

Safety and Efficacy of Through-the-Scope Fully Covered Self-Expanding Metal Stents Across Diverse Benign and Malignant Esophageal Pathologies - A Retrospective Cohort Study (with video)

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Abstract

Background and Aims

Through-the-scope (TTS) fully covered self-expanding metal stents (FCSEMSs) are an emerging endoscopic stent platform that permit deployment through the working channel of a therapeutic endoscope under continuous endoscopic visualization, frequently without fluoroscopy. Compared with conventional over-the-wire (OTW) systems, TTS stents may offer practical advantages, including improved positional control in angulated or surgically altered anatomy, reduced reliance on fluoroscopy, and broader procedural accessibility. However, published experience with TTS FCSEMSs is limited and mainly focused primarily on malignant dysphagia, and data supporting their use across broader esophageal and foregut indications, including luminal defects, bleeding, and complex benign conditions, remain limited. We aimed to evaluate the safety, technical success, clinical outcomes, and migration profile of TTS FCSEMSs deployed across diverse benign and malignant esophageal and foregut indications in routine clinical practice and to contextualize these findings within the published OTW SEMS literature.

Methods

We conducted a single-center retrospective cohort study of consecutive adults undergoing TTS FCSEMS placement at Ruby Memorial Hospital, West Virginia University (January 2020–August 2025). Indications included malignant obstruction and a broad range of benign pathologies: refractory peptic, radiation-induced, and anastomotic strictures; post-sleeve gastrectomy and anastomotic leaks; iatrogenic and spontaneous perforations; esophageal fistulas; ulcer-related hemorrhage; and eroded intragastric devices. Technical success was defined as complete stent deployment at the intended location. Clinical success was defined as 30-day reintervention-free survival and/or meaningful symptomatic improvement at 14 days. Migration-free survival was analyzed using Kaplan-Meier methods, and adverse events were classified by standardized criteria.

Results

Sixty-four patients underwent 64 index TTS FCSEMS procedures (27 benign, 37 malignant); median age was 63 years. Indications spanned strictures (20.3%), malignancy (57.8%), leaks (9.4%), perforations (6.3%), fistulas (1.6%), bleeding ulcers (3.1%), and eroded gastric band (1.6%). Technical success was 100% in both groups. Clinical success was achieved in 44 of 64 patients (68.8%): 66.7% benign, 70.3% malignant. Fluoroscopy was used in only 46.9% of procedures. Stent migration occurred in 7 patients (10.9%); all were managed endoscopically. Overall adverse events occurred in 11 patients (17.2%), comprising intolerance requiring removal (7.8%), tissue overgrowth (6.3%), and bleeding (3.1%). No perforations or procedure-related deaths occurred. Migration rates were substantially lower than historical OTW series (25–40%), attributable in part to endoscopic fixation in 79.7% of cases.

Conclusions

TTS FCSEMS placement demonstrated high technical success, acceptable clinical effectiveness, and a favorable safety profile across a broad spectrum of benign and malignant esophageal and foregut indications beyond malignant dysphagia. The platform allowed frequent deployment without fluoroscopy and may offer practical advantages in challenging anatomy and urgent clinical scenarios. Endoscopic fixation was commonly used and may have contributed to the low observed migration rate. Further prospective comparative studies are needed.

INTRODUCTION

Self-expanding metal stents (SEMS) are essential tools in interventional gastroenterology, enabling restoration of luminal patency and structural integrity. Available in uncovered, partially covered, and fully covered configurations, SEMS exert radial force to relieve obstruction, seal luminal defects, and facilitate oral intake while avoiding or delaying surgical intervention. [1, 2] In the esophagus, stent therapy has become an established treatment for malignant dysphagia and refractory benign strictures. Fully covered SEMS (FCSEMSs) offer the additional advantages of removability and reduced tissue ingrowth, and have increasingly been used for other benign foregut conditions, including postoperative leaks, anastomotic dehiscence, fistulas, and perforations. [3, 4]

Conventional esophageal SEMS are commonly deployed using over-the-wire (OTW) delivery systems, typically under fluoroscopic guidance. This technique is well validated and widely practiced. However, OTW deployment requires guidewire access, fluoroscopy availability, and coordinated procedural workflows. These requirements can create logistical barriers, delay intervention in urgent settings, increase reliance on specialized endoscopy or fluoroscopy units, and limit access in resource-constrained environments.

Through-the-scope (TTS) stent delivery systems permit stent deployment directly through the working channel of a therapeutic endoscope under continuous endoscopic visualization, frequently without fluoroscopy. This design can simplify procedural workflow, improve real-time positional control, reduce dependence on fluoroscopy, and facilitate stent placement in anatomically challenging or surgically altered anatomy. The ability to perform stent deployment and, when needed, endoscopic fixation during the same session under direct visualization represents a meaningful procedural advantage, particularly in complex or urgent clinical scenarios.

Most published experience with TTS esophageal FCSEMSs has focused on palliation of malignant dysphagia. However, the clinical scenarios in which esophageal stents are used extend beyond malignant obstruction and include refractory benign strictures, postoperative leaks, anastomotic dehiscence, iatrogenic perforations, fistulas, bleeding, and complications of bariatric or foregut surgery. These conditions often require precise deployment in difficult positions, making TTS technology potentially attractive.

Current European Society of Gastrointestinal Endoscopy (ESGE) guidelines endorse partially covered or fully covered SEMS for palliation of malignant dysphagia and support their use in selected benign

indications, including refractory benign strictures and luminal defects. [1] However, the evidence base supporting esophageal stenting is derived largely from OTW stent series. Data evaluating TTS FCSEMS performance across a broader spectrum of benign and malignant esophageal pathology remain limited.

In this study, we evaluated the technical success, clinical outcomes, migration rates, and adverse events associated with TTS FCSEMS placement across diverse benign and malignant indications in routine clinical practice. We also contextualized these findings within the broader SEMS literature to better define the potential role of TTS FCSEMSs as an accessible and versatile endoscopic stenting platform.

METHODS

Study Design and Population

We retrospectively reviewed medical records of consecutive adult patients (age ≥ 18 years) who underwent TTS FCSEMS placement at Ruby Memorial Hospital, West Virginia University, between January 2020 and August 2025. This study was approved by the WVU Institutional Review Board (protocol 2304757276).

Benign indications included: refractory peptic, radiation-induced, and anastomotic (esophagojejunal or gastrojejunal) strictures; post-sleeve gastrectomy and anastomotic leaks; iatrogenic or spontaneous esophageal and duodenal perforations; benign esophageal fistulas; ulcer-related bleeding; and intragastric device erosion (lap band). Malignant indications included primary or recurrent esophageal and gastroesophageal junction malignancies presenting with dysphagia, obstruction, or malignant fistula.

Cases were excluded if a stent was already in situ at the time of the index procedure, if patients were younger than 18 years or pregnant, or if clinical or procedural data were incomplete. Extracted variables included patient demographics, comorbidities, lesion characteristics (location, length, diameter), procedural details (stent model, size, fixation approach, fluoroscopy or guidewire use), and outcomes.

Procedural Technique

All procedures were performed by experienced advanced endoscopists (SS, ST, MK) under general anesthesia or monitored anesthesia care using a therapeutic upper endoscope with a large-caliber working channel. Stents used included the HANAROSTENT (Olympus America, Center Valley, PA) and Niti-S (Taewoong-Medical Co., Ltd., Ilsan, Korea). Procedures were conducted under direct endoscopic visualization, with or without fluoroscopic assistance at operator discretion.

For strictures, the stenotic segment was delineated endoscopically and, when necessary, fluoroscopically. A 0.035-inch long guidewire was advanced across the narrowed lumen, the delivery system was introduced over the guidewire, and the stent was deployed to cover the stricture with at least

2-cm overlap at both margins. Balloon dilation of strictures was performed before deployment in selected cases to facilitate deep guidewire passage, luminal access, and support accurate stent positioning, particularly when fluoroscopy was not used.

For luminal defects (leaks, perforations, fistulas), the stent was positioned to completely cover the defect margins, diverting luminal contents and allowing controlled internal drainage when clinically indicated. For bleeding or dehiscence, the stent served as a mechanical barrier.

Stent fixation was performed in most procedures to mitigate migration. Fixation techniques were selected based on anatomical location, tissue quality, and operator judgment: over-the-scope suturing (OverStitch, Apollo Endosurgery, Austin, TX), through-the-scope suturing (X-Tack, Apollo Endosurgery), and over-the-scope clips (Stentfix, Ovesco Endoscopy, Tübingen, Germany).

Stent placement and suturing are depicted in Video 1.

Outcome Definitions

Technical success was defined as complete stent deployment and expansion at the intended location, confirmed endoscopically and/or fluoroscopically. Clinical success was defined as meaningful symptomatic improvement or resolution within approximately 14 days and 30-day reintervention-free survival. For strictures, clinical success was determined by improvement on the Ogilvie dysphagia scale (0 = no dysphagia; 4 = complete dysphagia). For luminal defects, clinical success required endoscopic or radiographic evidence of defect closure or control with symptom resolution. For hemorrhage, clinical success required hemostasis.

Migration was defined as stent displacement beyond the target lesion, confirmed endoscopically or radiographically. Other adverse events (AEs) included bleeding, perforation, tissue overgrowth causing obstruction, food impaction, and premature stent removal due to intolerance (nausea, chest pain, or reflux). Dwell time was measured from placement to removal, migration, death, or last available follow-up.

Statistical Analysis

Continuous data are summarized as medians with interquartile ranges (IQR) or means with standard deviations (SD). Categorical data are presented as frequencies and proportions. 95% confidence intervals for proportions were computed using the Wilson/Brown hybrid method. Time-to-event outcomes were analyzed using the Kaplan-Meier product-limit method. All analyses were performed in MATLAB R2024b (The MathWorks Inc., Natick, MA, USA).

RESULTS

Cohort Characteristics

Sixty-four patients underwent TTS FCSEMS placement during the study period: 27 with benign indications and 37 with malignant strictures (Table 1). Median age was 63 years (IQR 50–71); the malignant subgroup was predominantly male (83.8%), whereas the benign group had a more balanced sex distribution (female: 63%).

Table 1
Patient and Procedure Characteristics

Characteristic	Overall (n = 64)	Benign (n = 27)	Malignant (n = 37)
Age, years - median (IQR)	63 (50–71)	59 (43–67)	66 (58–74)
Female sex, n (%)	23 (35.9)	17 (63.0)	6 (16.2)
White race, n (%)	62 (96.9)	26 (96.3)	36 (97.3)
Diabetes, n (%)	23 (35.9)	7 (25.9)	16 (43.2)
Hypertension, n (%)	35 (54.7)	11 (40.7)	24 (64.9)
Coronary artery disease, n (%)	14 (21.9)	0 (0)	14 (37.8)
Indication, n (%)			
Stricture	13 (20.3)	13 (48.1)	-
Leak	6 (9.4)	6 (22.2)	-
Perforation	4 (6.3)	4 (14.8)	-
Fistula	1 (1.6)	1 (3.7)	-
Bleeding ulcer	2 (3.1)	2 (7.4)	-
Eroded device (lap band)	1 (1.6)	1 (3.7)	-
Malignancy	37 (57.8)	-	37 (100)
Lesion site, n (%)			
GE junction	25 (39.1)	14 (51.9)	11 (29.7)
Lower esophagus	20 (31.3)	9 (33.3)	11 (29.7)
Mid esophagus	9 (14.1)	4 (14.8)	5 (13.5)
Mid/lower esophagus	6 (9.4)	0 (0)	6 (16.2)
Fluoroscopy used, n (%)	30 (46.9)	12 (44.4)	18 (48.6)
Guidewire used, n (%)	60 (93.8)	25 (92.6)	35 (94.6)
Stent fixed, n (%)	51 (79.7)	23 (85.2)	28 (75.7)
Fixation method (of fixed stents)			
Over-the-scope suturing (OverStitch)	41 (80.4)	14 (60.9)	27 (96.4)
Over-the-scope clips (Stentfix)	5 (9.8)	5 (21.7)	0 (0)
Through-the-scope suturing (X-Tack)	5 (9.8)	4 (17.4)	1 (3.6)
IQR, interquartile range; GE, gastroesophageal			

Characteristic	Overall (n = 64)	Benign (n = 27)	Malignant (n = 37)
Median dwell time, days (IQR)	31 (12–70)	27 (11–50)	34 (13–92)
IQR, interquartile range; GE, gastroesophageal			

In the benign subgroup, indications were distributed across strictures (48.1%), leaks (22.2%), perforations (14.8%), bleeding ulcers (7.4%), fistula (3.7%), and eroded lap band (3.7%). Peptic strictures (n = 7) were the most frequent stricture type, followed by radiation-induced (n = 4) and anastomotic (n = 2) strictures; all stricture patients had a history of prior endoscopic dilation. Leaks were predominantly post-sleeve gastrectomy (n = 4) with additional cases of Roux-en-Y and esophagojejunal anastomotic dehiscence. Perforations included duodenal ulcer perforations, a GE junction perforation, and an iatrogenic mid-esophageal perforation. The most common benign lesion locations were the GE junction (51.9%) and lower esophagus (33.3%). Baseline dysphagia in the stricture cohort was score 2 in 9 patients (69.2%) and score 3 in 4 patients (30.8%).

In the malignant subgroup, esophageal adenocarcinoma accounted for 81.1% of cases, followed by squamous cell carcinoma (13.5%) and neuroendocrine tumors (5.4%). Baseline dysphagia was high: score 3 in 56.8% and score 4 in 32.4% of patients. The majority of malignant lesions were located in the lower esophagus or GE junction (67.6%). Stents most commonly deployed were 20 mm x 100 mm, 120 mm, and 150 mm.

Most procedures involved guidewire assistance (overall 93.8%; benign 92.6%; malignant 94.6%). Fluoroscopy was used in 46.9% of procedures overall (benign 44.4%; malignant 48.6%), reflecting frequent deployment under endoscopy alone. Stent fixation was performed in 79.7% of cases (benign 85.2%; malignant 75.7%), with over-the-scope suturing (OverStitch) as the predominant technique across both subgroups (benign 60.9%; malignant 96.4%). Median dwell time was 27 days in the benign and 34 days in the malignant subgroup.

Outcomes

Outcome data are presented in Table 2. Technical success was achieved in all 64 procedures (100%). Clinical success was achieved in 44 of 64 patients (68.8%, 95% CI 57.3–78.5%): 18 of 27 benign (66.7%, 95% CI 47.8–81.4%) and 26 of 37 malignant (70.3%, 95% CI 54.2–82.5%).

Table 2
Outcomes

Outcome	Overall (n = 64)	Benign (n = 27)	Malignant (n = 37)
Technical success, n (%)	64 (100)	27 (100)	37 (100)
Clinical success, n (%) [95% CI]	44 (68.8) [57.3–78.5]	18 (66.7) [47.8–81.4]	26 (70.3) [54.2–82.5]
Stent migration, n (%)	7 (10.9)	2 (7.4)	5 (13.5)
Adverse events (overall), n (%) [95% CI]	11 (17.2) [9.8–28.3]	3 (11.1) [3.9–28.1]	8 (21.6) [11.1–37.8]
Intolerance requiring removal (incl. food impaction)	5 (7.8)	2 (7.4)	3 (8.1)
Bleeding	2 (3.1)	1 (3.7)	1 (2.7)
Tissue overgrowth causing obstruction	4 (6.3)	0 (0)	4 (10.8)
Perforation	0 (0)	0 (0)	0 (0)
Median migration-free survival, days	-	58	167
CI, confidence interval			

Among benign stricture patients, 7 of 13 (53.8%) achieved complete dysphagia resolution (score 0) at two weeks, with a further 4 (30.8%) improving to score 1. Among malignant patients, 12 (32.4%) improved to score 0–1 and an additional 9 (24.3%) to score 2 at two weeks. Clinical success at two weeks was not evaluable in 5 malignant patients: 3 died, 1 had early stent migration requiring removal, and 1 entered hospice care.

Stent migration occurred in 7 of 64 patients (10.9%): 2 benign (7.4%) and 5 malignant (13.5%). Kaplan-Meier estimates for migration-free survival are shown in Fig. 1; median migration-free survival was 58 days in the benign subgroup and 167 days in the malignant subgroup. All migrated stents were retrieved endoscopically without sequelae.

Adverse events occurred in 11 of 64 patients (17.2%). In the benign subgroup, 2 patients (7.4%) required stent removal for intolerance and 1 (3.7%) experienced bleeding. In the malignant subgroup, tissue overgrowth with obstruction was noted in 4 patients (10.8%), 3 (8.1%) required removal for intolerance (including food impaction), and 1 (2.7%) had bleeding. No perforations or procedure-related deaths occurred.

DISCUSSION

This study presents, to our knowledge, one of the most comprehensive real-world evaluations of through-the-scope (TTS) fully covered self-expanding metal stents (FCSEMSs) across a broad spectrum

of benign and malignant esophageal and foregut indications. In addition to malignant obstruction and refractory benign strictures, indications included postoperative leaks, anastomotic dehiscence, perforations, fistulas, ulcer-related bleeding, and eroded intragastric devices. Across diverse clinical scenarios, technical success was achieved in all cases (100%), and clinical success was achieved in 68.8% of patients, with similar rates in benign (66.7%) and malignant (70.3%) subgroups. Stent migration occurred in 10.9% of patients, the overall adverse event rate was 17.2%, and no procedure-related perforations or deaths were observed.

A central question in contemporary esophageal stenting is how TTS platforms should be positioned relative to established over-the-wire (OTW) systems. OTW stents remain widely used and have several important advantages, including broad availability, familiarity, larger stent diameters (e.g., 23 mm), and higher radial force. These features may be advantageous in selected cases, particularly in cases with dilated gastrointestinal lumen. However, newer TTS FCSEMSs are now available in diameters up to 22 mm, substantially closing the size gap. The key differentiating limitation of TTS stents is lower radial force, which is largely a product of their constrained delivery profile and represents a real but manageable challenge. In this cohort, endoscopic fixation (applied in 79.7% of cases) effectively mitigated this disadvantage: migration rates of 10.9% compare favorably to the 25–40% migration rates reported in OTW SEMS series without fixation. [5, 6] These findings suggest that the combination of a TTS stent with endoscopic fixation can replicate the migration resistance of conventional OTW deployment — while preserving the procedural simplicity that defines TTS technology.

The ability to deploy TTS FCSEMSs without fluoroscopy is another important practical advantage. Conventional OTW deployment often requires guidewire access, fluoroscopy-guided positioning, stent loading, and coordination with radiology or a fluoroscopy-equipped suite. In our cohort, stent placement was performed without fluoroscopy in more than half of procedures (53.1%). Reducing reliance on fluoroscopy may lower radiation exposure to patients and staff and remove a logistical bottleneck that can delay treatment in urgent settings, such as iatrogenic perforation or bleeding. This feature may be particularly relevant in community hospitals, resource-limited settings, or endoscopy units without immediate fluoroscopy availability. It may also broaden the accessibility of esophageal stenting to gastroenterologists and endoscopists who do not routinely perform fluoroscopy-guided interventions, provided appropriate training, patient selection, and support for stent fixation are available.

Prior studies of TTS esophageal stents have focused primarily on malignant dysphagia. Mangiavillano et al. reported high technical success with no early major adverse events, and Vermeulen et al. reported high technical success and short-term clinical improvement in malignant cases. [7, 8] Our findings are consistent with the technical reliability reported in these studies and extend the experience to a broader range of benign and malignant foregut indications, including post-bariatric leaks, anastomotic dehiscence, perforations, fistulas, and hemorrhage.

These are clinical scenarios in which direct endoscopic visualization and precise deployment may offer important anatomical and workflow advantages. In altered or angulated postsurgical anatomy, TTS

deployment may be particularly useful. OTW positioning can be limited by the larger caliber and relative rigidity of conventional stent delivery systems, as well as by difficulty maintaining guidewire access, reduced wire stability, or loss of traction across angulated segments. In contrast, TTS systems allow the endoscope to be advanced directly to the target site, enabling controlled stent deployment under continuous endoscopic visualization even in challenging anatomy. This may be particularly advantageous when treating leaks, fistulas, or luminal defects located in the stomach, duodenum, at surgical anastomoses, or within surgically altered foregut anatomy, where precise positioning and controlled deployment are critical.

In our study, functional outcomes were clinically meaningful. In the benign stricture cohort, 84.6% of patients improved to a dysphagia score of 0–1 within approximately 2 weeks, consistent with effective luminal restoration. In the malignant cohort, baseline dysphagia was severe, with 89.2% of patients having a dysphagia score of 3–4. At approximately 2 weeks, 32.4% improved to a score of 0–1, and an additional 24.3% improved to a score of 2, reflecting meaningful short-term palliation. Beyond strictures and malignant obstruction, TTS FCSEMSs were also used for bleeding, leaks, and perforations, where they provided mechanical tamponade, luminal coverage, internal diversion, or structural support.

Adverse events were consistent with known limitations of esophageal and foregut stenting. Tissue overgrowth causing obstruction occurred exclusively in the malignant subgroup (10.8%), likely reflecting progressive tumor growth at the stent margins. Although the fully covered configuration reduces tissue ingrowth through the stent interstices, it does not prevent tumor overgrowth at the proximal or distal ends with longer dwell times. Intolerance requiring removal (7.8%) was comparable across subgroups and consistent with published rates. No procedure-related perforations or deaths occurred, supporting the procedural safety of TTS deployment in experienced hands.

This study has several limitations. The retrospective, single-center design introduces selection bias and limits generalizability. The cohort included heterogeneous indications, and clinical success was necessarily defined according to indication, which may limit direct comparison across subgroups. Dysphagia improvement was partly patient-reported and therefore subjective. Long-term outcomes were limited by early mortality in the malignant subgroup and incomplete follow-up in some benign cases. Stent fixation was used in most procedures, making it difficult to isolate the independent effect of the TTS platform from the effect of fixation. The absence of a direct OTW comparator group precludes direct head-to-head comparison; OTW benchmarks are drawn from published literature and may reflect differences in patient selection, stent design, or era of practice.

Despite these limitations, this study provides a broad real-world characterization of TTS FCSEMSs across diverse esophageal and foregut pathologies. TTS demonstrated high technical feasibility, acceptable clinical outcomes, low migration rates when frequently combined with endoscopic fixation, and a favorable safety profile. Further prospective evaluation of TTS SEMSs for benign and malignant foregut indications is needed.

CONCLUSION

TTS FCSEMS placement is a safe, technically reliable and broadly applicable endoscopic approach for selected benign and malignant esophageal and foregut conditions beyond malignant dysphagia, including refractory strictures, leaks, perforations, fistulas, bleeding, and postoperative complications. In this single-center cohort, TTS FCSEMSs achieved technical success, acceptable clinical success, low migration rates when commonly combined with endoscopic fixation, and no procedure-related perforations or deaths. The ability to deploy these stents under direct endoscopic visualization, frequently without fluoroscopy, may offer important workflow, access, and deployment advantages. Prospective comparative studies are warranted to define optimal patient selection, fixation strategies, dwell times, and the role of TTS FCSEMSs relative to conventional OTW stent platforms.

Abbreviations

TTS
through-the-scope
FCSEMS(s)
fully covered self-expanding metal stent(s)
OTW
over-the-wire
SEMS
self-expanding metal stent
ESGE
European Society of Gastrointestinal Endoscopy
WVU
West Virginia University
IRB
Institutional Review Board
GE
gastroesophageal
AE(s)
adverse event(s)
IQR
interquartile range
SD
standard deviation
CI
confidence interval

Declarations

Author contributions:

VM, SS: Conception and design, Interpretation of the data, drafting of article, Intellectual content and final approval of the manuscript

VM, AAA, AB, DA: study search, review and selection, data collection and synthesis

SM, VM, MH: statistical analysis of data and interpretation of results

All authors: critical revision of the article for important intellectual content and final approval of the article.

Disclosures: SS: Consultant for Boston Scientific, Fractyl, and Olympus; ST: Consultant for Steris; all other authors declare no conflicts of interest.

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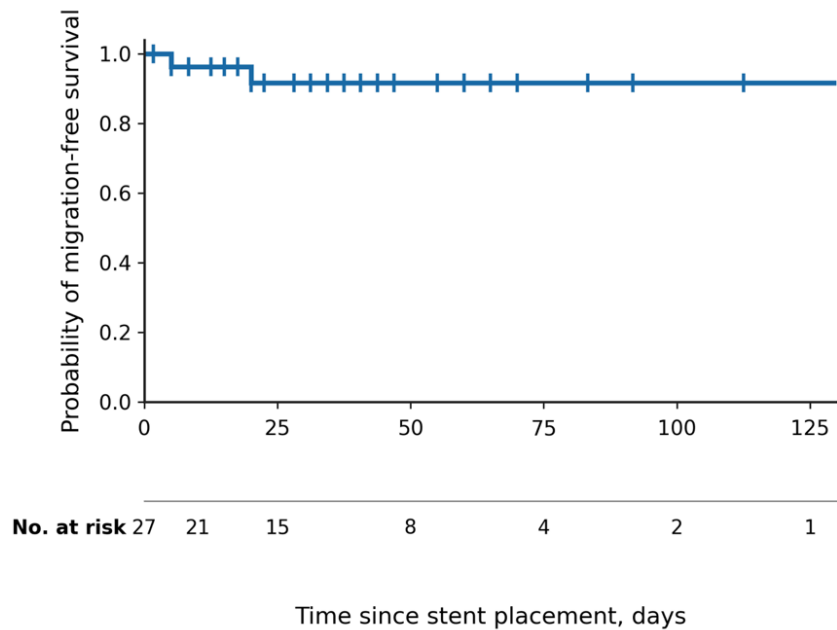
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Figures

A. Benign etiology



B. Malignant etiology

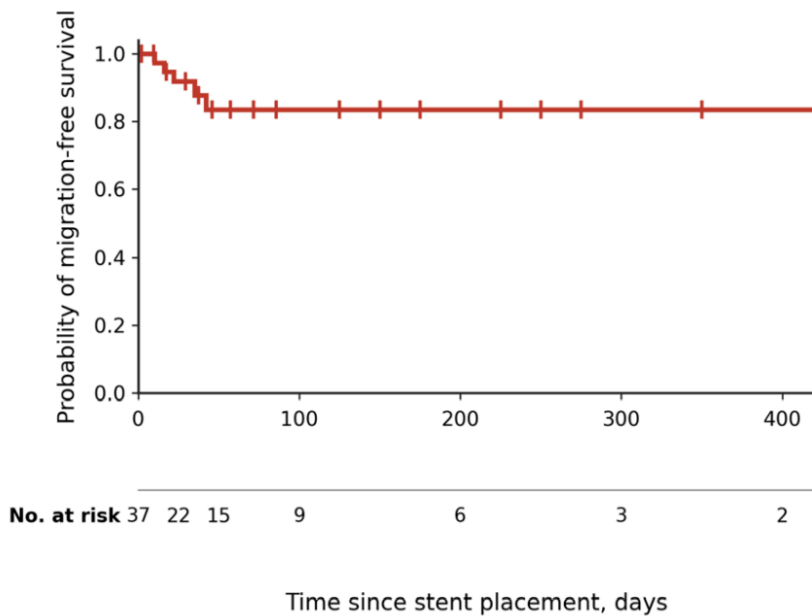


Figure 1

Kaplan-Meier estimates of migration-free survival following TTS FCSEMS placement for (A) benign and (B) malignant esophageal pathologies. The x-axis represents time in days from stent placement; the y-axis represents the probability of remaining migration-free. Numbers at risk are shown below each curve at prespecified time intervals.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [TTSSEMStentPlacement.mp4](#)