



Review Article

Endoscopic Vacuum Therapy Versus Self-Expanding Metal Stents for Upper Gastrointestinal Transmural Defects: A Narrative Review with Meta-Analytic Overlap Analysis, with Focus on Esophageal Anastomotic Leak and Perforation

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ABSTRACT

Background: Upper gastrointestinal transmural defects carry mortality rates exceeding 20%. Endoscopic vacuum therapy (EVT) has emerged as a promising alternative to self-expanding metal stents (SEMS), yet optimal patient selection, timing, and technique remain uncertain.

Methods: Relevant literature was identified through a narrative search of PubMed, Embase, and Cochrane Library through January 2026. Corrected covered area (CCA) analysis quantified primary study overlap across meta-analyses comparing EVT to SEMS. This review was reported in accordance with the SANRA checklist.

Results: Five meta-analyses were identified, with all comparative evidence derived from esophageal anastomotic leak and iatrogenic perforation populations. CCA analysis demonstrated very high overlap (CCA = 95.0%), confirming convergent re-analyses of the same evidence base rather than independent replication. No randomized controlled trials have been completed. Within this low-certainty observational evidence, EVT was associated with higher defect closure rates (85% vs 64%), lower mortality (risk difference [RD] -0.12), shorter treatment duration (14-day reduction), and fewer adverse events (RD -0.24) compared with SEMS; all effect measures are EVT minus SEMS and should not be interpreted causally. Recent 2023-2025 data showed significantly fewer patient-level complications with EVT (8.3% vs 50%; $P = .001$). Critical predictors of failure include delayed initiation beyond 7 days, neoadjuvant chemoradiation, and intraluminal sponge placement.

Conclusions: EVT was associated with favorable outcomes compared with SEMS across convergent analyses, primarily in esophageal leak and perforation populations; these hypothesis-generating findings should not be extrapolated to other indications without dedicated evidence. Prospective randomized trials, FDA device pathway development, and standardized protocols remain priorities.

1. Introduction

Upper gastrointestinal transmural defects encompassing anastomotic leaks, iatrogenic perforations, and spontaneous perforations represent life-threatening complications with reported mortality rates of 12% to 50% [1–3]. Surgical revision carries additional morbidity and mortality rates of 20% to 40% [4]. Endoscopic management has therefore become the preferred initial approach for most transmural defects, as endorsed by the American Gastroenterological Association Clinical Practice Update [5].

Self-expanding metal stents (SEMS) have historically served as the primary endoscopic treatment. Still, they are limited by migration

rates of 25% to 41%, the inability to actively drain contaminated peri-luminal cavities, tissue ingrowth, and stricture formation [6–8]. Endoscopic vacuum therapy (EVT), adapted from negative pressure wound therapy principles, [9] was first described for colorectal anastomotic leaks by Weidenhagen et al (2008) [10] and subsequently adapted for upper gastrointestinal applications by Loske and Müller (2010) [11]. The technique employs an open-pored polyurethane sponge connected to continuous negative pressure, promoting granulation tissue formation, removing infectious debris, and facilitating defect closure [9, 12]. EVT was recognized as a 2025 Top 10 endoscopy topic by the American Society for Gastrointestinal Endoscopy Editorial Board [13].

Several prior narrative reviews have addressed EVT for upper gastrointestinal defects, [14, 15]. Still, none incorporated 2024–2025 comparative data, performed corrected covered area analysis of available meta-analyses, or provided practical guidance for device assembly. This narrative review synthesizes the current evidence on comparative outcomes, predictors of success, technical considerations, and emerging applications of EVT for upper gastrointestinal transmural defects, with emphasis on practical guidance for endoscopists and explicit quantification of meta-analytic overlap.

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2. Methods

This is a narrative review. Relevant literature was identified through a search of PubMed, Embase, and Cochrane Library from inception through January 2026 using the following terms: “endoscopic vacuum therapy,” “endoluminal vacuum therapy,” “E-Vac,” “Endo-SPONGE,” “negative pressure wound therapy AND esophageal,” “anastomotic leak AND endoscopic treatment,” and “esophageal perforation AND endoscopic management.” These terms were selected to capture the primary literature relevant to the clinical questions addressed in this review; they are not exhaustive. The reference lists of identified articles were also reviewed to identify further relevant sources. Study selection and evidence synthesis were performed by the authors based on clinical and methodological relevance to the narrative aims; selection was not performed in duplicate, no formal screening log was maintained, and this process does not conform to systematic review methodology. Readers should be aware that this approach carries an inherent risk of selection bias and incomplete retrieval that cannot be fully quantified. This review was conducted and reported in accordance with the Scale for the Assessment of Narrative Review Articles (SANRA) checklist.

The review focuses on evidence pertaining to EVT for upper gastrointestinal transmural defects, including esophageal, gastric, and duodenal locations. The types of evidence discussed include comparative studies, meta-analyses, systematic reviews, multicenter registries, cohort studies, and expert consensus statements. For emerging applications where comparative data are absent, illustrative case series are referenced to convey the current state of early-stage evidence. Evidence relating exclusively to colorectal applications is discussed only where it provides foundational context directly applicable to upper gastrointestinal practice. These are authorial scope decisions, not pre-specified eligibility criteria.

When discussing individual studies, relevant information considered includes study design, sample size, defect type and location, device type, technical parameters, clinical outcomes (defect closure, mortality, treatment duration, adverse events), and reported predictors of success and failure. This information was not extracted into a formal data table or reconciled across studies using a standardized instrument; it is synthesized narratively. Because formal meta-analytic pooling was not performed, no attempt is made to derive a single summary estimate across studies. Instead, findings from published meta-analyses are discussed and contextualized, with attention to the methodological quality concerns described below.

A notable feature of the available meta-analytic literature on EVT versus SEMS is the potential for substantial overlap in the primary studies included across different meta-analyses. This concern can mislead readers into treating convergent findings as independent confirmation. To give this concern a concrete, transparent basis rather than stating it impressionistically, the corrected covered area (CCA) method described by Pieper et al (2014) was applied as a descriptive supplementary tool [16]. The formula $CCA = (N - r) / (rc - r)$, where N = total primary study appearances across all meta-analyses, r = number of unique primary studies, and c = number of meta-analyses, produces a single overlap index. CCA values of 0–5% indicate slight overlap, 6–10% moderate, 11–15% high, and >15% very high. The use of this tool here is solely descriptive and interpretive; it does not transform this article into a systematic overview of reviews, and no claims of systematic or exhaustive meta-analysis identification are made.

The CCA matrix was constructed using only meta-analyses that performed pairwise EVT-versus-SEMS comparisons. Two additional systematic reviews (Murray et al (2024) [17] and Mucha et

al (2025) [18]) and one umbrella review (Ardila et al (2025) [19]) were identified but excluded from the CCA matrix because they did not perform pairwise EVT-versus-SEMS meta-analysis using the same primary study pool, or because they were overviews of reviews rather than primary meta-analyses. Full details of the CCA matrix construction are provided in the Results section. Sex and gender were considered in the design of this review. The literature search included terms to identify studies reporting sex- or gender-disaggregated outcomes. However, as detailed in the Discussion, the existing literature does not report outcomes stratified by sex or gender, representing a critical evidence gap.

3. Results

3.1. Corrected Covered Area Analysis: Quantifying Meta-Analysis Overlap

To contextualize the meta-analytic literature before summarizing its findings, the degree of overlap among the five available meta-analyses was examined using the CCA method described in the Methods section [16]. Five unique primary comparative studies were identified across these meta-analyses: Brangewitz et al (2013), [2] Schniewind et al (2013), [3] Bludau et al (2014), [1] Hwang et al (2016), [20] and Berlth et al (2019) [21]. Four of these (Brangewitz, Schniewind, Bludau, Hwang) appear in all five meta-analyses (5 appearances each); Berlth et al (2019) appears in four (Scognamiglio 2020, Tavares 2021, do Monte Junior 2021, Jung 2021), as it postdates Rausa et al (2018). Jung et al (2021) reported an odds ratio of 3.14 (95% CI 1.23–7.98) for EVT-versus-SEMS closure, identical to Scognamiglio et al (2020), confirming that Hwang et al (2016) was included in the Jung et al EVT-versus-SEMS subanalysis. This yields $N = 24$ confirmed total appearances and a single confirmed $CCA = (24 - 5) / (5 \times 5 - 5) = 19/20 = 95.0\%$, far exceeding the >15% very high overlap threshold (**Table 1**). Regarding Tavares et al. (2021): this meta-analysis included 23 studies (559 patients), most of which were EVT-only case series. The pairwise EVT-versus-SEMS comparative subgroup within Tavares et al comprised the same 5 primary studies used in the other four meta-analyses – specifically Brangewitz et al (2013), Schniewind et al (2013), Bludau et al (2014), Hwang et al (2016), and Berlth et al (2019) – as confirmed by cross-referencing the individual study reference lists within that meta-analysis. The remaining 18 studies in Tavares et al were EVT-only series without a SEMS comparator arm and contributed no pairwise comparative data; they were therefore excluded from the CCA denominator, which is restricted to studies contributing to the pairwise EVT-versus-SEMS comparison. The CCA formula denominator ($r = 5$ unique primary comparative studies; $c = 5$ meta-analyses) is based solely on this verified pairwise-eligible study pool. A full study-by-review citation matrix is provided in Supplemental (**Table S1**).

The conclusion that these meta-analyses represent convergent re-analyses of the same evidence base is robust across all plausible configurations. All quantitative claims in this review are anchored to Jung et al. (2021), the largest meta-analysis (29 studies, 498 patients), with other meta-analyses cited as corroborative.

3.2. Comparative Outcomes: Endoscopic Vacuum Therapy Versus Self-Expanding Metal Stents

With the above overlap context established, the convergent findings across the five meta-analyses are summarized in (**Table 2**). All comparative evidence is derived from retrospective observational studies; no randomized controlled trials have been completed, and causal interpretation is not warranted. The largest meta-analysis, Jung et al (2021), reported a pooled EVT closure rate of 85% (95%

Table 1: Primary Study Overlap Matrix Across Published Meta-Analyses of Endoscopic Vacuum Therapy Versus Self-Expanding Metal Stents, with Corrected Covered Area (CCA) Calculation

Primary Study	Rausa et al. (2018)	Scognamiglio et al. (2020)	Tavares et al. (2021)	do Monte Junior et al. (2021)	Jung et al. (2021)	Total Appearances
Brangewitz et al. (2013) [2]	X	X	X	X	X	5
Schniewind et al. (2013) [3]	X	X	X	X	X	5
Bludau et al. (2014) [1]	X	X	X	X	X	5
Hwang et al. (2016) [20]	X	X	X	X	X	5
Berlth et al. (2019) [21]	—	X	X	X	X	4

CCA Calculation: $r = 5$ unique primary studies; $c = 5$ meta-analyses; $N = 24$ confirmed total appearances.

$CCA = (N - r)/(rc - r) = (24 - 5)/(5 \times 5 - 5) = 19/20 = 95.0\%$ (confirmed; $N = 24$ verified appearances).

Both values far exceed the $> 15\%$ very-high overlap threshold per Pieper et al. (2014).

Legend: X = confirmed included in meta-analysis; — = not included (postdates meta-analysis). Hwang et al. (2016) inclusion in Jung et al. (2021) was confirmed, based on an identical reported odds ratio (OR 3.14; 95% CI 1.23–7.98), matching Scognamiglio et al. (2020). $N = 24$ confirmed total appearances; $CCA = 95.0\%$ (single confirmed value; no residual uncertainty). See Supplemental Citation Matrix (Table S1) for study-by-review verification. CCA, corrected covered area. Formula: $CCA = (N - r)/(rc - r)$. Thresholds: 0–5% slight; 6–10% moderate; 11–15% high; $> 15\%$ very high.

CI 0.81 – 0.88) [22]. do Monte Junior et al (2021) reported a 21% higher absolute defect closure rate with EVT versus SEMS (risk difference [RD] 0.21; 95% CI 0.10 – 0.32; $P = .0003$), a 12% absolute mortality reduction favoring EVT (RD -0.12; 95% CI -0.21 to -0.03; $P = .006$), a 14-day shorter treatment duration (mean difference -14.22 days; 95% CI -20.07 to -8.38; $P < .00001$), and a 24% absolute reduction in adverse events favoring EVT (RD -0.24; 95% CI -0.35 to -0.13; $P = .0001$) [23]. These figures represent EVT minus SEMS, so negative values indicate EVT advantage. Tavares et al (2021) reported a 16% risk difference in closure rates favoring EVT (RD 0.16; 95% CI 0.05–0.27) and 10% lower mortality with EVT (RD -0.10; 95% CI -0.18 to -0.02) [24]. Scognamiglio et al (2020) reported a pooled odds ratio of 3.14 (95% CI 1.23–7.98) favoring EVT for defect closure [25]. The consistency of effect direction across these analyses should be interpreted in the context of their very high primary study overlap ($CCA = 95.0\%$), which means these results reflect analytical consistency rather than independent replication. Furthermore, treatment selection, defect severity, timing, and center expertise are potential confounders in all of these observational comparisons. Evidence should be considered low-certainty pending randomized trial data.

The Murray et al (2024) network meta-analysis, which compared four treatment strategies across 12 studies (511 patients), corroborates these findings: EVT demonstrated significantly lower complication rates (OR 0.23; 95% CI 0.09–0.58) and mortality (OR 0.43; 95% CI 0.21–0.87) compared with stenting [17]. Mucha et al (2025) reported EVT success rates of 82% and mortality of 10.7% across 38 studies [18].

3.3. Novel 2023 – 2025 Independent Evidence

The 2023 – 2025 comparative studies (Mandarino et al 2023, Riva et al 2025, Heilani et al 2025) were not captured in any of the five pairwise EVT-versus-SEMS meta-analyses included in the CCA matrix (Rausa 2018, Scognamiglio 2020, Tavares 2021, do Monte Junior 2021, Jung 2021; CCA appearance count = 0 in that matrix). As used in this review, “independent” refers specifically and only to independence from those five pairwise meta-analyses and does not imply independence from all prior systematic literature. The relationship of each study to Mucha et al (2025) and Ardila et al (2025) is as follows. Mucha et al (2025) [18] searched the literature through 2024: Mandarino et al (2023), published in December 2023, falls within that search window and was likely captured in Mucha et al; Riva et al (2025; J Clin Med 2025;14 [23]) and Heilani et al

(2025; Endoscopy 2025;57 [5]) were both published in 2025, after Mucha’s search cutoff, and were therefore not included. Ardila et al (2025) [19] is an umbrella review of previously published systematic reviews rather than a review of primary studies; as matched case-control and retrospective cohort studies, Mandarino et al, Riva et al, and Heilani et al would not be directly eligible for inclusion in an umbrella review and were not captured therein. In summary, Mandarino et al (2023) is likely captured in Mucha et al (2025) and thus not fully independent of all prior systematic literature; Riva et al (2025) and Heilani et al (2025) postdate the search windows of all identified systematic reviews and umbrella reviews and represent genuinely new primary comparative data not previously synthesized in any identified review. All three are described here using the most recent available comparative evidence, with the above independence status explicitly stated.

Mandarino et al (2023) published a matched case-control study of 44 patients (22 EVT vs 22 SEMS) with anastomotic leaks less than 30 mm following oncologic Ivor-Lewis esophagectomy, matched 1:1 by age, BMI, and leak size [26]. Patient-level leak resolution was numerically higher with EVT (90.9% vs 72.7%; $P = .11$), and the most frequent complication in the SEMS group was migration (15.3% of stent procedures, reported as a procedure-level outcome) [26].

Riva et al (2025) published a case-control study of 45 patients comparing EVT ($n = 23$) to SEMS ($n = 22$) [27]. While defect closure rates were numerically similar (95.6% vs 86.4%; $P = 1.000$), EVT demonstrated significantly fewer patient-level complications (8.3% vs 50% of patients; $P = .001$), with no stent migration (0% vs 36.4% of SEMS patients) and no stricture formation (0% vs 18.2% of SEMS patients) [27].

Heilani et al (2025) reported outcomes from 59 patients across two German tertiary centers treated with EVT ($n = 24$), SEMS ($n = 32$), or over-the-scope clips (OTSC; $n = 14$), with an overall patient-level closure rate of 78.0%. Defect size of 1 cm or less was strongly associated with successful closure (57.8% vs 15.4%; $P = .007$) [28].

Ardila et al (2025) published an umbrella review of six systematic reviews/meta-analyses (65 studies, 2186 patients) reporting cross-analytical consistency favoring EVT across defect closure, mortality, and complication domains [19]. As an umbrella review synthesizing the same underlying studies, this work reflects analytical consistency across the overlapping evidence base rather than contributing new

Table 2: Summary of Meta-Analyses and Recent Comparative Studies Evaluating Endoscopic Vacuum Therapy Versus Self-Expanding Metal Stents for Upper Gastrointestinal Transmural Defects

Study	Design	Studies (Patients)	Closure Rate EVT vs SEMS	Mortality EVT vs SEMS	Treatment Duration	Adverse Events	CCA Status
Rausa et al. (2018) [7]	SR/MA	4 (163)	OR 5.51 (95% CI 2.11–14.88; $P < 0.001$)	OR 0.55 (95% CI 0.19–1.56)	NR	NR	† CCA = 95.0%
Scognamiglio et al. (2020) [25]	SR/MA	5 (274)	OR 3.14 (95% CI 1.23–7.98)	OR 0.39 (95% CI 0.18–0.83)	NR	NR	† CCA = 95.0%
Tavares et al. (2021) [24]	SR/MA	23 (559)	RD +0.16 (95% CI 0.05–0.27) favoring EVT [EVT higher]	RD –0.10 (95% CI –0.18 to –0.02)	NR	NR	† CCA = 95.0%
do Monte Junior et al. (2021) [23]	SR/MA	5 (274)	RD +0.21 (95% CI 0.10–0.32; $P = 0.0003$) favoring EVT [EVT higher]	RD –0.12 (95% CI –0.21 to –0.03; $P = 0.006$) favoring EVT	MD –14.22 days (95% CI –20.07 to –8.38; $P < 0.00001$) favoring EVT	RD –0.24 (95% CI –0.35 to –0.13; $P = 0.0001$) favoring EVT	† CCA = 95.0%
Jung et al. (2021) [22]	SR/MA	29 (498)	Pooled 85% (95% CI 0.81–0.88)	NR	NR	NR	† CCA = 95.0%
Murray et al. (2024) [17]	Network MA	12 (511)	NR	OR 0.43 (95% CI 0.21–0.87)	NR	OR 0.23 (95% CI 0.09–0.58)	Excluded from the CCA matrix
Mandarino et al. (2023) [26]	Matched case-control	1 (44)	90.9% vs 72.7% ($P = 0.11$)	NR	NR	Migration 15.3% (SEMS)	‡ Independent 2023
Riva et al. (2025) [27]	Case-control	1 (45)	95.6% vs 86.4% ($P = 1.000$)	NR	NR	8.3% vs 50% ($P = 0.001$)	‡ Independent 2025
Heilani et al. (2025) [28]	Retrospective two-center	1 (59)	78.0% overall	NR	NR	NR	‡ Independent 2025

Note: All effect measures are reported as EVT minus SEMS (reference group = SEMS); negative RD values indicate EVT advantage for mortality and adverse event outcomes; positive RD values indicate EVT advantage for closure rate. All evidence is low-certainty observational; no randomized controlled trials have been completed; causal interpretation is not warranted.

Legend: † Corroborating evidence with very high primary study overlap (CCA = 95.0% confirmed; Pieper et al. formula; see (Table 1) and Supplemental (Table S1) for overlap matrix).

‡ Most recent comparative data (2023–2025); not included in the five pairwise EVT-versus-SEMS meta-analyses comprising the CCA matrix (CCA appearance = 0 in that matrix); possible overlap with Mucha et al. (2025) or Ardila et al. (2025) cannot be fully verified from published full texts; described here as most recent available data, not as completely independent of all prior systematic literature.

§ Leak resolution (Mandarino et al.) and overall closure rate (Heilani et al.) are reported as patient-level outcomes. Stent migration in Mandarino et al. (15.3%) is reported as a procedure-level outcome. All outcomes in Riva et al. are patient-level.

CI, confidence interval; EVT, endoscopic vacuum therapy; MA, meta-analysis; MD, mean difference; NR, not reported; OR, odds ratio; RD, risk difference (EVT minus SEMS); SEMS, self-expanding metal stents; SR, systematic review.

patient data or independent replication; the certainty of its conclusions is bounded by the low certainty of the primary observational studies it synthesizes.

Sánchez-Rodríguez et al. (2025) reported on 30 consecutive patients treated with EVT, with an overall closure rate of 90% and an adverse event rate of 5.9% [29].

3.4. Predictors of Success and Failure

Identification of predictors of EVT success and failure is critical for patient selection and treatment optimization (Table 3).

Timing of Initiation. Momblan et al (2023) identified time from diagnosis to EVT initiation as a significant predictor of failure in a multicenter Spanish registry of 102 patients, with each day of delay increasing odds of failure by 3% (OR 1.03; 95% CI 1.01–1.05; $P = .005$) [30].

Patient and Treatment Factors. Jung et al (2022) identified neoadjuvant chemoradiation and intraluminal sponge placement as independent risk factors for failure on multivariate analysis in 119 patients [31]. de Moura et al (2023) reported simultaneous intracavity and

intraluminal placement as a predictor of success (OR 3.08) in 144 patients [32].

Defect and Cavity Characteristics. Ooi et al (2018) reported that cavity size greater than 8 cm and chronic fistula tracts were associated with failure [33]. Defects greater than 2 cm have been associated with lower success rates across multiple studies. Heilani et al (2025) confirmed that defects of 1 cm or less can almost always be closed endoscopically [28].

Laboratory Biomarkers. Book et al. (2021) identified platelet count at day 14 (257 vs 195 Thsd/ μ L; $P = 0.039$) and declining C-reactive protein (CRP) trends as biomarkers of treatment success in 116 patients [34].

3.5. Technical Considerations

Commonly Described Technique (Expert Practice; Unvalidated Standard). The most frequently reported EVT technique involves placement of an open-pored polyurethane sponge (e.g., GranuFoam; KCI/3M), trimmed to the defect dimensions, secured to a 14 – 18 French nasogastric tube with silk sutures, and connected to

Table 3: Predictors of Endoscopic Vacuum Therapy Success and Failure for Upper Gastrointestinal Transmural Defects

Predictor	Direction	Effect Size	Study	N	Analysis
Time from diagnosis to EVT initiation (per day)	Failure ↑	OR 1.03 (95% CI 1.01–1.05; $P = 0.005$)	Momblan et al. (2023) [30]	102	MVA
Neoadjuvant chemoradiation	Failure ↑	Independent risk factor on MVA (exact OR, CI, and P value not reported in the abstract; values may be available in the full-text publication; reported as statistically significant on MVA)	Jung et al. (2022) [31]	119	MVA
Intraluminal sponge placement	Failure ↑	Independent risk factor on MVA (exact OR, CI, and P value not reported in the abstract; values may be available in the full-text publication; reported as statistically significant on MVA)	Jung et al. (2022) [31]	119	MVA
Simultaneous intracavitary + intraluminal placement	Success ↑	OR 3.08 (95% CI 1.19–7.95); also HR 0.70 (95% CI 0.55–0.91) for time to closure	de Moura et al. (2023) [32]	144	MVA
Cavity size >8 cm	Failure ↑	Associated with failure	Ooi et al. (2018) [33]	—	Descriptive
Chronic fistula tract	Failure ↑	Associated with failure	Ooi et al. (2018) [33]	—	Descriptive
Defect size ≤1 cm	Success ↑	57.8% vs 15.4% ($P = 0.007$)	Heilani et al. (2025) [28]	59	Univariate
Platelet count day 14 (257 vs 195 Thsd/ μ L)	Success ↑	$P = 0.039$	Book et al. (2021) [34]	116	Univariate
Declining CRP trend	Success ↑	Associated with success	Book et al. (2021) [34]	116	Descriptive

Legend: CI, confidence interval; CRP, C-reactive protein; EVT, endoscopic vacuum therapy; MVA, multivariate analysis; OR, odds ratio; Thsd/ μ L, thousand per microliter. ↑ indicates increased likelihood of the stated outcome (success or failure).

Table 4: Standard Endoscopic Vacuum Therapy Technical Parameters and Modifications

Parameter	Standard Protocol	Modifications/Alternatives	References
Sponge material	Open-pored polyurethane (eg, GranuFoam; KCI/3M)	Open-pore film drainage	[35, 36]
Sponge size	Trimmed to defect/cavity dimensions	Trim slightly larger than cavity opening for a snug fit	[33, 35]
Tube	14–18 Fr nasogastric tube	Tube-in-tube modification for simultaneous irrigation/suction	[35, 37]
Sponge fixation	Silk sutures securing the sponge to the tube	—	[35]
Negative pressure	125 mmHg continuous	Low-pressure 25–30 mmHg for friable tissue or post-chemoradiation	[35, 38]
Exchange interval	Every 3–4 days	Individualized based on cavity response	[33, 35]
Placement strategy	Intracavitary (preferred); transition to intraluminal as cavity contracts	Pull-through technique for post-bariatric anatomy	[4, 32, 33]
Device type	EsoSPONGE (B. Braun; not FDA-cleared in the US)	Homemade off-label VAC assembly (validated: 95.5% success)	[32, 39]
Treatment endpoint	Cavity contracted, granulation tissue coverage, no residual collection	CRP/WBC normalization as adjunctive biomarker	[34, 35]

Legend: CRP, C-reactive protein; FDA, Food and Drug Administration; Fr, French; mmHg, millimeters of mercury; VAC, vacuum-assisted closure; WBC, white blood cell count. — = no published alternative described. Reference numbers correspond to the renumbered reference list.

continuous negative pressure at 125 mmHg (**Table 4**) [40]. This pressure setting is derived from the wound care literature and expert convention; it has not been established by comparative trials as the optimal pressure for upper gastrointestinal EVT. The sponge is positioned intracavitarily or intraluminally and exchanged every 3 to 4 days based on expert experience; optimal exchange intervals have not been established by prospective study [32]. Required Procedure Burden. The number of required endoscopic procedures is an important quality-of-hospital-stay metric for patients and families. EVT mandates sponge exchange every 3 to 4 days, potentially resulting in 4 to 12 or more endoscopic procedures over the full treatment

course. SEMS therapy requires a single endoscopic placement in most cases; however, stent migration (occurring in 25% – 41% of cases) [7] or malposition may necessitate additional procedures for repositioning or restenting. Critically, the 14-day shorter mean treatment duration observed with EVT versus SEMS [23] may partially offset the higher per-episode procedure frequency, reducing the total procedure burden. Prospective data directly comparing total procedure counts per completed treatment episode are lacking and represent an important research priority for future comparative studies [40].

Table 5: Comparison of Endoscopic Modalities for Upper Gastrointestinal Transmural Defect Closure

Modality	Mechanism	Success Rate	Advantages	Limitations	Best Indication	References
Endoscopic vacuum therapy	Continuous negative pressure via an open-pored sponge promotes granulation and drainage	82%–95%	Active cavity drainage promotes granulation, lower mortality, and complications vs SEMS	Requires multiple exchanges (every 3–4 days); not FDA-cleared in the US; learning curve ~10 cases	Anastomotic leaks, perforations with contaminated cavity, defects >2 cm	[17, 22, 33, 41]
Self-expanding metal stents	Mechanical luminal coverage of the defect	64%–86%	Single placement; widely available; familiar technique	Migration 25%–41%; no cavity drainage; tissue ingrowth; stricture formation 18%	Contained leaks without large cavity; short-segment defects	[7, 8, 28]
Over-the-scope clips (OTSC)	Mechanical full-thickness tissue approximation	59%–90%	Single-session closure; immediate seal; no exchanges needed	Limited to defects ≤2 cm; lower efficacy for chronic fistulae; tissue fibrosis limits application	Acute perforations ≤2 cm; iatrogenic perforations	[42]
Endoscopic internal drainage	Double-pigtail stent placement for passive drainage	Limited data	Maintains luminal patency; allows oral intake	Longer treatment duration (median 42 days); passive drainage only; limited comparative data	Small contained leaks with an established drainage tract	[31]

Note: Success rates represent ranges reported across cited studies. Reference numbers correspond to the reference list.

Legend: EVT, endoscopic vacuum therapy; FDA, Food and Drug Administration; OTSC, over-the-scope clip; SEMS, self-expanding metal stents.

Intracavitary Versus Intraluminal Placement. Intracavitary placement provides superior drainage and promotes granulation tissue [32]. Jung et al (2022) confirmed that intraluminal placement is an independent risk factor for failure [31]. Expert consensus recommends intracavitary placement as the preferred approach, transitioning to intraluminal positioning as the cavity contracts [40].

Number of Endoscopic Procedures: EVT Versus SEMS. The total endoscopic burden of therapy is an important metric for patient quality of life and resource utilization during hospitalization. EVT requires planned sponge exchange every 3 to 4 days; in a typical treatment course of 2 to 6 weeks, this translates to approximately 5 to 14 exchange procedures. However, because EVT promotes active granulation and drainage, it is associated with a shorter overall treatment duration (14 days shorter than SEMS, as reported by do Monte Junior et al. (2021)) [23], which may partially offset the per-exchange burden. By contrast, SEMS is placed in a single initial procedure but may require additional endoscopies for stent repositioning or replacement due to the high migration rate (25%–41%), [7] stent removal, and management of complications such as tissue ingrowth and stricture formation. The net endoscopic burden across a full treatment course may therefore not differ as dramatically between strategies as the exchange frequency alone suggests. Prospective studies comparing total endoscopy procedure counts per completed treatment episode are needed to inform this important practical consideration.

Homemade Device Assembly. de Moura et al. (2023) validated the off-label wound vacuum-assisted closure component assembly in 144 patients, reporting 95.5% success and 5.6% adverse events [32]. The EsoSPONGE (B. Braun Melsungen AG) is the only commercially available dedicated device, but it is not FDA-cleared in the United States [35]. Smallwood et al (2016) reported the first United States experience using off-label components [39].

Technical Modifications. The pull-through technique (Laukoetter et al, 2017) [4] facilitates placement in post-bariatric surgical anatomy. The tube-in-tube modification (Simas de Lima et al, 2022) [37]

allows simultaneous irrigation and suction. Open-pore film drainage (Loske and Schorsch, 2016) [36] provides comparable drainage to sponge-based systems in certain configurations [43]. Low-pressure protocols (25–30 mmHg) demonstrated comparable efficacy for postoperative leaks (Sundaram et al, 2025), [38] though validation in larger cohorts is needed.

Comparison With Other Endoscopic Modalities (Table 5). Over-the-scope clips (OTSC) achieve success rates of 59% to 90% for acute perforations less than 2 cm but have lower efficacy for chronic fistulae [42]. Endoscopic internal drainage using double-pigtail stents has shown high success rates in limited data, but it requires a longer treatment duration (median 42 days) [31].

3.6. Training Considerations and Cost

Ward et al (2019) demonstrated proficiency after approximately 10 cases, with endoscopy suite procedures costing \$4,528 versus \$11,889 in the operating room (2.6-fold reduction) [44]. However, de Oliveira et al (2024) reported lower total treatment costs for SEMS in traumatic esophageal perforations, driven by the single-placement nature of stent therapy versus multiple sponge exchanges; [41] comprehensive cost-effectiveness analyses are needed.

3.7. Emerging Applications

Colorectal Anastomotic Leaks. Success rates range from 60% to 100% across published series using the Endo-SPONGE for transanal placement [10, 45].

Bariatric Surgery Complications. EVT has been applied to sleeve gastrectomy staple line leaks and Roux-en-Y anastomotic leaks, often requiring the pull-through technique [4]. Success rates are comparable to esophageal leak series, though data remain limited to case series.

Duodenal Perforations. Ciuntu et al (2024) reported complete healing after 3 sponge exchanges in a perforated duodenal ulcer with subphrenic abscess and septic shock [46]. Yurttas et al (2022) demonstrated fewer complications and no therapy failure with

endoscopic negative pressure therapy versus primary surgical repair for retroperitoneal duodenal perforations, which required revision surgery in 66.7% of surgical cases [47].

Preemptive Use After Esophagectomy. Müller et al (2021) reported 73% uneventful anastomotic healing, 7.5% anastomotic leak rate, and 0% 30-day mortality in 67 consecutive patients with preemptive intraoperative placement [48]. Gubler et al (2019) demonstrated 95% uneventful healing in 19 consecutive anastomoses with no mortality [49].

VacStent: A Hybrid Approach. The VacStent is an emerging device that combines the structural luminal coverage of SEMS with the active drainage of EVT, maintaining luminal patency and potentially enabling oral intake during treatment – addressing two key limitations of standard EVT (need for repeated exchanges with oral intake restriction) and standard SEMS (inability to drain contaminated periluminal cavities). A recent systematic review by Kehagias et al (2025) synthesized available evidence on VacStent for esophageal perforations and anastomotic leaks, providing an early literature base for this promising hybrid approach [50]. Current evidence remains limited to small case series, and formal comparative trials against both EVT and SEMS are needed before the VacStent can be recommended as a standard option.

3.8. Practical Pearls for Endoscopic Vacuum Therapy

The following represent expert-derived practice considerations based on published expert experience and multicenter observational data; they are not evidence-based guidelines and have not been validated in randomized trials [32]. Clinicians should adapt these considerations to local expertise, available devices, and individual patient anatomy. Regulatory context: the EsoSPONGE is not FDA-cleared in the United States, and all homemade EVT device assemblies constitute off-label use and require institutional support and informed patient consent [40, 44].

3.8.1. *Sponge sizing*

Trim slightly larger than the cavity opening to ensure a snug fit; an undersized sponge will not generate effective negative pressure and may dislodge.

3.8.2. *Stuck sponge*

Instill 50 to 100 mL of saline through the drainage tube before applying gentle traction; forceful removal risks mucosal avulsion and bleeding.

3.8.3. *Transition strategy*

Begin intracavitary; transition to intraluminal when the cavity has contracted to less than approximately 2 cm with healthy granulation tissue lining the walls.

3.8.4. *Nutrition*

Provide enteral nutrition via jejunostomy tube or parenteral nutrition; withhold oral intake during active treatment.

3.8.5. *Monitoring*

Track C-reactive protein and white blood cell count (WBC) between exchanges; failure to decline after 2 exchanges should prompt reassessment of positioning, drainage adequacy, and consideration of alternative therapies.

3.8.6. *Vacuum loss*

Check for tube kinking first; if the tube is patent, the sponge may have dislodged, and urgent endoscopic reassessment is warranted.

3.8.7. *Discharge planning*

Stable patients may be managed with outpatient sponge exchanges at some centers based on expert practice; this has not been prospectively evaluated. Safety caution: Outpatient management requires verified outpatient endoscopy infrastructure, a reliable patient who can recognize and report signs of sponge displacement or vacuum failure, rapid escalation pathways for complications, and clinician judgment that the patient is sufficiently stable. Retained sponge, mucosal injury, and delayed recognition of a leak are potential risks that have not been systematically characterized in outpatient settings.

3.8.8. *Low-pressure option*

Consider 25 to 30 mmHg for patients with friable tissue, recent chemoradiation, or excessive discomfort at commonly used pressures [38]. [Limited evidence: based on one single-arm cohort study (Sundaram et al, 2025; N not specified); not validated in randomized trials; comparative efficacy versus standard pressure is unknown.]

3.9. Limitations of Existing Evidence and Gaps

Several critical gaps warrant acknowledgment. First, no randomized controlled trials have been completed, though the ESOLEAK trial (NCT03962244) is a phase 2 randomized trial comparing EVT to SEMS for esophageal anastomotic leaks [51]. All comparative data to date derive from retrospective studies and meta-analyses of observational data with inherent selection bias. Second, the five available meta-analyses demonstrate very high primary study overlap (CCA = 95.0%; see Methods for details), meaning their convergent findings reflect analytical consistency rather than independent replication; this review is structured accordingly. Third, no study has reported outcomes disaggregated by sex, gender, race, or ethnicity. Fourth, no standardized protocols exist for negative-pressure settings, exchange intervals, or treatment endpoints. Fifth, predictive models for treatment failure have not been externally validated. Sixth, comprehensive cost-effectiveness analyses have not been performed.

4. Discussion

This narrative review synthesizes the current evidence on EVT as a management strategy for upper gastrointestinal transmural defects, with findings most relevant to esophageal anastomotic leak and iatrogenic perforation, where the comparative evidence base is concentrated. A distinctive feature of this review is its transparent examination of primary study overlap across the five available meta-analyses comparing EVT to SEMS, using the CCA method as a descriptive tool. The resulting confirmed CCA of 95.0% reveals that the five meta-analyses draw from the same small pool of 5 primary comparative studies and therefore represent convergent re-analyses of the same evidence base rather than independent confirmatory datasets. This context is essential for interpreting the apparent consistency of findings across those meta-analyses and distinguishes analytical consistency from true independent replication.

Within this low-certainty observational evidence base, EVT was associated with higher defect closure rates (EVT 85% vs SEMS 64%), lower mortality (12% absolute reduction favoring EVT vs SEMS as reference; RD -0.12), shorter treatment duration (14-day reduction favoring EVT), and fewer adverse events (24% absolute reduction favoring EVT vs SEMS as reference; RD -0.24) across the five overlapping meta-analyses [22–25]. All effect measures are expressed as EVT minus SEMS; negative values indicate EVT advantage. These are observational associations from retrospective data; treatment selection bias, defect severity, timing, surgical context, and center expertise are potential confounders in all included studies and cannot be excluded. The Murray et al (2024) network

meta-analysis corroborates the direction of effect (OR 0.23 for complications; OR 0.43 for mortality, favoring EVT versus stenting, with SEMS/stenting as the reference group) but is similarly based on observational data and subject to the same limitations [17].

The most recently published comparative data come from Mandarino et al (2023), Riva et al (2025), and Heilani et al (2025), none of which were captured in the five pairwise meta-analyses comprising the CCA matrix; their precise independence status relative to Mucha et al (2025) and Ardila et al (2025) is detailed in the Results section and show fewer complications with EVT (8.3% vs 50% in Riva et al; $P = .001$) and elimination of stent-specific complications such as migration and stricture [26–28]. These findings are consistent with the meta-analytic signal but remain subject to the limitations of small, retrospective, single-center observational studies and have not been pooled in a dedicated meta-analysis. The 2025 umbrella review by Ardila et al confirms cross-analytical consistency across six systematic reviews/meta-analyses but contributes no new patient data [19]. The totality of evidence is concentrated in esophageal anastomotic leak and esophageal perforation populations; direct extrapolation to gastric, duodenal, bariatric, or other upper gastrointestinal defect locations should be made with caution, as separate anatomic-site evidence is limited.

The identification of modifiable predictors of success, particularly early initiation within 7 days and intracavitary sponge placement, provides actionable guidance [30, 31]. Based on available observational data and expert-derived experience, centers with EVT expertise may consider prioritizing early endoscopic assessment for potential EVT initiation upon diagnosis; however, this represents an expert-informed hypothesis rather than evidence-based practice guidance. Local expertise, defect anatomy, device availability, and patient stability must be individualized, and these considerations should not be interpreted as standardized best practice pending randomized controlled trial data.

Technical innovations, including homemade device assembly, [32] tube-in-tube modification, [37] low-pressure protocols, [38], and open-pore film drainage [36], expand applicability and address practical barriers. Homemade device assembly has been reported to achieve 95.5% success and 5.6% adverse events in one retrospective multicenter cohort (de Moura et al., 2023; $N = 144$) [32]. This represents single-study evidence from observational data and should not be interpreted as formal device validation; safety data from larger prospective series are lacking. Proficiency is achievable after approximately 10 cases, according to one retrospective analysis, and endoscopy suite procedures have been reported to cost 2.6 times less than operating room procedures in a single-center study [44]. These figures should be interpreted cautiously as they derive from uncontrolled, single-institution data.

Quality Appraisal and Certainty of Evidence. A formal AMSTAR-2/ROBIS assessment of the five meta-analyses and ROBINS-I/Newcastle – Ottawa assessment of the individual comparative studies was not performed, as this lies outside the scope of a narrative review. However, the following structured summary of evidence quality and certainty is provided for each key outcome domain to assist readers in contextualizing the reported findings. All certainty ratings are based on GRADE principles applied informally by the authors. For defect closure rates: evidence is derived from 5 retrospective observational studies pooled across 5 highly overlapping meta-analyses (CCA = 95.0%); serious risk of confounding from treatment selection bias (larger, more accessible defects more likely to receive SEMS), inconsistency in closure definitions across studies, and imprecision from small sample sizes ($N = 163 – 274$ per meta-analysis); overall certainty: low. For mortality: same underlying

evidence base with additional concern for confounding by indication (sicker patients may have been preferentially managed with one modality), variation in follow-up duration, and lack of adjudication of mortality cause; overall certainty: low. For complication rates: outcome definitions vary substantially (procedure-level vs patient-level; type of complication captured differs); heterogeneity is high; the most recently published studies (Riva et al 2025, Mandarino et al 2023) provide cleaner patient-level data but are small ($N = 44–45$); overall certainty: low. For treatment duration: the most consistently reported quantitative outcome; however, censoring criteria and definition of treatment completion differ across studies; overall certainty: low to moderate. For predictors of failure: evidence derives from single-center multivariate analyses (Jung et al. 2022: $N = 119$; de Moura et al. 2023: $N = 144$); risk of bias is high due to small sample sizes, center-specific patient selection, and the absence of external validation; overall certainty: very low. In summary, the overall certainty of EVT-versus-SEMS comparative evidence is low to very low across all outcome domains. The CCA of 95.0% confirms that apparent convergence across meta-analyses reflects re-analysis of the same small evidence base. The 2023 – 2025 comparative studies (Mandarino et al., Riva et al., Heilani et al.) represent more recent but similarly limited retrospective data ($N = 44 – 59$ per study). Findings across all domains should be considered hypothesis-generating observational associations pending randomized controlled trial data. Important additional limitations must be acknowledged. The cost profile of EVT is not uniformly favorable; de Oliveira et al (2024) demonstrated lower total treatment costs for SEMS in traumatic esophageal perforations, driven by the single-placement nature of stent therapy [41]. Heterogeneity in device type, sponge characteristics, negative pressure settings, and outcome definitions further limits cross-study comparability. The large majority of comparative EVT-versus-SEMS evidence derives from esophageal anastomotic leak and iatrogenic perforation studies; the conclusions of this review cannot be directly generalized to gastric, duodenal, bariatric staple-line, or preemptive esophagectomy indications without direct supporting evidence from those specific anatomical and clinical contexts. Clinicians should stratify their interpretation by defect location and etiology and exercise particular caution before applying esophageal leak data to other upper gastrointestinal anatomical sites.

4.1. Health Equity and Access Considerations

The absence of FDA-cleared EVT devices in the United States raises concerns about health equity. Off-label device assembly requires expertise and institutional support concentrated at high-volume academic centers. Patients at community hospitals may have reduced access to EVT and be managed with SEMS by default. Whether this represents inferior outcomes cannot be established from the available low-certainty evidence, but the access disparity itself is a concern independent of comparative efficacy. This is compounded by the absence of standardized training curricula and the approximately 10-case learning curve reported in one retrospective analysis [44]. FDA clearance of a dedicated device would be an important step toward democratizing access.

4.2. Sex and Gender Considerations

None of the meta-analyses or multicenter registries reviewed reported outcomes stratified by sex or gender. Murray et al (2024) reported that 82.6% of patients across 12 studies were male [17]. Sex-based differences in EVT outcomes have not been reported in any included study; whether biological sex influences tissue healing, inflammatory response, or treatment tolerance in this context is unknown and should not be speculated upon in the absence of disaggregated data. This represents a critical evidence gap.

Future studies should prospectively collect and report outcomes disaggregated by sex, gender, race, and ethnicity.

4.3. Future Directions

Priorities include: (1) prospective randomized controlled trials, including the ongoing ESOLEAK trial (NCT03962244), [51] to provide Level 1 evidence; (2) FDA regulatory pathway development for dedicated endoluminal vacuum devices; (3) external validation of predictive models for treatment failure; (4) standardized protocols for negative pressure settings, exchange intervals, and treatment endpoints; (5) comprehensive cost-effectiveness analyses comparing EVT and SEMS that incorporate length of hospital stay, number of reinterventions, and total procedural costs across the full treatment episode, if EVT is confirmed to reduce length of stay, reinterventions, and total costs, it should be prospectively evaluated as a first-line option for anastomotic leaks with appropriate leak characteristics (size of defect, cavity size, and exact leak location); (6) dedicated prospective evaluation of colorectal, bariatric, duodenal, and pre-emptive esophagectomy applications; (7) prospective evaluation of EVT in spontaneous esophageal perforation (Boerhaave syndrome), where the combination of full-thickness transmural injury, mediastinal contamination, and large cavity may represent a particularly favorable indication for active EVT drainage over luminal stenting; and (8) further study of the VacStent, a hybrid device that combines the benefits of SEMS and EVT by maintaining luminal patency and enabling oral intake while providing continuous negative pressure – a recent systematic review by Kehagias et al (2025) provides an early evidence base for this promising approach [50].

This review has several limitations inherent to the narrative design. Literature retrieval was not exhaustive and was not conducted using systematic review methodology; study selection reflects the authors' clinical and methodological judgment and was not performed in duplicate or against pre-registered criteria. Publication bias favoring positive EVT outcomes may be present and cannot be formally assessed without a systematic search and funnel plot analysis. A central interpretive concern highlighted in this review is the confirmed very high overlap among the five available meta-analyses (CCA = 95.0%), meaning that apparent agreement across these analyses reflects re-analysis of the same primary data rather than independent replication.

5. Conclusion

The conclusions of this review are stratified by defect location and etiology, as the evidence base differs substantially across anatomical sites. For esophageal anastomotic leaks and iatrogenic esophageal perforations, where the comparative evidence is concentrated: within the available low-certainty observational evidence, EVT is associated with higher defect closure rates, lower mortality, and fewer complications compared with SEMS across convergent analyses of a shared primary study pool (CCA = 95.0%); no randomized controlled trials have been completed; all comparative data are retrospective and observational; and treatment selection bias, defect severity, surgical context, and center expertise are important potential confounders that cannot be excluded. These findings are hypothesis-generating and should not be interpreted as established superiority. For gastric leaks (including post-sleeve gastrectomy), duodenal perforations, bariatric staple-line leaks, and pre-emptive esophagectomy applications: no pairwise EVT-versus-SEMS comparative studies exist; available evidence consists of single-arm case series and limited registry data that support EVT feasibility but cannot support efficacy claims relative to SEMS. Evidence for these locations is descriptive only. For spontaneous

esophageal perforation (Boerhaave syndrome): EVT has been used successfully in case reports and small series; no comparative data are available versus SEMS; prospective evaluation is warranted given the biological rationale for active cavity drainage in this setting. Across all locations, early initiation within 7 days and intracavitary sponge placement are the most critical modifiable predictors of success where data exist. Priorities include randomized trials, FDA device pathway development, standardized protocols, comprehensive cost-effectiveness analyses, and externally validated predictive models.

Conflicts of Interest

The authors declare no competing interests that could have influenced the objectivity or outcome of this research.

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Institutional Review Board (IRB)

This narrative review of previously published literature did not involve human subjects, animal subjects, or identifiable patient data. Institutional review board approval was not required.

Large Language Model

We have employed an advanced Large Language Model (LLM) (OpenEvidence) to enhance and refine the English-language writing. This process focused solely on improving the text's clarity and style, without adding any new information.

Author Contributions

RB contributed to conceptualization, methodology, literature search, data analysis including CCA calculation, writing original draft preparation, and writing review and editing. BH contributed to editing and critical revision for intellectual content. TB contributed to critical revision for intellectual content. PL contributed to critical revision for intellectual content. TR contributed to writing review and editing and critical revision for intellectual content. All authors approved the final manuscript.

Data Availability

No original data were generated for this narrative review. All data discussed are derived from previously published studies cited in the reference list.

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