Obesity Surgery (2025) 35:5496–5514
https://doi.org/10.1007/s11695-025-08294-6

REVIEW

Endoscopic Treatment of Staple-Line Leaks After Sleeve Gastrectomy in Patients with Obesity: Which One is the Best Option, if Any? A Systematic Review with Meta-Analysis and Meta-regression

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Received: 15 June 2025 / Revised: 18 September 2025 / Accepted: 19 September 2025 / Published online: 20 October 2025

Abstract
Laparoscopic sleeve gastrectomy (LSG) is the most common bariatric surgery, with staple-line leak (SLL) as its most severe complication. Various endoscopic treatments exist, but no universal algorithm is established. The aim of this paper is to estimate the success rates of different endoscopic techniques for SLL management. A search of Medline, Embase, and SCOPUS identified studies on endoscopic treatments. Pooled success rates were calculated using random-effects modeling. Seventy-nine studies (2205 patients) showed an overall success rate of 84.1%. Double-pigtail drainage (90.07%), endoscopic vacuum therapy (90.2%), and septotomy (88.25%) were most effective. Meta-regression indicated significantly higher success with double-pigtail drainage ($p=0.035$). Endoscopic treatments, especially double-pigtail drainage and vacuum therapy, are highly effective for SLL. Further research is needed to compare techniques and evaluate additional clinical factors.

Keywords Obesity · Metabolic and bariatric endoscopy · Endoscopic treatment · Systematic review · Meta-analysis · Meta-regression · Laparoscopic sleeve gastrectomy (LSG) · Staple-line leak (SLL)

Key points

- Laparoscopic sleeve gastrectomy (LSG) is the most performed primary bariatric intervention.
- The most life-threatening complication of LSG is the staple-line leak (SLL).
- Among the proposed options to treat SLL, the endoscopic approaches are a very useful option.
- Our study shows the efficacy of double-pigtail and endo-vacuum treatments in managing SLL after LSG.

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Introduction

Laparoscopic sleeve gastrectomy (LSG) is currently the most common bariatric procedure worldwide, accounting for 45–75% of primary interventions in the USA, with favorable outcomes in terms of weight loss [1, 2]. The most serious complication of LSG is a staple-line leak (SLL), with an average reported incidence ranging from 0 to 7%

[3], although the trend is decreasing [4]. Despite this, the life-threatening nature of this complication demands careful consideration [5, 6].

Several surgical and non-surgical strategies have been proposed for managing SLL after LSG. The American Society for Metabolic and Bariatric and Surgery (ASMBS) recommends conservative, non-surgical treatment as the first-line approach, with endoscopic procedures—including stenting, pigtail drainage, over-the-scope clips (OTSC) or through-the-scope clips (TTSC), vacuum therapy, septotomy, and tissue sealants representing valuable options [4].

Unfortunately, the available evidence remains inconclusive due to the numerical inconsistency (case reports or short case series) and the high heterogeneity of the most published literature data (very often based on retrospective observational studies). As a result, no universally accepted management algorithm has yet been established [7]. The best evidence could be provided by prospective randomized clinical trials, but these are difficult to perform for practical and ethical reasons.

Therefore, we performed a systematic review with meta-analysis of the most recent literature on the endoscopic treatments for SLL after LSG, including tissue sealants, internal drainage, stenting, clipping, vacuum therapy, septotomy, endoscopic suturing, and occluders.

This paper aims to analyze, on the grounds of the literature-based findings, the different techniques of endoscopic management of staple-line leaks after LSG, assessing and comparing their technical characteristics, successful closure rate, and technical and clinical outcomes.

Material and Methods

The systematic review and the meta-analysis were performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines [8].

Search Strategy

A systematic search of the Medline, Embase, and SCOPUS databases from inception to January 11, 2024, was conducted using the terms "sleeve," "gastrectomy," "complication," "leak," "dehiscence," "fistula," "endoscopic," "management," and "treatment"; related words; and Medical Headings (Supplementary File 1, Search strategy for Medline). The search was limited to articles published in English, and there was no restriction according to the publication status. The reference list of selected studies was screened to identify additional potentially relevant studies.

Study Selection

To be selected for the meta-analysis, the studies had to meet the following criteria: (1) to include patients who underwent sleeve gastrectomy and subsequently developed a leak from the staple-line; (2) these patients had to undergo an endoscopic treatment of the leak as first- or second-line treatment; (3) to report outcomes of the endoscopic treatment; (4) to include at least five patients, to prevent instability and imprecision in the meta-analytic model. Conference abstracts and non-human studies were excluded.

Data Extraction and Quality Assessment

Four reviewers (P.M., C.A., M.R., V.R.) extracted data from each selected study regarding the first author, publication year, country of origin, design, number of included patients with a diagnosis of SLL, SLL classification according to the timing of occurrence (acute, early, and chronic), location (esophagogastric junction), type and characteristics of the endoscopic treatment, if the endoscopic treatment was performed as first- or second-line treatment, if the endoscopic treatment was combined or not with additional treatments, and number of successful cases. If the study reported the success rate of different endoscopic approaches, these data were analyzed separately to estimate the efficacy of different interventions. Similarly, whenever possible, the efficacy of the endoscopic treatments was analyzed according to the location and timing of the occurrence of SLL. The quality of each study was evaluated by a modified version of the Newcastle–Ottawa scale for the assessment of the quality of non-randomized studies [9]. By this tool, each study quality was appraised by exploring four domains related to patient selection, outcome measurement tools, outcome assessment, and adjustment for confounders.

Statistical Analysis

The primary outcome was the overall success rate of the endoscopic treatments. Secondary outcomes were the success rate of each type of endoscopic treatment, and according to leak location, timing of occurrence, and line of treatment, the complication rate of the endoscopic treatment.

The success rate was calculated by dividing the number of patients achieving success with the endoscopic treatment by the total number of patients undergoing the endoscopic treatment. Pooled rates, expressed as a percentage, rounded to one decimal place, with 95% confidence intervals, were computed using a random-effect model according to the DerSimonian and Laird method [10]. The Freeman-Tukey double arcsine transformation of the prevalence was used to incorporate in the pooled analysis also studies with rates equal to 0% [11]. The presence of heterogeneity among the studies was assessed by the Cochrane Q test and quantified with the inconsistency index (I^2), with I^2 values of 25, 50, and 75% considered indicative of low, moderate, and high statistical heterogeneity [12]. To further explore and address heterogeneity, subgroup analyses and random-effects meta-regression (restricted maximum likelihood method) were performed to evaluate the impact of treatment type, leak location, timing of occurrence, and line of treatment on treatment success [13]. Influence analysis was performed by leaving each study out in turn and re-computing the summary effect to assess the impact of each study on the overall estimate and heterogeneity. Publication bias was assessed by using Egger's linear regression method [14]. A p-value < 0.05 was considered statistically significant. R version 3.6.1 (2019, The R Foundation for Statistical Computing) was used for statistical analyses.

Results

Study Selection and Characteristics

A total of 79 studies met the inclusion criteria and were selected for this meta-analysis according to Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) (Fig. 1). The characteristics of the included studies are reported in Table 1. A total of 2205 patients undergoing endoscopic treatment for a staple-line leak following sleeve gastrectomy were included in this meta-analysis.

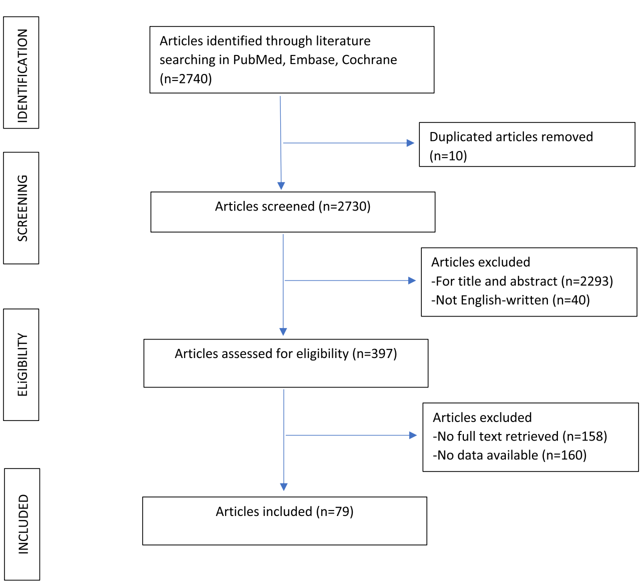


Fig. 1 Articles selection flowchart according to preferred reporting items for systematic reviews and meta-analyses (PRISMA)

Forty-seven studies reported information regarding the timing of staple-line leak occurrence [2, 7, 15–59], while 48 studies reported information regarding leak location [2, 7, 15–17, 19, 21–31, 34–37, 39, 40, 43–45, 47–52, 54, 55, 57, 58, 60–71].

Quality Assessment and Publication Bias

Quality assessment of the included studies according to the Newcastle–Ottawa scale is reported in Table 2. The funnel plot showed symmetry (Supplementary File 2), confirmed by Egger's regression test ($p = 0.151$), which indicates the absence of publication bias.

Success Rate of the Endoscopic Treatments

The endoscopic treatment of SLL showed an overall pooled success rate of 84.1% (95% CI, 79.59 to 88.22, Fig. 2) with evidence of high heterogeneity among the studies ($I^2 = 81.87\%$, $Q = 575.97$; $p < 0.0001$). Influence analysis indicated the robustness of this result, showing that, leaving each study out in turn, the summary estimate of the overall success rate varied between − 1.2% and + 0.41%.

Thirteen studies [19, 22, 26, 28, 37, 40, 41, 43, 50, 59, 72–74] reported data about the success rate of endoscopic treatments according to the line of treatment. As first- and second-line treatments, endoscopic methods achieved a success rate of 78.75% (95% CI, 63.78 to 91.07) and 79.12% (95% CI, 63.97 to 91.54), respectively, with no significant difference between the treatments ($p = 0.172$).

Twelve studies [18, 21, 22, 24, 29, 39, 40, 45, 47, 56, 62, 66] reported the treatment success rate according to the timing of treatment. Six studies [22, 37, 41, 43, 50, 59] reported a success rate of 78.1% (95% CI, 48.3 to 98.3) in the case of acute SLL. The success rate in the case of chronic leak was 74.5% (96% CI, 57.8 to 88.7), according to six studies [19, 22, 26, 40, 41, 43]. The success rate in the case of early leak was 84.5% (95% CI, 71.8 to 94.6), according to ten studies [19, 22, 26, 37, 40, 41, 43, 50, 59, 74]. Meta-regression analysis showed that the success rate of endoscopic treatment was independent of the timing of leak occurrence ($p = 0.543$). Also, meta-regression analysis showed that the success rate of the different endoscopic treatment methods was independent of the location of leaks ($p = 0.053$).

After the index endoscopic treatment, 22.62% (95% CI, 16.57 to 29.19) of the patients required an additional procedure according to 63 studies [2, 5, 15–31, 34–47, 50–60, 63–70, 75–86]. A complication related to the endoscopic treatment was reported in 63 studies [7, 15–17, 19–25, 27–38, 40–45, 47, 50–62, 64–71, 75, 77–79, 82–89] with an incidence of 26.7% (95% CI, 21.5 to 32).

Table 1 Characteristics of the included studies

STUDY	Year	Patients (no.)	Country	Treatment type	Details	Success (no.)	Leaks localizations	Time from surgery to leak	Complications (no.)
Aburajab et al	2017	5	USA	Stent, Clips	FCSEMS, OTSC	5	-	-	2
Alamdari et al	2018	8	Iran	Stent	FCSEMS	7	GOJ = 7; distal = 1	Acute = 1; early = 6; chronic = 1	1
Assalia et al	2018	24	Israel	Sealant	Fibrine glue	23	GOJ = 24; distal = 0	Acute = 10; early = 9; chronic = 5	0
Baretta et al	2015	9	Brazil	Septotomy	Endoscopic stricturotomy	8	GOJ = 9; distal = 0	-	1
Archid et al	2020	8	Germany	EVT	Endoscopic vacuum therapy	7	GOJ = 7; distal = 1	Acute = 0; early = 8; chronic = 0	1
Manta et al	2016	6	Italy	Stent, clips	SEMS, OTSC	3	-	Acute = 3; early = 3; chronic = 0	-
Bona et al	2020	8	Italy	Stent, clips	Esophageal mega stent, OTSC	7	GOJ = 8; distal = 0	Acute = 0; early = 7; chronic = 1	1
Bashah et al	2020	73	Qatar	Stent, clips	Double-pigtail stent, OTSC	66	-	-	2
Yimcharoen et al	2011	6	USA	Stent	Fully and partially covered SEMS	4	-	Acute = 2; early = 0; chronic = 4	2
Aljahdli et al	2021	11	Saudi Arabia	Stent	FCSEMS	9	GOJ = 10; distal = 1	Acute = 2; early = 8; chronic = 1	5
Almadi et al	2018	64	Saudi Arabia	Stent	Fully and partially covered SEMS	60	GOJ = 64; distal = 0	Acute = 32; early = 29; chronic = 3	9
Boerlage et al	2018	13	Netherlands	Stent	FCSEMS	9	-	-	3
Périssé et al	2015	23	Brazil	Stent	FCSEMS	19	GOJ = 23; distal = 0	-	6
Alazmi et al	2014	17	Kuwait	Stent	SEMS, SEPS	13		Acute = 10; early = 6; chronic = 1	6
Al-Kurd et al	2018	14	Israel	Stent, clips	OTSC, non-OTSC clip, stent	6	-	-	-
Billman et al	2021	23	Germany	Stent	Esophageal mega stent, FCSEMS	16	-	-	7
Archid et al	2021	27	Germany	Stent, EVT	SEMS, EVT	17	GOJ = 26; distal = 1	Acute = 7; early = 20; chronic = 0	12
Balagué et al	2021	44	Spain	Stent, clips, sealant	SEMS, OTSC, TTS, sealant	28	GOJ = 39; distal = 5	Acute = 18; early = 26; chronic = 0	25
Caiazzo et al	2020	100	France	Stent	Double-pigtail stent, covered stent	4	GOJ = 79; distal = 21	Acute = 60; early = 33; chronic = 7	-
Benosman et al	2018	26	France	Stent, clips	Double-pigtail stent, SEMS, TTS, OTSC	23	GOJ = 26; distal = 0	-	12

Table 1 (continued)

STUDY	Year	Patients (no.)	Country	Treatment type	Details	Success (no.)	Leaks localizations	Time from surgery to leak	Complications (no.)
Balagué et al	2020	42	Spain	Stent	Fully and partially covered SEMS	23	-	-	18
Fuentes-Valenzuela et al	2021	5	Spain	Stent	Double-pigtail stent	5	GOJ = 5; distal = 5	Acute = 3; early = 1; chronic = 1	1
Garofalo et al	2017	11	Canada	Stent, clips	Double-pigtail stent, SEMS, OTSC	11	GOJ = 11; distal = 0	Acute = 2; early = 8; chronic = 1	2
Hany et al	2021	44	Egypt	Stent	Covered SEMS	33	GOJ = 35; distal = 9	Acute = 0; early = 44; chronic = 0	11
Diaz et al	2020	5	USA	Septotomy	Endoscopic stricturotomy	5	GOJ = 5; distal = 0	Acute = 1; early = 4; chronic = 0	-
Foo et al	2017	6	Australia	Stent	Double-pigtail stent, FCSEMS	6	GOJ = 6; distal = 0	-	-
Ferraz et al	2021	21	Brazil	Stent	SEMS	20	GOJ = 19; distal = 2	Acute = 5; early = 16; chronic = 0	1
Casella et al	2009	6	Italy	Stent, sealant	Covered stent, glue	6	GOJ = 5; distal = 1	Acute = 3; early = 3; chronic = 0	0
Donatelli et al	2015	67	France	Stent	Double-pigtail stent	59	GOJ = 56; distal = 11	Acute = 26; early = 32; chronic = 9	6
Guzaiz et al	2016	12	Saudi Arabia	Stent	Covered SEMS	12	-	-	6
de Moura et al	2019	37	Brazil	Stent	Covered SEMS	29	GOJ = 35; distal = 2	Acute = 10; early = 27; chronic = 0	4
Fishman et al	2015	26	Israel	Stent	SEMS	17	GOJ = 25; distal = 1	Acute = 1; early = 17; chronic = 8	5
Donatelli et al	2014	21	France	Stent	Double-pigtail stent	12	GOJ = 19; distal = 2	-	2
Donatelli et al	2021	275	France	Stent	SEMS, double-pigtail stent	246	-	-	-
Csendes et al	2010	16	Chile	Endoscopic treatment	-	16	GOJ = 14; distal = 2	Acute = 7; early = 9; chronic = 0	1
Christophorou et al	2015	110	France	Stent, clips, sealant	FCSEMS, PCSEMS, double-pigtail stent, OTSC, glue	81	-	Acute = 50; early = 42; chronic = 18	18
Gonzalez et al	2015	15	France	Stent	Mega stent	12	-	-	-
Gonzalez et al	2018	44	France	Stent	Double-pigtail stent	37	-	Acute = 3; early = 33; chronic = 8	11
El-Sayes et al	2017	27	Egypt	Stent	Covered SEMS	23	-	-	-
Lazzarin et al	2020	5	Italy	Stent	Double-pigtail stent	5	GOJ = 5; distal = 0	Acute = 3; early = 2; chronic = 0	0

Table 1 (continued)

STUDY	Year	Patients (no.)	Country	Treatment type	Details	Success (no.)	Leaks localizations	Time from surgery to leak	Complications (no.)
Mahadev et al	2017	9	USA	Septotomy	Endoscopic stricturotomy	6	GOJ = 9; distal = 0	-	0
Mohammad et al	2019	8	Egypt	Stent	Mega stent	7	GOJ = 5; distal = 3	Acute = 4; early = 4; chronic = 0	1
Klimczak et al	2018	14	Poland	Stent	Mega stent	10	GOJ = 14; distal = 0	Acute = 1; early = 12; chronic = 1	9
Krishnan et al	2019	16	USA	Stent	SEMS	15	-	-	2
Talbot et al	2017	21	Australia	Stent, clips	FCSEMS, PCSEMS, TTS, OTSC	18	-	-	3
Leenders et al	2013	6	Netherlands	Stent	FCSEMS	5	GOJ = 3; distal = 3	Acute = 3; early = 3; chronic = 0	2
Moon et al	2015	15	USA	Stent, clips, sealant	SEMS, TTS, fibrine glue	14	GOJ = 15; distal = 0	Acute = 3; early = 9; chronic = 3	-
Lamb et al	2020	5	USA	Stent, endoscopic suturing	-	5	-	Acute = 0; early = 4; chronic = 1	1
Pequignot et al	2012	25	France	Stent	Double-pigtail stent, covered stent	19	GOJ = 19; distal = 6	Acute = 14; early = 11; chronic = 0	9
Mercky et al	2015	18	France	Clips	OTSC, non-OTSC clip, stent	18	-	Acute = 0; early = 5; chronic = 13	6
Leeds et al	2016	9	USA	EVT	Endoscopic vacuum therapy	8	-	Acute = 1; early = 3; chronic = 4	2
Keren et al	2015	26	Israel	Clips	OTSC	21	GOJ = 22; distal = 4	Acute = 10; early = 15; chronic = 1	0
del Campo et al	2018	24	USA	Stent	SEMS	14	GOJ = 18; distal = 6	Acute = 5; early = 8; chronic = 9	10
Olmi et al	2020	66	Italy	Stent, clips	SEMS, double-pigtail stent, OTSC	63	GOJ = 53; distal = 13	Acute = 30; early = 30; chronic = 6	13
Mizrahi et al	2021	26	Israel	Stent, clips, sealant	SEMS, OTSC, fibrine glue	14	GOJ = 26; distal = 0	Acute = 11; early = 8; chronic = 6 (1 unknown)	26
Manos et al	2021	53	France	Stent, endoscopic suturing	Double-pigtail stent, stricturotomy	51	-	Acute = 19; early = 25; chronic = 9	-
Lorenzo et al	2018	100	France	Stent, clips	SEMS, double-pigtail stent, OTSC	86	GOJ = 89; distal = 11	Acute = 44; early = 56; chronic = 0	68
Orive-Calzada et al	2014	11	Spain	Stent	SEMS	8	-	-	-
Juza et al	2015	5	USA	Stent	SEMS	5	GOJ = 3; distal = 2	Acute = 4; early = 1; chronic = 0	-

Table 1 (continued)

STUDY	Year	Patients (no.)	Country	Treatment type	Details	Success (no.)	Leaks localizations	Time from surgery to leak	Complications (no.)
Murino et al	2015	55	Belgium	Stent	SEMS	42	-	-	-
Nimeri et al	2016	14	Arab Emirates	Stent	SEMS	14	GOJ = 13; distal = 1	Acute = 11; early = 1; chronic = 2	-
Spyropoulos et al	2012	8	Greece	Stent, sealant	SEMS, fibrine glue	8	GOJ = 8; distal = 0	-	4
Corona et al	2013	6	Italy	Stent	SEMS	3	-	-	1
Vix et al	2015	7	Taiwan	Stent	SEMS	2	GOJ = 7; distal = 0	-	2
Tan et al	2010	8	Australia	Stent	SEMS	4	GOJ = 8; distal = 0	Acute = 5; early = 3; chronic = 0	4
Nedelcu et al	2015	19	France	Stent	SEMS, double-pigtail stent	19	-	-	2
van Wezenbeek et al	2016	7	Netherlands	Stent, clips	SEMS, OTSC	6	GOJ = 7; distal = 0	-	6
Smallwood et al	2016	6	USA	EVT, clips	Endoscopic vacuum therapy, OTSC	6	-	-	0
Simon et al	2013	9	France	Stent	SEMS	7	GOJ = 9; distal = 0	Acute = 0; early = 6; chronic = 3	2
Shnell et al	2017	8	Israel	Endoscopic suturing	Septotomy	8	GOJ = 8; distal = 0	-	0
Southwell et al	2016	21	New Zealand	Stent	SEMS	15	GOJ = 15; distal = 6	Acute = 6; early = 12; chronic = 3	10
Quezada et al	2015	19	Chile	Stent	FCSEMS	18	GOJ = 19; distal = 0	Acute = 9; early = 6; chronic = 4	10
Rebibo et al	2016	20	France	Stent	SEMS, double-pigtail stent	19	-	Acute = 13; early = 4; chronic = 3	3
Siddique et al	2020	20	Kuwait	Stent	SEMS, double-pigtail stent	17	-	Acute = 0; early = 9; chronic = 11	2
Smith et al	2019	85	USA	Stent, clips, endoscopic suturing	SEMS, OTSC, endoscopic suturing	62	GOJ = 74; distal = 11	Acute = 13; early = 47; chronic = 25	34
Tringali et al	2017	10	Italy	Stent	FCSEMS	8	GOJ = 10; distal = 0	-	2
Shoar et al	2017	73	USA	Stent, clips	SEMS, OTSC	63	-	-	10
Sakran et al	2013	11	Israel	Stent, clips, sealant	SEMS, OTSC, Fibrine glue	5	-	-	-
Ward et al	2021	23	USA	Stent, EVT, clips	SEMS, endoscopic vacuum therapy, OTSC	23	-	-	-

FCSEMS fully covered self-expanding esophageal metal stents, *OTSC* over-the-scope clip, *EVT* endoscopic vacuum therapy, *GOJ* GastrOesophageal Junction, *SEPS* self-expandable plastic stent, *TTS* through-the-scope clip

Table 2 Quality assessment of the included studies according to the Newcastle–Ottawa scale

STUDY	Selection	Sample size	Staple-line leak definition	Adjustment for confounders	Staple-line leak healing definition
Aburajab et al	High	High	Low	High	Low
Alamdari et al	High	High	Low	High	Low
Assalia et al	High	High	Low	High	Low
Baretta et al	High	High	Low	High	Low
Archid et al	High	High	Low	Low	Low
Manta et al	High	High	Low	Low	Low
Bona et al	High	High	Low	Low	Low
Bashah et al	High	High	Low	High	Low
Yimcharoen et al	High	High	Low	High	Low
Aljahdli et al	High	High	Low	High	Low
Almadi et al	High	High	Low	High	Low
Boerlage et al	Low	High	Low	High	Low
Périssé et al	High	High	Low	High	Low
Alazmi et al	High	High	Low	High	Low
Al-Kurd et al	High	High	Low	High	Low
Billman et al	Low	High	Low	High	Low
Archid et al	High	High	Low	High	Low
Balagué et al	High	High	Low	Low	Low
Caiazzo et al	High	High	Low	High	Low
Benosman et al	High	High	Low	Low	Low
Balagué et al	High	High	Low	Low	Low
Fuentes-Valenzuela et al	High	High	Low	high	Low
Garofalo et al	High	High	Low	Low	Low
Hany et al	High	High	Low	Low	Low
Diaz et al	High	High	Low	Low	Low
Foo et al	High	High	Low	High	Low
Ferraz et al	High	High	Low	High	Low
Casella et al	Low	High	Low	Low	Low
Donatelli et al	High	High	Low	Low	Low
Guzaiz et al	Low	High	Low	HIgh	Low
de Moura et al	High	High	Low	HIgh	Low
Fishman et al	High	High	Low	HIgh	Low
Donatelli et al	High	High	Low	Low	Low
Donatelli et al	High	High	Low	Low	Low
Csendes et al	High	High	Low	High	Low
Christophorou et al	High	High	Low	High	Low

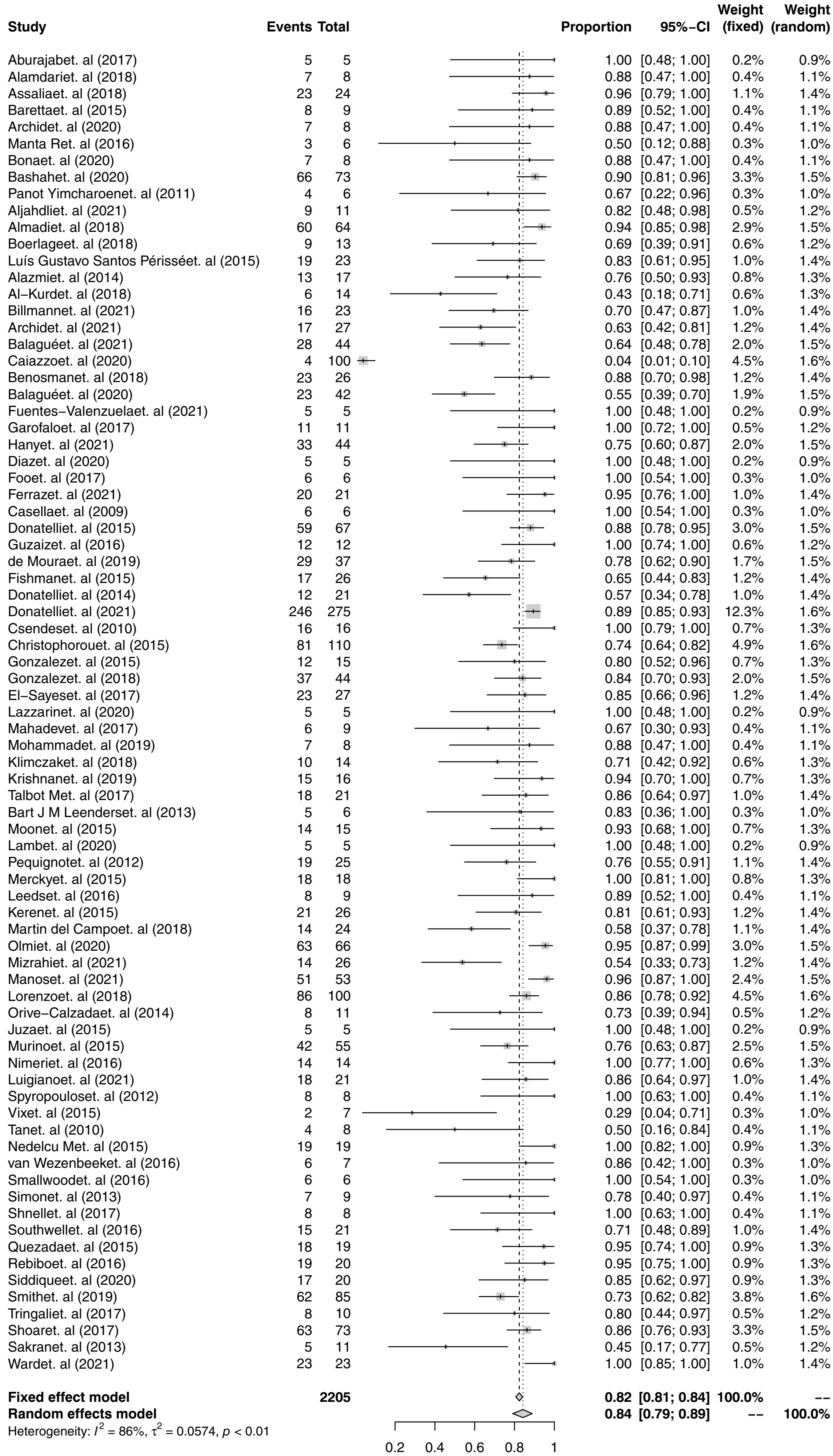
Table 2 (continued)

STUDY	Selection	Sample size	Staple-line leak definition	Adjustment for confounders	Staple-line leak healing definition
Gonzalez et al	High	High	Low	Low	Low
Gonzalez et al	High	High	Low	Low	Low
El-Sayes et al	High	High	Low	High	Low
Lazzarin et al	High	High	Low	High	Low
Mahadev et al	High	High	Low	High	Low
Mohammad et al	High	High	Low	High	Low
Klimczak et al	High	High	Low	High	Low
Krishnan et al	High	High	Low	High	Low
Talbot et al	High	High	Low	High	Low
Leenders et al	High	High	Low	High	Low
Moon et al	High	High	Low	Low	Low
Lamb et al	High	High	Low	High	Low
Pequignot et al	High	High	Low	Low	Low
Mercky et al	High	High	Low	Low	Low
Leeds et al	High	High	Low	High	Low
Keren et al	High	High	Low	High	Low
del Campo et al	High	High	Low	High	Low
Olmi et al	High	High	Low	Low	Low
Mizrahi et al	High	High	Low	Low	Low
Manos et al	Low	High	Low	High	Low
Lorenzo et al	High	High	Low	Low	Low
Orive-Calzada et al	High	High	Low	High	Low
Juza et al	High	High	Low	High	Low
Murino et al	High	High	Low	High	Low
Nimeri et al	High	High	Low	High	Low
Spyropoulos et al	High	High	Low	High	Low
Corona et al	High	High	Low	High	Low
Vix et al	High	High	Low	High	Low
Tan et al	High	High	Low	Low	Low
Nedelcu et al	High	High	Low	High	Low
van Wezenbeek et al	High	High	Low	High	Low
Smallwood et al	High	High	Low	Low	Low
Simon et al	High	High	Low	High	Low
Shnell et al	Low	High	Low	High	Low
Southwell et al	High	High	Low	High	Low
Quezada et al	High	High	Low	High	Low

Table 2 (continued)

STUDY	Selection	Sample size	Staple-line leak definition	Adjustment for confounders	Staple-line leak healing definition
Rebibo et al	High	High	Low	Low	Low
Siddique et al	High	High	Low	High	Low
Smith et al	High	High	Low	High	Low
Tringali et al	High	High	Low	High	Low
Shoar et al	High	High	Low	High	Low
Sakran et al	Low	High	Low	High	Low
Ward et al	High	High	Low	low	Low
				Risk of bias	
Selection (representativeness of the sample)	Consecutive patients			Low	
	Non-consecutive patients			High	
	Not described			High	
Sample size	Justified			Low	
	Not justified			High	
Detection (staple-line leak definition)	Described			Low	
	Not described			High	
Adjustment for confounders (outcomes reported according to treatment type or timing of treatment)	Adjusted for confounders			Low	
	No adjustment for confounders			High	
Detection (staple-line leak healing definition)	Described			Low	
	No description			High	

Fig. 2 Overall pooled success rate of endoscopic treatments for staple-line leaks



Efficacy of Different Endoscopic Treatments

In total, 70 studies reported the success rates specific to one or more endoscopic treatments.

Ten studies [18, 22, 24, 39, 45, 47, 62, 66, 85, 87] reported a pooled success rate of endoscopic clipping (OTSC or TTS) of 65.98% (95% CI, 41.32 to 87.68) as shown in Fig. 3. Double-pig tail drainage achieved a pooled SLL closure in 90.07% (95% CI, 73.99 to 99.66) of the patients, according to ten studies [23, 24, 27, 34, 40, 45, 47, 56, 62, 64] (Fig. 3). The success rate of endoscopic vacuum therapy was 90.2% (95% CI, 76.31 to 99.09) in four studies [17, 21, 42, 85]

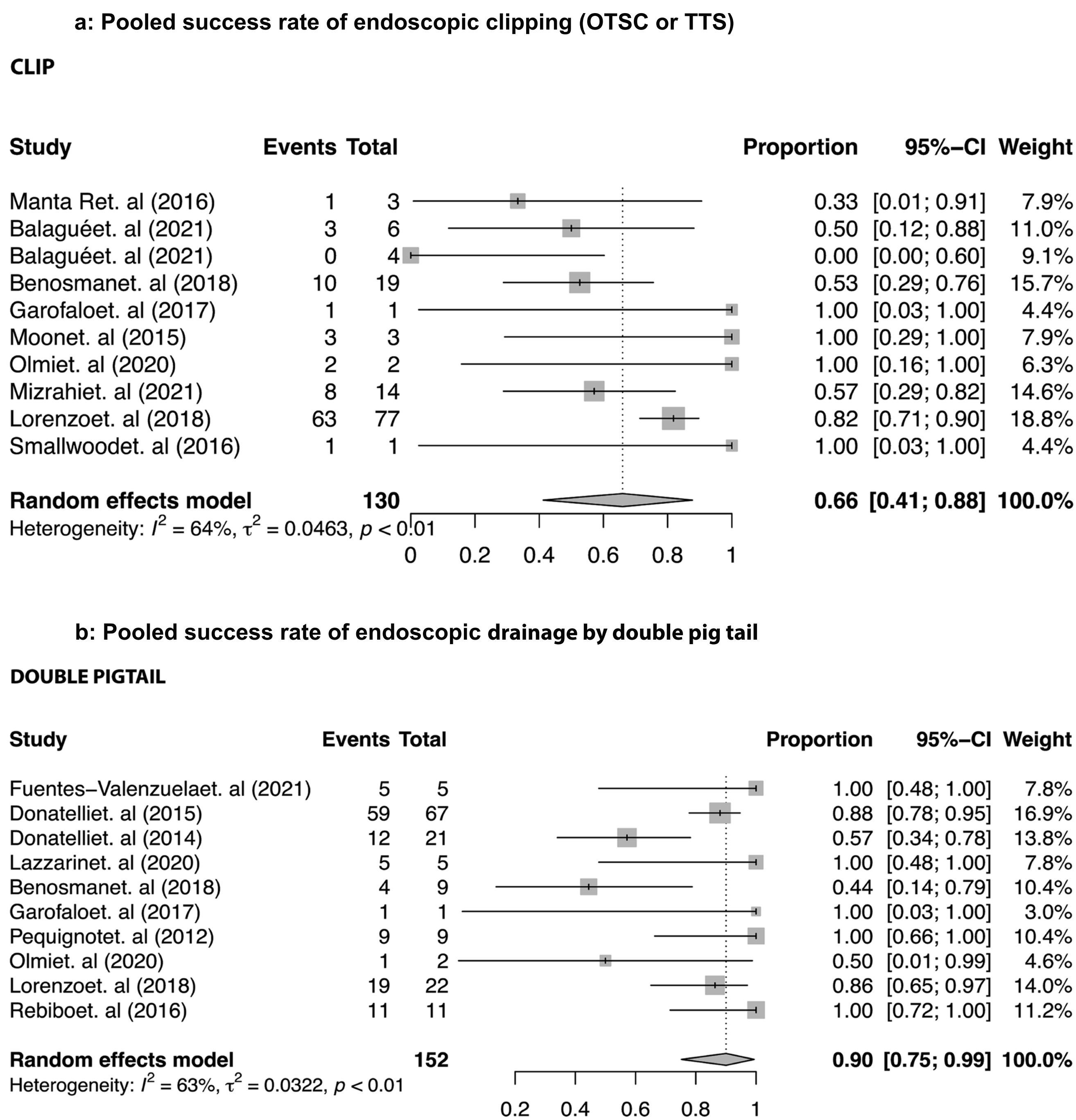


Fig. 3 Pooled success rate of the endoscopic clipping (OTSC or TTS) and drainage by double pig tail

(Fig. 4). Three studies [60, 65, 70] reported data on the efficacy of septotomy, with a pooled efficacy observed in 88.25% (95% CI, 63.56 to 100) of the cases (Fig. 4). Sealant application showed a success in 56% (95% CI, 60.3 to 99.3) according to five studies [16, 22, 29, 39, 66] (Fig. 4).

Thirty-three studies [15, 18, 20–22, 24, 29–31, 35, 36, 39, 40, 44, 45, 47, 48, 55–58, 61, 62, 66, 68, 71, 72, 78, 79, 82, 83, 87, 90] reported data on the application of stents, with a pooled success rate of 79.8% (95% CI, 73.4 to 85.64) as shown in Fig. 5.

Meta-regression analysis showed a statistically significant association between the use of double pig tails and a higher success rate ($p = 0.035$). A similar trend was also observed for endoscopic vacuum therapy ($p = 0.052$).

Discussion

LSG is currently the most commonly performed bariatric procedure worldwide, accounting for up to 75% of the primary interventions in the USA [1, 2]. This popularity is because LSG involves only the stomach, avoiding anastomosis and, consequently, the risk of internal hernias during follow-up. It also preserves the pylorus, allowing normal gastric emptying and a less severe rebound hypoglycemia [1, 91–93]. Another advantage is that, in case of serious complications, it can be converted into a bypass operation.

On the other hand, within the specific complications of LSG, SLL is the most serious, with highly related mortality [6]. The incidence of SLL after primary LSG varies in published series between 0.5 and 7% with a mean value of 2.5%, depending on surgical volume and the surgeon's experience [4, 7, 94–98]. More recent data show an SLL reduction of over 50%, from 2.5% to approximately 1.1% [4, 99]. However, these figures derived from the registers of the International Societies of Bariatric Surgery are likely underestimated. The ASMBS, evaluating several series of different experienced surgeons, reported a leak rate after LSG between 16 and 20% [4, 96]. Furthermore, the lack of anastomosis and the perceived technical simplicity of the procedure have encouraged many general surgeons to perform LSG in non-specialized bariatric centers. Complications from such cases are often not reported in international registries, leading to significant data loss [6].

The causes of SLL after LSG can be recognized as mechanical or ischemic reasons, both involving increased intraluminal pressure exceeding the strength of the tissue and/or staple line [4, 5]. The clinical and symptomatic appearance of the leak is often subtle; thus, a timely and appropriate treatment is essential to minimize inflammatory and septic complications. However, the patient's immunoreactive attitude affects more than the therapeutic timing alone in determining the endogenous response. For these reasons, morbidity and mortality can develop despite the correct treatment of the SLL [4, 100].

The endoscopic management of this life-threatening complication has been attempted using several different therapeutic approaches. Unfortunately, the small sample sizes and heterogeneity of published series make direct comparisons unreliable. Many reports refer to patients undergoing multiple, sequential treatments—surgical or endoscopic—making interpretation even more complex [3, 22, 101]. Prospective randomized trials would provide the most reliable evidence, but such studies are unlikely due to practical and ethical limitations. Consequently, no universally accepted treatment algorithm currently exists.

For all these reasons, to address this problem, we conducted a systematic review of the literature and a meta-analysis with meta-regression analysis to identify the best endoscopic treatment of SLL after SG.

Our analysis highlights several key findings. First, we must understand that the endoscopic treatments seem to have similar outcomes as both first- and second-line therapy. This could be because the non-endoscopic first-line therapy (often a radiological drainage) does not modify the anatomic features of the SLL and does not compromise the outcomes of the endoscopic treatments, even if applied as second-line therapies in case of first-line therapy failure.

Second, success rates tend to decline in early, acute, and chronic leaks, although this trend does not reach statistical significance due to the limited number of studies reporting these data ($n = 6$). There is, indeed, a relationship between the timing of the leak and its success treatment rate due to the hardness of the tissue border of the leak: the harder and more callous the edge of the leak, the more difficult it is for endoscopic treatment to be successful [3, 22, 101].

Our findings confirm the superior performance of double-pigtail stents and dedicated mega-stents. This, probably, is because they do not promote direct closure of the leak, but favor healing by secondary intention, together with drainage, for double pig tails, or after radiological drainage, for mega-stents. Perhaps the favorable results of VAC therapy, which stimulates drainage and healing by secondary intention, should be interpreted in this direction.

The worst results, however, are obtained with glues and clips. This depends, mainly, on the dimensions of the leak because the use of biological glues is indicated in case of leaks of a few mm in diameter, anyway less of 1 cm [3, 22, 101], and these situations are typical of very few cases. The evidence on clips is less consistent, as many series pool results for over-the-scope clips (OTSC) and through-the-scope clips (TTSC), despite their differing efficacy. This depends on the dimension and on the timing of the leak, as we already said above. Finally, we must consider that the sleeve is a low-volume and high-pressure system between two functioning sphincters (cardia and pylorus). Thus, even

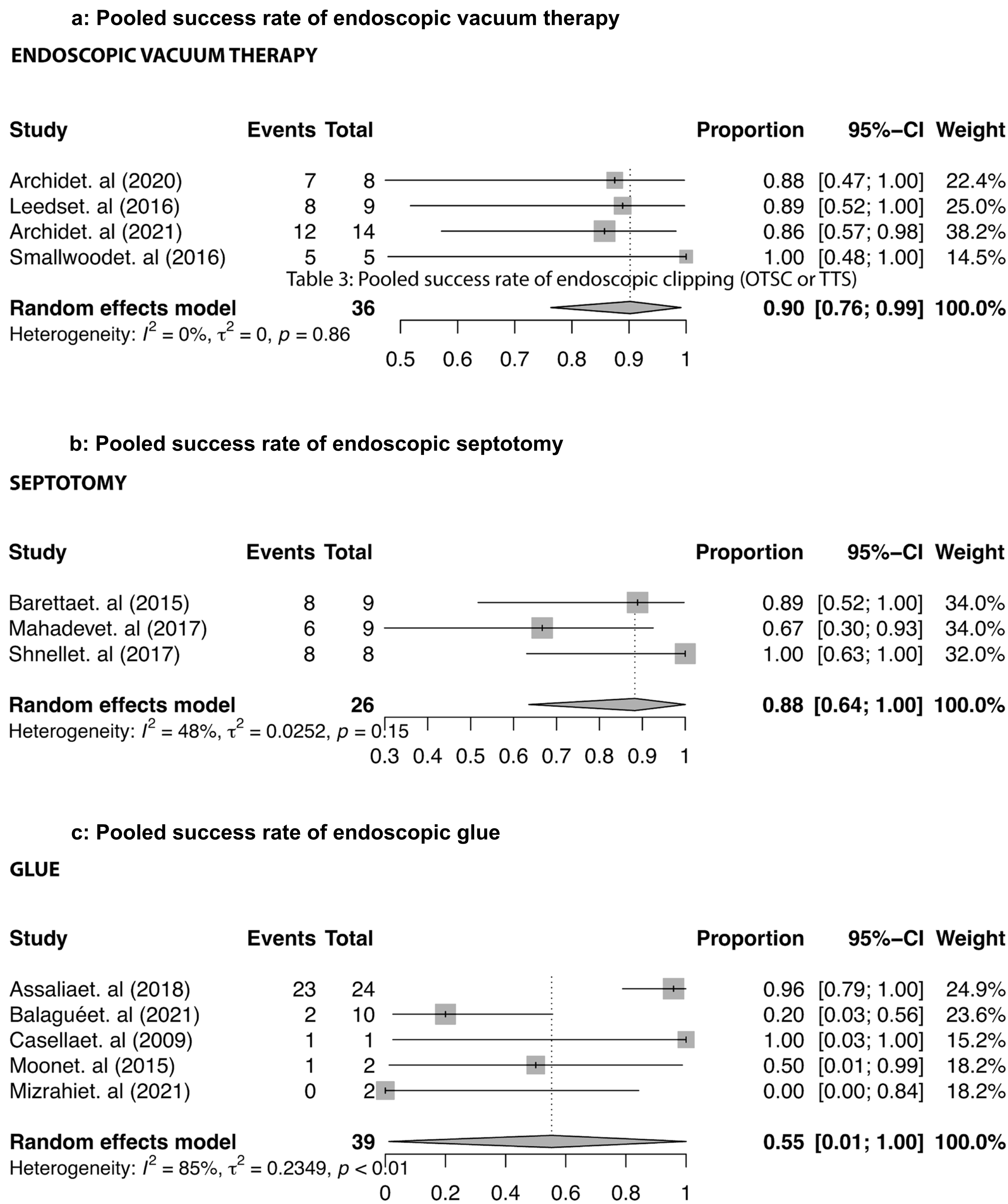


Fig. 4 Pooled success rate of the endoscopic vacuum therapy, septotomy, and glue

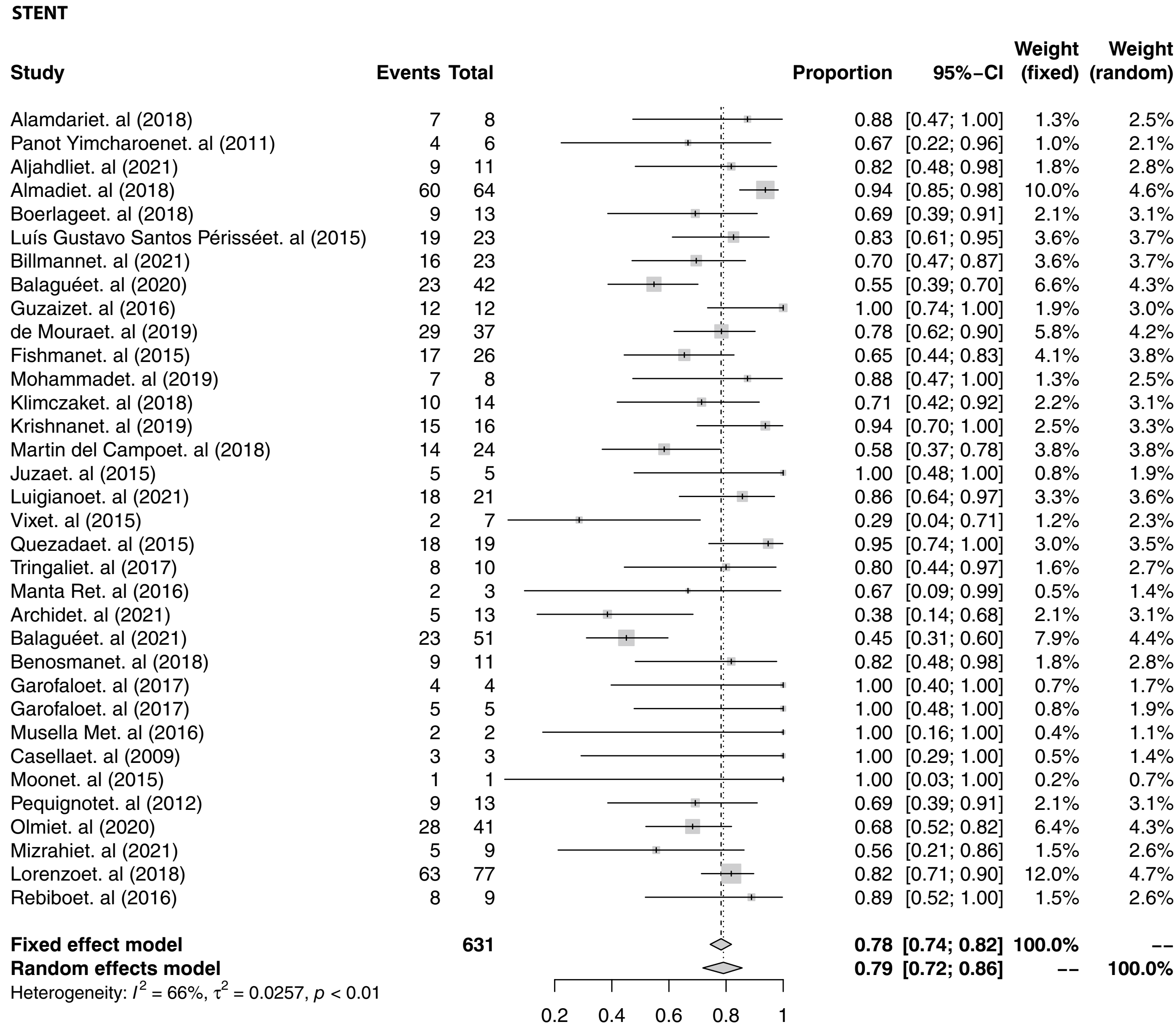


Fig. 5 Pooled success rate of the endoscopic stenting

modest increases in endoluminal pressure can exceed the holding force of the clips, leading to a treatment failure [3, 22, 101].

We focused our review on endoscopic modalities because they are recommended as the first-line, conservative approach for SLL; accordingly, we aimed to compare the relative effectiveness of these techniques to inform evidence-based selection within that initial step of care. Surgical management remains integral to a step-up algorithm and is reserved for situations in which non-operative/endoscopic strategies are inappropriate or have failed—namely hemodynamic instability, diffuse peritonitis, or suspected gastric ischemia requiring urgent operative source control; large, devitalized, or otherwise non-closable defects; undrainable or inaccessible collections and ongoing sepsis despite adequate endoscopic and radiologic drainage and refractory leaks after sequential endoscopic attempts, for which several published algorithms advocate early or salvage surgical repair.

Strengths and Limitations

The strength of the meta-analysis is represented by the high number of studies, which, on the one hand, encompasses all the endoscopic treatments described in the literature and, on the other hand, provides high statistical power, particularly for the meta-regression analyses.

The main limitation is represented by the fact that the vast majority of the included studies were retrospective, with intrinsic methodological limitations, and the observed success rates were derived from highly heterogeneous populations and treatment contexts. Such variability in study design, patient selection, and reporting standards inevitably affects the robustness of pooled estimates. Although statistical heterogeneity was systematically assessed and addressed through subgroup analyses, random-effects modeling, and meta-regression, residual heterogeneity cannot be fully eliminated and should be taken into account when interpreting the findings. Therefore, while our results highlight promising trends, they should not be regarded as conclusive evidence of interchangeability among techniques, but rather as an informed synthesis of the best available—yet imperfect—data. These constraints underscore the need for more rigorous future research. In a setting in which randomized trials are logistically and ethically difficult to perform, prospective multicenter registries with standardized definitions of outcomes, uniform leak classification, and clearly reported endpoints would provide more reliable evidence. Such efforts are essential to translate current evidence into reproducible algorithms that can be consistently applied in clinical practice.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11695-025-08294-6.

Author Contribution Conception and design: G.G and S.M; Data collection: A.C., R.M., R.V and M.P; Assembly of data: A.C, M.P, R.M and M.C.G; Data analysis: G.G. and M.C.G; Drafting of the manuscript: G.G and M.M. Substantial contribution to revision of the manuscript critically for important intellectual content: A.P. and M.M. All the authors approved the final manuscript.

Funding Open access funding provided by Università degli Studi di Napoli Federico II within the CRUI-CARE Agreement.

Data Availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

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