Evaluating no fixation, endoscopic suture fixation, and an over-the-scope clip for anchoring fully covered self-expandable metal stents in benign upper GI conditions: a comparative multicenter international study (with video)

Amit Mehta, MD,[1] Ashraf Ashhab, MD,[1] Apurva Shrigiriwar, MD,[1] Redeat Assefa, MD,[1] Andrew Canakis, DO,[2] Michael Frohlinger, MD,[2] Christopher A. Bouvette, MD,[3] Gregus Matus, MD,[4] Paul Punkenhofer, MD,[4] Francesco Vito Mandarino, MD,[5] Francesco Azzolini, MD,[5] Jamil S. Samaan, MD,[6] Rashmi Advani, MD,[6] Shivani K. Desai, MD,[7] Bradley Confer, DO,[7] Vikas K. Sangwan, MD,[7] Jonh J. Pineda-Bonilla, MD,[8] David P. Lee, MD,[9] Kinnari Modi, MD,[9] Chiemeziem Eke, MD,[9] Moritz Schiemer, MD,[10] Elena Rondini, MD,[11] Werner Dolak, MD,[12] Emil Agarunov, MD,[15] Margaret Duku, MD,[13] Andrea Telese, MD,[13] Rishi Pawa, MD,[14] Swati Pawa, MD,[14] Natividad Zaragoza Velasco, MD,[16] Jad Farha, MD,[1] Rickisha Berrien-Lopez, MD,[1] Sherifatu Abu, MD,[1] Charlee K. McLean-Powell, MD,[1] Raymond E. Kim, MD,[2] Amir Rumman, MD,[3] Georg O. Spaun, MD,[4] Paolo G. Arcidiacono, MD,[5] Kenneth H. Park, MD,[6] Harshit S. Khara, MD,[7] David L. Diehl, MD,[7] Prashant Kedia, MD,[9] Armin Kuellmer, MD,[10] Raffaele Manta, MD,[11] Tamas A. Gonda, MD,[15] Vinay Sehgal, MD,[13] Rehan Haidry, MD,[13] Mouen A. Khashab, MD[1]

Baltimore, Maryland; Norman, Oklahoma; Los Angeles, California; Danville, Pennsylvania; Salem, Virginia; Dallas, Texas; Winston-Salem, North Carolina; New York, New York, USA; Oberösterreich, Wien, Austria; Milano, Perugia, Italy; Baden-Württemberg, Germany; London, United Kingdom; Lleida, Spain

GRAPHICAL ABSTRACT

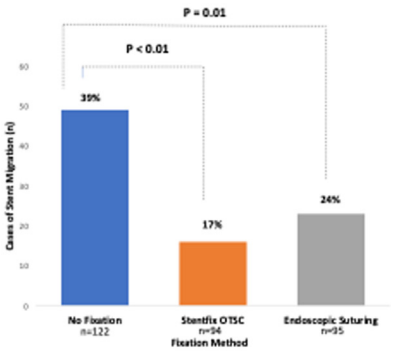
Evaluating no fixation, endoscopic suture fixation, and an over-the-scope clip for anchoring fully covered self-expanding metal stents in benign upper gastrointestinal conditions: a comparative multicenter international study (with video)

Methods and Cohort

- 9 U.S. and 7 European Medical Centers
- A retrospective review of adults who underwent fully covered self-expandable metal stent placement for benign upper gastrointestinal indications (n = 311 patients)

Multivariable logistic regression analysis of factors associated with stent migration

	Adjusted odds ratio	95% confidence interval	P value
History of prior stenting	0.51	0.25-1.05	0.06
Stent length ≤120mm vs. >120mm	2.17	1.18-3.97	0.01
Fixation method			
Suture vs. No Fixation	0.46	0.23-0 .91	0.02
Stentfix OTSC vs. No Fixation	0.34	0.17- 0.70	<0.01



CONCLUSION:

Stent fixation using Stentfix OTSC is safe and effective at preventing stent migration, and may also result in improved clinical response

Background and Aims: Fully covered self-expandable metal stents (FCSEMSs) are widely used in benign upper GI conditions, but stent migration remains a limitation. An over-the-scope clip (OTSC) device (Stentfix {SF],

Ovesco Endoscopy) for stent anchoring has recently been developed. The aim of this study was to evaluate the effect of OTSC fixation on FCSEMS migration rate.

Methods: In this retrospective review of consecutive patients who underwent FCSEMS placement for benign upper GI conditions from January 2011 to October 2022 at 16 centers, the primary outcome was rate of stent migration. The secondary outcomes were clinical success and adverse events.

Results: A total of 311 (no fixation [NF] 122, SF 94, endoscopic suturing [ES] 95) patients underwent 316 stenting procedures. Compared with the NF group (n = 49, 39%), the rates of stent migration were significantly lower in the SF (n = 16, 17%, $P = .001$) and ES (n = 23, 24%, $P = .01$) groups. The rates of stent migration were not different between the SF and ES groups ($P = .2$). On multivariate analysis, SF (odds ratio [OR], 0.34, 95% CI, 0.17-0.70, $P < .01$) and ES (OR, 0.46, 95% CI, 0.23-0.91; $P = .02$) were independently associated with decreased risk of stent migration. Compared with the NF group (n = 64; 52%), there were higher rates of clinical success in the SF (n = 64; 68%; $P = .03$) and ES (n = 66; 69%; $P = .02$) groups. There was no significant difference in the rates of adverse events among the 3 groups.

Conclusion: Stent fixation using OTSCs is safe and effective at preventing stent migration and may also result in improved clinical response. (Gastrointest Endosc 2025;101:589-97.)

(footnotes appear on last page of article)

Since their introduction in the 1990s, self-expandable metal stents (SEMSs) have been used for the management of a multitude of benign and malignant GI conditions.[1] There are 3 different types of SEMSs: fully covered SEMSs (FCSEMSs), partially covered SEMSs, and uncovered SEMSs.[2] Compared with the other 2 types, FCSEMSs are easier to remove owing to a silicone covering that prevents tissue or tumor ingrowth. Consequently, FCSEMSs are more commonly used in the management of benign upper gastrointestinal (UGI) diseases.[3] In addition to their use for the management of benign esophageal strictures, FCSEMSs have been used for the treatment of fistulas, leaks, perforations, and refractory acute variceal bleeding.[3,4] However, a drawback of using FCSEMs in benign UGI diseases is the risk of stent migration, which may be as high as 55%.[3,5] To mitigate this risk, several endoscopic anchoring techniques have been proposed, with variable success rates.

Endoscopic suturing (ES) of stents has been done with the use of an ES device (OverStitch, Boston Scientific, Marlborough, Mass, USA). A meta-analysis of 14 studies assessing suturing to anchor esophageal stents showed a reduction in migration rates compared with no suturing, with high technical success rates and a low risk of adverse events (AEs).[6] However, in addition to limited data regarding suturing techniques, high cost, and the need for specific training, ES has not found widespread use.[3,5,7]

Over-the-scope clips (OTSCs; Ovesco Endoscopy, Tübingen, Germany) also have been used for stent fixation, with significant reduction (0%-15%) in SEMS migration rates.[8,9] The Stentfix OTSC system is a newly developed device with a modified cap shape, which can be positioned parallel to the stent opening, allowing for optimal stent mesh and tissue capture by the clip. There are limited data showing low migration rates associated with OTSC anchoring.[10,11]

The optimal method for stent fixation remains unclear. A single retrospective study assessed the rates of stent migration after ES or OTSC fixation compared with no fixation (NF)[12] and found higher clinical success rates (defined as resolution of the indication after stent placement), lower risk of migration, and lower risk of overall AEs with OTSC fixation compared with ES or NF. Limitations of that study were inclusion of malignant causes of obstruction, inclusion of SEMSs for lower GI diseases, and a single-center study design.

There have been no previous multicenter studies comparing the rates of FCSEMS migration for benign UGI conditions in cases undergoing fixation with ES or OTSCs compared with NF. The aims of the present study were to (1) evaluate the effect of OTSC fixation on SEMS migration rate and (2) compare outcomes of patients who underwent OTSC fixation (Stentfix [SF]) with those of patients who underwent ES fixation or NF.

METHODS

This was a multicenter retrospective cohort study. Data were collected from electronic medical records of patients who underwent endoscopic esophageal stent placement for benign conditions, including those with subsequent fixation with the use of ES or OTSCs, and those who did not undergo stent fixation. Benign conditions included nonmalignant strictures, fistulas, perforations, leaks, and variceal bleeding. Data were collected from 9 U.S. centers and 7 European centers from 2011 to 2022. A total of 28 investigators were involved in the procedures across all 16 participating

centers. The institutional review board for each contributing center approved this study. The Institutional Review Board at Johns Hopkins approved this study on October 11, 2022. Data on patient factors were collected, including demographics, type and site of pathology, history of previous stenting, and history of previous stent migration. Data on stent factors were also collected, including type, diameter, length, fixation method, whether the stent crossed the gastroesophageal junction, and duration of placement (calculated from the date of placement to the date of removal or spontaneous migration). Procedural factors including technical success and length of procedure also were recorded.

Inclusion criteria included patients who underwent FCSEMS placement with or without fixation. Exclusion criteria included placement of partially covered or uncovered SEMSs, malignant esophageal pathology, and early removal of the placed stent (defined as removal before the date intended at the time of placement). The decision to exclude cases where stents were removed earlier than intended was made because the dwell time of stents was thought to affect the risk of stent migration, with shorter dwell time possibly reducing the risk of migration. Furthermore, the clinician's decision to remove the stent early adds an additional confounding variable, because it is likely that the endoscopist is more likely to remove stents early if there is a perceived potential for migration or other adverse events.

Esophageal stent placement

The type, diameter, and length of the FCSEMS was at the discretion of the endoscopist. Through-the-scope (TTS) stents were deployed endoscopically over a guidewire under direct endoscopic visualization with or without additional fluoroscopic evaluation. Non-TTS stents were placed under fluoroscopic guidance.

ES fixation

Fixation of FCSEMSs by ES was performed using previously described methods.[13,14] Briefly, the OverStitch suturing device was mounted on a double-channel gastroscope. The suturing device is coupled with an accessory channel, through which the suture anchor with a detachable needle is threaded, as well as a handle that attaches to the port of the working channel. Sutures were placed along the proximal metal stent loops and esophageal wall, with the number of sutures placed according to the discretion of the endoscopist (Fig. 1). The decision to use or not use the helix device during stent fixation with ES also was at the discretion of the endoscopist. In the present study, the helix device was not used in any of the suture fixation cases.

OTSC fixation

OTSC fixation was performed using a dedicated OTSC fixation system (Stentfix). The device was mounted on an upper endoscope and a hand wheel was fixed on the endoscope working channel. The cap opening was then positioned to appose the proximal esophageal stent edge and the adjacent esophageal wall. Suction was then applied to capture the edge of the stent and the esophageal wall, with subsequent deployment of the clip by turning the wheel (Fig. 1; Video 1, available online at www.giejournal.org).

Definitions

Clinical outcomes of patients in the NF group were compared with those of patients who underwent fixation with ES or SF. Stent migration was defined as endoscopically or radiologically confirmed movement of the stent from the initial location such that the intended area to be bridged was no longer covered. Clinical success was defined by resolution of the indication of stent placement after removal. Technical success was defined as successful deployment of the stent in the intended position. In the ES arm, technical success also included successful deployment of sutures to anchor the stent, and in the SC arm it included successful OTSC placement to capture the stent and esophageal mucosa.

Statistical analysis

All statistical analysis was performed with the use of Stata 13.0 (Stata Corp, College Station, Tex, USA). Continuous variables were summarized as mean ± SD and compared with the use of analysis of variance or Student *t* test in univariable analysis. Categoric variables were summarized as n (%) and compared with the use of chi-squared or Fisher exact test in univariable analysis. Logistic regression was used to analyze the effect of various factors on the odds of stent migration in the 3 groups. Multivariable modeling was used to examine the association among the 3 groups in terms of stent migration. All tests were 2-tailed with an alpha of .05. A P value $<.05$ was considered to be statistically significant.

RESULTS

A total of 311 patients (mean age , 60 ± 15.7 years; 49.5% male) underwent 316 stenting procedures. A total of 122 patients (39.2%) underwent NF, 94 patients (30.2%) SF, and 95 patients (30.5%) ES. There was no significant difference among the 3 groups regarding age, sex, site of pathology, history of previous stenting, history of previous stent migration, indication for stent placement, stent diameter, and stent length (Table 1). Among patients who underwent ES, 2 sutures were used in 69 cases (73%), and 1 suture was used in 26 cases (27%). Among patients who underwent SF, a single clip was used in all cases.

Stent placement was performed for benign strictures in 174 patients (56%), leaks/fistulas/perforations in 135

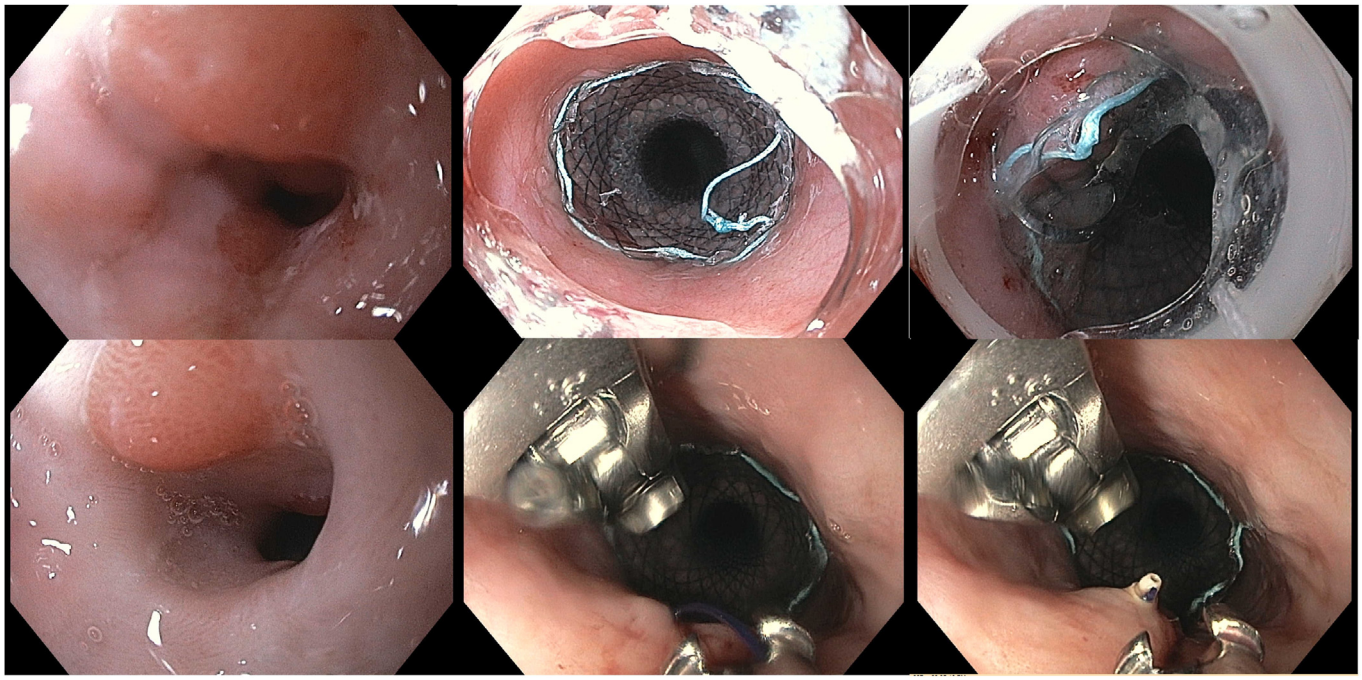


Figure 1. Stent fixation techniques. **Top,** Stent fixation with endoscopic suturing. **Bottom,** Stent fixation with the dedicated over-the-scope clip device fixation system.

patients (43%), and refractory variceal bleeding in 2 patients (0.6%). Of this cohort, 307 patients (98.7%) underwent 1 stenting procedure, 3 patients (1%) underwent 2 procedures, and 1 patient (0.3%) underwent 3 procedures. Stents remained in position and were functional for a median of 31 days (interquartile range [IQR], 20-60 days). The stents placed for benign strictures were in situ for a median of 49 days (IQR, 29-75 days), the stents placed for leaks/fistulas/perforations were in situ for a median of 28 days (IQR, 9-60 days), and the stents placed for refractory variceal bleeding were in situ for a median of 8 days (IQR, 1-7 days).

The 316 stents that were placed included the WallFlex (Boston Scientific; 133 stents, 42.1%), Agile (Boston Scientific; 9 stents, 2.8%), Alimaxx-E (Merit Medical, South Jordan, Utah, USA; 29 stents, 9.2 %), Niti-S (Taewoong Medical, Seoul, South Korea; 71 stents, 22.5 %), Hanarostent (M.I. Tech., Seoul, South Korea; 9 stents, 2.8 %), Bonastent (EndoChoice, Alpharetta, Ga, USA; 15 stents, 4.7 %), EndoMAXX (Merit Medical; 23 stents, 7.3 %) stents, Evolution (Cook, Winston-Salem, NC, USA; 9 stents, 2.8%), Gore Viabil (W.L. Gore & Associates, Flagstaff, Ariz, USA; 3 stents, 1%), Danis Seal (Ella-CS, Hradec Králové, Czech Republic; 12 stents, 3.8 %), Aixstent (Leufen Medical GmbH, Aachen, Germany; 1 stent, 0.3%), and Micro-Tech (Micro-Tech Medical Company, Nanjing, China; 2 stents, 0.6%). Stent diameter and stent length were not significantly different among the 3 groups (Table 1).

The mean procedure duration was 41.7 ± 34.5 minutes for the NF group, 79.5 ± 53.3 minutes for the ES group, and 66 ± 44.9 minutes for the SF group. The NF group had a significantly shorter procedure duration compared with both the ES group ($P < .01$) and the SF group ($P < .01$). The procedure duration for the SF group was numerically shorter compared with the ES group but did not reach statistical significance ($P = .06$).

In our cohort, stent migration occurred in 88 of the 316 cases (28%) a median of 29 days (IQR, 9-49 days) after index stent placement. Stent migration was identified during both routine follow-up endoscopy and on-demand imaging study or endoscopy when evaluating unexpected changes in clinical presentation. Aside from stent migration, a total of 34 AEs occurred (11% per procedure). Of the 311 patients in our cohort, 186 (59.8%) had follow-up data available after stent removal. The median follow-up after stent removal was 256 days (IQR, 85-600 days).

In the NF group, stent removal was completed in 115 of 127 cases. The most frequent reason the stent could not be removed endoscopically was stent migration (n = 11; 92%). In 1 case, there was a tight stricture proximal to the stent that precluded removal. All stents were removed with rat-tooth forceps. In the ES group, stent removal was completed in 89 of 95 cases. The stent was not retrieved in 4 cases owing to stent migration and in 2 cases owing to loss of patient to follow-up. All stents were removed with the use of endoscopic scissors or a loop cutter to cut the suture, followed by rat-tooth forceps. In the SF group, endoscopic removal of the stent was achieved in 86 of 94 cases. The stent was not retrieved in 4 cases owing to patient death from medical AEs unrelated to the stent, in 3 cases owing to loss of patient to follow-up, and in 1 case owing to stent

TABLE 1. Baseline patient characteristics

	NF group (n = 122)	SF group (n = 94)	ES group (n = 95)	*P* value
Age, y	60 ± 16	62 ± 14	56 ± 16	.12
Male sex	60 (49)	47 (50)	47 (59)	.09
Site of pathology				.08
Esophagus	102 (84)	81 (86)	74 (78)	
Stomach	19 (16)	12 (13)	18 (19)	
Small bowel	1 (1)	1 (1)	3 (3)	
History of previous stenting	36 (30)	31 (33)	32 (34)	.92
History of previous stent migration	16 (13)	14 (15)	18 (19)	.37
Distal end of stent				.23
In the esophagus	37 (36)	46 (57)	38 (51)	
Below the gastroesophageal junction	65 (64)	35 (43)	36 (49)	
Indication for stent placement				.86
Stricture	67 (55)	55 (59)	52 (55)	
Idiopathic	16	13	9	
Anastomotic stricture	15	7	24	
Radiation	5	12	0	
Peptic stricture	14	8	17	
Caustic stricture	4	2	0	
Other causes	13	13	2	
Leak/fistula/perforation	53 (43)	39 (41)	43 (45)	
After bariatric surgery	3	6	10	
Anastomotic leak	32	18	22	
Iatrogenic perforation	12	13	10	
Other causes	6	2	1	
Other indications	2 (2)	0 (0)	0 (0)	
Refractory variceal bleeding	2	0	0	
Size of lesion, mm	13.3 ± 14.6	12.8 ± 8.7	12.0 ± 10.8	.79
Stent diameter				.08
≤18 mm	52 (41)	44 (47)	41 (43)	
>18 mm	75 (59)	50 (53)	54 (57)	
Stent length				.83
<12 cm	56 (44)	44 (47)	52 (55)	
≥12 cm	71 (56)	50 (53)	43 (45)	
Adjunctive endoscopic treatment with stent placement				.66
Dilatation	12 (9.4)	8 (8.5)	5 (5.3)	
Incisional therapy	3 (2.4)	1 (1.1)	1 (1.1)	
Kenalog injection	1 (0.8)	1 (1.1)	1 (1.1)	

Values are mean ± SD or n (%).
ES, Endoscopic suture fixation, *NF*, no fixation, *SF*, Stentfix over-the-scope clip device.

migration requiring surgical removal. Only 7 cases (7.4%) required the use of the dedicated clip removal system (Remove DC cutter; Ovesco Endoscopy) before stent removal. In the remaining 92.6% of cases (n = 87), the stent and clip were successfully removed with the use of rat-tooth forceps alone. There were no reported cases of spontaneous OTSC detachment. In all 3 groups, there were no reported AEs associated with stent removal.

The technical success rate of stent fixation was 100% for SF and 98% for ES. Compared with the NF group (n = 49; 39%), the rates of stent migration were significantly lower in the SF group (n = 16; 17%; *P* = .001) and the ES group

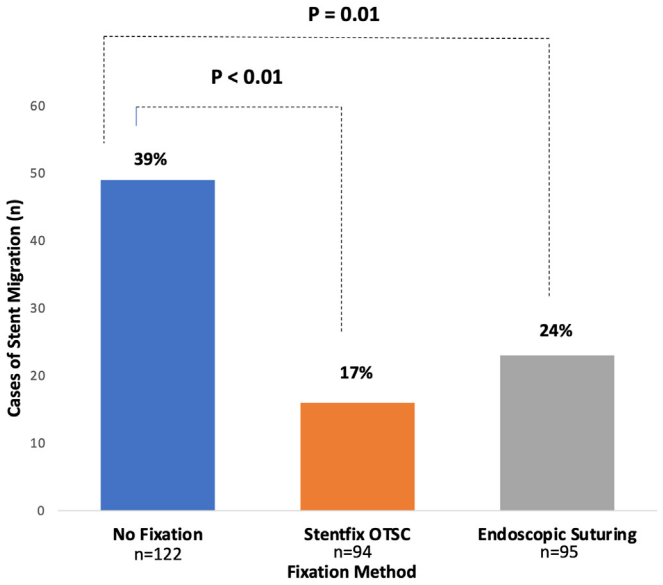


Figure 2. Comparison of stent migration with and without stent fixation. *OTSC*, Over-the-scope clip device.

(n = 23; 24%; $P = .01$) (Fig. 2). The rates of stent migration were not different between the SF and ES groups ($P = .2$). The median time to stent migration for the SF group (38 ± 68 days) was significantly greater than for the NF group (24 ± 26 days; $P = .04$). The median time to stent migration for the ES group (34 ± 37 days) was also greater than the NF group (24 ± 26 days), but the difference was not statistically significant ($P = .1$).

On univariate analysis, a history of previous stenting (odds ratio [OR], 0.51; 95% confidence interval [CI], 0.27-0.96; $P = .03$) and stent fixation with both SF (OR, 0.36; 95% CI, 0.18-0.72; $P < .01$) and ES (OR, 0.52; 95% CI, 0.27-0.99; $P = .04$) were associated with a decreased risk of stent migration. In contrast, shorter stent length, which was defined as <12 cm, was associated with an increased risk of stent migration (OR, 1.97; 95% CI, 1.15-3.37; $P = .01$). On multivariate analysis, shorter stent length (OR, 2.17; 95% CI, 1.18-3.97; $P = .01$) was independently associated with an increased risk of stent migration, whereas anchoring with either SF (OR, 0.34; 95% CI, 0.17-0.70; $P < .01$) or ES (OR, 0.46; 95% CI, 0.23-0.91; $P = .02$) was independently associated with a decreased risk of stent migration (Table 2).

Clinical success was achieved in 194 patients (62%), including 94 (70%) with leaks/fistulas/perforations, 98 (56%) with benign strictures, and 2 (100%) with refractory variceal bleeding. Compared with the NF group (n = 64; 52%), there were higher rates of clinical success in the SF (n = 64; 68%; $P = .03$) and ES (n = 66; 69%; $P = .02$) groups. Of the 119 patients (38%) that did not respond to endoscopic stenting, 40 patients (30%) were being treated for leaks/fistulas/perforation and 78 (44%) for a benign stricture. Of those patients, 74 (62%) were subsequently managed with further endoscopic intervention, 10 (8%) with surgical intervention, 3 (2.5%) with diet restriction, and 2 (2%) with PEG placement. Furthermore, 5 patients (4%) ultimately died from causes unrelated to the procedure, and 30 patients (25%) lacked further follow-up data.

The rate of stent-related AEs, excluding stent migration, was not significantly different in the NF group (n = 19; 15%) compared with the ES (n = 9; 9.5%; $P = .3$) and SF (n = 10; 10.6%; $P = .4$) groups. In all groups, the most frequent AE was stent-related ulceration (n = 17), followed by chest pain (n = 7). There were no AEs directly related to either stent fixation technique (Table 3). Finally, for those migrated stents that could not be retrieved, there were no reported AEs attributed to the migrated stents permitted to pass spontaneously.

DISCUSSION

In this comparative study, we found that stent fixation using either a dedicated OTSC fixation system or ES in patients with benign UGI conditions was associated with a significant reduction in stent migration and improved clinical response compared with NF. There was no significant difference found between OTSC fixation and ES in terms of the rate of stent migration, clinical success, and AEs.

We found that in a cohort of patients with benign UGI diseases, OTSC fixation appeared to be clinically effective. Use of OTSC fixation was associated with both a lower rate of stent migration (17% vs 39%) and a longer time to stent migration (38 vs 24 days) compared with NF. Stent fixation with ES also was associated with a lower rate of stent migration compared with NF (24% vs 39%). When comparing the 2 stent fixation methods, we found no significant difference in rate or time to stent migration between OTSC fixation and ES, in contrast to the study by Park et al.[12] There were, however, some important differences between the 2 studies that could account for the divergent findings. First, the previous study included colonic stents, whereas ours evaluated stent placement for only UGI diseases. Furthermore, the 57% rate of stent migration after ES was significantly higher than either our study (24%) or previous reports in the literature (16%).[5-7,12] We also found that stent length affected the frequency of migration, with a shorter stent length being independently associated with an increased risk of stent migration. These results are consistent with those reported in other prior studies.[5]

Overall, clinical success was achieved in 196 patients (63%). Compared with patients without stent fixation, we found that patients who underwent stent fixation with either OTSC placement or ES had a higher rate of clinical success. These results are consistent with previous studies demonstrating stent fixation results in improved clinical success.[5-7,12] It is unlikely that the stent fixation technique used had any direct therapeutic benefit but was rather an indirect

TABLE 2. Factors associated with stent migration

	OR	95 % CI	*P* value
Univariate logistic regression analysis (crude OR)			
Age	1.00	0.98-1.01	.76
Indications (strictures vs leaks/fistulas/perforations)	1.33	0.78-2.27	.28
History of previous stenting	0.51	0.27-0.96	.03
Previous history of stent migration	1.12	0.49-2.55	.78
Stent length $\leq$120 mm vs >120 mm	1.97	1.15-3.37	.01
Fixation method			
Suture vs no fixation	0.52	0.27-0.99	.04
SF OTSC vs no fixation	0.36	0.18-0.72	<.01
Distal end of stent (in the esophagus vs below the gastroesophageal junction)	1.30	0.76-2.21	.33
Multivariable logistic regression analysis (adjusted OR)			
History of previous stenting	0.51	0.25-1.05	.06
Stent length $\leq$120 mm vs >120 mm	2.17	1.18-3.97	.01
Fixation method			
Suture vs no fixation	0.46	0.23-0 .91	.02
SF OTSC vs no fixation	0.34	0.17- 0.70	<.01

OR, Odds ratio, *SF OTSC*, Stentfix over-the-scope clip device.

TABLE 3. Stent-related adverse events

	NF group	SF OTSC group	ES group
No. of stent procedures	127	94	95
Total adverse events	19 (15%)	10 (10.6%)	9 (9.5%)
Stent-related ulceration	7	5	5
Refractory chest/abdominal pain	3	3	1
Stent obstruction due to tissue overgrowth	6	0	1
Stent fracture	0	0	1
Stent collapse	0	1	0
Perforation	1	0	1
Aspiration pneumonia	1	0	0
Reflux	0	1	0
Stricture formation	1	0	0

ES, Endoscopic suture fixation, *NF*, no fixation, *SF OTSC*, Stentfix over-the-scope clip device.

clinical benefit from the observed reduction in stent migration rates. The clinical success of the stent therapy, however, is multifactorial and only partially related to stent dwell time and the presence of stent migration. These other factors likely account for why the clinical success difference between the NF and fixation groups was smaller relative to the migration rate difference. When comparing SF and ES, we did not observe a significant difference in the rate of clinical success. This result is again different from the only other study to directly compare the 2 fixation techniques, which reported a higher rate of clinical success with SF compared with ES.[12]

We did not find that OTSC fixation negatively affected the technical success of stent removal or increased the risk of AEs. The OTSC and stent were removed together with the use of rat-tooth forceps in the majority (92.6%) of cases, with only 7 cases requiring the dedicated clip removal system. There were also no reported AEs associated with stent removal or use of the clip removal system. In our experience, during the removal procedure, the OTSC was found in place attached to the stent but more superficially adherent to the underlying esophageal wall. This may be due to the technique for clip deployment, which involves capturing both stent and esophageal wall and relies only on suction without

the aid of twin grasper or other adjunctive tools. The smaller profile of the dedicated OTSC fixation device (15.9 mm outer diameter and 7 mm depth) also may contribute to the more superficial attachment we observed.

There is a cost benefit in using the OTSC compared with ES. The dedicated OTSC fixation system is priced at $649 in the U.S., whereas the most common endoscopic suturing platform, the OverStitch system, costs approximately $1500 (which includes the cost of the device, 2 sutures, and cinches). The OTSC can be used with the same therapeutic single-channel gastroscope used for stent deployment, whereas the OverStitch requires the use of a dual-channel gastroscope, adding further cost related to additional scope reprocessing. In the present study, removal of the OTSC also was more cost-effective compared with ES, because the OTSC and stent were removed together with the use of rat-tooth forceps in most cases. In all endoscopic suturing cases, the endoscopic scissors (priced at $365 per device) were also required to cut the sutures before stent removal. Finally, even in cases where the clip removal system (Remove DC cutter) was required, the cost per device is around $400, which is still significantly less than the combined cost of the suturing system and endoscopic scissors.

The dedicated OTSC fixation system was introduced in 2019, but despite its advantages and availability for many years, it has not been widely adopted as a fixation technique. One of the reasons for this may be that alternative approaches to fixation, with TTS clips and ES, were both available well before the development of the OTSC fixation system. Endoscopic clips have been available since 1975 and endoscopists are all generally comfortable with their use. The OverStitch system received approval in 2011, and with the increased application of this device for bariatric endoscopy and defect closure, an increasing number of endoscopists are proficient in its use. Another barrier to wider use of the OTSC is the concern over removal of the clip at the time of stent removal. In the past, there was no standard technique for OTSC removal. Since the approval of the dedicated clip removal system (Remove DC cutter) in 2017, the removal process has become simplified. Still, many centers do not have easy access to the removal system and are not trained in its use. Interestingly, in the present study, we found that stent removal with the OTSC was managed in most cases with the use of rat-tooth forceps and only rarely required the removal system.

There are several limitations to our study. The retrospective nature of the study introduces inherent bias given a lack of patient randomization. Furthermore, not all relevant clinical data regarding the patients in the cohort were reported. The decision to perform stent fixation and the choice of using the OTSC versus ES was left to the individual endoscopist, possibly resulting in selection bias. Other factors, such as anatomic considerations like the Hill grade of the gastroesophageal junction, that could potentially further affect the endoscopists decision regarding the need for stent fixation and the technique used were not captured by the patient demographics collected in our study. Finally, the suturing technique was not standardized, with the number of stitches, the depth of suturing into the tissue, and decision to use or not use the helix being dependent on the endoscopist's discretion—all of which could result in differences in efficacy of stent fixation.

In conclusion, we provide support for the use of endoscopic fixation for FCSEMSs used for benign UGI conditions. The Stentfix dedicated OTSC fixation system is safe, efficient, and effective at decreasing the incidence of stent migration. It may also result in improved clinical response, likely owing to the reduction in stent migration. It is technically easier to use than the ES platform, it is more cost-effective, and removal of the OTSC does not typically require complex techniques beyond rat-tooth forceps. Ultimately, larger prospective studies are needed to validate these findings.

DISCLOSURE

The following authors disclosed financial relationships: B. Confer: consultant for Boston Scientific. J.J. Pineda-Bonilla: consultant for Boston Scientific. R. Pawa: consultant for Boston Scientific and Cook Medical. S. Pawa: consultant for Boston Scientific. R.E. Kim: consultant for Boston Scientific and Cook Medical. H.S. Khara: consultant for Boston Scientific, Cook Medical, ConMed, Pentax, Medtronic, and Olympus. G.O. Spaun: consultant for Boston Scientific. K.H. Park: consultant for Olympus, Endorobotics, MicroTech. D.D. Diehl: consultant for Boston Scientific, Micro-Tech, Lumendi, Merit, Pentax, Actuated Medical, Steris, and Olympus. P. Kedia: consultant for Boston Scientific, Medtronic, and Olympus. M.A. Khashab: consultant for Boston Scientific and Olympus; royalties from Elsevier and UpToDate. The other authors disclosed no financial relationships.

REFERENCES

1. Reijm AN, Didden P, Schelling SJC, et al. Self-expandable metal stent placement for malignant esophageal strictures—changes in clinical outcomes over time. Endoscopy 2019;51:18-29.
2. El Hajj II, Imperiale TF, Rex DK, et al. Treatment of esophageal leaks, fistulae, and perforations with temporary stents: evaluation of efficacy, adverse events, and factors associated with successful outcomes. Gastrointest Endosc 2014;79:589-98.
3. Bakken JC, Wong K, Song LM, et al. Use of a fully covered self-expandable metal stent for the treatment of benign esophageal diseases. Gastrointest Endosc 2010;72:712-20.
4. Schiemer M, Bettinger D, Mueller J, et al. Reduction of esophageal stent migration rate with a novel over-the-scope fixation device (with video). Gastrointest Endosc 2022;96:1-8.
5. Ngamruengphong S, Sharaiha RZ, Sethi A, et al. Endoscopic suturing for the prevention of stent migration in benign upper gastrointestinal conditions: a comparative multicenter study. Endoscopy 2016;48:802-8.
6. Law R, Prabhu A, Fujii-Lau L, Shannon C, Singh S. Stent migration following endoscopic suture fixation of esophageal self-expandable

metal stents: a systematic review and meta-analysis. Surg Endosc 2018;32:675-81.
7. Bick BL, Imperiale TF, Johnson CS, et al. Endoscopic suturing of esophageal fully covered self-expanding metal stents reduces rates of stent migration. Gastrointest Endosc 2017;86:1015-21.
8. Irani S, Baron TH, Gluck M, et al. Preventing migration of fully covered esophageal stents with an over-the-scope clip device (with videos). Gastrointest Endosc 2014;79:844-51.
9. Watanabe K, Hikichi T, Nakamura J, et al. Feasibility of esophageal stent fixation with an over-the-scope-clip for malignant esophageal strictures to prevent migration. Endosc Int Open 2017;5:e1044-9.
10. Conio M, Savarese MF, Baron TH, et al. A newly designed over-the-scope-clip device to prevent fully covered metal stents migration: a pilot study. Techn Innovat Gastrointest Endosc 2020;22:167-71.
11. Zimmer V. Sequential duodeno-biliary double metal stenting in Mutignani type I obstruction facilitated by Stentfix OTSC anchoring device. Ann Gastroenterol 2021;34:286.
12. Park KH, Lew D, Samaan J, et al. Comparison of no stent fixation, endoscopic suturing, and a novel over-the-scope clip for stent fixation in preventing migration of fully covered self-expanding metal stents: a retrospective comparative study (with video). Gastrointest Endosc 2022;96:771-9.
13. Kantsevoy SV, Bitner M. Esophageal stent fixation with endoscopic suturing device (with video). Gastrointest Endosc 2012;76:1251-5.
14. Sharaiha RZ, Kumta NA, Doukides TP, et al. Esophageal stenting with sutures: time to redefine our standards? Journal of clinical gastroenterology 2015;49:e57-60.

Abbreviations: AE, adverse event; ES, endoscopic suturing; FCSEMS, fully covered self-expandable metal stent; NF, no fixation; OTSC, over-the-scope clip device; SF, Stentfix OTSC; TTS, through-the-scope; UGI, upper GI.

This video can be viewed directly from the *GIE* website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

0016-5107/$36.00
https://doi.org/10.1016/j.gie.2024.08.015

Received March 26, 2024. Accepted August 15, 2024.

Current affiliations: Johns Hopkins Medicine, Baltimore, Maryland, USA (1), University of Maryland Medical System, Baltimore, Maryland, USA (2), University of Oklahoma, Norman, Oklahoma, USA (3), Ordensklinikum Linz, Oberösterreich, Austria (4), IRCCS Ospedale San Raffaele, Milano, Italy (5), Cedars-Sinai Medical Center, Los Angeles, California, USA (6), Geisinger Medical Center, Danville, Pennsylvania, USA (7), Lewis Gale Medical Center, Salem, Virginia, USA (8), Methodist Dallas Medical Center, Dallas, Texas, USA (9), Universitatsklinikum Freiburg, Baden-Württemberg, Germany (10), Azienda Ospedaliera di Perugia, Perugia, Italy (11), Medizinische Universitat Wien, Wien, Austria (12), University College London, London, United Kingdom (13), Wake Forest Baptist Health, Winston-Salem, North Carolina, USA (14), NYU Langone Health, New York, New York, USA (15), Hospital Universitari Arnau de Vilanova, Lleida, Catalunya, Spain (16).

Reprint requests: Mouen A. Khashab, MD, Department of Gastroenterology, Johns Hopkins University, 1800 Orleans St, Baltimore, MD 21287. E-mail: moritz.schiemer@rbk.de.