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Original Research Article

Treatment Outcomes of Sclerotherapy in Hemorrhoids: A Prospective Observational Study from a Tertiary Care Hospital in Tripura, India

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Abstract:

Background: Hemorrhoidal disease is a common anorectal condition causing significant morbidity and impaired quality of life. Sclerotherapy has been increasingly utilized as a minimally invasive and cost-effective therapeutic option, particularly in resource-limited settings.

Objective: To evaluate the short-term and mid-term outcomes of sclerotherapy in patients presenting with bleeding hemorrhoids.

Methods: A prospective observational study was conducted in the Department of General Surgery, Agartala Government Medical College & GBP Hospital, Tripura, over 18 months. A total of 270 patients with bleeding hemorrhoids were enrolled. Following proctoscopic diagnosis, patients received sclerotherapy using 5% phenol in almond oil, sodium tetradecyl sulphate, or polidocanol. Clinical outcomes were assessed at 1 week, 1 month, 3 months, and 6 months post-procedure.

Results: The mean age of participants was 41.3 years, with a male predominance (64.1%). On proctoscopy, Grade II hemorrhoids were more common (61.1%) than Grade I (38.9%). Symptom resolution was achieved in 94.4% of patients after one week. The recurrence rate of bleeding within six months was 9.8%. Post-procedural complications occurred in 7.9% of cases, most being minor (tenesmus, dizziness, chest pain). Only 7.9% required additional sclerotherapy sessions.

Conclusion: Sclerotherapy is a safe, effective, and minimally invasive outpatient procedure for the management of Grade I and II hemorrhoids. Its high symptom resolution and low recurrence rates support its continued use, particularly in regions with limited surgical resources.

Keywords: Hemorrhoids, Sclerotherapy, Phenol, Polidocanol, Recurrence, Tripura.

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Introduction

Hemorrhoids are vascular cushions within the anal canal formed by the anastomosis of rectal arteries and veins. Pathological engorgement and displacement of these cushions result in hemorrhoidal disease, which is categorized into internal and external types based on anatomical position [1,2]. Internal hemorrhoids arise above the dentate line and are lined by columnar epithelium, while external hemorrhoids develop below it and are covered with squamous epithelium [3,4].

Hemorrhoidal disease is one of the most common anorectal disorders worldwide, with nearly half of adults experiencing it by the age of 50 [5]. The condition is associated with multiple risk factors including dietary habits, bowel irregularities, poor hygiene, and sedentary lifestyle [6,7]. Symptoms such as rectal bleeding, pain, swelling, and pruritus significantly reduce patients' quality of life [8,9].

Treatment options vary from conservative measures like dietary and lifestyle modifications to surgical interventions. Although conventional surgery is effective, it is often associated with considerable post-operative pain and longer recovery [10]. Minimally invasive outpatient-based therapies such as sclerotherapy offer an effective alternative, especially for Grade I and II hemorrhoids [11,12].

Sclerotherapy involves injection of sclerosants such as phenol in almond oil, sodium tetradecyl sulphate, or polidocanol, which induce fibrosis and shrink hemorrhoidal tissue. Polidocanol foam in particular has been shown to reduce recurrence and minimize complications compared to traditional sclerosants [13,14].

Although several Indian studies have reported favorable outcomes of sclerotherapy, there is limited evidence from the northeastern region of India. Therefore, the present study was conducted to evaluate the

clinical outcomes of sclerotherapy for bleeding hemorrhoids in a tertiary care hospital in Tripura.

Materials and Methods

Study Design and Setting: This was a prospective observational study conducted in the Department of General Surgery, Agartala Government Medical College & GBP Hospital, Tripura. The institution is the only government-run tertiary care hospital serving the population of the state, thereby ensuring wide patient coverage.

Study Population: All patients presenting to the Surgery Outpatient Department (OPD) with bleeding hemorrhoids during the study period were considered eligible.

Study Period: The study was conducted over a period of 18 months.

Inclusion Criteria:

Patients presenting with hemorrhoids and ongoing rectal bleeding.

Exclusion Criteria:

- Patients unwilling to participate in the study.
- Patients with contraindications to sclerotherapy such as ischemic heart disease, deep vein thrombosis, thrombosed hemorrhoids, chronic kidney disease, inflammatory bowel disease, anorectal carcinoma, pregnancy, or bleeding disorders.
- Patients with known allergy to sclerosants.

Sample Size: Based on previous Indian studies reporting a 10–30% non-response rate to sclerotherapy, the prevalence of therapy failure was assumed to be 20% for calculation purposes. With a precision of 5% and a 95% confidence level, the sample size was calculated as 246. After adding 10% to account for attrition, the final sample size was fixed at 270 patients.

Sampling Method: Non-probability convenient sampling technique was used.

Recruitment and Procedure: Eligible patients were enrolled after providing written informed consent in their preferred language (English, Bengali, or Kokborok). Baseline demographic and clinical data were recorded using a semi-structured proforma. Sclerotherapy was performed following departmental protocols. A 3 ml dose of sclerosant (5% phenol in almond oil, polidocanol, or sodium tetradecyl sulphate) was injected submucosally into the hemorrhoidal tissue under proctoscopic guidance. The sclerosant used was based on availability in the department.

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Outcome Measures:

- Cessation of active bleeding at one week postprocedure.
- Complications observed within seven days.
- Recurrence of bleeding at 1, 3, and 6 months.
- Requirement of additional sclerotherapy sessions

Data Collection and Analysis: Data were entered into MS Excel and analyzed using SPSS version 26.0. Descriptive statistics (frequency, percentage, mean \pm SD) were used for demographic and clinical characteristics. Chi-square test and other appropriate statistical tests were applied where relevant. A p-value <0.05 was considered statistically significant.

Ethical Considerations: The study protocol was approved by the Institutional Ethics Committee of Agartala Government Medical College, Tripura. Written informed consent was obtained from all participants, and confidentiality was strictly maintained.

Results

A total of 270 patients with bleeding hemorrhoids were included. The mean age was 41.3 ± 16.9 years (range: 18-88 years). The majority belonged to the 30-59-year age group, with males comprising 64.1% of cases. Comorbidities were present in 19.3%, most commonly hypertension and diabetes mellitus (Table 1)

Table 1: Demographic characteristics of study participants

Variable	Category	Frequency (n)	Percentage (%)
Age group (years)	18–29	85	31.5
	30–59	137	50.7
	≥60	48	17.8
Gender	Male	173	64.1
	Female	97	35.9
Comorbidities	Present	52	19.3
	Absent	218	80.7

All patients presented with bleeding per rectum, while constipation (32.2%) and anal swelling (28.5%) were frequently associated complaints.

Proctoscopy showed Grade II hemorrhoids in 61.1% of cases, while 38.9% had Grade I disease (Table 2).

Table 2: Clinical presentation and proctoscopic findings

Clinical Feature / Grade	Frequency (n)	Percentage (%)
Bleeding per rectum	270	100
Constipation	87	32.2
Swelling at anal verge	77	28.5
Perianal discomfort/itching	17	6.3
Proctoscopy		
Grade I hemorrhoids	105	38.9
Grade II hemorrhoids	165	61.1

Regarding treatment, 5% phenol in almond oil was the most commonly used sclerosant (80%), followed by sodium tetradecyl sulphate (16.3%) and polidocanol (3.7%). Post-operative complications

occurred in 7.9% of patients, predominantly minor symptoms such as tenesmus, dizziness, and chest pain (Table 3).

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Table 3: Sclerosing agents used and treatment-related complications

Variable	Category	Frequency (n)	Percentage (%)
Sclerosing Agent	5% Phenol in almond oil	216	80.0
	Sodium tetradecyl sulphate	44	16.3
	Polidocanol	10	3.7
Post-op Complications	Present	21	7.9
-	Absent	244	92.1
Type of Complications	Tenesmus	6	2.3
	Dizziness	5	1.9
	Chest pain	4	1.5
	Urinary retention	4	1.5
	Anorectal abscess	2	0.7
	Allergic reaction	1	0.4

At one week post-sclerotherapy, 94.4% of patients were symptom-free. Symptom resolution remained above 94% throughout follow-up. The overall recurrence rate of bleeding at 6 months was 9.8% (Table

4). Out of 265 evaluable patients, recurrence of bleeding was observed in 9.8%. The majority (90.2%) remained symptom-free at six months follow-up (Fig. 1).

Table 4: Treatment outcomes during follow-up

Follow-up Time	Symptom Free (n, %)	Recurrence (n, %)	Lost to Follow-up (n, %)
1 week	255 (94.4%)	14 (5.2%)	1 (0.4%)
1 month	257 (95.2%)	10 (3.7%)	3 (1.1%)
3 months	258 (95.6%)	7 (2.6%)	5 (1.9%)
6 months	256 (94.8%)	9 (3.3%)	5 (1.9%)

Recurrence of Bleeding at 6 Months

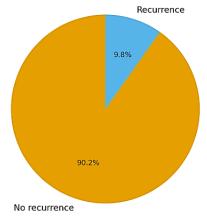


Figure 1: Recurrence of bleeding at 6 months

(Bar chart or pie chart representation from thesis data – showing: No recurrence = 90.2%, Recurrence = 9.8%)

Discussion

This prospective observational study evaluated the outcomes of sclerotherapy in the management of bleeding hemorrhoids among patients attending a tertiary care hospital in Tripura. The findings suggest that sclerotherapy provides excellent short-term relief with an acceptable recurrence rate in the midterm.

The mean age of patients was 41.3 years, consistent with previous Indian studies where hemorrhoids were most prevalent in middle-aged adults [15,16]. Male predominance in our study (64.1%) also aligns with earlier reports, which have shown higher occurrence among men compared to women [17].

Bleeding per rectum was the most common presenting symptom (100%), accompanied by constipation (32.2%) and anal swelling (28.5%). This pattern matches the observations of Ambedkar et al., who reported rectal bleeding as the hallmark feature in early hemorrhoidal disease [18]. Similar findings were reported by Cabrera Garrido et al., who highlighted anal bleeding and prolapse as the most consistent symptoms [19].

Proctoscopic examination revealed a predominance of Grade II hemorrhoids (61.1%). This is higher compared to some Indian studies that documented a larger proportion of Grade I disease [20]. The difference may be attributed to variations in healthcare-seeking behavior and late presentation in our population.

Symptom resolution was achieved in 94.4% of patients one week after sclerotherapy. Comparable results were observed by Shekhar et al., who reported an 82–98% resolution rate using polidocanol foam [21], and Mishra et al., who found 94.7% success with polidocanol compared to 84% with phenol [22]. Our recurrence rate of 9.8% at six months is within the range of 2–16% reported in the literature [23,24].

Post-procedural complications occurred in 7.9% of patients, which is lower than the 33–35% reported in some studies using polidocanol [25]. Most of our complications were minor, in agreement with Goglia et al., who reported low complication rates with automated device-assisted sclerotherapy [26].

The majority of patients (92.1%) required only a single session, with 7.9% needing additional sclerotherapy. This is comparable to the findings of Agarwal et al., where 18% required multiple sessions [27].

A unique aspect of our study was the predominant use of 5% phenol in almond oil (80%). While phenol

remains effective and cost-efficient, recent studies highlight the advantages of polidocanol, including fewer recurrences and higher patient satisfaction [22,25,28]. In our limited polidocanol group, recurrence was absent, though complications were higher, suggesting the need for further comparative trials with larger sample sizes.

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Overall, our study confirms sclerotherapy as a safe, effective, and minimally invasive treatment for Grade I and II hemorrhoids, especially relevant in resource-limited settings like Northeast India.

Conclusion

Sclerotherapy is a reliable first-line treatment option for Grade I and II hemorrhoids presenting with active bleeding. The present study demonstrated a high rate of symptom resolution (94.4% at one week), a low recurrence rate (9.8% at six months), and a low incidence of complications (7.9%). Most patients required only a single treatment session.

Given its safety, cost-effectiveness, and applicability in outpatient settings, sclerotherapy should be strongly considered in primary management protocols. Future randomized controlled studies with longer follow-up and standardized sclerosant use are warranted to further refine treatment strategies.

References

- 1. Peery AF, Sandler RS, Galanko JA, Bresalier RS, Figueiredo JC, Ahnen DJ, et al. Risk Factors for Hemorrhoids on Screening Colonoscopy. PLoS One. 2015;10:e0139100.
- 2. Halverson A. Hemorrhoids. Clin Colon Rectal Surg. 2007; 20:77–85.
- 3. Trompetto M, Clerico G, Cocorullo GF, Giordano P, Marino F, Martellucci J, et al. Evaluation and management of hemorrhoids: Italian society of colorectal surgery (SICCR) consensus statement. Tech Coloproctol. 2015; 19:567–75
- 4. Sun Z, Migaly J. Review of Hemorrhoid Disease: Presentation and Management. Clin Colon Rectal Surg. 2016; 29:22–9.
- 5. Riss S, Weiser FA, Schwameis K, Riss T, Mittlböck M, Steiner G, et al. The prevalence of hemorrhoids in adults. Int J Colorectal Dis. 2012; 27:215–20.
- Rubbini M, Ascanelli S, Fabbian F. Hemorrhoidal disease: is it time for a new classification? Int J Colorectal Dis. 2018; 33:831–3.
- Lee JH, Kim HE, Kang JH, Shin JY, Song YM. Factors Associated with Hemorrhoids in Korean Adults: Korean National Health and Nutrition Examination Survey. Korean J Fam Med. 2014; 35:227–36.
- 8. Bleday R, Pena JP, Rothenberger DA, Goldberg SM, Buls JG. Symptomatic hemorrhoids:

e-ISSN: 0975-9506, p-ISSN: 2961-6093

- current incidence and complications of operative therapy. Dis Colon Rectum. 1992; 35:477–81
- Sanchez C, Chinn BT. Hemorrhoids. Clin Colon Rectal Surg. 2011; 24:5–13.
- Guttenplan M. The Evaluation and Office Management of Hemorrhoids for the Gastroenterologist. Curr Gastroenterol Rep. 2017; 19:30.
- 11. Lobascio P, Laforgia R, Novelli E, Perrone F, Di Salvo M, Pezzolla A, et al. Short-Term Results of Sclerotherapy with 3% Polidocanol Foam for Symptomatic Second- and Third-Degree Hemorrhoidal Disease. J Invest Surg. 2021; 34:1059–65.
- 12. Lisi G, Campanelli M, Grande S, Milito G, Grande M. Sclerotherapy with 3% polidocanol foam for third- and fourth-degree hemorrhoids as "bridge treatment" during the COVID-19 pandemic in Italy. Int J Colorectal Dis. 2021; 36:1321–2.
- 13. Gallo G, Ronconi M, Trompetto M. Sclerotherapy with 3% polidocanol foam: revolutionizing outpatient treatment in patients with haemorrhoidal disease. Updates Surg. 2021; 73:2029–30.
- 14. Gallo G, Picciariello A, Armellin C, Lori E, Tomasicchio G, Di Tanna GL, et al. Sclerotherapy for hemorrhoidal disease: systematic review and meta-analysis. Tech Coloproctol. 2024; 28:1–11.
- 15. Naing L, Winn T, Rusli BN. Practical issues in calculating the sample size for prevalence studies. Arch Orofac Sci. 2006; 1:9–14.
- Ambedkar V, Singh A, Singh V, Singh Rana D.
 A prospective study on role of sclerotherapy in management of first- and second-degree haemorrhoids. J Evid Based Med Healthc. 2016;5(61):5007–9.
- 17. Shah TA, Modi YS, Parmar RH, Sharma C. Randomized study to evaluate the effectiveness of injection sclerotherapy for bleeding Grade I hemorrhoids on outpatient basis. J Indian Med Assoc. 2020;118(7):36–8.
- 18. Mukadam PN, Kothari KV, Patel AV, Patel UV. A study of clinical features and presentation of patients with Grade I & II haemorrhoids and injection sclerotherapy as a treatment modality. Int Surg J. 2022;9(2):847–51.
- 19. Cabrera Garrido J, Lopez Gonzalez G. Effective non-surgical treatment of hemorrhoids with sclerosing foam and novel injection device. Gastroenterol Endosc. 2024; 2:176–80.

- Shekhar R, Gupta VK. Efficacy of foam sclerotherapy in treatment of Grade I and Grade II bleeding hemorrhoids at Nalanda Medical College and Hospital, Patna. Int Surg J. 2020; 7:2925–8.
- 21. Shekhar R, Gupta VK. Efficacy of foam sclerotherapy in treatment of Grade I and II bleeding hemorrhoids at Nalanda Medical College and Hospital, Patna. Int Surg J. 2020; 7:2925–8.
- Mishra S, Sahoo AK, Elamurugan TP, Jagdish S. Polidocanol versus phenol in oil injection sclerotherapy in treatment of internal hemorrhoids: A randomized controlled trial. Turk J Gastroenterol. 2020; 31:378–83.
- 23. Khan SFA, Yadav A, Patel P. Role of sclerotherapy in management of symptomatic firstand second-degree internal haemorrhoids. IOSR J Dent Med Sci. 2022;21(6):56–61.
- 24. Agrawal P, Saxena AK, Verma P, Yadav A, Sahni R, Parkar ZL, et al. Effectiveness of foam sclerotherapy in treatment of symptomatic haemorrhoidal diseases at a tertiary care hospital, Agra, Uttar Pradesh, India: A prospective interventional study. Int J Anat Radiol Surg. 2023;12(1):SO17–SO20.
- 25. Khan SFA, Yadav A, Patel P. Role of sclerotherapy in management of symptomatic first-and second-degree internal haemorrhoids. IOSR J Dent Med Sci. 2022;21(6):56–61.
- 26. Goglia M, Nigro C, Aurello P, Diaco E, Trompetto M, Gallo G. Preliminary results of the first 50 patients undergoing sclerotherapy for II-degree hemorrhoidal disease using an automated device. Front Surg. 2022; 9:882030.
- 27. Agrawal P, Saxena AK, Verma P, Yadav A, Sahni R, Parkar ZL, et al. Effectiveness of foam sclerotherapy in treatment of symptomatic haemorrhoidal diseases at a tertiary care hospital, Agra, Uttar Pradesh, India: A prospective interventional study. Int J Anat Radiol Surg. 2023;12(1):SO17–SO20.
- Shafi A, HamayunKhan M, Ahmad T, Mahmood K. Compare the effectiveness of 5% phenol almond oil versus polidocanol sclerotherapy in patients with second degree hemorrhoids. Pak J Med Health Sci. 2021;15(3):730– 2.
- 29. Mukadam PN, Kothari KV, Patel AV, Patel UV. A study of clinical features and presentation of patients with Grade I & II haemorrhoids and injection sclerotherapy as a treatment modality. Int Surg J. 2022;9(2):847–51.