

**A prospective study of comparing banding versus sclerotherapy in the management of internal haemorrhoids**

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**Conflicts of Interest:** Nil

**Abstract**

**Background:** Haemorrhoidal disease is one of the most common anorectal disorders encountered in surgical practice. Internal haemorrhoids frequently present with bleeding, prolapse, pain, and discomfort, significantly affecting patients' quality of life. Rubber Band Ligation (RBL) and Injection Sclerotherapy are widely used outpatient treatment modalities for second- and third-degree internal haemorrhoids. However, controversy remains regarding their comparative efficacy and long-term outcomes.

**Aim:** To compare the efficacy and safety of Rubber Band Ligation and Injection Sclerotherapy in the management of second- and third-degree internal haemorrhoids.

**Materials and Methods:** This prospective, single-blind, randomized controlled study was conducted in the Department of General Surgery, Varun Arjun Medical College and Rohilkhand Hospital, Shahjahanpur, Uttar Pradesh, India, from November 2022 to October 2024. A total of 70 patients diagnosed with second- and third-degree internal haemorrhoids were enrolled and randomly allocated into two groups. Thirty-five patients underwent

Rubber Band Ligation (RBL group), while thirty-five patients underwent Injection Sclerotherapy using 3% polidocanol (Sclerotherapy group). Patients were evaluated clinically and proctoscopically before treatment. Follow-up assessments were performed on the 7th day, 30th day, and 3rd month after treatment. Primary outcome measures included bleeding and pain, while secondary outcomes included discharge, recurrence, and postoperative complications. Statistical analysis was performed using SPSS version 26.0, and a p-value <0.05 was considered statistically significant.

**Results:** The mean age of the study population was 38.95 ± 10.65 years, with no significant difference between groups (p=0.62). Gender distribution was comparable (p=0.808). Baseline bleeding severity, discharge, and haemorrhoid grade were similar between the groups. On the 7th postoperative day, bleeding control was significantly better in the RBL group compared with the Sclerotherapy group (p=0.002). Severe bleeding was observed in 20% of patients undergoing Sclerotherapy, whereas none of the patients treated with RBL experienced severe bleeding. At 30 days, complete cessation of bleeding was observed in 80.0% of patients in the RBL group compared with 54.3% in the Sclerotherapy group (p=0.038).

At the 3-month follow-up, all patients (100%) in the RBL group achieved complete resolution of bleeding, whereas 31.4% of patients in the Sclerotherapy group continued to experience mild bleeding (p<0.001). Postoperative complications were significantly lower in the RBL group. Minor recurrence was observed in 17.1% of patients treated with RBL, whereas persistent symptoms (25.7%) and recurrence (17.1%) were observed exclusively in the Sclerotherapy group (p<0.001).

**Conclusion;** Both Rubber Band Ligation and Injection Sclerotherapy are effective outpatient procedures for the management of second- and third-degree internal haemorrhoids. However, Rubber Band Ligation demonstrated superior efficacy in controlling bleeding, achieving symptom resolution, and reducing recurrence rates. The procedure was associated with better long-term outcomes and fewer clinically significant complications. Therefore, Rubber Band Ligation may be considered the preferred treatment modality for symptomatic second- and third-degree internal haemorrhoids.

**Keywords:** Internal haemorrhoids, Rubber Band Ligation, Sclerotherapy, Polidocanol, Bleeding, Recurrence, Outpatient treatment, Proctoscopy.

### Introduction

Haemorrhoidal disease is one of the most common anorectal disorders encountered in surgical practice and affects a substantial proportion of the adult population worldwide. Haemorrhoids are vascular cushions composed of connective tissue, smooth muscle fibers, and arteriovenous channels located within the anal canal. Under normal physiological conditions, these structures contribute to anal continence and facilitate closure of the anal canal. Enlargement, inflammation, or downward displacement of these cushions results in symptomatic haemorrhoidal disease<sup>1</sup>.

The prevalence of haemorrhoids has been reported to range from 4% to 39% in the general population, with peak incidence occurring between the third and sixth decades of life<sup>2</sup>. Common predisposing factors include chronic constipation, prolonged straining during defecation, low-fiber diet, obesity, pregnancy, sedentary lifestyle, and increased intra-abdominal pressure.<sup>3</sup>

Internal haemorrhoids arise above the dentate line and are classified into four grades according to the degree of

prolapse. Second-degree haemorrhoids prolapse during defecation but reduce spontaneously, whereas third-degree haemorrhoids require manual reduction<sup>4</sup>. These grades commonly present with painless rectal bleeding, prolapse, mucus discharge, discomfort, and pruritus ani. The management of haemorrhoids depends upon symptom severity and disease grade. Conservative treatment consisting of dietary modification, increased fiber intake, stool softeners, and lifestyle changes remains the first-line treatment for early disease. However, patients with symptomatic second- and third-degree haemorrhoids often require office-based procedures or surgical intervention<sup>5</sup>.

Rubber Band Ligation (RBL) and Injection Sclerotherapy are among the most commonly performed outpatient procedures for internal haemorrhoids. RBL, introduced by Barron in 1963, involves placement of a rubber band around the base of the haemorrhoidal tissue, resulting in ischemic necrosis, fibrosis, and fixation of the mucosa<sup>6</sup>. Numerous studies have demonstrated high efficacy and low recurrence rates with this procedure<sup>7</sup>.

Injection Sclerotherapy involves the submucosal injection of a sclerosant agent into the haemorrhoidal tissue. The resulting inflammatory response induces fibrosis and vascular obliteration, leading to reduction in haemorrhoidal size and symptoms<sup>8</sup>. Polidocanol has emerged as a commonly used sclerosant because of its safety profile and effectiveness<sup>9</sup>.

Despite the widespread use of both treatment modalities, controversy remains regarding their relative efficacy, complication rates, recurrence patterns, and long-term outcomes. Therefore, the present prospective randomized study was undertaken to compare Rubber Band Ligation and Sclerotherapy in the management of second- and third-degree internal haemorrhoids.

## Materials and Methods

### Study Design and Setting

This prospective, single-blind, randomised controlled study was conducted in the Department of General Surgery at Varun Arjun Medical College and Rohilkhand Hospital, Banthra, Shahjahanpur, Uttar Pradesh, India. The hospital is a tertiary-care teaching institution serving a large urban, semi-urban, and rural population. Patients presenting to the General Surgery Outpatient Department (OPD) with symptomatic haemorrhoids were screened for eligibility.

### Study Duration

The study was carried out over a period of two years, from November 2022 to October 2024.

### Study Population

Patients diagnosed with second- and third-degree haemorrhoids based on clinical examination and proctoscopic findings were considered for inclusion.

### Inclusion Criteria

- Patients aged between 18 and 70 years.
- Patients of either gender.
- Clinically and proctoscopically confirmed cases of second- or third-degree haemorrhoids.

### Exclusion Criteria

- First-degree haemorrhoids or irreducible/prolapsed haemorrhoids.
- Presence of acute anal fissure.
- Coexisting anorectal malignancy.
- Previous history of anorectal surgery.

### Sample Size and Randomization

A total of 70 eligible patients were enrolled in the study. Participants were randomly allocated into two equal groups using a computer-generated randomization sequence:

- **Group A (Sclerotherapy Group):** 35 patients underwent sclerotherapy.
- **Group B (Rubber Band Ligation Group):** 35 patients underwent rubber band ligation (RBL).

Randomization ensured equal and unbiased distribution of participants between the treatment groups. The study followed a single-blind design, wherein patients were unaware of the treatment modality administered.

### Preoperative Evaluation

All participants provided written informed consent before enrollment. A detailed medical history and thorough clinical examination were performed. Routine laboratory investigations included:

- Complete Blood Count (CBC)
- Liver Function Tests (LFTs)
- Renal Function Tests (RFTs)
- Prothrombin Time (PT)
- International Normalized Ratio (INR)

Digital rectal examination and proctoscopic evaluation were conducted to confirm the diagnosis and grade the haemorrhoids.

### Intervention Procedures

#### Rubber Band Ligation (RBL)

Patients were placed in the Sims' left lateral position. No anesthesia was administered. The procedure was performed using a McGown ligator. Two to three rubber bands were applied above the dentate line during each session. Additional treatment sessions were scheduled when required to achieve complete ligation. Analgesics were prescribed when necessary.

#### Sclerotherapy

Patients were positioned in Sims' position and examined using a proctoscope. A 3% polidocanol solution was used as the sclerosant agent. Using a Gabriel syringe fitted with a fine needle, 2–3 mL of sclerosant was injected into the

submucosal plane above the dentate line. Correct placement of the injection was confirmed by the appearance of the characteristic “striation sign.”

### Postoperative Management

Following the procedure, all patients received standard postoperative care, including:

- Hot sitz baths with potassium permanganate (KMnO<sub>4</sub>).
- High-fiber diet recommendations.
- Adequate oral fluid intake.
- Stool softeners to prevent constipation and straining.

Patients were monitored for postoperative complications including pain, bleeding, fever, anal discharge, and recurrence.

### Outcome Measures

Patients were assessed at three follow-up intervals:

1. Day 7 (short-term follow-up)
2. Day 30 (intermediate follow-up)
3. Month 3 (long-term follow-up)

The primary outcome measures included rectal bleeding and pain. Secondary outcome measures included anal discharge, recurrence, infection, and other postoperative complications.

### Bleeding Score System

| Score | Severity | Description                            |
|-------|----------|----------------------------------------|
| 3     | Severe   | Reddened toilet bowl                   |
| 2     | Moderate | Blood on stool surface                 |
| 1     | Mild     | Blood spots on toilet paper or fingers |

### Visual Analogue Scale (VAS) for Pain

| VAS Score | Interpretation |
|-----------|----------------|
| 0–2       | Mild Pain      |
| 3–4       | Moderate Pain  |
| 5–6       | Severe Pain    |

### Pilot Study

Prior to commencement of the main study, a pilot study was conducted on a small group of patients undergoing RBL and sclerotherapy. The pilot study assessed the feasibility of the study protocol and validated the use of the Bleeding Score System and Visual Analogue Scale (VAS) for outcome assessment. The findings confirmed the suitability of the study methodology and assessment tools.

### Validity and Reliability

To ensure methodological rigor, the study incorporated:

- Computer-generated randomization to minimize selection bias.
- Single-blind design to reduce participant-related bias.
- Standardized outcome assessment tools, including the Bleeding Score System and VAS.
- Uniform procedural techniques and postoperative care protocols for all participants.

### Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee of Varun Arjun Medical College and Rohilkhand Hospital, Banthra, Shahjahanpur, Uttar Pradesh, India. Written informed consent was obtained from all participants prior to enrollment. Confidentiality and anonymity of patient information were maintained throughout the study.

### Statistical Analysis

Data were entered and analyzed using Statistical Package for Social Sciences (SPSS) software version 26.0. Descriptive statistics such as mean, standard deviation, frequency, and percentage were used to summarize demographic and clinical characteristics. Comparative analysis between the two treatment groups was performed using the Chi-square test for categorical variables and Student's t-test for continuous variables. A p-value of less than 0.05 was considered statistically significant.

### Result and Observations

Table 1: Baseline Demographic Characteristics of Study Participants

| Variable    | RBL Group (n=35) | Sclerotherapy Group (n=35) | Total (n=70)  | p-value |
|-------------|------------------|----------------------------|---------------|---------|
| Age (years) | 38.3 ± 10.0      | 39.6 ± 11.3                | 38.95 ± 10.65 | 0.62*   |
| Gender      |                  |                            |               | 0.808†  |
| Male        | 21 (60.0%)       | 20 (57.1%)                 | 41 (58.6%)    |         |
| Female      | 14 (40.0%)       | 15 (42.9%)                 | 29 (41.4%)    |         |

Table 2: Distribution of Baseline Chief Complaints in RBL and Sclerotherapy Groups

| Variable          | Category          | RBL (n=35) | Sclerotherapy (n=35) | Total (n=70) | p-value |
|-------------------|-------------------|------------|----------------------|--------------|---------|
| Bleeding Severity | Moderate Bleeding | 14 (40.0%) | 12 (34.3%)           | 26 (37.1%)   | 0.621   |
|                   | Severe Bleeding   | 21 (60.0%) | 23 (65.7%)           | 44 (62.9%)   |         |
| Pain (VAS Score)  | 2                 | 3 (8.6%)   | 12 (34.3%)           | 15 (21.4%)   | 0.035*  |
|                   | 3                 | 1 (2.9%)   | 1 (2.9%)             | 2 (2.9%)     |         |
|                   | 4                 | 13 (37.1%) | 5 (14.3%)            | 18 (25.7%)   |         |
|                   | 5                 | 6 (17.1%)  | 9 (25.7%)            | 15 (21.4%)   |         |

|           |     |            |            |            |       |
|-----------|-----|------------|------------|------------|-------|
|           | 6   | 12 (34.3%) | 8 (22.9%)  | 20 (28.6%) |       |
| Discharge | Yes | 22 (62.9%) | 23 (65.7%) | 45 (64.3%) | 0.803 |
|           | No  | 13 (37.1%) | 12 (34.3%) | 25 (35.7%) |       |

Values are expressed as number (%).

\*Statistically significant ( $p < 0.05$ ).

Table 3: Distribution of Degree of Haemorrhoids and Post-Treatment Bleeding Outcomes in RBL and Sclerotherapy Groups

| Variable                             | Category          | RBL (n=35) | Sclerotherapy (n=35) | Total (n=70) | p-value |
|--------------------------------------|-------------------|------------|----------------------|--------------|---------|
| Degree of Haemorrhoids (Proctoscopy) | 2nd Degree        | 13 (37.1%) | 13 (37.1%)           | 26 (37.1%)   | 1.000   |
|                                      | 3rd Degree        | 22 (62.9%) | 22 (62.9%)           | 44 (62.9%)   |         |
| Bleeding on 7th Day                  | Mild Bleeding     | 18 (51.4%) | 7 (20.0%)            | 25 (35.7%)   | 0.002*  |
|                                      | Moderate Bleeding | 17 (48.6%) | 21 (60.0%)           | 38 (54.3%)   |         |
|                                      | Severe Bleeding   | 0 (0.0%)   | 7 (20.0%)            | 7 (10.0%)    |         |
| Bleeding on 30th Day                 | Mild Bleeding     | 7 (20.0%)  | 13 (37.1%)           | 20 (28.6%)   | 0.038*  |
|                                      | Moderate Bleeding | 0 (0.0%)   | 3 (8.6%)             | 3 (4.3%)     |         |
|                                      | No Bleeding       | 28 (80.0%) | 19 (54.3%)           | 47 (67.1%)   |         |

Values are expressed as number (%).

\*Statistically significant ( $p < 0.05$ ).

Table 4: Distribution of Bleeding at 3 Months and Post-Operative Complications in RBL and Sclerotherapy Groups

| Variable                     | Category            | RBL (n=35)  | Sclerotherapy (n=35) | Total (n=70) | p-value |
|------------------------------|---------------------|-------------|----------------------|--------------|---------|
| Bleeding at 3rd Month        | Mild Bleeding       | 0 (0.0%)    | 11 (31.4%)           | 11 (15.7%)   | <0.001* |
|                              | No Bleeding         | 35 (100.0%) | 24 (68.6%)           | 59 (84.3%)   |         |
| Post-Operative Complications | Minor Recurrence    | 6 (17.1%)   | 0 (0.0%)             | 6 (8.6%)     | <0.001* |
|                              | Persistent Symptoms | 0 (0.0%)    | 9 (25.7%)            | 9 (12.9%)    |         |
|                              | Recurrence          | 0 (0.0%)    | 6 (17.1%)            | 6 (8.6%)     |         |
|                              | No Complication     | 29 (82.9%)  | 20 (57.1%)           | 49 (70.0%)   |         |

Values are expressed as number (%).

\*Statistically significant ( $p < 0.05$ ).

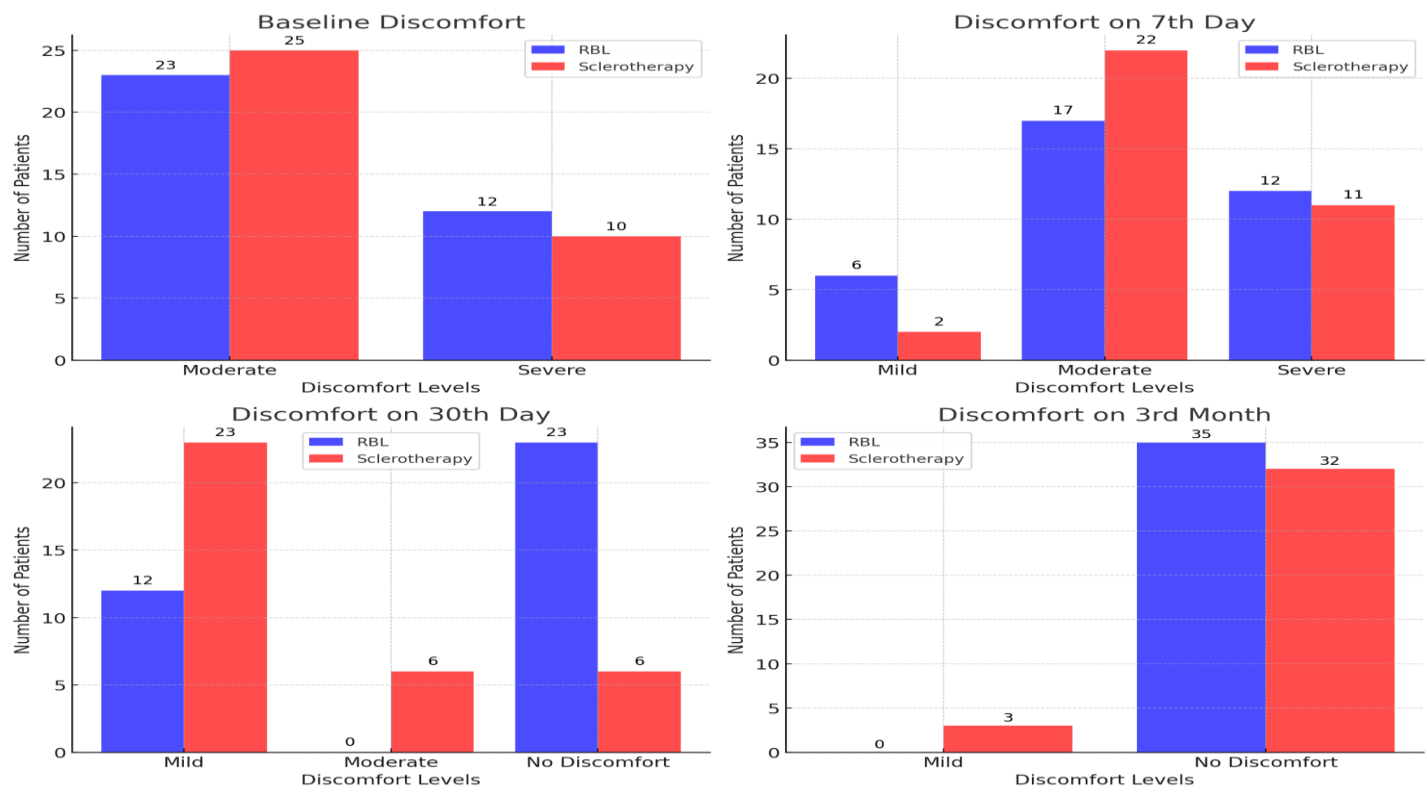


Figure 1: Comparison Between RBL and Sclerotherapy Groups in Terms of Discomfort Over Time

## Discussion

The present study compared the efficacy and safety of Rubber Band Ligation and Sclerotherapy in seventy patients with second- and third-degree internal haemorrhoids. The findings suggest that RBL is associated with superior bleeding control and better long-term outcomes than Sclerotherapy.

The demographic characteristics of the study population were comparable. The mean age was approximately 39 years, which is consistent with previous reports demonstrating that haemorrhoidal disease is most prevalent among middle-aged adults<sup>2</sup>. There was no statistically significant difference in age or gender distribution between the groups, indicating successful randomization.

Baseline clinical characteristics including bleeding severity, anal discharge, and haemorrhoid grade were comparable between treatment groups. The equal

distribution of second- and third-degree haemorrhoids ensured that treatment outcomes could be reliably attributed to the interventions rather than differences in disease severity.

Control of bleeding was the primary outcome measure. On the seventh postoperative day, patients treated with RBL demonstrated significantly better bleeding control than those receiving Sclerotherapy. Severe bleeding was absent in the RBL group but occurred in 20% of patients treated with Sclerotherapy. These findings indicate a more rapid therapeutic response with RBL and are comparable to the observations reported by MacRae and McLeod<sup>7</sup>.

At the 30-day follow-up, 80% of patients in the RBL group experienced complete resolution of bleeding compared with 54.3% in the Sclerotherapy group. The difference remained statistically significant, suggesting superior intermediate-term efficacy of RBL.

The advantage of RBL became more pronounced at the three-month follow-up. All patients treated with RBL achieved complete resolution of bleeding, whereas approximately one-third of patients in the Sclerotherapy group continued to experience mild bleeding. This finding is consistent with previous studies that reported lower recurrence rates and better long-term symptom control following RBL<sup>10</sup>.

The superior effectiveness of RBL can be explained by its mechanism of action. The procedure produces ischemic necrosis followed by fibrosis and fixation of the haemorrhoidal tissue, thereby correcting both bleeding and prolapse. In contrast, Sclerotherapy primarily induces fibrosis through chemical irritation and may therefore be less effective in advanced haemorrhoidal disease<sup>6,8</sup>.

Postoperative complications also favored RBL. Although minor recurrence occurred in a small number of patients treated with RBL, persistent symptoms and major recurrence were absent. Conversely, patients treated with Sclerotherapy demonstrated significantly higher rates of persistent symptoms and recurrence. These findings support previous reports suggesting greater durability of symptom control following RBL<sup>7,10</sup>.

The strengths of the present study include its prospective design, randomized allocation, standardized treatment protocols, and structured follow-up. Nevertheless, certain limitations should be acknowledged. The study was conducted at a single center with a relatively small sample size, and the follow-up period was limited to three months. Further multicenter studies with larger populations and longer follow-up are needed to validate these findings.

### Conclusion

Rubber Band Ligation and Sclerotherapy are both effective outpatient procedures for the treatment of

second- and third-degree internal haemorrhoids. However, Rubber Band Ligation demonstrated significantly superior outcomes in terms of bleeding control, symptom resolution, and prevention of recurrence. Patients undergoing RBL experienced lower rates of persistent symptoms and better long-term results compared with those treated with Sclerotherapy. Based on the findings of the present study, Rubber Band Ligation may be considered the preferred treatment modality for symptomatic second- and third-degree internal haemorrhoids.

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