cm from incisor but crosses GEJ, this would be categorized as long, distal lesion. Finally, stent body diameter less than 22 mm was classified as small diameter stent, whereas stent diameter larger than 22 mm was classified as large diameter stent.

Post procedure follow-up

For in-patient esophageal stent placement, chest X-ray (either portable or anteroposterior and lateral) was obtained within 24 hours of placement to confirm the presence of stent in its desired location. For out-patients, instructions and orders were given to receive X-ray. Pertinent follow-up records were obtained from EPIC® EMR system with specific focus on: any oncology, GI, or thoracic surgery clinic follow-up visit note, radiographic imaging(s) of any kind, subsequent endoscopic procedures, readmission/discharge notes, and expiration note if existed. Clinical details on stent migration, development of major adverse outcome (defined as above), percutaneous endoscopic gastrostomy (PEG) insertion, and successful endoscopic stent retrieval (if attempted) were sought. We did not search for the degree of dysphagia improvement as not all the patients were provided with dysphagia assessment score prior to SEMS placement.

Table 1 Patient Characteristics at Baseline

Characteristic (total = 85)	Malignant (n = 55)	Benign (n = 30)
Age (yr)	67.3 ± 14.5	60.4 ± 15.4
Sex		
Male (n = 68)	46/68 (67.6)	22/68 (32.4)
Female (n = 17)	9/17 (52.9)	8/17 (47.1)
Lesion location		
Proximal (n = 16)	5/55 (9.1)	11/30 (36.7)
Mid (n = 22)	13/55 (23.6)	9/30 (30.0)
Distal (n = 47)	37/55 (67.3)	10/30 (33.3)
Lesion length		
Short (n = 31)	10/31 (32.3)	21/31 (67.7)
Long (n = 54)	45/54 (83.3)	9/54 (16.7)
Body mass index (kg/m ²)	24.1 ± 5.8	25.8 ± 7.7

Values are presented as mean ± standard deviation or number (%).

Data collection

The primary outcome of interest was stent migration. For the purpose of this study, following patient demographic data were gathered; age, gender, patient body mass index (BMI) prior to stent placement and etiology (benign vs malignant, and details of benign lesion if applicable) of their symptoms. Regarding the details of endoscopic findings, following data were collected: location and length of lesion, brand and type of stent used (partially covered vs fully covered) including the dimension of the stent, and technical success defined as above. Subsequent to stent placement, following data were ascertained from electronic medical records: duration of meaningful follow up after stent placement, major adverse outcomes and patient tolerability defined as above.

Statistical analysis

Data are presented as mean ± standard deviation, median (25th, 75th percentiles) or number (%). In order to assess factors associated with stent migration, univariable and multivariable generalized linear mixed models were used to account for multiple stent placements per patient; an independent correlation structure was used to model the within-subject correlation. For the univariable analysis, stent migration was modeled as the outcome with each factor as the independent predictor separately. An automated stepwise variable selection method performed on 1,000 bootstrap samples was used to choose the final multivariable model. Stent migration was modeled as the outcome and all factors were considered for inclusion; variables with inclusion rate of at least 50% were included in the final model. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA).

Results

From January 2013 to June 2015, there were 154 cases (124 patients) of esophageal SEMS use in our institution. Of those, 105 cases (85 patients) met the inclusion criteria (68.2%). Of 49 cases (39 patients) that were excluded from the study, 13 cases were excluded due to esophageal stent placement outside of study inclusion criteria (i.e., use of esophageal SEMS in treating lesions beyond the confinement of esophagus or GE junction), and 36 cases were excluded due to lack of meaningful follow up medical record (often due to patient leaving our system to receive further care elsewhere, or being placed in hospice care immediately after

Table 2 Distribution of Disease Type, Length of Lesion, Type of Stent Used Based on Lesion Location

	Total (n = 105)	Proximal lesion (n = 16)	Middle lesion (n = 33)	Distal lesion (n = 56)
Lesion length				
Short (n = 37)	8 (50.0)	15 (45.5)	14 (25.0)	
Long (n = 68)	8 (50.0)	18 (54.5)	42 (75.0)	
Stent type				
Fully covered (n = 63)	13 (81.3)	25 (75.8)	25 (44.6)	
Partially covered (n = 42)	3 (18.8)	8 (24.2)	31 (55.4)	
Benign vs malignant				
Benign (n = 41)	11 (68.8)	16 (48.5)	14 (25.0)	
Malignant (n = 64)	5 (31.3)	17 (51.5)	42 (75.0)	

Values are presented as number (%).

the procedure).

Table 1 summarizes the patient demographic data including BMI and lesion characteristics, while Table 2 summarizes distribution of lesion length, lesion type and type of stent use in respect to the location of lesion. Of the 85 patients included, 55 patients (64.7%) had malignant diseases while 30 patients (35.3%) had benign conditions requiring SEMS placement. In 16 patients (18.8%) had lesion located in proximal esophagus, compared to 22 patients (25.9%) with mid esophageal lesion and 47 patients (55.3%) with distal esophageal lesion. Of 85 patients included, 31 patients (36.5%) had lesion shorter than 3 cm, whereas 54 patients (63.5%) had lesion longer than 3 cm.

Forty-two SEMS placement cases (40.0%) used partially covered self-expandable metal stent (PCSEMS), while fully covered self-expandable metal stents (FCSEMSs) were used in 63 cases (60.0%). In 52 cases (49.5%), small diameter SEMSs were deployed, while large diameter stents were used in 53 cases.

Technical success rate was reported as 98.1% (103/105 cases) with two cases (1.9%) of technical failure due to incomplete expansion of stent flare, requiring removal and re-insertion. Overall patient tolerability was reported as 94% with 6 cases of esophageal stent removal due to intolerable pain ($n = 4$) and worsening obstructive symptoms of intractable vomiting and regurgitation ($n = 2$).

For the patients with obstructive dysphagia, given lack of

quantifiable measure of symptom relief (i.e., lack of dysphagia score) in significant number of cases, subsequent placement of percutaneous feeding tube (PEG) used as the surrogate of ineffective SEMS placement. Of those 65 patients (88 cases) who received esophageal stent for the symptoms of dysphagia, 6 patients (9.2%) eventually underwent PEG tube placement due to worsening dysphagia. Thus, it was concluded that SEMS placement either improved the symptoms of dysphagia or at least halted the exacerbation in 90.8% of the patient.

Table 4 Multivariable Analysis of Factors Associated with Stent Migration

Factor	Odds ratio (95% confidence interval)	P-value
Benign vs malignant lesion	10.2 (3.0–34.2)	< 0.001*
Distal vs midial/proximal location	6.2 (1.7–22.5)	0.006*
Fully vs partially covered stent	10.2 (3.0–34.2)	< 0.001*

Odds ratios and P-values were obtained using generalized linear mixed models to account for multiple stent placements per patient.

* $P < 0.05$.

Table 3 Univariable Analysis of Factors Associated with Stent Migration

Factor	No migration ($n = 77$)	Migration ($n = 28$)	Odds ratio (95% confidence interval)	P-value
Gender				
Female	14 (18.2)	5 (17.9)	Reference	-
Male	63 (81.8)	23 (82.1)	1.02 (0.36–2.9)	0.97
Body mass index	24.7 $\pm$ 6.5	24.7 $\pm$ 7.2	1.00 (0.94–1.07)	0.99
Lesion type				
Benign	23 (29.9)	18 (64.3)	4.2 (1.7–10.7)	0.002*
Malignant	54 (70.1)	10 (35.7)	Reference	-
Location				
Distal	40 (51.9)	16 (57.1)	Reference	-
Midial	23 (29.9)	10 (35.7)	1.09 (0.41–2.9)	0.87
Proximal	14 (18.2)	2 (7.1)	0.36 (0.07–1.8)	0.21
Lesion length				
Short	23 (29.9)	14 (50.0)	2.3 (0.99–5.6)	0.05
Long	54 (70.1)	14 (50.0)	Reference	-
Manufacturer				
Boston Scientific	52 (67.6)	15 (53.6)	Reference	-
M.I.Tech	12 (15.5)	6 (21.4)	1.9 (0.64–5.6)	0.25
Cook Medical	6 (7.7)	3 (10.7)	1.7 (0.37–8.1)	0.48
Taewoong Medical	7 (9.1)	4 (14.3)	2.0 (0.44–8.8)	0.37
Stent size (mm)	20.7 $\pm$ 2.5	20.2 $\pm$ 2.3	0.92 (0.77–1.10)	0.34
Stent size				
Short	35 (45.5)	16 (57.1)	1.6 (0.66–3.9)	0.29
Long	42 (54.5)	12 (42.9)	Reference	-
Type				
Partially covered	38 (49.4)	4 (14.3)	Reference	-
Fully covered	39 (50.6)	24 (85.7)	5.8 (2.0–17.1)	0.001*

Values are presented as number (%) or mean $\pm$ standard deviation.

Odds ratios and P-values were obtained using generalized linear mixed models to account for multiple stent placements per patient.

* $P < 0.05$.

Overall rate of stent migration and interval

Table 3 summarizes univariable analysis of patient and device factors considered to be potential risk factors SEMS migration, while Table 4 summarizes the multivariable analysis of three statistically significant risk factors of SEMS migration. There were 28 cases of stent migration (26.7% overall) reported, requiring either SEMS adjustment or replacement. The mean number of days from stent insertion to repeat endoscopy for management of migration was 35 days (range, 2–117 days). Sixteen cases (57.1%) of stent migration/endoscopic rectification took place within 30 days of initial stent insertion, and the 12 cases (42.9%) of stent migration took place at least 30 days after initial stent placement.

Migration rate based on indication

Of 28 cases of SEMS migration, 10 cases of stent migration occurred in the malignant disease group (35.7%), compared to 18 cases (64.3%) in benign disease group. This difference in migration rate was statistically significant ($P = 0.002$). When multivariable analysis was performed, the finding was even more statistically significant ($P < 0.001$) with odds ratio (OR) of 10.2 with SEMS use in benign disease resulting in stent migration. Of 18 stent migration occurred in benign group, 16 cases (88.9%) were from fully covered stent use, whereas 8 cases of stent migration occurred in malignant group were from using fully covered stent cases (80.0%). Comparable rate of FCSEMS migration in both groups (88.9% vs 80.0%) enable us to conclude that SEMS use in benign disease is an independent risk factor of SEMS migration.

Stent migration based on lesion location and length

Within the group with proximal lesion location ($n = 16$ with 13 FCSEMS and 3 PCSEMS use), 2 cases of stent migration were reported. In the mid esophageal lesion group ($n = 33$ with 25 FCSEMS and 8 PCSEMS use), 10 cases of migration were reported. Finally, among the group with distal esophageal lesion ($n = 56$ with 25 FCSEMS and 31 PCSEMS), 16 cases of stent migration were reported. The migration rate among these lesion locations was not statistically significant if compared one against another. However, when distal lesion was compared to proximal/mid esophageal lesion, our multivariable analysis showed statistically significant risk of stent migration with distal disease compared to proximal/mid lesion ($P = 0.006$, OR = 6.2).

Thirty-seven cases of SEMS placement were performed to

treat short lesion (see definition), while 68 cases of SEMS placement were performed to treat long lesion. There were 14 cases SEMS migration in short lesion group (37.8%), compared to 14 cases in long lesion group (20.5%). This difference was statistically significant ($P = 0.05$) in the univariable analysis. However, this statistical significance was not maintained when the multivariable analysis was performed on the same factor.

Stent migration based on stent design and brand

Degree of stent coverage

Among 42 cases of PCSEMS use, 10 cases (23.8%) were for treatment of benign conditions, and 32 cases (76.2%) were for the treatment of malignant disease. In 63 FCSEMS cases, 30 cases (47.6%) were for the treatment of benign conditions and 33 cases (52.4%) were performed for treating malignant obstruction. The rate of stent migration in PCSEMS was 9.5% (4/42 cases) compared to 38.1% (24/63 cases) in FCSEMS group. The univariable analysis showed the difference to be statistically significant ($P = 0.001$) with subsequent multivariable analysis validating this finding ($P < 0.001$, OR = 10.2).

Stent diameter

When migration rate was compared between larger stent group ($n = 53$) and smaller diameter stent group ($n = 52$), 15 cases (28.8%) of stent migration occurred in smaller diameter stent group, compared to 13 cases (24.5%) in larger diameter stent group. The difference was not statistically significant.

Stent manufacturer

SEMS from 4 different manufacturers were compared; Wall-Flex[®] FCSEMSs (Boston Scientific) with 67 cases, Hanaro[®] esophageal FC stents (M.I.Tech) with 18 cases, and Niti-S[®] fully covered stents (Taewoong Medical) in 11 cases, and Evolution esophageal stent (Cook Medical) in 9 cases. The differences in migration rates among SEMS from four manufacturers were not statistically significant. This finding was consistent with the results from previous studies comparing complication rates of several brands of esophageal stents.^{10,11}

Stent migration rate based on body mass index

Stent migration rate based on the patient's BMI at the time of stent placement was also assessed. The BMI difference between migration and no migration groups was not statistically significant.

Table 5 Characteristics and Distribution of Self-Expandable Metal Stent Placement in Benign Conditions of Esophagus

Indication and subtype	Migration	Fully covered vs partially covered stent use	Fully covered stent migrated (fully covered migration/fully covered stent use)
Stricture/stenosis ($n = 25$)	10 (40.0)	17:8	8/17 (47.1)
Extrinsic compression ($n = 6$)	1 (16.7)	5:1	1/5 (20.0)
Radiation induced ($n = 6$)	2 (33.3)	3:3	1/3 (33.3)
Surgical/anastomotic ($n = 7$)	3 (42.9)	3:4	2/3 (66.7)
Inflammatory ($n = 6$)	4 (66.7)	6:0	4/6 (66.7)
Leak/perforation/fistula ($n = 16$)	8 (50.0)	14:2	6/14 (42.9)
Fistula ($n = 5$)	2 (40.0)	5:0	2/5 (40.0)
Perforation ($n = 3$)	0 (0)	3:0	0/3 (0)
Surgical leak ($n = 8$)	6 (75.0)	6:2	4/6 (66.7)

Values are presented as number (%) or number only.

cant ($P = 0.99$).

Subgroup analysis: self-expandable metal stent in benign disease

Benign conditions requiring stent placement were further categorized into stricture/stenosis group and leak/perforation/fistula group (Table 5). The purpose this exercise was to see whether there statistically significant difference in stent migration exists between these two groups. There were 10 migrations (40.0%) reported in stricture/stenosis group vs 8 migrations (50.0%) in leak/perforation/fistula group. The difference in migration rate was not statistically significant ($P = 0.53$). To eliminate potential confounding effect of stent type, we then only compared migration rate of FCSEMS between two groups. Again, the difference in the migration rates of FCSEMS in stenosis/stricture group (47.1%) was not statistically significant ($P = 0.815$) compared to the migration rate of FCSEMS in leak/perforation/fistula group (42.9%).

Other serious adverse events

Based on the pre-determined definition of serious adverse outcomes, 6 cases (5.7%) of serious adverse outcomes were reported; 2 cases (1.9%) of stent erosion into broncho-pulmonary structures (confirmed by bronchoscopy and CT), one case (0.9%) of life threatening aspiration pneumonia within 24 hours of SEMS placement, one case (0.9%) of stent migration requiring surgical retrieval, and 2 cases (1.9%) of hemodynamically significant GI bleeding requiring emergent endoscopy.

There were 35 total endoscopic retrieval attempts for migrated SEMS. Endoscopic removal was successful in 33 cases (94.3%). In one case, the migrated stent was retrieved surgically. And in another, another stent was placed to cross the tissue overgrowth which prohibited safe retrieval of migrated stent.

Discussion

This was a retrospective study aimed at identifying predictive features associated with esophageal stent migration. We deemed the volume of cases presented in this study (more than 100 less than three-year span from a single institution) affords us to draw a reasonably confident association between the risk factors and adverse outcome of interest (stent migration) without the concern for type I error.

Overall migration rate of SEMS in our study (26.7%) closely resembles the reported range of stent migration. A meta-analysis published in 2011 by Thomas et al,¹² analyzing data pooled from 8 studies involving 199 patients, reported stent migration rate of 26.4%. An another meta-analysis evaluating safety and efficacy of SEMS in preceding neoadjuvant chemotherapy of esophageal cancer reported stent migration rate of 32%.¹³

Our univariable and subsequent multivariable analyses have confirmed some of the disease and device related characteristics that were reported to be predictors of stent migration from previously published studies, namely use of fully covered stent and stent use in benign esophageal lesion. While our univariable analysis suggested the increased stent migration with shorter length of lesion, this did not translate into statistically significant difference when multivariable analysis was performed. A possible explanation of the finding is that overwhelming majority of benign disease was categorized as short lesion (30 out of 41 cases) whereas only 7 cases out of 64 malignant lesions were classified as short hence serving as significant confounder.

In our univariable analysis, three-way comparison of stent mi-

gration rate among proximal, middle and distal esophageal lesion did not find statistically significant difference. However, when SEMS placement in distal lesion was compared with combined proximal/mid esophageal lesion, the difference in migration rate was statistically significant ($P = 0.006$). This finding is consistent with previous esophageal stent migration studies, and is likely due to the fact that stent placement in distal esophagus invariably crosses GE junction, resulting in the compromise of LES function.

In contrast to some of previous studies suggesting smaller stent diameter as a risk factor for stent migration,^{14,15} our study did not find a statistically significant difference in migration rate based on stent diameter ($P = 0.34$). It is possible that since the stents used in that study differ from stents studied in ours, the difference in stent design and specification (wire weaving method, design of proximal flare, and radial force) may have contributed to this discrepancy.

A total of 5.7% rate of major adverse outcome reported in our study is comparable with the major adverse outcome rates from other studies that used similar definitions.^{9,16} Two cases of stent erosion into broncho-pulmonary structure occurred in the patients with previous radiation treatment to their esophagus with subsequent development of radiation induced stricture. Although small in number, it appears that serious adverse outcomes with SEMS placement occurred more frequently in previously irradiated (i.e., chemoradiation) esophagus, as some studies suggested in the past.¹⁷

Time and time again, numerous literatures have supported high degree of effectiveness in relieving symptoms of dysphagia stemming from obstructive cause with esophageal SEMS.¹⁷⁻²² Reported efficacy rate of dysphagia relief with SEMS use typically is often greater than 85% in many studies published to date.^{5,23} On the other hand, an equally impressive number of studies have reported overall complication rate of esophageal SEMS placement in complex issue.²⁴ Thus, well-deserved reservation of SEMS use in malignant setting stems from this significant rate of myriad of complications that occur with the SEMS placement. In fact, Ross et al²⁵ from MD Anderson group reported decrease in the number of esophageal stent use in their institution. Citing the inherent risk of endoluminal stent placement and availability of more effective chemoradiation, the authors concluded that SEMSs "fall short" of an ideal palliative method. Certainly, high rate of esophageal SEMS migration (especially in the era of fully covered stent use prior to neoadjuvant therapy) makes an argument against this statement difficult, especially if an alternative treatment option, such as brachytherapy, can offer equivalent, longer sustained response with perhaps less complications.^{26,27}

Naturally, endoscopic frontiers and device manufacturers have endeavored to solve this most common significant adverse outcome with many improvements in stent design, endoscopic techniques and, innovation in material incorporated. Yet, the construct of "ideal" stent continues to elude. An ideal SEMS used in obstructing lesion should provide adequate initial force to overcome the opposing, obstructive pressure of the primary lesion as well as sustained radial force to maintain luminal patency. This dynamic force should be carefully balanced with accommodative quality so that the force of stent itself would not cause luminal compromise. Furthermore, an ideal stent should overcome migratory tendency augmented by peristalsis and gravity while resisting inevitable tissue ingrowth/overgrowth as long as possible. With increasing use of SEMS in benign conditions, its removability becomes an integral component of an ideal SMES. As of 2015, there are more than 6 manufacturers providing more than 10 varieties of SEMS in USA (Table 6, Fig. 2). Materials used in esophageal stent extend

Table 6. Esophageal Stents Currently Available in the United States

Manufacturer and product name	Material and design	Outer diameter (mm)	Available length (cm)
Boston Scientific			
Ultraflex (noncovered)	Nitinol	18 (proximal flare, 23)	7, 10, 12, 15
Ultraflex (covered)	Nitinol (polyurethane)	18 (proximal flare, 23)	10 (covered portion, 7)
		23 (proximal flare, 28)	12 (covered portion, 9)
			15 (covered portion, 12)
WallFlex® (partially covered)	Nitinol (silicone-coated except flares)	18 (proximal flare, 23)	Same as Ultraflex® covered
		23 (proximal flare, 28)	
WallFlex® (fully covered)	Nitinol (silicone coated)	18 (proximal flare, 25)	10,12,15
		23 (proximal flare, 28)	
Cook Medical			
Evolution esophageal (fully covered)	Nitinol (internal and external silicone coating)	18 (flange, 23)	8, 10, 12
		20 (flange, 25)	
Evolution esophageal (partially covered)	Nitinol (internal and external silicone coating)	20 (flange, 25)	8, 10, 12.5, 15
M.I.Tech			
Hanaro® stent esophagus CCC (fully covered)	Nitinol	18 (flare, 24)	10, 12, 15
		22 (flare, 28)	
EndoChoice			
Bonastent® esophageal stent	Nitinol (internal silicone coating)	18	6, 8, 10, 12, 14, 16
Taewoong Medical			
Niti-S® esophageal covered stent (fully covered)	Nitinol (polyurethane)	16 (ends, 24)	6, 8, 10, 12, 15
		18 (ends, 26)	
		20 (ends, 28)	
Merit Medical Endotek			
Alimaxx-ES esophageal stent (fully covered)	Nitinol (polyurethane)	12, 14, 16, 18, 22	7, 10, 12
EndoMaxx	Nitinol (silicone)	19, 23	7, 10, 12, 15

Fig. 2. Currently available fully covered self-expandable metal stent in USA. From left to right: Bonastent® (EndoChoice), WallFlex® (Boston Scientific), Evolution (Cook Medical), EndoMaxx (Merit Medical Endotek), Niti-S® (Taewoong Medical), and Hanaro® esophageal CCC (M.I.Tech).

beyond metal alloy to plastic polymers and biodegradable material.²⁸ Biodegradable stent is currently unavailable in USA, and self-expandable plastic stent (Polyflex®; Boston Scientific) is in a redesigning phase.

Retrospective nature of this study poses some notable limitations.²⁹ A substantial portion of patients were lost to follow up in our study (23%). This leaves a room for significant data collection bias. Secondly, the lack of pre-defined, quantifiable measure of efficacy (such as degree of improvement of dysphagia score before and after stent placement) makes evaluating true efficacy difficult. When the proportion of patient that ended up with PEG

tube placement was used a surrogate of clinical failure, the proportion of patients who benefited from SEMS placement to relieve their obstructive dysphagia in our study was comparable (91.8%) to that of previously reported studies.¹⁵ Finally, recognizing that rate of delayed complication is increases with longer duration of follow up, lack of pre-determined follow up duration and use of heterogeneous and broad range of number follow up days in our study makes accurate assessment of complication rate challenging.

In conclusion, while SEMS placement in esophagus is safe and effective, significant rate of stent migration continues to hamper provision of predictable and durable benefit to many patients. Our study showed use of fully covered SEMS, SEMS use in benign esophageal lesion and SEMS placement in distal esophagus to be statistically significant predictors of stent migration. Formidable challenges remain in optimizing SEMS use in the disease of esophagus. Thus, large, independent prospective studies in the future are necessary and justified to resolve these issues.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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