

Fully-covered metal stents with endoscopic suturing vs. partially-covered metal stents for benign upper gastrointestinal diseases: a comparative study




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ABSTRACT

Background and study aims Self-expandable metallic stents (SEMS) have been increasingly used in benign conditions (e. g. strictures, fistulas, leaks, and perforations). Fully covered SEMS (FSEMS) were introduced to avoid undesirable consequences of partially covered SEMS (PSEMS), but come with higher risk of stent migration. Endoscopic suturing (ES) for stent fixation has been shown to reduce migration of FSEMS. Our aim was to compare the outcomes of FSEMS with ES (FS/ES) versus PSEMS in patients with benign upper gastrointestinal conditions.

Patients and methods We retrospectively identified all patients who underwent stent placement for benign gastrointestinal conditions at seven US tertiary-care centers. Patients were divided into two groups: FSEMS with ES (FS/ES group) and PSEMS (PSEMS group). Clinical outcomes between the two groups were compared.

Results A total of 74 (FS/ES 46, PSEMS 28) patients were included. On multivariable analysis, there was no significant difference in rate of stent migration between FS/ES (43%) and PSEMS (15%) (adjusted odds ratio 0.56; 95% CI 0.15–2.00). Clinical success was similar [68% vs. 64%; $P=0.81$]. Rate of adverse events (AEs) was higher in PSEMS group [13 (46%) vs. 10 (21%); $P=0.03$]. Difficult stent removal was higher in the PSEMS group ($n=5$; 17%) vs. 0% in the FS/ES group; $P=0.005$.

Conclusions The proportion of stent migration of FS/ES and PSEMS are similar. Rates of other stent-related AEs were higher in the PSEMS group. PSEMS was associated with tissue ingrowth or overgrowth leading to difficult stent removal, and secondary stricture formation. Thus, FSEMS with ES for stent fixation may be the preferred modality over PSEMS for the treatment of benign upper gastrointestinal conditions.

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Introduction

The use of self-expandable metal stents (SEMS) for endoscopic management of malignant upper gastrointestinal diseases is well-established [1]. There is a growing body of literature that supports the increasing use of SEMS for successful endoscopic management of benign upper gastrointestinal conditions, such as refractory strictures, leaks, fistulae, and spontaneous or iatrogenic perforations [2–8].

Partially-covered SEMS (PSEMS) have uncovered metal mesh ends that allow for tissue embedding in order to increase adherence to the intended location. However, when used for benign upper gastrointestinal conditions, PSEMS have been associated with serious AEs, such as challenging stent removal, due to the stents' inherent risk of stimulating mucosal hyperplasia, and subsequent stricture and fistulae formation [9,10]. Fully covered self-expandable metal stents (FSEMS) were introduced to avoid these AEs, but consequently are associated with increased risk of stent migration [11,12]. Despite above mentioned stent-related AEs, PSEMS is still commonly used for benign upper gastrointestinal conditions due to perception of its low risk of stent migration [3,11–14].

Stent migration remains a major limitation for FSEMS and can occur in up to one-third of cases [3,8,15–17]. It is associated with need for endoscopic re-intervention, increased health-care costs, and AEs such as bowel perforation or obstruction [18]. As a result, various techniques have been developed to anchor stents. Endoscopic suturing (ES) has recently been described for stent fixation in order to reduce stent migration [19]. Recently, a 2016 multicenter study found that endoscopically sutured FSEMS placed for benign upper gastrointestinal conditions proved superior to non-sutured FSEMS in the prevention of stent migration [20].

Available data suggested that both endoscopic suturing for FSEMS and PSEMS reduce risk of stent migration for benign upper gastrointestinal diseases as compared to FSEMS alone without fixation. To date, comparative studies evaluating the outcomes of patients with benign upper gastrointestinal diseases treated with FSEMS and ES as compared to PSEMS are lacking. The primary objective of this study was to assess the frequency of stent migration among patients who underwent endoscopically sutured FSEMS placement and that of patients who underwent PSEMS placement. This study also sought to evaluate stent-related AEs and clinical success with respect to the underlying pathology. We hypothesized that FSEMS plus ES may have advantages over PSEMS in term of decreased risk of stent migration, and at the same time avoid unwanted AEs of tissue hyperplasia from PSEMS.

Patients and methods

In this retrospective cohort study, data were collected from the electronic medical records of patients who underwent endoluminal stent placement for benign upper gastrointestinal conditions, defined as strictures, fistulae, leaks and perforations, at seven U.S. tertiary care centers between January 1, 2007 and January 1, 2015. Inclusion criteria included patients who under-

went either FSEMS placement with ES for stent fixation (FS/ES group) or PSEMS placement (PSEMS group). Exclusion criteria included patients who underwent FSEMS placement without ES or with an alternative method of stent fixation, and patients who underwent PSEMS with any form of stent fixation. The Institutional Review Board for each contributing center approved this study. The results of 44 patients in this study were previously included in a prior manuscript with long-term follow-up data provided [8].

FSEMS placement with ES was performed by methods as previously described [19,21]. Briefly, the OverStitch suturing device (Apollo Endosurgery, Austin, TX) is mounted on a double-channel upper gastrointestinal endoscope. The suturing device is coupled with an accessory channel, through with the suture anchor with a detachable needle is threaded, as well as a handle that attaches to the port of the working channel. This configuration allows for increased dexterity in needle transfer and consequently of the suture through both stent and tissue. In this study, sutures were placed along the proximal metal stent loops and esophageal wall, with the number of sutures placed per the discretion of the endoscopist. For stent removal, the sutures were cut off with a loop cutter or endoscopic scissors and the stent handled with a snare or grasping forceps.

Data on patient factors, including demographics, details of the indication for stent placement such as size and location of the upper gastrointestinal condition, history of prior endoscopic stenting, and history of prior stent migration were collected. Data on stent factors, including type, diameter, length, location of placement with respect to the distal portion, and duration of use, calculated from the date of stent placement to the date of removal or spontaneous migration, were also collected. Patients were followed until date of last known follow-up.

Definitions

Clinical outcomes of patients in the FS/ES group were compared against those in the PSEMS group. Outcome measures included stent migration, defined as endoscopically or radiologically confirmed movement of the stent from the initial location such that the intended area to be covered was no longer covered; clinical success of stent placement; defined as endoscopically or radiologically confirmed resolution of the underlying benign upper gastrointestinal pathology following stent removal; and procedure-related AEs. Technical success was defined as the successful deployment of the stent in its proper position. Clinical success was defined as resolution of a stricture or closure of a fistula/leak/perforation as documented by clinical and endoscopic/radiological follow-up after stent removal. In the FS/ES group, technical success also included the successful deployment of suture to anchor the stent.

Statistical analysis

Categorical data were presented using frequency counts and percentages. Continuous data were presented as means \pm standard deviation or as median and interquartile range (IQR) (P25-P75). Between the two groups, chi-squared test and Fisher's exact test were used for categorical data comparisons, with

t-test and Mann-Whitney U test for continuous data comparisons, where appropriate. Logistic regression was used to analyze the effect of various factors on the odds of either stent migration or clinical success in the two groups. Multivariable modeling was used to examine the association between the two groups with respect to stent migration. *P* values of <0.05 were considered significant. Statistical analyses were performed with SPSS v16.0 (Chicago, IL).

Results

A total of 74 (46 in the FS/ES group and 28 in the PSEMS group) patients (males 53%, mean age 53 years) were included. Stent placement was performed for benign strictures in 32 (43%) cases and leaks/fistulae/perforations in 42 (57%) cases. In the FS/ES group, the mean number of sutures used for stent fixation [median (p25 and p75)] was 1 (1–2) sutures. Technical success was 100% in both groups. Of these 74 patients, 51 (69%) underwent one stenting procedure, 12 (16%) underwent two procedures and the remaining patients underwent three or more procedures. The median duration that stents remained in position and were functional was 56 days (IQR 25–98) before they were removed at planned stent removal or migrated.

Overall, stent migration as determined endoscopically and/or radiologically occurred in 19 patients (26%) at a median of 56 days (IQR 16–102) after the index procedures. Besides stent migration, a total of 28 AEs (31%) occurred after stenting procedures.

The median follow-up after stent removal was 184 days (IQR 47–259 days). Clinical success with resolution of underlying condition was achieved in 49 patients (65%), including 22 patients (67%) with benign strictures and 27 patients (64%) with leaks/fistulae/perforations.

Comparative analysis: stent migration, clinical success and adverse events

A total of 28 patients were in the PSEMS group and 46 patients were in the FS/ES group. Characteristics of the two study groups are shown in ► **Table 1**. Both groups were similar in terms of age, gender, location of lesion, and location of distal end of the stent. There were no significant differences in the proportion of patients who had undergone prior endoscopic stent procedure or proportion of patients who had prior stent migration between the two groups. However, the FS/ES group had a higher proportion of patients with leaks/fistulae, a higher proportion of longer stents (>12 cm in length) and a higher proportion of larger diameter stent (>18 mm).

Stent migration occurred in 43% [12/28] the PSEMS group and 15% [7/46] in the FS/ES group after the index procedure (*P*=0.01). Univariable analysis of factors associated with stent migration is shown in ► **Table 2**. Endoscopic suturing for stent fixation was significantly associated with decreased odds of stent migration as compared to PSEMS (odds ratio [OR] 0.23, 95% CI 0.08–0.72, *P*=0.01). Factors that were associated with increased odds of stent migration included stricture indication, shorter stents and smaller-diameter stents. In the multivariable analysis adjusting for indications, prior history of stent migra-

tion, stent length, stent diameter and stent fixation; there was no statistically significant difference in the rate of stent migration between FS/ES and PSEMS (adjusted odds ratio 0.56; 95% CI 0.15–2.00; *P*=0.37) (► **Table 3**).

The rate of AEs was higher in the PSEMS group: 13 (46%) vs. 10 (21%) in the FS/ES group (*P*=0.03). ► **Table 4** lists the types of AEs reported during the study period. Secondary stricture formation due to tissue ingrowth occurred in 3 patients (10%) in the PSEMS group and none in the FS/ES group (*P*=0.05). The strictures were successfully treated by endoscopic balloon dilation and/or stenting in all three patients. Tracheoesophageal fistula occurred in one patient in the PSEMS group. Surgery was recommended, but the patient refused. Perforation occurred in one patient in the FS/ES group during stent insertion and the patient underwent emergency surgery. In the FS/ES group, there were no AEs related to suture placement and/or suture removal. Difficult stent removal due to tissue ingrowth/overgrowth was reported in 5 patients (17%) in the PSEMS group which was higher than that of the FS/ES group (0%) (*P*=0.005). All of these 5 patients required stent-in-stent technique for removal of the embedded stents.

Clinical success after stent removal was achieved in 30 (64%) patients in the FS/ES group and 19 (68%) in the PSEMS group (*P*=0.81). In logistic regression analysis of factors associated with clinical success, there was no statistically significant difference in clinical success between the type of stent (FSEMS with ES vs. PSEMS) (OR 0.83 95% CI 0.31–2.25; *P*=0.72) (► **Table 5**). However, the PSEMS group required significantly more procedures than FS/ES group (1.86±0.9 vs. 1.26±0.6; *P*=0.006) to achieve clinical response.

Discussion

In this large multicenter retrospective study, we found that rate of stent migration with endoscopically sutured FSEMS in benign upper gastrointestinal diseases was similar to that of PSEMS. However, rates of other stent-related AEs were higher in the PSEMS group. PSEMS was associated with tissue ingrowth or overgrowth leading to difficult stent removal, secondary stricture formation and associated with increased the number of required endoscopic sessions. Thus, FSEMS with endoscopic suturing for stent fixation may be the preferred modality over PSEMS for the treatment of benign upper gastrointestinal conditions.

Endoscopic stent placement with SEMS has become a viable minimally invasive treatment option for various benign upper gastrointestinal conditions. However, the major unresolved problems of stent therapy are stent migration and tissue ingrowth or overgrowth. Fully covered metal stents, as compared to non-fully covered metal stents, is associated with increased risk of stent migration because of the lack of traction on the esophageal wall [1, 3, 17, 22]. Tissue hyperplasia or new stricture formation has been reported as high as 41% to 53% after PSEMS placement [12, 23]. Ingrowth or overgrowth of the granulation tissue either through the stent or at either end of the uncovered stent lead to stent embedding and subsequent difficult stent removal. In addition, the stent, particularly at

► **Table 1** Baseline patient characteristics.

	PSEMS group (n = 28)	FS/ES group (n = 46)	P value
Age, mean ± SD, years	50 ± 15	54 ± 17	0.38
Male sex, n (%)	12 (43%)	21 (46%)	0.82
Site of pathology, n (%)			0.33
▪ Esophagus	21 (75%)	39 (85%)	
▪ Stomach	6 (21%)	7 (15%)	
▪ Duodenum	1 (4%)	0 (0)	
History of prior stenting, n (%)	13 (46%)	13 (26%)	0.08
History of prior stent migration, n (%)	10 (36%)	8 (19%)	0.12
Distal end of stent, n (%)			0.72
▪ In the esophagus	4 (14%)	5 (11%)	
▪ Below the gastroesophageal junction	24 (86%)	41 (89%)	
Indication for stent placement			0.001
▪ Stricture, n (%)	19 (68%)	13 (28%)	
– Anastomotic stricture	11	2	
– Radiation	1	3	
– Peptic stricture	1	2	
– Other causes	6	6	
▪ Leak/ fistula/ perforation, n (%)	9 (32%)	33 (72%)	
– Post-bariatric surgery	4	22	
– Anastomotic leak	0	7	
– Iatrogenic perforation	1	2	
– Other causes	4	2	
Stent diameter, n (%) (missing; n = 1)			0.001
▪ ≤ 18 mm	22 (79%)	16 (36%)	
▪ > 18 mm	6 (21%)	29 (64%)	
Stent length			0.02
▪ ≤ 10 cm	9 (32%)	4 (9%)	
▪ > 10 cm	19 (68%)	42 (91%)	

PSEMS, partially-covered self-expandable metallic stents; FS/ES, PSEMS with endoscopic suturing.

the uncovered ends, cause mechanical injury on the esophageal wall and fibrosis resulting in new stricture formation. Secondary stricture requires additional endoscopic intervention with dilation and/or stenting.

Removal of embedded PSEMS is technically challenging. Serious AEs, such as esophageal perforation, avulsion, fistula, have been reported following removal of the embedded PSEMS [9, 13]. The “stent-in-stent technique” has been described as a rescue technique for removal of the embedded PSEMS. In this technique, a fully covered self-expandable stent is placed inside the PSEMS to induce pressure necrosis of ingrown tissue. Subsequent removal of both stents is performed after a period of 10–14 days. This technique is highly effective for removal of

the embedded stent. However, it requires additional stents, another procedure and increased costs in order to remove a PSEMS [14, 24].

Due to the stent-related AEs described above, the use of PSEMS in the treatment of benign diseases is controversial. Despite these drawbacks, some experts recommended PSEMS for benign upper gastrointestinal diseases such as refractory strictures, leaks, fistulas and perforations; especially in patients with history of fully-covered stent migration or patients at high risk of catastrophic AEs with stent migration [3, 14].

PSEMS are associated with lower rates of stent migration, ranges from 9% to 31% in benign upper gastrointestinal conditions [12, 23]. In contrast, the rate of migration of FSEMS is as

► **Table 2** Univariable logistic regression analysis of factors associated with stent migration.

Characteristics	Odds ratio	95% confidence interval	P value
Age	1.003	0.97–1.03	0.86
Sex (male vs. female ¹)	2.06	0.18–2.06	0.18
Indications (strictures vs. leaks/fistulas/perforations ¹)	4.11	1.34–12.53	0.01
Prior history of stent migration (yes vs. no ¹)	2.12	0.67–6.67	0.19
Stent length (≤ 10 cm vs. > 10 cm ¹)	4.76	1.35–16.79	0.01
Stent type (FS/ES vs. PSEMS ¹)	0.23	0.08–0.72	0.01
Stent diameter (≤ 18 mm vs. > 18 mm ¹)	5.05	1.48–17.25	0.01
Distal end of stent (in the esophagus ¹ vs. below the gastroesophageal junction)	1.24	0.23–6.56	0.80
Dilation of stricture before stent placement (yes vs. no ¹) (in stricture group)	0.84	0.21–3.46	0.81

¹ Reference group; PSEMS, partially-covered self-expandable metallic stents; FS/ES, PSEMS with endoscopic suturing

► **Table 3** Multivariable logistic regression analysis of factors associated with stent migration.

Characteristics	Adjusted odds ratio ¹	95% confidence interval	P value
Indications (strictures vs. leaks/fistulas/perforations ²)	1.42	0.32–6.26	0.64
Prior history of stent migration (yes vs. no ²)	0.57	0.16–2.12	0.41
Stent length (≤ 10 cm vs. > 10 cm ²)	2.76	0.65–11.63	0.16
Stent diameter (≤ 18 mm vs. > 18 mm ²)	2.18	0.45–10.37	0.32
Stent type (FS/ES vs. PSEMS ²)	0.56	0.15–2.00	0.37

¹ Adjusted for age, sex, indication, prior history of stent migration, stent length, stent diameter, and type of stent (FS/ES vs. PSEMS); PSEMS, partially-covered self-expandable metallic stents; FS/ES, FSEMS with endoscopic suturing

² Reference group;

► **Table 4** Adverse events after treatment with endoscopic stenting (ES) for FCSEMS and PSEMS for benign upper gastrointestinal conditions.

Adverse events	PSEMS group	FS/ES group	P value
Number of stent procedures	28	46	
Total adverse events, n (%)	13 (46%)	10 (21%)	0.03
▪ Chest/abdominal pain	1	7	
▪ Stent obstruction due to tissue overgrowth	1	0	
▪ Hemorrhage	2	1	
▪ Stricture formation due to the stent	3	0	
▪ Perforation	0	1	
▪ Aspiration pneumonia	0	1	
▪ Tracheoesophageal fistula	1	0	
▪ Difficulty removing the embedded stent	5 (17%)	0 (0%)	0.005
– Required stent-in-stent technique for stent removal	5	0	

PSEMS, partially-covered self-expandable metallic stents; FS/ES, FSEMS with endoscopic suturing.

high as 26%–36% [6, 16, 17, 22]. Thus, various techniques have been developed in attempts to prevent migration of FSEMS, such as stent fixation with through-the-scope clips [25], over-

the-scope clips [26] and endoscopic suturing [8, 19]. In a proof of biomechanical ex vivo study, endoscopic suturing provided significantly higher migration resistance compared with clip

► **Table 5** Univariable logistic regression analysis of factors associated with clinical success.

Characteristics	Odds ratio	95% confidence interval	P value
Indications (strictures vs. leaks/fistulas/perforations ¹)	1.11	0.42–2.90	0.83
Prior history of stent migration (yes vs. no ¹)	1.53	0.51–4.62	0.49
Stent length (≤ 10 cm vs. > 10 cm ¹)	0.58	0.16–2.14	0.42
Stent type (FS/ES vs. PSEMS ¹)	0.83	0.31–2.25	0.72
Stent diameter (≤ 18 mm vs. > 18 mm ¹)	1.04	0.40–2.69	0.93
Distal end of stent (in the esophagus* vs. below the gastroesophageal junction)	0.20	0.02–1.74	0.14
Dilation of stricture before stent placement (yes vs. no ¹) (in stricture group)	1.96	0.49–7.88	0.34

¹ Reference group; PSEMS, partially-covered self-expandable metallic stents; FS/ES, FSEMS with endoscopic suturing.

fixation or stent placement without fixation [27]. This technique is relatively simple and easy to use. The reported technical success rate of endoscopic suturing for stent anchorage is 100% and the average time for stent fixation is only 12.5 minutes [19, 28].

A recent multicenter study, including 125 patients with benign upper gastrointestinal conditions has shown that endoscopic suturing for fixation of FSEMS is safe and associated with decreased migration rate compared to no stent fixation (16% vs. 33%; $P=0.03$). Endoscopic suturing for stent fixation appeared to protect against stent migration in patients with a history of stent migration (adjusted odds ratio of 0.09; 95% CI 0.02–0.47; $P=0.002$). It may also improve clinical response, likely because of the reduction in stent migration [8].

Given that endoscopic suturing is safe, effective to prevent stent migration and be able to avoid AEs from tissue ingrowth or overgrowth from PSEMS, using FSEMS plus ES for stent fixation should be a preferred alternative to PSEMS in benign upper gastrointestinal diseases.

There are some limitations to this study. This was a retrospective and some detail data including procedural information were not available. Additionally, the decision to select treatment options either endoscopic suturing for stent fixation or placement of PSEMS was on the basis of endoscopist preference and device availability. This may introduce selection bias. Finally, optimal technique of endoscopic suturing has not been clearly defined. There were minor variations in the suturing technique such as number of suture or use of an endoscopic tissue grasper device during suturing, which could lead to differences in holding strength of suture anchors and its efficacy in preventing stent migration. The efficacy of suturing on prevention of stent migration may be affected by the learning curve. Because each center performed only a small number of suturing cases, we are unable to assess the learning curve effect on stent migration outcomes.

Conclusion

In conclusion, in benign upper gastrointestinal diseases, treatment with FSEMS with ES for stent fixation appears to be equally effective to PSEMS in term of preventing stent migration and

achieving clinical success. Additionally, FSEMS with ES is safer and avoids AEs related to PSEMS, particularly tissue ingrowth or overgrowth, new stricture formation and difficulties with stent removal. FSEMS with ES may be the preferred treatment options to PSEMS for benign upper gastrointestinal conditions. Future large prospective studies aiming to assess the efficacy of endosuturing for the prevention of stent migration and cost effectiveness analysis of this technique are warranted.

Competing interests

Dr. Khashab is a consultant for Boston Scientific. Dr. Sethi acts as a consultant for Boston Scientific and Xlumera and has received travel expenses for unrelated meetings from Beacon Endoscope and Mauna Kea Technologies. Dr. Kalloo is a founding member, equity Holder and consultant for Apollo Endosurgery. Dr. Poneris acts as a consultant for Boston Scientific. Dr. Rogart acts as a consultant for Boston Scientific. Dr. DiMaio is a consultant and speaker for Boston Scientific. Dr. Singh is a consultant for Abbvie, D-Pharm, and Santarus. Dr. Kumbhari is a consultant for Boston Scientific, Apollo Endosurgery and Medtronic.

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