

Migration Rates, Clinical and Technical Success for Fixated Compared to Non-Fixated Fully Covered Esophageal Self-Expandable Metal Stents (FC-SEMS)

Priyaranjan Kata^{1*}, Vinay Jahagirdar², Bhanu Siva Mohan Pinnam³, Harsh K Patel⁴, Viveksandeep Thoguluva Chandrasekar⁵, Madhav Desai⁶, Prateek Sharma^{3,7} and Abhilash Periseti⁷

¹Department of Medicine MedStar St. Mary's Hospital Leonardtown, MD 20650, USA

²Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine, Richmond, VA, 23298, USA

³Kansas University Medical Center, Kansas City, Kansas, USA

⁴Midwest Digestive Health and Nutrition, Des Plaines, IL

⁵Department of Gastroenterology and Hepatology, Augusta University, Augusta, Georgia, USA

⁶Division of Gastroenterology, UTHealth, McGovern Medical School, Houston, Texas, USA

⁷Kansas City VA Medical Center, Kansas City, Missouri, USA

*Corresponding author

Priyaranjan Kata, Department of Medicine MedStar St. Mary's Hospital Leonardtown, MD 20650, USA.

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ABSTRACT

Background: Stent migration is a known complication of fully covered self-expandable esophageal metal stents (FC-SEMS), leading to reduced efficacy and repeat endoscopic intervention. Whether fixation reduces migration and improves outcomes in FC-SEMS specifically has not been established.

Methods: PubMed and Embase were searched from inception through June 2025 for studies comparing fixated and non-fixated stents. A random-effects model was used; methodological quality was assessed using a structured scoring system adapted from the Newcastle-Ottawa Scale. Prespecified subgroup analyses were performed for sutured fixation.

Results: Twenty-two studies comprising 2,337 stent placements (1,058 fixated; 1,279 non-fixated) were included. The pooled migration rate was significantly lower with fixation compared with non-fixation (15% vs. 40%; RR 0.49, 95% CI 0.38–0.63; $p < 0.01$). In the sutured fixation subgroup, the pooled migration rate was 13% (RR 0.49, 95% CI 0.37–0.65; $p < 0.01$). Technical success was near-universal in both groups, and adverse event rates were comparable (14% vs. 19%; risk ratio 0.86; $p = 0.41$). Overall fixation showed a non-significant trend toward higher clinical success (62% vs. 45%; RR 1.27, 0.98–1.66; $p = 0.07$); however, sutured fixation significantly improved clinical success compared with non-fixated stents (64% vs. 45%; RR 1.33, 1.05–1.69; $p = 0.02$).

Conclusions: Endoscopic fixation reduces migration of these stents by approximately 50% without increasing adverse events. Of the fixation methods, sutured fixation improved clinical success by 30% (not observed with overall fixation) and should be routinely considered when FC-SEMS are placed in high-risk settings.

Keywords: Esophageal stenting, Stent migration, Over-the-scope clip, Fully covered self-expandable metal stents, Meta analysis

Introduction

Esophageal self-expanding metal stents (SEMSs) are deployed for the treatment of benign and malignant conditions of the esophagus, including strictures, perforations, leaks, and fistulas [1,2]. In malignant disease, SEMS remain the principal strategy for rapid palliation of dysphagia through restoration

of luminal patency [3]. The use of fully covered SEMS for esophageal malignancy has increased modestly over the past 10 years (20-40% in esophageal malignancy-based device registries), making them a prevalent subset of esophageal stenting procedures, with variable usage among institutions. Most esophageal stents placed for malignancy are SEMS, with a shift from partially covered (PC-SEMS) to fully covered design (FC-SEMS), due to reduced tumor ingrowth and enhanced ease of removal [1,4].

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SEMS can be classified as either partially covered (PC-SEMS) or fully covered (FC-SEMS). PC-SEMS incorporate uncovered mesh segments that permit tissue ingrowth and intrinsic anchoring, at the expense of mucosal embedment and reduced removability [2,5]. On the contrary, FC-SEMS minimizes tissue ingrowth and facilitates retrieval, a design advantage offset by its higher propensity for migration, as retention depends primarily on radial force and luminal apposition [2,4].

Stent migration remains the principal limitation of FC-SEMS therapy. In benign esophageal disease, multicenter data demonstrate total migration rates of approximately 30%, with clinically relevant migration requiring reintervention approaching 17% in some series [6]. A large multicenter study specifically evaluating malignant dysphagia reported migration in approximately 25% of patients treated with FC-SEMS [7], while single-center and comparative studies of predominantly benign indications have reported migration rates for non-fixated FC-SEMS extending to 50–65%, depending on indication and study design [6, 8, 9]. Pooled estimates from prior meta-analysis place migration for non-fixated stents in the 40–50% range [10,11]. To mitigate this risk, multiple anchoring techniques have been increasingly used, including through-the-scope clips, over-the-scope clip (OTSC) anchoring, and endoscopic suturing [8,9,12,13]. Although prior comparative studies and meta-analyses support the benefit of fixation, many of these syntheses pooled FC-SEMS with PC-SEMS despite their fundamentally different baseline migration profiles, limiting inference about the stent subtype at greatest intrinsic risk of displacement [10,11,14].

Recent multicenter comparative studies and randomized data have further strengthened the evidence for fixation in both benign and malignant indications [15-18]. Contemporary guidelines endorse fixation in high-risk scenarios, including patients with prior stent migration or where stent displacement would compromise therapeutic intent [1]. Despite ongoing advances in FC-SEMS design, stent migration remains a clinically relevant limitation [4,19]. To address gaps in the existing evidence and provide clinically actionable data specific to FC-SEMS, we conducted a systematic review and meta-analysis comparing fixated and non-fixated FC-SEMS with respect to migration, clinical success, technical success, and adverse events.

Methods

Search Strategy

A comprehensive search of PubMed and Embase was performed from inception through June 2025 in accordance with PRISMA

guidelines. Medical Subject Headings (MeSH) terms included “Stents,” “Self-Expandable Metallic Stents,” “Esophageal Stenosis,” “Esophagoscopy,” and “Foreign Body Migration.” These were combined with free-text terms including “esophageal stent,” “self-expanding metal stent,” “SEMS,” “fully covered,” “FC-SEMS,” “stent migration,” “endoscopic suturing,” “over-the-scope clip,” “OTSC,” “stent fixation,” and “stent anchoring.” The search was limited to adult human studies with no language restriction. Reference lists of included studies and relevant reviews were manually searched to identify additional eligible articles.

Inclusion and Exclusion Criteria

Studies were eligible if they reported adult patients undergoing placement of fully covered self-expanding metal stents (FC-SEMSs) in the esophagus or upper GI tract. Compared outcomes between fixated stents (endoscopic suturing or clip fixation) and non-fixated stents. Presented data for at least one primary or secondary outcome (migration, technical success, clinical success, adverse events). All the studies included were original comparative studies (prospective, retrospective cohorts) and case series.

Outcomes

The primary outcome was stent migration, defined as clinically significant stent displacement requiring endoscopic or surgical intervention or resulting in loss of therapeutic efficacy. Secondary outcomes included technical success (successful stent deployment in the intended position, with effective fixation when attempted), clinical success (resolution or adequate improvement of the presenting condition), and adverse events (including perforation, hemorrhage, chest or abdominal pain, gastroesophageal reflux, food impaction, stent obstruction, or death), classified in accordance with established endoscopic reporting standards [20].

Data Extraction and Quality Assessment

Data extraction was performed independently by two investigators (PK, VJ) using a standardized electronic form; discrepancies were resolved by consensus or, when required, by adjudication of a senior reviewer. Methodological quality was assessed using a structured scoring system adapted from the Newcastle-Ottawa Scale (NOS). Each criterion was scored 0, 0.5, or 1, yielding a maximum score of 7; studies were classified as high (score >6), medium (4–6), or low quality (<4). The single RCT was additionally evaluated using the Cochrane Risk of Bias 2 (RoB 2) tool. Detailed assessments are provided in Supplementary Table 1.

Supplementary Table 1: Quality Assessment of Included Studies

Study	Selection (max 4 pts)	Comparability	Outcome (max 3 pts)	Score (/7)	Quality					
	C1 Representativeness	C2 Cohort size	C3 Outcomes info	C4 Outcome absent	C5 Comparability	C6 Clinical assessment	C7 Follow-up duration	C8 Follow-up adequacy	Score	Quality
Scoring:	1=pop; 0.5=MC; 0=SC	>40=1; 20–39=0.5; <20=0	Counts=1; %=0.5; unclear=0	Absent=1; present=0	NA	Yes=1; no=0	Yes=1; NR=0	All=1; >50%=0.5; ≤0=NR	Max 7	>6 High; 4–6 Medium; <4 Low
Kantsevov, 2012	0	N/A	0.5	1	NA	0	0	0	1.5	Low
Gonzalez, 2014	0	N/A	0	1	NA	0	0	0	1.0	Low
Catalano, 2014	0	N/A	0	1	NA	0	0	0	1.0	Low

Sharaiha, 2015	0.5	1	0.5	1	NA	0.5	0	0	3.5	Low
Sendino, 2015	0	1	0.5	1	NA	0.5	0	0	3.0	Low
Felice, 2015	0	1	0.5	1	NA	0.5	0	0	3.0	Low
Johnson, 2015	0	N/A	0	1	NA	0	0	0	1.0	Low
Ngamruengphong, 2016	0.5	1	1	1	NA	1	1	1	6.5	High
Bick, 2017	0	1	1	1	NA	1	1	0.5	5.5	Medium
Rieder, 2017	0	0	1	1	NA	1	1	1	5.0	Medium
Yang, 2017	0.5	1	1	1	NA	1	0.5	0.5	5.5	Medium
Wright, 2017	0	1	1	1	NA	1	1	1	6.0	Medium
Albarrak, 2018	0	1	0.5	1	NA	0	0	0	2.5	Low
Ngamruengphong, 2018‡	0.5	1	1	1	NA	1	1	1	6.5	High
Marya, 2020	0.5	1	0.5	1	NA	0.5	0	0	3.5	Low
Obaitan, 2021	0	1	0.5	1	NA	0.5	0	0	3.0	Low
Agha, 2022	0.5	1	1	1	NA	1	1	1	6.5	High
Coronel, 2022	0	1	0.5	1	NA	0	0	0	2.5	Low
Nehme, 2022	0	1	0.5	1	NA	0.5	0	0	3.0	Low
Park, 2022	0	1	1	1	NA	1	1	1	6.0	Medium
Singh, 2025	0	1	1	1	NA	1	1	1	6.0	Medium
Mehta, 2025	1	1	1	1	NA	1	1	1	7.0	High

NR, not reported; MC, multi-center; SC, single-center; pop, population-based.

Statistical Analysis

Pooled proportion analysis was performed using a random-effects model with Restricted Maximum Likelihood (REML) estimation, incorporating all contributing studies, including single-arm series; comparative analysis estimating pooled RRs with 95% confidence intervals (CIs) was restricted to studies with both fixated and non-fixated arms. Heterogeneity was quantified using the Cochran Q test and the I² statistic; values >50% indicate substantial heterogeneity. Statistical significance was defined at a two-tailed p-value <0.05. Prespecified subgroup analyses were performed by fixation technique, with a focused analysis restricted to endoscopic suturing (Table:1). All analyses were performed using Stata, version 18.

Table 1: Characteristics of Included Studies (n = 22)

Study, Year	Country	Setting	Study Design	Total N	Fixated (n)	Non-fixated (n)	Fixation Modality	Indication	Study Period
Kantsevov, 2012 [28]	USA	Single-center	Retrospective	7	7	—	Endoscopic suturing	Benign	NR
Gonzalez, 2014 [29]	Spain	Single-center	Retrospective	2	3	—	Endoscopic suturing	Mixed	NR
Catalano, 2014 [30]	USA	Single-center	Case series	8	8	—	Endoscopic suturing	Mixed	NR
Sharaiha, 2015 [21]	USA	Multi-center	Retrospective	37	17	20	Endoscopic suturing	Mixed	2011–2013
Sendino, 2015 [31]	USA	Single-center	Retrospective	71	37	34	Endoscopic suturing	Mixed	2013–2014
Felice, 2015 [32]	USA	Single-center	Retrospective	50	26	24	Endoscopic suturing	Mixed	2012–2014
Johnson, 2015 [38]	USA	Single-center	Retrospective	4	4	—	Endoscopic suturing	Mixed	NR
Ngamruengphong, 2016 [24]	USA	Multi-center	Retrospective	224	58	166	Endoscopic suturing	Benign	2007–2014
Bick, 2017 [9]	USA	Single-center	Retrospective	146	32	114	Endoscopic suturing	Benign	2005–2015
Rieder, 2017 [25]	Austria	Single-center	Prospective	5	9†	—	TTS clip / Endoscopic suturing	Benign	2013–2015
Yang, 2017 [17]	USA	Multi-center	Retrospective	93	26	67	Endoscopic suturing	Malignant	2011–2015
Wright, 2017 [8]	USA	Single-center	Retrospective	62	21	41	Endoscopic suturing	Mixed	2012–2015

Study	Country	Design	Study Type	Fixated (n)	Non-fixated (n)	Total (n)	Stent Type	Quality	Year
Albarrak, 2018 [33]	USA	Single-center	Retrospective	35	18	17	Endoscopic suturing	Mixed	2014–2017
Ngamruengphong, 2018 [26]	USA	Multi-center	Retrospective	74	46	28	Endoscopic suturing	Benign	2007–2015
Marya, 2020 [34]	USA	Multi-center	Retrospective	187	59	128	Endoscopic suturing	Mixed	NR
Obaitan, 2021 [35]	USA	Single-center	Retrospective	113	42	71	Endoscopic suturing	Mixed	2006–2019
Agha, 2022 [27]	USA	Multi-center	Retrospective	220	114	106	Endoscopic suturing / OTSC	Mixed	2013–2021
Coronel, 2022 [36]	USA	Single-center	Retrospective	42†	21	21	Endoscopic suturing / OTSC / TTS clip	Mixed	2017–2020
Nehme, 2022 [37]	USA	Single-center	Retrospective	108	54	54	Endoscopic suturing / OTSC	Mixed	2019–2021
Park, 2022 [15]	USA	Single-center	Retrospective	218	194	239	Endoscopic suturing / OTSC	Mixed	2013–2021
Singh, 2025 [18]	USA	Single-center	Randomized trial	46	24	22	Endoscopic suturing	Mixed	2021–2022
Mehta, 2025 [16]	Multinational	Multi-center	Retrospective	311	189	127	Endoscopic suturing / OTSC	Benign	2011–2022

NR, not reported; OTSC, over-the-scope clip; TTS, through-the-scope clip.

Results

Twenty-two studies were included, comprising a total of 2,337 stent placements across 1,058 fixated and 1,279 non-fixated FC-SEMS (Table: 2). Four studies were rated high quality on adapted NOS assessment (score >6/7), six moderate quality (score 4–6), and twelve low quality (score <4), the latter predominantly reflecting abstract-only reporting with limited methodological disclosure Table: 3. The single RCT demonstrated low overall risk of bias on RoB 2 appraisal.

Table 2: Pooled outcomes: Fixated Versus non-Fixated FC-SEMS

Outcome	Fixated, pooled proportion (95% CI)	Non-fixated, pooled proportion (95% CI)	RR (95% CI)	Studies, n	I ² (%)
Stent migration	15% (9–22)	40% (31–50)	0.49 (0.38–0.63)	17	55.7
Adverse events	14% (7–23)	19% (13–27)	0.86 (0.59–1.23)	14	65.1
Technical success	100% (99–100)	99% (94–100)	1.00 (0.99–1.01)	10	0.04
Clinical success	62% (45–78)	45% (27–64)	1.27 (0.98–1.66)	6	78.9

CI, confidence interval; FC-SEMS, fully covered self-expandable metal stent; RR, risk ratio.

Table 3: Subgroup Analysis: Sutured Fixation Versus non-Fixated FC-SEMS

Outcome	Pooled proportion (95% CI)	RR (95% CI); p value	Studies, n	I ² (%)
Stent migration	13% (7–21)	0.49 (0.37–0.65); p < 0.01	17	59.3
Adverse events	14% (6–25)	0.84 (0.58–1.23); p = 0.38	13	61.6
Technical success	100% (100–100)	1.00 (0.99–1.02); p = 0.67	9	0
Clinical success†	64% (48–79)	1.33 (1.05–1.69); p = 0.02	6	72.2

CI, confidence interval; RR, risk ratio.

Primary outcome: Migration rates

The pooled migration rate for fixated stents (22 studies) was 15% (95% CI: 9–22%), compared with 40% (95% CI: 31–50%) for non-fixated stents (17 studies). As shown in Figure: 1, fixation was associated with a significantly lower risk of migration (RR = 0.49, 95% CI: 0.38–0.63; I² = 55.67%; p < 0.01). On subgroup analysis restricted to sutured fixation (22 studies), the pooled migration rate was 13% (95% CI: 7–21%), with a similarly significant reduction in migration risk compared with non-fixated stents (RR = 0.49, 95% CI: 0.37–0.65; I² = 59.3%; p < 0.01).

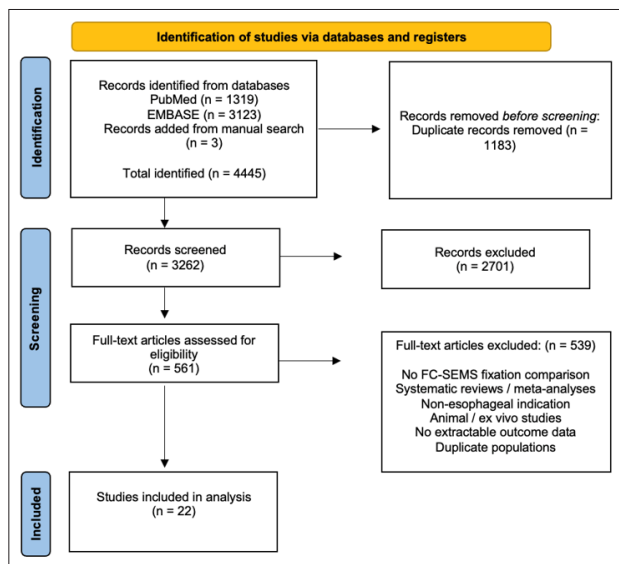


Figure 1: Prisma Flowchart of Study Selection

Secondary outcome: Adverse events

The pooled adverse event rate for fixated stents was 14% (95% CI: 7–23%) across 17 studies reporting adverse event data; 5 studies did not report this outcome and were excluded from this analysis. For non-fixated stents (14 studies), the pooled rate was 19% (95% CI: 13–27%). Rates of adverse events were comparable between groups (RR = 0.86, 95% CI: 0.59–1.23; I²

= 65.14%; p = 0.41). On subgroup analysis, sutured fixation (16 studies) demonstrated an adverse event rate of 14% (95% CI: 6–25%), also comparable to non-fixated stents (RR = 0.84, 95% CI: 0.58–1.23; I² = 62%; p = 0.38).

Secondary outcome: Technical success

The pooled technical success rate for fixated stents (13 studies) was 100% (95% CI: 99–100%), compared with 99% (95% CI: 94–100%) for non-fixated stents across 10 comparative studies. There was no significant difference between groups (RR = 1.00, 95% CI: 0.99–1.01; I² = 0.04%; p = 0.83). On subgroup analysis, sutured fixation (12 studies) achieved a pooled technical success rate of 100% with no heterogeneity (I² = 0%).

Secondary outcome: Clinical success

The pooled clinical success rate for fixated stents (7 studies) was 62% (95% CI: 45–78%), compared with 45% (95% CI: 27–64%) for non-fixated stents (6 studies). In the overall fixated versus non-fixated comparison (6 comparative studies), fixation was associated with a trend toward higher clinical success that did not reach statistical significance (RR = 1.27, 95% CI: 0.98–1.66; I² = 79%; p = 0.07) (Figure: 2). On subgroup analysis, the pooled clinical success rate for sutured fixation (7 studies) was 64% (95% CI: 48–79%); in the comparative analysis against non-fixated stents (6 studies), sutured fixation was associated with a statistically significant improvement in clinical success (RR = 1.33, 95% CI: 1.05–1.69; I² = 72%; p = 0.02). Figure:3.

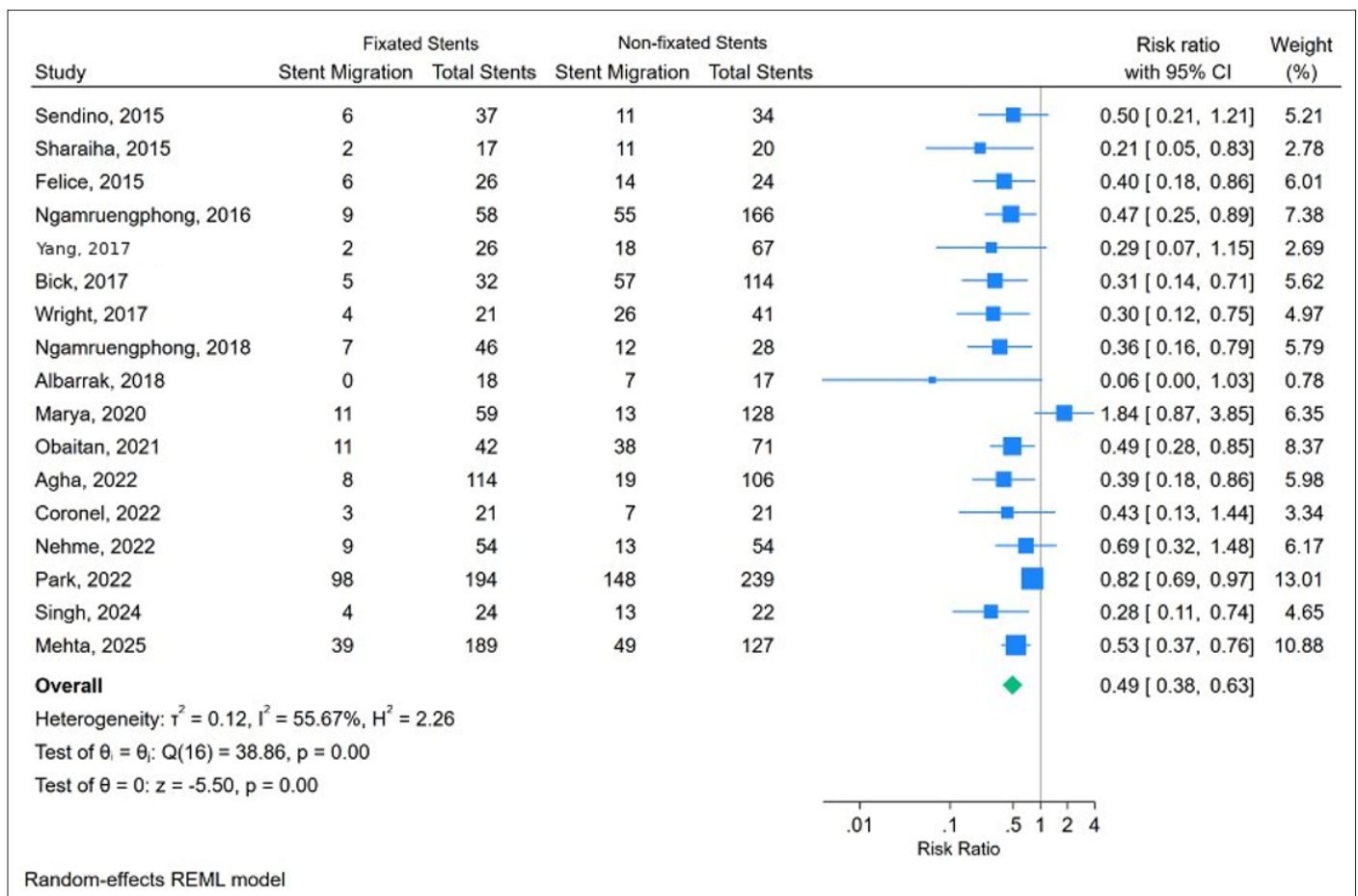


Figure 2: Forest Plot: Stent Migration, Fixated Versus non-Fixated FC-SEMS

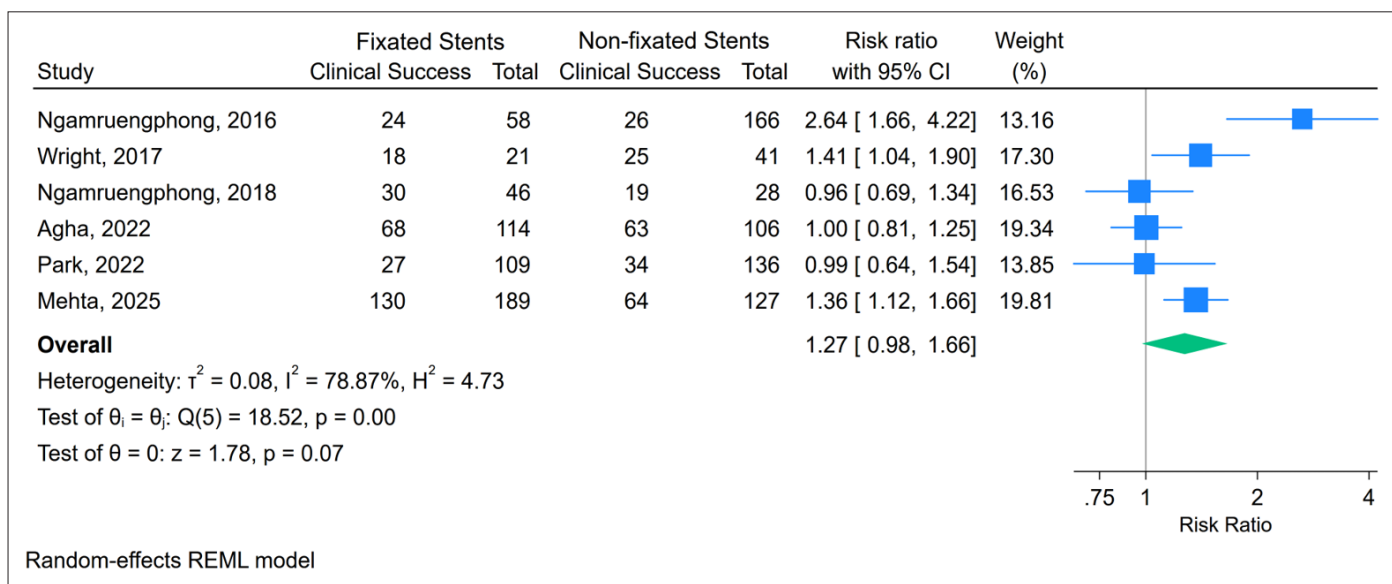


Figure 3: Forest Plot: Clinical Success, Fixed Versus non-Fixed FC-SEMS

Discussion

Prior meta-analyses evaluating fixation strategies have pooled FC-SEMS with PC-SEMS, which limits their applicability to clinical decisions specific to fully covered devices [10, 11, 14]. Because PC-SEMS resist migration through tissue ingrowth into uncovered mesh, they inherently have lower migration rates and could bias the estimation of fixation benefit when pooled with FC-SEMS. In this study, we provide more precise estimates of the effect size for FC-SEMS, which has not been reported in prior meta-analyses restricted exclusively to FC-SEMS, and our estimates more accurately reflect the clinical question at hand. The reduced migration rates in endoscopic fixation of FC-SEMS of 15% with fixation and 40% without fixation (RR 0.49; $p < 0.01$). These findings align closely with the 14.9% and 44.6%, respectively, reported by Papaefthymiou et al. [10]. The more conservative relative risk reduction in our analysis (51%) compared with theirs (80%) most likely reflects the removal of PC-SEMS from the fixated group.

Heterogeneity for migration was moderate ($I^2 = 55\text{--}59\%$), most likely reflecting variation in patient indication, stent dimensions, follow-up duration, and the definition of clinically significant migration across studies. Select circumstances with significant luminal narrowing, such as advanced malignant obstruction or a high-grade stricture, limit anchoring of FC-SEMS in the esophagus, as the tight stenosis itself provides sufficient intrinsic fixation. Placement without anchoring may also be considered when anchoring is not feasible, including situations with elevated bleeding risk, a small-caliber esophagus, or technical difficulty that prevents secure fixation. Evidence defining specific patient or lesion characteristics that reliably ensure safe non-anchored FC-SEMS placement remains limited [16,20,21].

Current guidelines endorse stent fixation in high-risk clinical scenarios. The European Society of Gastrointestinal Endoscopy (ESGE) recommends considering endoscopic suturing or OTSC fixation of FC-SEMS in patients who have previously experienced stent migration [1]. The American Gastroenterological Association (AGA) similarly advises consideration of stent-

anchoring methods when FC-SEMS are placed in the setting of malignant esophageal obstruction [3,16]. These findings provide quantitative support for both recommendations, demonstrating 51% relative reduction in migration risk and a statistically significant improvement in clinical success with sutured fixation ($p=0.02$), and extend their applicability to the FC-SEMS population specifically.

Individual fixation modalities have been evaluated in several meta-analyses and cohort studies, though conclusions regarding the optimal technique have varied. In a network meta-analysis, Gangwani et al. found a directional but non-significant reduction in migration with endoscopic suturing compared with no fixation (OR 0.62, 95% CI 0.26–1.45) and no clear benefit with clip-based fixation [14]. Papaefthymiou et al., by contrast, found that all three fixation approaches, including endoscopic suturing (OR 0.23, 95% CI 0.10–0.53), OTSC anchoring (OR 0.31, 95% CI 0.17–0.58), and through-the-scope clips (OR 0.10, 95% CI 0.03–0.38), significantly reduced migration without statistically significant differences among them [10]. These findings are broadly consistent with multiple comparative studies [8, 9, 13, 15, 16, 21], and the pooled sutured fixation migration rate of 13% in this analysis compares favorably with the 15.9% reported by Law et al. [11] and with the 19% and 16% rates observed by Wright et al. and Bick et al. in prior comparative cohort studies [8, 9]. Jena et al. further reported, in a meta-analysis specific to OTSC fixation, a pooled migration rate of 10% overall and as low as 8% for esophageal SEMs, supporting OTSC anchoring as an effective alternative to suturing [22]. Device-specific data from Schiemer et al. demonstrated meaningful reductions in migration using a dedicated OTSC fixation system compared with historical controls [23]. The Singh et al. randomized controlled trial provides the most rigorous evidence to date, showing that endoscopic suturing significantly reduced stent migration and prolonged time to migration without an increase in adverse events [18].

Sutured fixation achieved a statistically significant improvement in clinical success compared with non-fixated stents (RR 1.33,

95% CI 1.05–1.69; $p = 0.02$), whereas overall fixation did not (RR 1.27, 95% CI 0.98–1.66; $p = 0.07$), pointing to a technique specific mechanism beyond simple stent retention. Technical success was near-universal in both groups, indicating that the observed difference in clinical outcomes does not reflect deployment failure. One possible explanation is that suture-based anchoring provides greater mechanical stability than clip fixation alone, limiting not only complete stent migration but also partial axial drift, where the stent shifts enough to compromise luminal coverage without constituting a clinically apparent migration event. Such partial displacement would impair therapeutic efficacy without being captured in migration counts. This is supported by data from Mehta et al., who reported significantly higher clinical success with OTSC fixation ($n = 64$; 68%; $P = 0.03$) and endoscopic suturing ($n = 66$; 69%; $P = 0.02$) compared with no fixation ($n = 64$; 52%) [16]. Wright et al. similarly reported clinical success of 86% with suture fixation versus 61% without fixation [8], and Yang et al. reported consistent directional improvement with suture fixation in the neoadjuvant esophageal cancer setting [17].

Pooled adverse event rates were comparable between groups (14% vs. 19%), consistent with the safety profiles reported by Mehta et al. [16] and Singh et al. [18] and supporting the overall tolerability of fixation. Adverse event heterogeneity was higher ($I^2 = 62$ –65%), likely driven by differences in complication ascertainment and reporting practices across institutions and study periods. Clinical success showed the greatest heterogeneity ($I^2 = 72$ –79%), expected given its indication-specific nature: resolution of a benign stricture, closure of a postoperative fistula, and palliation of malignant dysphagia represent fundamentally different therapeutic endpoints with distinct time horizons and benchmarks.

Strengths and Limitations

By restricting inclusion to FC-SEMS, this analysis eliminates the confounding effect of PC-SEMS tissue ingrowth and isolates the stent population at greatest intrinsic migration risk, a distinction that prior meta-analyses have not made. The inclusion of the most recent multicenter international study [16] and the first RCT evaluating suture fixation for FC-SEMS [18] ensures the analysis reflects the current evidence base.

The majority of studies were retrospective, and 10 of 22 were available only as conference abstracts, limiting the granularity of the data that could be extracted and contributing to methodological heterogeneity. Formal statistical testing for publication bias was not performed; selective reporting bias cannot be excluded. Definitions of clinical success were not standardized: some studies defined success as avoidance of reintervention or maintenance of luminal patency in benign disease, whereas others defined success as symptom resolution or dysphagia relief in the malignant setting, limiting direct cross-study comparisons. Follow-up data were inconsistently reported, precluding pooled analysis of time to migration. A minority of studies incorporated PC-SEMS in their non-fixated control arms, introducing potential residual confounding; this applies notably to the Bick 2017 and Ngamruengphong 2018 analyses, and sensitivity analyses excluding these studies were not performed [24–38].

Conclusion

Endoscopic fixation reduces FC-SEMS migration by approximately 50% without increasing adverse events or compromising technical success. Sutured fixation was further associated with a statistically significant improvement in clinical success, an effect not seen with overall fixation, suggesting a specific advantage of suture-based anchoring in maintaining therapeutic stent positioning. Fixation should be routinely considered when FC-SEMS are placed in settings associated with high migration risk. Adequately powered, multicenter randomized trials comparing sutured fixation against OTSC anchoring, with pre-specified definitions of clinical success stratified by indication, are required before formal guideline recommendations can be made.

Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors. Therefore, institutional review board (IRB) approval was not required.

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