

Endoscopic suture fixation is associated with reduced migration of esophageal fully covered self-expandable metal stents (FCSEMS)

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Abstract

Background Esophageal fully covered self-expandable metal stents (FCSEMS) are indicated for the management of benign and malignant conditions of the esophagus including perforations, leaks, and strictures. FCSEMS are resistant to tissue ingrowth and are removable; however, stent migration occurs in 30–55% of cases. Endoscopic suture fixation of FCSEMS has been utilized to decrease the risk of stent migration though data supporting this practice remain limited. The primary aim of this study was to compare clinical outcomes and migration rate of patients who underwent placement of esophageal FCSEMS with and without endoscopic suture fixation.

Methods Our single-center, retrospective, cohort study includes patients who underwent esophageal FCSEMS placement with and without endoscopic suture fixation between January 1, 2012, and November 11, 2015. Baseline patient characteristics, procedural details, and clinical outcomes were abstracted. Logistic regression was performed to identify clinical and technical factors associated with outcomes and stent migration.

Results A total of 51 patients underwent 62 FCSEMS placements, including 21 procedures with endoscopic suture fixation and 41 without. Suture fixation was

associated with reduced risk of stent migration (OR 0.13, 95% CI 0.03–0.47). Prior stent migration was associated with significantly higher risk of subsequent migration (OR 6.4, 95% CI 1.6–26.0). Stent migration was associated with lower likelihood of clinical success (OR 0.21, 95% CI 0.06–0.69). There was a trend toward higher clinical success among patients undergoing suture fixation (85.7 vs. 60.9%, $p = 0.07$).

Conclusions Endoscopic suture fixation of FCSEMS was associated with a reduced stent migration rate. Appropriate patient selection for suture fixation of FCSEMS may lead to reduced migration in high-risk patients.

Keywords Suture fixation · Stent migration · Fully covered self-expandable metal stent

Esophageal SEMs are available in fully covered, partially-covered, or uncovered designs. Esophageal fully covered self-expandable metal stents (FCSEMS) are indicated for the management of benign and malignant conditions of the esophagus including perforations, leaks, and strictures [1–4]. Esophageal FCSEMS (1) provide resistance to tissue ingrowth in malignant or benign strictures, (2) provide a luminal seal over perforations, leaks, and fistulae, and (3) are generally retrievable without difficulty. Historically, the major limitation of FCSEMS placement has been stent migration, occurring in up to 30–55% of cases [2–4].

Attempts at preventing stent migration have included the use of standard through-the-scope hemoclips and over-the-scope clipping devices [5, 6]. More recently, endoscopic suture anchoring of FCSEMS has been utilized to decrease the risk of stent migration [1, 2, 7]. One small retrospective study reported a reduced rate of stent migration among patients that underwent suture fixation compared to non-

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anchored controls (11.7 vs. 55%), though logistic regression modeling to determine the independent effect of suture fixation was not performed [2]. Based on currently published literature, the independent effect of suture fixation on esophageal FCSEMS migration remains uncertain.

Methods

Study design and aims

This was a retrospective cohort study of patients undergoing esophageal FCSEMS placement at a single academic medical center. The study protocol was approved by the Institutional Review Board of the University of Michigan Health System (#HUM00108120). The primary aim was to compare rate of stent migration of patients who underwent placement of esophageal FCSEMS with endoscopic suture fixation to patients who underwent FCSEMS placement without suture fixation. The secondary aims of the study were to compare clinical outcomes and to identify predictors of esophageal FCSEMS migration among these patients.

Patients

The endoscopy database at the University of Michigan Health System was reviewed to identify cases of esophageal FCSEMS placement between January 1, 2012, and November 11, 2015, for any indication. Endoscopic suture fixation was performed using the OverStitch endoscopic suturing device (Apollo Endosurgery; Austin, Texas) at the discretion of the performing endoscopist. Patients ≥ 18 years of age were included in the study. The electronic medical record and endoscopy database were queried to obtain pertinent clinical information related to patient demographics, endoscopic and radiologic findings, and outcomes data including early and late adverse events. Patient charts were reviewed manually and using an electronic medical record search tool (EMERSE) to identify outcomes [8].

Outcomes

The outcome measures were technical success rate, clinical success rate, and stent migration rate. Technical success was defined as successful stent deployment and suture fixation, if performed. Clinical success was categorized based on the response of the primary indication for stent placement. Complete response was defined as resolution of the primary indication for stent placement (i.e., complete healing of esophageal perforation or fistula, or resolution of dysphagia) at time of stent removal. Partial response was

defined as improvement in the primary indication for stent placement (i.e., reduction in size of perforation or fistula, or improved dysphagia) at time of stent removal. No response was defined as no improvement in primary indication for stent placement or premature stent removal due to intolerance (i.e., intolerable dysphagia, chest pain, or gastroesophageal reflux). Overall clinical success was defined as a composite of complete and partial responses. Stent migration was identified radiographically and/or endoscopically as reported by the performing endoscopist in the endoscopy procedure report.

Statistical analyses

Patient data were analyzed using SAS statistical software (SAS Institute, Cary, North Carolina, USA). Groups (sutured vs. non-sutured) were compared using Student's *t* test for continuous values or Fisher's exact test for proportions. Multivariable logistic regression analysis was performed to test the association between endoscopic suture fixation and (1) overall clinical success and (2) stent migration. Univariable logistic regression analysis was performed to identify important covariates to include in multivariable models. The independent variables included in the univariable regression analysis were age, sex, stent brand (Boston Scientific Wallflex, Merit Endotek Alimaxx ES, other), stent diameter, procedural indication (perforation, leak, stricture, fistula), prior stent placement, and prior stent migration. Covariates in the multivariable models were ultimately chosen based on significance in univariable model and/or clinical importance. Adjustments for specific covariates in individual models are described in table legends (Tables 3, 4). Odds ratios (ORs) and 95% confidence intervals (CI) per status of predictor variables were calculated for outcome variables. A two-sided 0.05 β was used to declare statistical significance.

Results

Baseline characteristics

From January 1, 2012, to November 11, 2015, 51 patients underwent 62 procedures to place esophageal FCSEMS. Twenty patients underwent 21 FCSEMS placements with suture fixation, and thirty-one patients underwent 41 esophageal FCSEMS placements without suture fixation. Patients were predominantly male (69%) with mean age 57 ± 16.8 years. Most stents were placed for esophageal perforation (46.7%, 29/62) or anastomotic leak (24.2%, 15/62). Of 15 procedures performed for management of anastomotic leak, 4/15 procedures were performed for esophagojejunostomy leak and 11/15 procedures were

performed for esophagogastronomy leak. One patient in the suture fixation group underwent concomitant endoscopic suture closure of an anastomotic defect at the time of stent placement; however, no additional primary luminal adjunctive therapies (suture closure, clip placement, sealant injection) were performed in either group at time of stent placement. Table 1 reports further patient characteristics stratified by utilization of endoscopic suture fixation. There were no significant differences in procedural indication or brand of FCSEMS used between the groups.

Migration rate

Stent migration occurred in 48.3% of procedures overall (Table 2). Patients who underwent suture fixation of FCSEMS had a significantly lower migration rate

compared to patients who did not (19.0 vs. 63.4%, $p = 0.0012$). To determine the independent effect of endoscopic suture fixation on stent migration rate, we performed multivariable logistic regression analysis. On univariable analysis, procedural indication, age, sex, stent diameter, and stent brand were not associated with stent migration. Prior stent migration was highly associated with subsequent stent migration on univariable analysis (OR 6.4, 95% CI 1.6–26.0, $p = 0.008$) and was included in multivariable model and also was subject to separate multivariable regression analysis (Table 3). On univariable analysis, suture fixation was associated with an 87% reduction in odds of stent migration (OR 0.13, 95% CI 0.03–0.47, $p = 0.001$). This association remained significant in multivariable logistic regression analysis using models adjusted for procedural indication and prior stent

Table 1 Baseline characteristics

	Sutured stents (%)	Non-sutured stents (%)	<i>p</i> value
<i>Total patients</i>	20	31	
<i>Total stent placements</i>	21	41	
<i>Age, mean (SD) (years)</i>	59.3 (13.5)	57.1 (15.8)	0.61
<i>Gender</i>			
Male	75%	65%	0.54
Female	25%	35%	
<i>Indication for stent</i>			
<i>Perforation</i>			
Benign	9/21 (42.8)	17/41 (41.4)	0.43
Malignant	1/21 (4.7)	2/41 (4.8)	1.0
<i>Stricture</i>			
Benign	2/21 (9.5)	8/41 (19.5)	0.47
Malignant	2/21 (9.5)	2/41 (4.8)	1.0
<i>Fistula</i>			
Anastomotic leak	1/21 (4.7)	3/41 (7.3)	1.0
	6/21 (28.5)	9/41 (21.9)	0.75
<i>Location of stent</i>			
Distal esophagus	11/21 (52.3)	17/41 (41.4)	1.0
Mid esophagus	2/21 (9.5)	7/41 (17.0)	0.70
Proximal esophagus	0/21 (0)	2/41 (4.8)	1.0
Anastomotic site	8/21 (38.0)	15/41 (36.5)	1.0
Crosses GEJ (native anatomy)	11/13 (84.6)	18/26 (69.2)	0.44
<i>Prior stent placements</i>			
Stent w/o fixation	6/21 (28.5)	12/41 (29.2)	1.0
Prior migration?	4/21 (19.0)	9/41 (21.9)	1.0
Stent w/fixation	1/21 (4.7)	0/41 (0)	0.33
Prior migration	0/21 (0)	0/41 (0)	1.0
<i>Type of stent</i>			
Wallflex	11/21 (52.3)	14/41 (34.1)	0.18
Alimaxx ES	4/21 (19.0)	16/41 (39.0)	0.15
Bonastent	0/21 (0)	2/41 (4.8)	0.54
Taewong	0/21 (0)	1/41 (2.4)	1.0
Data not available	6/21 (28.5)	8/41 (19.5)	0.52

Table 2 Clinical outcomes

	Sutured stents (%)	Non-sutured stents (%)	<i>p</i> value
<i>Technical success</i>	100%	100%	NS
<i>Overall clinical success</i>	18/21 (85.7)	25/41 (60.9)	0.07
Complete response	12/21 (57.1)	16/41 (39.0)	0.19
Partial response	6/21 (28.5)	9/41 (21.9)	0.75
<i>Migration rate</i>	4/21 (19.0)	26/41 (63.4)	0.0012
Prior stent	3/6 (50)	10/12 (83.3)	0.27
No prior stent	1/15 (6.6)	16/29 (55.1)	0.0026
<i>Time to migration</i> median, (IQR), days	15.5 (6.5–79)	22 (3–55)	0.97
<i>Stent dwell time</i> median, (IQR), days	38 (29–45)	35 (15–55)	0.88

Table 3 Multivariable logistic regression of stent migration after FCSEMS placement

Variable	OR	95% Confidence limits		<i>p</i> value
<i>Suture fixation</i>				
Unadjusted	0.13	0.03	0.47	0.001
Model 1	0.13	0.04	0.48	0.002
Model 1 + prior stent w/migration	0.07	0.014	0.39	0.002
<i>Prior stent w/migration</i>				
Unadjusted	6.4	1.6	26.0	0.008
Model 1	6.7	1.6	28.2	0.008
Model 1 + suture fixation	13.1	2.1	83.4	0.006

Model 1: Procedural Indication (fistula/leak, stricture, perforation)

placement with migration. On multivariable logistic regression analysis, prior stent placement with migration was associated with 13.1-fold increase in odds of subsequent stent migration after adjusting for suture fixation and procedural indication (OR 13.1, 95% CI 2.1–83.4, $p = 0.006$). Of patients who underwent suture fixation of FCSEMS, 6 patients had prior non-sutured stent placements with migration. These individuals subsequently experienced 50% stent migration rate despite use of suture fixation (Table 2).

Technical and clinical outcomes

Endoscopic placement and suture fixation of esophageal FCSEMS was successful in 100% of cases (Table 2). There was a trend toward greater overall clinical success (composite endpoint of complete and partial response) among patients who underwent suture fixation of FCSEMS compared to those who did not (85.7 vs. 60.9%, $p = 0.07$). On univariable analysis, procedural indication, prior stent placement, age, sex, and stent brand were not associated with overall clinical success. On univariable analysis, stent migration was associated with significantly lower likelihood of overall clinical success (OR 0.21, 95% CI 0.06–0.69, $p = 0.01$) (Table 4). This association remained significant in multivariable logistic regression analysis using models adjusted for procedural indication, prior stent

Table 4 Multivariable logistic regression of overall clinical success after FCSEMS placement

Variable	OR	95% Confidence limits		<i>p</i> value
<i>Suture fixation</i>				
Unadjusted	3.8	0.97	15.1	0.05
Model 1	3.8	0.95	15.2	0.06
Model 2	3.8	0.95	15.3	0.06
Model 2 + stent migration	2.1	0.44	9.7	0.34
<i>Stent migration</i>				
Unadjusted	0.21	0.06	0.69	0.01
Model 1	0.19	0.05	0.69	0.1
Model 2	0.17	0.04	0.64	0.009
Model 2 + suture fixation	0.22	0.05	0.94	0.04

Model 1: Procedural Indication (fistula/leak, stricture, perforation);
Model 2: Procedural Indication + Prior stent placement

placement, and suture fixation. On univariable analysis, suture fixation was associated with near-significant increased likelihood of clinical success (OR 3.8, 95% CI 0.97–15.1, $p = 0.05$). This association did not reach significance after adjusting for procedural indication, prior stent placement, and stent migration, though direction of trend remained consistent. The overall stent dwell time and time to stent migration (in cases where migration occurred) were similar between groups (Table 2).

Adverse events

Two suture-related adverse events occurred in twenty-one total procedures. One suture misfire occurred that extended the duration of procedure, but led to no other clinical consequences. In one patient, a newly placed FCSEMS was inadvertently removed when the gastroscope with an attached endoscopic suturing device was withdrawn from the patient. This led to small superficial mucosal tear that was of no clinical consequence; however, immediate stent replacement was required to address the primary procedural indication. There were no difficulties in removing sutured FCSEMS reported in any patients. In all cases where the sutures remained intact at the time of stent removal, the sutures were cut with endoscopic scissors or loop cutters and stents removed with rat-toothed forceps.

Discussion

Consistent with published literature, our study demonstrates that endoscopic suture fixation of esophageal FCSEMS can be performed with a high degree of technical success (100%) and low risk of adverse events (9.5%). Our data suggest that stent migration occurs greater than threefold more frequently in patients who undergo placement of a FCSEMS without suture fixation to the esophageal wall compared to those patients with suture fixation (63.4 vs. 19%). In our multivariable logistic regression model, use of endoscopic suture fixation was independently associated with an 87–93% reduction in odds of stent migration. Endoscopic suture fixation of FCSEMS was also associated with a near-significant ($p = 0.05$) increase in odds of overall clinical success independent of procedural indication. Importantly, we identified prior stent placement with migration as a highly significant independent risk factor for subsequent stent migration, with associated increased odds of migration of as high as 13.1-fold.

Endoscopic suture fixation of FCSEMS significantly reduced but did not eliminate risk of stent migration. Prior stent migration remained a significant risk factor for subsequent stent migration even among individuals undergoing endoscopic suture fixation. With multivariable regression modeling, we could not identify additional patient or procedural characteristics that would explain this strong association observed in this cohort. There may be unmeasurable or poorly measurable factors such as frequent forceful retching, suboptimal stent seating, or possibly superficial suture placement that account for these observations.

The optimal approach of endoscopic fixation of esophageal FCSEMS to prevent migration has not yet been

established. The use of endoscopic clips to prevent migration has been well described, albeit with variable success. Through-the-scope (TTS) endoclips and over-the-scope (OTS) clipping devices have been used to affix the proximal stent flange to the esophageal wall. The data regarding TTS endoclips for stent fixation have been largely disappointing due to the inability to provide a durable and reliable attachment to the esophageal wall [9]. Conversely, data on OTS clipping devices appear more promising. In a recently published cohort of patients with prior FCSEMS migration, Irani et al. [10] showed an 85% reduction in stent migration when an OTS clipping device (OTSC; Ovesco, Tübingen, Germany) was used to anchor the FCSEMS. As mentioned previously, published data suggest a reduced rate of stent migration among patients that underwent suture fixation of esophageal FCSEMS compared to non-anchored controls (11.7 vs. 55%) [2]. OTS clipping devices and endoscopic suturing both appear to be promising techniques for reducing FCSEMS migration, but come with an increase in procedural costs (~\$300–\$800) which must be considered. To our knowledge, randomized controlled studies directly comparing OTS clipping devices to endoscopic suturing have not been performed.

Our study has several limitations. Notably, this was a single-center, retrospective study with a relatively small number of patients. There was substantial heterogeneity in the indication for FCSEMS placement, and decision to perform endoscopic suture fixation of stent was determined by the performing endoscopist without a defined protocol in terms of number of sutures used, location of sutures, suture pattern (i.e., running or interrupted), or indication for suture placement. There was likely a bias in favor of suture fixation in patients with a perceived higher risk of stent migration, which may have dampened the observed beneficial effect of suture fixation if performed primarily in the highest risk patients.

Endoscopic suture fixation of FCSEMS appears to be a promising technique to reduce risk of stent migration. In this study, stent migration and overall clinical success shared an inverse relationship. As the indication for esophageal stent placement is often a highly morbid condition (perforation, anastomotic leak), techniques that may improve overall clinical success should be strongly considered. Stent migration may also be associated with increased need for subsequent endoscopic procedures to remove or reposition migrated stents in order to achieve a desired clinical endpoint. While suture fixation was independently associated with significantly reduced risk of stent migration, the migration rate remained ~20% these patients. Future innovation should focus on evaluation of technique of suture placement for stent fixation and patient selection to optimize cost effectiveness of this technology

to further minimize the risk of migration of FCSEMS and improve patient outcomes.

Author contributions AW was involved in data collection, statistical analysis, and drafting of the manuscript. AC, AOB, E-JW, GE, RK, and PC were involved in critical review and final manuscript approval. BJE was involved in critical review, statistical analysis, and final manuscript approval. RL was involved in article conception, drafting of the manuscript, and final manuscript approval.

Compliance with ethical standards

Disclosures Authors Andrew Wright, Andrew Chang, Aarti Oza Bedi, Erik-Jan Wamsteker, Grace Elta, Richard S. Kwon, Phillip Carrott, B. Joseph Elmunzer, and Ryan Law declare that they have no conflicts of interests or financial disclosure ties to disclose.

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