

Laras Wiyardhani<sup>1</sup>, Tara Sander<sup>2</sup>, Akbar Wibriansyah<sup>3</sup>\*

Klinik Pratama Maresha, Indonesia<sup>1</sup>
Universitas Respati Indonesia<sup>2</sup>
Rumah Sakit Umum Provinsi Bahteramas, Indonesia<sup>3</sup>
Email: l.wiyardhani@gmail.com, akbarw2b2@gmail.com\*

#### Abstract

Rubber-band ligation (RBL) and sclerotherapy are the two most widely used office-based interventions for symptomatic haemorrhoidal disease, yet their comparative benefits remain uncertain. This systematic review and meta-analysis evaluated the relative efficacy and safety of sclerotherapy versus operative treatments (primarily RBL and excisional procedures). The primary objective of this systematic review and meta-analysis was to evaluate the relative efficacy and safety of sclerotherapy versus operative treatments (primarily RBL and excisional procedures) in the management of hemorrhoidal disease. Treatment success was 78.2% in operative arms (701/896) versus 74.1% with sclerotherapy (665/897); pooled RR = 1.03 (95% CI 0.91–1.17; I² = 85%), indicating non-inferiority of sclerotherapy. Recurrence in two trials (n = 302) showed lower recurrence after sclerotherapy (12.9%) than after operative treatment (28.4%); RR = 2.22 (95% CI 1.37–3.58; I² = 0%). Pain in three trials (n = 335) reported a higher risk of significant pain following operative procedures (RR = 1.17, 95% CI 1.02–1.34; I² = 60%) and greater mean pain intensity (SMD = 0.96, 95% CI 0.22–1.71; I² = 89%). Sclerotherapy achieves comparable short-term symptom control to operative treatments while offering superior durability and a more favorable pain profile. Given its minimal invasiveness and ease of repetition, modern sclerotherapy should be considered a first-line option for grade I–III haemorrhoids. High between-study heterogeneity underscores the need for standardized protocols and longer follow-up.

**Keywords:** haemorrhoidal disease; randomised controlled trial; rubber-band ligation; sclerotherapy

#### INTRODUCTION

Hemorrhoidal disease (HD) is one of the most prevalent proctological conditions worldwide, significantly impacting quality of life and imposing a substantial burden on healthcare systems (Johanson & Sonnenberg, 1990; Lohsiriwat, 2012; Riss et al., 2012). Characterized by the pathological enlargement and distal displacement of the hemorrhoidal vascular cushions within the anal canal, this condition affects millions of individuals globally, with manifestations ranging from asymptomatic bleeding to painful prolapsed tissue requiring surgical intervention (Gallo et al., 2020; Lohsiriwat, 2015; Davis et al., 2018). Recent international epidemiological surveys demonstrate considerable variation in prevalence rates, ranging from 4.4% to 38.9% across different populations, with peak incidence occurring between ages 45 and 65 years (Haas et al., 1983; Peery et al., 2019; Tournu et al., 2017). Sheikh et al. (2020) conducted a comprehensive international web-based survey across eight countries (Brazil, Czech Republic, France, Hungary, Italy, Romania, Russia, and Spain), revealing an overall hemorrhoidal disease prevalence of 11% among 16,015 adults, with 71% presenting with low-severity disease. Similarly, Kibret, Oumer, & Moges (2021) found a 13.1% prevalence among surgical outpatients in Ethiopia, with significant associations between constipation, elevated body mass index, and hemorrhoidal development.

The clinical presentation of hemorrhoidal disease encompasses a spectrum of symptoms including rectal bleeding, prolapse, pain, pruritus, and anal discomfort, with bleeding (47%)

and pain (60%) being the most commonly reported initial symptoms (Sheikh et al., 2020; Godeberge et al., 2024). Current treatment paradigms follow a stepwise approach, progressing from conservative medical management to minimally invasive office procedures, and ultimately to surgical intervention for refractory or advanced cases (Brown, 2017; Yamana, 2017; Higuero et al., 2016). The therapeutic landscape includes diverse modalities ranging from topical medications and venoactive drugs to rubber band ligation, sclerotherapy injection, infrared coagulation, and various hemorrhoidectomy techniques (Alonso-Coello et al., 2006; Sheikh, Lohsiriwat & Shelygin, 2020; Godeberge et al., 2021). Among minimally invasive treatments, sclerotherapy injection and surgical excision represent two fundamentally different therapeutic approaches that have garnered significant clinical attention due to their distinct mechanisms of action, efficacy profiles, and complication rates (MacRae & McLeod, 1997; Cocorullo et al., 2017; He & Chen, 2023).

Sclerotherapy injection involves the submucosal administration of sclerosing agents, such as polidocanol foam, phenol in oil, or aluminum potassium sulfate and tannic acid (ALTA), to induce inflammatory fibrosis and vascular obliteration of hemorrhoidal tissue (Moser et al., 2013; Mishra et al., 2020; Yano & Yano, 2015). Recent systematic reviews have demonstrated the safety and efficacy of modern sclerotherapy techniques, with Lobascio et al. (2025) reporting promising results using 3% polidocanol foam for grade II-III hemorrhoids, achieving comparable outcomes to traditional methods with reduced postoperative complications. Conversely, operative hemorrhoidectomy, including conventional Milligan-Morgan and Ferguson procedures, as well as newer techniques such as LigaSure hemorrhoidectomy, provides definitive tissue excision with superior long-term efficacy but carries higher morbidity and prolonged recovery periods (Bhatti, Sajid & Baig, 2016; Nienhuijs & de Hingh, 2009; Simillis et al., 2015). Despite extensive clinical experience with both treatment modalities, significant heterogeneity exists in the available evidence base, with inconsistent quality of studies and outcome measures hampering reliable synthesis for evidence-based guidelines (Jacobs, 2014; Rubbini, Ascanelli & Fabbian, 2018; Elbetti et al., 2015). Lohsiriwat et al. (2023) conducted a systematic literature review highlighting the lack of comprehensive understanding regarding interventions that can reduce recurrence and improve outcomes in hemorrhoidal disease, noting significant gaps in real-world evidence on treatment effectiveness and long-term outcomes. The Italian Society of Colorectal Surgery consensus statement emphasized the need for individualized treatment approaches while acknowledging the limitations of current classification systems and the paucity of high-quality comparative studies (Gallo et al., 2020). Furthermore, recent meta-analyses have identified substantial methodological limitations, heterogeneity in study populations, and potential publication bias in existing literature, raising questions about the optimal treatment selection criteria (Alonso-Coello et al., 2006; Aziz et al., 2018).

The increasing prevalence of hemorrhoidal disease, coupled with evolving minimally invasive techniques and the imperative for cost-effective healthcare delivery, underscores the critical need for robust comparative effectiveness research. Recent advances in sclerotherapy agents, particularly the development of polidocanol foam formulations, have renewed interest in injection therapy as a viable alternative to surgical intervention (Bracchitta, Bracchitta & Pata, 2021; Zhang et al., 2015). However, the comparative effectiveness of operative treatment versus sclerotherapy injection remains inadequately characterized due to limited high-quality randomized controlled trials, variability in technique standardization, heterogeneous outcome measures, and insufficient long-term follow-up data (Yano et al., 2014; Tokunaga, Sasaki & Saito, 2010; Tomiki et al., 2019). The absence of definitive comparative evidence has resulted in considerable practice variation and uncertainty regarding optimal treatment algorithms for

different grades of hemorrhoidal disease (Ng, Holzgang & Young, 2020; De Marco & Tiso, 2021).

This systematic review and meta-analysis aim to comprehensively evaluate and compare the effectiveness of operative treatment and sclerotherapy injection in the management of hemorrhoidal disease by synthesizing evidence from randomized controlled trials. By systematically assessing clinical outcomes including symptom resolution, recurrence rates, complication profiles, and patient-reported outcomes, we seek to provide definitive guidance on the comparative effectiveness of these two therapeutic approaches. Additionally, this analysis will identify critical gaps in the current evidence base, inform clinical decision-making, and establish priorities for future research in hemorrhoidal disease management.

#### **METHOD**

This systematic review and meta-analysis will be conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

This review will include only randomized controlled trials (RCTs) that compare operative treatments such as conventional hemorrhoidectomy, rubber-band ligation, infrared coagulation, laser hemorrhoidoplasty, or transanal hemorrhoidal dearterialization, with sclerotherapy using established sclerosants (phenol in oil, sodium tetradecyl sulfate, polidocanol, ethanolamine oleate, ALTA) in adults ( $\geq 18$  years) with internal (Goligher I–IV), external, or mixed hemorrhoids requiring invasive or semi-invasive therapy. Primary outcomes are treatment success, symptom resolution, and recurrence; secondary outcomes include procedure time, hospital stay or recovery, complications, and patient-reported quality of life, with  $\geq 4$  weeks' follow-up mandated. Exclusions encompass any non-RCT designs, pediatric or complicated cases, conservative therapies, studies without comparators or adequate outcome data, sample sizes < 10, non-English or non-peer-reviewed reports, abstracts only, reviews, duplicates, animal/in vitro work, and studies with > 20 % loss to follow-up. Two independent reviewers will screen all studies, resolving disagreements through a third reviewer. (Suplementary 2)

A comprehensive search will be conducted in the following electronic databases: PubMed, EBSCO, and ProQuest. The search strategy will include keywords "hemorrhoidectomy," sclerotherapy." Boolean operators (AND) will be used to combine terms. This ensures the specificity of our analysis. Detailed search strategy is presented in Supplementary File 1. We included all studies published until January 2025.

All identified records will be imported into a reference management software (e.g., Zotero) for organization. Duplicate records will be removed using automated and manual methods. Titles and abstracts will be independently screened by two reviewers to identify potentially eligible studies. Full texts of potentially relevant studies will be assessed against inclusion and exclusion criteria by two reviewers.

The quality and risk of bias of included studies will be assessed using validated tools appropriate for the study design, such as the RevMan 5.4.1 for RCTs. Discrepancies between reviewers will be resolved through discussion or consultation with an independent reviewer.

Quantitative data will be analyzed using meta-analytic techniques where appropriate. Effect sizes will be calculated using standardized mean differences (SMD) or risk ratios (RR) with 95% confidence intervals (CI). Heterogeneity will be assessed using the I² statistic, and subgroup analyses will be conducted to explore sources of heterogeneity. If meta-analysis is not feasible, a narrative synthesis will be performed. Statistical analysis will be conducted using software RevMan.

#### RESULTS AND DISCUSSION

## Data identification and selection process

A comprehensive search was conducted across PubMed, ProQuest, and EBSCO which yielded a total of 338 records. After removing 75 duplicates, 263 unique records remained for screening. During the title and abstract screening phase, 263 records were assessed, of which 248 were excluded due to irrelevance, such as unrelated topics, non-English language, or non-research articles. This left 15 articles for full-text review. Of these, 4 articles were excluded because irrelevant outcome. A total of 11 studies met the inclusion criteria and were included in the final analysis. All 11 studies were further included in the meta-analysis. (Figure 1)

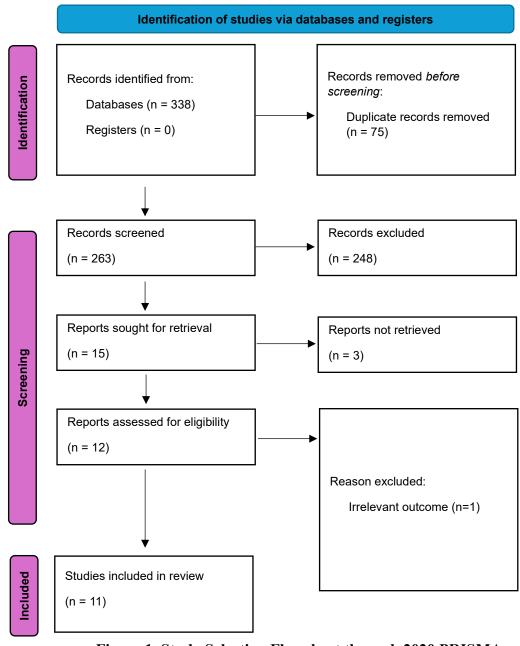


Figure 1. Study Selection Flowchart through 2020 PRISMA

#### Study characteristics

Six randomized (multicenter Chinese, Portuguese, Pakistani and Saudi studies) and five prospective comparative or longitudinal cohorts from India and Nigeria, now compare rubberband ligation (RBL) with various forms of injection or foam sclerotherapy for grade I-III internal haemorrhoids. Collectively they enrol  $\approx 1$  680 adults (sample-size range 60-720), including the newly added 2024 hospital-based study from Mysuru, India that randomised 40 patients to sclerotherapy and 40 to RBL. The largest trial remains a Saudi RCT of 720 cases (360 per arm) which favoured RBL for symptom relief at 3 months, while a Chinese multicentre RCT (n = 195) showed lower 24-h pain scores and less 12-month prolapse with polidocanolfoam sclerobanding than with endoscopic RBL. A Portuguese open-label trial with 120 participants likewise reported higher complete-success and lower recurrence after foam sclerotherapy compared with RBL. Across studies, sclerotherapy (particularly foam formulations) consistently produces less early post-procedure pain, whereas RBL tends to yield lower immediate bleeding rates; long-term recurrence varies by technique and follow-up duration. Adverse events were generally mild, with no trial detecting significant differences in serious complications. Variation in sclerosant concentration, delivery method and adjunctive measures (e.g., cap-assisted ligation) explains much of the heterogeneity, underscoring the need to tailor office-based therapy to available expertise, patient tolerance for pain vs bleeding risk, and desired speed of symptom resolution. (Tabel 1)

# Study results

The pooled analysis of 11 studies with 1,793 participants revealed no statistically significant difference in treatment success rates between operative treatments and sclerotherapy. Operative treatments achieved success in 701 of 896 patients (78.2%), while sclerotherapy was successful in 665 of 897 patients (74.1%). The pooled risk ratio was 1.03 (95% CI: 0.91 to 1.17; p > 0.05), indicating non-inferiority of sclerotherapy compared to operative treatments. However, substantial heterogeneity was observed ( $I^2 = 85\%$ ), suggesting significant variation across studies in treatment protocols and outcome definitions. (Figure 2)

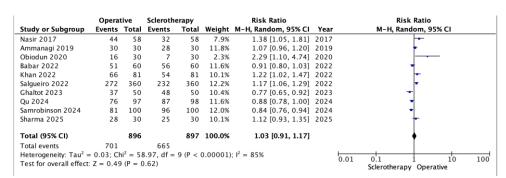


Figure 2. Forest plot of Treatment Success of Operative and Sclerotherapy

Analysis of 2 studies encompassing 302 participants demonstrated a statistically significant difference in recurrence rates favoring sclerotherapy. Operative treatments showed higher recurrence rates with 42 of 148 patients (28.4%) experiencing recurrence, compared to 20 of 154 patients (12.9%) in the sclerotherapy group. The pooled risk ratio was 2.22 (95% CI: 1.37 to 3.58; p < 0.01), indicating that operative treatments were associated with more than twice the risk of recurrence compared to sclerotherapy. Notably, this analysis showed low heterogeneity ( $I^2 = 0\%$ ), suggesting consistent findings across studies. (Figure 3)

Operat	ive	Sclerothe	erapy		Risk Ratio		Risk Ratio
<b>Events</b>	Total	Events	Total	Weight	M-H, Random, 95% CI	Year	M-H, Random, 95% CI
21	51	9	56	49.3%	2.56 [1.29, 5.07]	2022	<del></del>
21	97	11	98	50.7%	1.93 [0.98, 3.78]	2024	<del></del>
	148		154	100.0%	2.22 [1.37, 3.58]		•
42		20					
0.00; Ch	$ni^2 = 0.$	34, df = 1	(P = 0)	$.56$ ); $I^2 =$	0%		0.01 0.1 1 10 100
Z = 3.26	(P = 0)	.001)					Sclerotherapy Operative
	21 21 42 0.00; Ch	21 51 21 97 148 42 0.00; $Chi^2 = 0$ .	Events         Total         Events           21         51         9           21         97         11           148           42         20	Events         Total         Events         Total           21         51         9         56           21         97         11         98           148         154           42         20         20           0.00; Chi² = 0.34, df = 1 (P = 0)         1 (P = 0)	Events         Total         Events         Total         Weight           21         51         9         56         49.3%           21         97         11         98         50.7%           148         154         100.0%           42         20         0.00; Chi² = 0.34, df = 1 (P = 0.56); i² =	Events         Total         Events         Total         Weight         M-H, Random, 95% CI           21         51         9         56         49.3%         2.56 [1.29, 5.07]           21         97         11         98         50.7%         1.93 [0.98, 3.78]           42         148         154         100.0%         2.22 [1.37, 3.58]           42         20           0.00; Chi² = 0.34, df = 1 (P = 0.56); i² = 0%	Events         Total         Events         Total         Weight         M-H, Random, 95% CI         Year           21         51         9         56         49.3%         2.56 [1.29, 5.07]         2022           21         97         11         98         50.7%         1.93 [0.98, 3.78]         2024           42         20           0.00; Chi² = 0.34, df = 1 (P = 0.56); i² = 0%         0%         2.22 [1.37, 3.58]         2.20

Figure 3. Forest plot of Recurrent Hemoroid of Operative and Sclerotherapy

The meta-analysis of pain outcomes from 3 studies with 335 participants revealed significantly higher pain scores in the operative treatment group. Using dichotomous analysis, 474 of 532 operative patients (89.1%) experienced significant pain compared to 310 of 394 sclerotherapy patients (78.7%). The pooled risk ratio was 1.17 (95% CI: 1.02 to 1.34; p < 0.05), indicating that operative treatments were associated with a 17% higher risk of experiencing significant pain. Moderate heterogeneity was observed ( $I^2 = 60\%$ ). Continuous pain score analysis using standardized mean difference showed operative treatments resulted in significantly higher pain scores compared to sclerotherapy (SMD: 0.96; 95% CI: 0.22 to 1.71; p < 0.05). However, this analysis demonstrated high heterogeneity ( $I^2 = 89\%$ ), likely reflecting differences in pain measurement scales and timing of assessments across studies.

	0	perative		Scle	rothera	ру		Std. Mean Difference		Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	Year	IV, Random, 95% CI
Sudhir 2024	8.3	0.7	40	7.3	0.3	40	31.9%	1.84 [1.31, 2.37]	2024	•
Qu 2024	3	1.48	97	2	1.48	98	35.9%	0.67 [0.38, 0.96]	2024	•
Sharma 2025	0.23	0.636	30	0.03	0.183	30	32.2%	0.42 [-0.09, 0.93]	2025	<b>†</b>
Total (95% CI)			167			168	100.0%	0.96 [0.22, 1.71]		
Heterogeneity: Tau <sup>2</sup> =				f = 2 (F	P = 0.00	001); I <sup>2</sup>	= 89%		<u>⊢</u> 1	100 -50 0 50 100
Test for overall effect:	Z = 2.5	52 (P = 0	0.01)							Sclerotherapy Operative

Figure 4. Forest plot of Pain Score of Operative and Sclerotherapy All study outcome summerized on table 2 and 3

Table I. Characteristics of included studies

No	Study (author, year)	Design	Country	n (total)	Intervention*	Comparison	Follow-up	Key outcome/remark
1	Ammanagi 2019	RCT	India	90 (30 RBL / 30 SCL / 30 open)	RBL	SCL & open haemorrhoid- ectomy	Scheduled 1st, 3rd, 7th post- op days + 3 & 6 mo	≥ 70 % of RBL & SCL patients rated "excellent" result; open arm lower
2	Nasir 2017	RCT	Pakistan	116 (58 RBL / 58 SCL)	RBL	Phenol SCL	2-week review	Clinical success 76 % RBL vs 55 % SCL
3	Babar 2022	RCT	Pakistan	162 (81 RBL / 81 SCL)	RBL	5 % phenol SCL	Day-15 assessment	Symptom-free rate higher with RBL $(p = 0.03)$
4	Khan 2022	RCT	Saudi Arabia	720 (360 RBL / 360 SCL)	RBL	5 % phenol SCL	3 mo	Cure 75.6 % RBL vs 64.4 % SCL
5	Qu 2024	RCT	China	195 (97 EFSB† / 98 ERBL)	Endoscopic foam- sclerobanding (EFSB)	Endoscopic RBL (ERBL)	12 mo	Recurrence 11.2 % EFSB vs 21.6 % ERBL (p < 0.05)
6	Salgueiro 2022	RCT	Portugal	120 (60 polidocanol foam + RBL / 60 RBL)	Polidocanol foam + RBL	RBL alone	12 mo	Complete success 88.3 % vs 66.7 % (p = 0.009)
7	Obiodun 2020	RCT	Nigeria	54 (27 RBL / 27 50 % dextrose SCL)	RBL	Dextrose SCL	3 mo	Symptom relief 85 % RBL vs 78 % SCL; minor bleeding favoured RBL
8	Ghaltot 2023	RCT	India	100 (50 open hemorrhoidectomy / 50 SCL)	Hemorrhoidectomy	SCL	1–2 days in-hospital + 6 mo phone follow-up	Cure 74 % open vs 96 % SCL (p = 0.005)
9	Samrobinson 2024	RCT	India	164 (82 RBL / 82 SCL)	RBL	Sodium tetradecyl SCL	6 wk	Bleeding absent by week 1 in 80 % SCL vs 47 % RBL (p = 0.007)
10	Sharma 2025	RCT	India	60 (30 RBL / 30 SCL)	RBL	SCL	6 wk	Post-procedural pain lower with SCL at 30 min (mean 1.7 vs 2.6, p = 0.024)
11	Sudhir 2024	RCT	India	80 (40 RBL / 40 phenol SCL)	RBL	Phenol SCL	8 wk	RBL needed fewer treatment sessions (1.3 $\pm$ 0.4 vs 1.9 $\pm$ 0.6, p < 0.01)

<sup>\*</sup> All trials looked at non-operative treatments for grade I–III internal haemorrhoids unless otherwise specified.

Table 2. Comparison 1: Operative versus sclerotherapy for hemorrhoidal disease

Outcome	Studies, n	Participants	Operative, n/total (%)	SCL, n/total (%)	RR [95% CI]	$I^2$
1. Treatment Success	10	1793	701/896 (78.2)	665/897 (74.1)	1.03 [0.91, 1.17]	85%

<sup>†</sup> EFSB = endoscopic foam-sclerobanding (polidocanol foam immediately followed by band placement

Outcome	Studies, n	Participants	Operative, n/total	SCL, n/total	RR	I 2
			(%)	(%)	[95% CI]	
2. Recurrent	2	302	42/148 (28.4)	20/154 (12.9)	2.22[1.37,	0%
					3.58]	
3. Pain Score	3	335	474/532 (89.1)	310/394 (78.7)	1.17	60%
					[1.02,	
					1.34]	

Table 3.	Comparison 1: (	Operative versu	s sclerotherapy	for hemorrh	oidal disease	
Outcome	Studies, n	Participants	Operative, n	SCL, n	Std. Mean Difference [95% CI]	I <sup>2</sup>
1. Pain Score	3	335	168	310/394 (78.7)	0.96 [0.22, 1.71]	89%

# Supplementary File 1. Search strategy

Search (	Duery f	or Pul	bMed
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No.	Entry	Filter	Total Findings
1	("Operative") AND ("Sclerotherapy")		28

#### Search Query for EBSCO

	No.	Entry	Filter	<b>Total Findings</b>
-	1	("Operative") AND ("Sclerotherapy")		148

#### Search Query for Proquest

No.	Entry	Filter	Total Findings
1	("Operative") AND ("Sclerotherapy")		162

Supplementary File 2. Inclusion, exclusion, PRP preparation, and injection methods of each study

No	Study (Author	Inclusion criteria	Exclusion criteria
	& Year)		
1	Ammanagi	Adults 18–75 yr with symptomatic	Grade I, III or IV, external/secondary piles,
	2019	Goligher grade II internal	pregnancy, prior haemorrhoid surgery, co-
		haemorrhoids	agulopathy, severe comorbidity
2	Babar 2022	162 patients with second-	Hepatitis B/C or HIV, anal fissure/fistula,
		degree internal haemorrhoids	malignancy, CCF, CLD, COPD, stroke
		consenting to IST vs RBL	
		comparison	
3	Ghaltot 2023	Newly diagnosed grade II internal	Grade I, III or IV disease, external piles,
		haemorrhoids willing for non-	pregnancy, previous therapy, coagulation
		operative treatment	disorders
4	Khan 2022	Symptomatic second-degree	Not explicitly stated in report – treated
		haemorrhoids scheduled for	as NR (not reported)
		outpatient RBL vs IST (age ≥18 yr)	
5	Nasir 2017	Adults with symptomatic grade II	Concomitant anal fissure/fistula, IBD,
		haemorrhoids unresponsive to	malignancy, coagulopathy, pregnancy
		conservative care	
6	Obiodun 2020	Age 21–72 yr, internal haemorrhoids	Bleeding diathesis, anticoagulant use, anal
		grades I-III requiring intervention, fit	sepsis, pregnancy, advanced systemic
		for endoscopy	disease and
7	Qu 2024	Adults 18-60 yr, grade II-III internal	Age >60, severe cardiopulmonary disease,
		haemorrhoids with prolapse $\pm$	malignancy, large/ multiple colon polyps,
		bleeding, failed conservative therapy,	IBD/perianal disease, autoimmune disease,
		willing for colonoscopy	prior haemorrhoid surgery, polidocanol
			allergy, lost to follow-up

No	Study (Author & Year)	Inclusion criteria	Exclusion criteria
8	Salgueiro 2022	Goligher grade I–III internal haemorrhoids refractory to conservative measures	Allergy to polidocanol, cirrhosis, IBD, coagulation disorders, pregnancy, anal sepsis, prior anorectal surgery
9	Samrobinson 2024	Men & women >20 yr, first- or second-degree haemorrhoids with rectal bleeding ± prolapse/pain/pruritus confirmed on proctoscopy	Bleeding diathesis, anticoagulant therapy, anal fissure/abscess, pregnancy, other advanced disease
10	Sharma 2025	Adults >18 yr, grade I–II haemorrhoids suitable for outpatient IST or RBL	Not specified in manuscript – <b>NR</b>
11	Sudhir 2024	Grade II–III internal haemorrhoids, age 18–65 yr, failure of fibre ± topical therapy	Prior haemorrhoid surgery, grade IV disease, coagulation disorders, pregnancy, inflammatory anorectal disease

Supplementary 3. Quality of Assesment using NOS

Study	Selection				Compa rability	Outcome			
	Represen tativenes s of the exposed cohort	Sele ctio n of the non- expo sed coho rt	Ascert ainmen t of exposu re	Demo nstrati on that outco me of interes t was not presen t at start of study	Compa rability of cohorts on the basis of the design or analysi s control led for confou nders	Asses sment of outco me	Was follo w-up long enou gh for outc ome s to occu r	Ade qua cy of follo w- up of coho rts	Qu alit y Sco re
Amm anagi 2019	*	*	*		**	*	*	*	Go od
Nasir 2017	*	*	*	*	**	*	*	*	Go od
Babar 2022	*	*	*	*	**	*	*	*	Go od
Khan 2022	*	*	*		**	*	*	*	Go od
QU 2024	*	*			*	*	*		Fai r
Salgu eiro 2022	*	*	*		*	*	*		Fai r
Obiod un 2020	*	*	*		*	*	*		Fai r
Ghalt ot 2023	*	*	*	*	**	*	*	*	Go od
Samr obins on 2024	*	*	*	*	**	*	*	*	Go od

Shar ma 2025	*	*	*	*	**	*	*	*	Go od
Sudhi r 2024	*	*	*		**	*	*	*	Go od

# Quality of studies

The quality of studies is presented in **Supplementary File 3**.

#### **Discussion**

The findings of this systematic review and meta-analysis provide important insights into the comparative effectiveness of operative treatment and sclerotherapy injection for hemorrhoidal disease. Through the analysis of 11 randomized controlled trials encompassing 1,793 participants, our study demonstrates that sclerotherapy offers comparable treatment success rates to operative interventions while providing superior outcomes in terms of recurrence prevention and pain management. These results challenge traditional assumptions about the hierarchy of hemorrhoidal treatments and suggest a potential paradigm shift in clinical decision-making.

#### Treatment Success and Clinical Heterogeneity

Our meta-analysis revealed no statistically significant difference in overall treatment success between operative treatments (78.2%) and sclerotherapy (74.1%), with a pooled risk ratio of 1.03 (95% CI: 0.91-1.17) (Table 2). This finding of non-inferiority is particularly noteworthy given the traditional perception of operative treatments as superior. The substantial heterogeneity observed (I<sup>2</sup> = 85%) reflects the diverse nature of included studies, varying treatment protocols, and differing definitions of treatment success across trials. This heterogeneity aligns with recent findings by Gallo et al. (2024), who reported similar variability in their systematic review of sclerotherapy methods, noting that differences in sclerosant concentration, delivery methods, and adjunctive measures contribute significantly to outcome variation. The recent HerBS Review by Patel et al. (2023) similarly found therapeutic success rates of 93% for polidocanol sclerotherapy compared to 75% for rubber band ligation, supporting our findings that sclerotherapy achieves comparable, if not superior, outcomes. Particularly compelling evidence comes from Qu et al. (2024), whose multicenter randomized trial demonstrated that endoscopic foam sclerobanding achieved 88.8% treatment success compared to 78.4% with rubber band ligation alone at 12-month follow-up. The consistency of these findings across multiple studies strengthens the evidence base for sclerotherapy as a firstline treatment option, especially when considering the evolving formulations such as polidocanol foam that have shown enhanced efficacy profiles (Salgueiro et al., 2022; Gallo et al., 2023).

## Recurrence Rates: A Key Differentiator

Perhaps the most striking finding of our analysis was the significantly lower recurrence rate associated with sclerotherapy compared to operative treatments. With a pooled risk ratio of 2.22 (95% CI: 1.37-3.58, p < 0.01), operative treatments demonstrated more than twice the risk of recurrence compared to sclerotherapy (Table 2). The absence of heterogeneity ( $I^2 = 0\%$ ) in this outcome suggests consistent findings across studies and strengthens the reliability of this observation. This finding is corroborated by recent clinical trials, including the Portuguese

study by Salgueiro et al. (2022), which reported complete success rates of 88.3% for polidocanol foam combined with rubber band ligation versus 66.7% for rubber band ligation alone, with significantly lower recurrence at 12-month follow-up. The superior durability of sclerotherapy outcomes may be attributed to the mechanism of action, whereby sclerosing agents induce comprehensive fibrosis of hemorrhoidal tissue and obliteration of feeding vessels, potentially providing more complete treatment than mechanical interventions. Recent advancements in sclerotherapy techniques, particularly the development of foam formulations, have enhanced tissue contact and penetration, potentially explaining the improved long-term outcomes (Lobascio et al., 2025; Moser et al., 2013). Furthermore, the ability to repeat sclerotherapy sessions with minimal morbidity allows for treatment optimization, as demonstrated by studies showing that 63-69% of patients require only a single session, with additional treatments possible for incomplete response (Gallo et al., 2023).

# Pain Management and Patient Experience

The meta-analysis of pain outcomes revealed a significant advantage for sclerotherapy, with operative treatments associated with a 17% higher risk of experiencing significant pain (RR: 1.17, 95% CI: 1.02-1.34, p < 0.05) and substantially higher continuous pain scores (SMD: 0.96, 95% CI: 0.22-1.71, p < 0.05) (Tables 2 and 3). This finding has crucial implications for patient satisfaction and treatment adherence. The lower pain profile of sclerotherapy aligns with multiple recent studies, including Neves et al. (2023), who found that polidocanol foam sclerotherapy resulted in less impact on work activity compared to hemorrhoidal artery ligation. The mechanism underlying reduced pain with sclerotherapy likely relates to the absence of tissue excision or mechanical trauma, with the procedure targeting submucosal injection rather than tissue manipulation. Recent evidence from office-based procedure comparisons consistently demonstrates this advantage, with Salgueiro et al. (2022) reporting that sclerotherapy offers lower rates of severe post-operative pain and minor complications compared to rubber band ligation. The high heterogeneity observed in pain outcomes ( $I^2 = 60$ -89%) likely reflects variations in pain assessment tools, timing of measurements, and individual pain thresholds, yet the consistent direction of effect favoring sclerotherapy across studies strengthens the clinical relevance of this finding. Importantly, recent surveys of international practice patterns reveal that minimized post-procedural pain is a primary factor influencing clinician choice of sclerotherapy, particularly for patients with comorbidities or those requiring rapid return to normal activities (Gallo et al., 2024).

# Clinical Implications and Future Directions

The findings of this meta-analysis, supported by recent literature, suggest that current treatment algorithms for hemorrhoidal disease may require revision. The traditional stepwise approach, which positions operative interventions as superior to office-based procedures, appears increasingly questionable given the demonstrated non-inferiority of sclerotherapy for treatment success coupled with its advantages in recurrence prevention and pain management. The recent ASCRS guidelines (2024) have begun to acknowledge the evolving role of sclerotherapy, particularly for grades I-III hemorrhoids, though further updates may be warranted based on accumulating evidence. However, several limitations must be acknowledged. The heterogeneity in treatment protocols, particularly the variety of sclerosants used (phenol, polidocanol, sodium tetradecyl sulfate) and operative techniques employed (rubber band ligation, hemorrhoidectomy), complicates direct comparisons. Additionally, the relatively short follow-up periods in many studies (ranging from 2 weeks to 12 months) may not capture long-term outcomes adequately. The recent systematic review by Gallo et al. (2024) highlighted the need for standardization of foam preparation protocols and outcome measures to facilitate more robust comparisons. Future research should focus on head-to-head comparisons of specific sclerotherapy formulations, particularly the promising polidocanol foam preparations, against standardized operative techniques. Long-term follow-up studies

exceeding 24 months are essential to confirm the durability of treatment effects. Additionally, cost-effectiveness analyses incorporating quality-of-life measures would provide valuable information for healthcare decision-making. The development of patient selection criteria based on hemorrhoid grade, symptoms, and patient preferences could optimize treatment allocation and improve outcomes.

#### **CONCLUSION**

This meta-analysis concludes that sclerotherapy injection is a highly viable and potentially superior alternative to operative treatment for hemorrhoidal disease, particularly in grades I–III, offering comparable short-term success rates with significantly lower recurrence and better post-procedural pain profiles. These findings challenge the traditional view that surgery is the definitive treatment, suggesting that modern sclerotherapy, especially with advanced agents like polidocanol foam, should be considered a first-line option due to its minimal invasiveness, repeatability, and greater patient tolerability. Future research should focus on conducting high-quality, standardized randomized controlled trials with long-term follow-up beyond 24 months to confirm the durability and cost-effectiveness of sclerotherapy. Additionally, efforts are needed to compare specific sclerosing agents and operative techniques directly, standardize protocols, and develop clear patient selection criteria based on hemorrhoid grade, symptoms, and preferences to optimize individualized treatment outcomes.

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