



Sclerotherapy vs Band Ligation: A comparative study of efficacy and compliance in second degree Haemorrhoids

Dr. Sudhir S,¹ Dr. Harish Kumar P,² Dr. Muhamed Naufal Aftaalin,^{3*} Dr. Yamuna VS,⁴ Dr. Abhilash L⁵

¹Professor, Department of General Surgery, JSS Medical College and Hospital, JSS Academy of Higher Education and Research (DU), Mysore, Karnataka, India

²Associate Professor, Department of General Surgery, JSS Medical College and Hospital, JSS Academy of Higher Education and Research (DU), Mysore, Karnataka, India

³Junior Resident, Department of General Surgery, JSS Medical College and Hospital, JSS Academy of Higher Education and Research (DU), Mysore, Karnataka, India

⁴Assistant Professor, Department of General Surgery, JSS Medical College and Hospital, JSS Academy of Higher Education and Research (DU), Mysore, Karnataka, India

⁵Assistant Professor, Department of General Surgery, JSS Medical College and Hospital, JSS Academy of Higher Education and Research (DU), Mysore, Karnataka, India

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ABSTRACT:

Background: Sclerotherapy and rubber band ligation represent two widely employed minimally invasive procedures for managing grade II haemorrhoids.

Objectives: To compare the postoperative pain in patients undergoing sclerotherapy vs rubber band ligation for grade II haemorrhoids; and to compare the rate of recurrence after three months.

Methods: This was a hospital based, prospective comparative study conducted among patients presenting to the Department of General Surgery, JSS Medical College, Mysuru, Karnataka, India with symptomatic grade II haemorrhoids, between June 2022 to June 2024.

Results: A total of 80 patients were enrolled – 40 in Group A undergoing sclerotherapy, and 40 patients in Group B undergoing rubber band ligation. The baseline characteristics of the study groups namely age (in years), gender, presenting symptoms, mean duration of symptoms, vitals (including pulse rate, systolic and diastolic blood pressure), position of haemorrhoids in per rectal examination, and laboratory investigations did not vary significantly between the study groups ($p>0.05$). Pain scores, measured using the Visual Analogue Scale, showed no significant difference on Day 1 (mean 8.8), but by Day 3, Group A reported significantly lower pain (mean 7.3) compared to Group B (mean 8.3), a trend that persisted through Week 2 and Month 3. Per rectal bleeding was significantly higher in Group A on Day 1 (55% vs. 30%), but decreased over time, becoming statistically insignificant by Month 3. Recurrence rates were 15% for Group A and 10% for Group B, with no significant difference. Urinary retention occurred in 10% of Group A and 7.5% of Group B, while anal strictures and incontinence were present in a small percentage of both groups, with no significant differences observed for any of these complications.



Conclusion: Sclerotherapy resulted in lower pain scores and rubber band ligation had reduced incidence of early postoperative bleeding compared to sclerotherapy.

Introduction

Haemorrhoids, a common ailment affecting a substantial portion of the adult population (affecting individuals typically under the age of 50) worldwide, present a significant burden on healthcare systems and patient quality of life.(1) The common symptoms include prolapse, rectal bleeding, and pain. If left untreated, haemorrhoids can lead to complications such as persistent bleeding, thrombosis, strangulation, and ulceration.(2) The condition affects between 4.4% to 36.5% of the general population.(3) Haemorrhoids typically manifest at the left lateral, right anterior, and right posterior positions (3, 7, 11 O'clock positions).(4, 5) Classified into four grades based on severity, haemorrhoids range from mild discomfort to debilitating symptoms that impact daily activities and overall well-being.(6) Among these, grade II haemorrhoids, characterized by prolapse during defecation but spontaneous reduction afterward, pose challenges in management due to varied treatment options and outcomes.(7)

Various treatment options exist for haemorrhoids, ranging from surgical procedures like open or closed haemorrhoidectomy, which necessitate hospital admission, to non-surgical techniques like sclerotherapy and rubber band ligation, which can be performed as outpatient procedures.(8-10) Sclerotherapy and rubber band ligation are known for their shorter recovery times, reduced costs, and lower complication rates compared to traditional surgeries.(11) Sclerotherapy and rubber band ligation represent two widely employed minimally invasive procedures for managing grade II haemorrhoids.(12, 13) Sclerotherapy involves injecting a sclerosing agent into the hemorrhoidal tissue to induce fibrosis and reduce vascularity, thereby promoting shrinkage and symptom relief.(14) Alternatively, rubber band ligation entails placing a small rubber band at the base of the hemorrhoidal tissue, leading to ischemic necrosis and subsequent sloughing off, thus achieving resolution of symptoms.(11, 15)

While both techniques have demonstrated efficacy in clinical practice, comparative studies examining their relative effectiveness, safety profiles, and patient-reported outcomes remain limited. Existing literature suggests variability in pain perception, complication rates, and recurrence rates following these procedures.(16-18) Against this background, the aim of the present study was to determine the outcomes of patients undergoing sclerotherapy vs rubber band ligation for grade II haemorrhoids. The specific objectives were to compare the postoperative pain and rate of recurrence after three months in patients undergoing sclerotherapy vs rubber band ligation for grade II haemorrhoids in a tertiary healthcare facility.

Materials and Methods

This was a hospital based, prospective comparative study conducted among patients presenting to the outpatient department and/or inpatient wards of the Department of General Surgery, Jagadguru Sri Shivarathreshwara (JSS) Medical College, Mysuru, Karnataka, India between June 2022 and June 2024. The study was approved by the Institutional Human Ethics Committee (IHEC). The patients were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. All patients between 18 and 60 years of age, of both gender, presenting with symptomatic grade II haemorrhoids, and willing to provide informed written consent to participate in the study including surgical intervention (as a day care procedure for grade II haemorrhoids) and follow up were enrolled. However, patients with grade III and/or grade IV haemorrhoids, history of bleeding disorders, patients allergic to the sclerosant, history of mental illness, recurrent haemorrhoids, pregnant women, patients with haemorrhoids associated with other perianal conditions including fissure in ano, fistula in ano, and perianal infections, patients with irritable bowel disease (IBD), and haemorrhoids associated with malignancy were excluded from the study.



Abiodun et al.(19) (2020) noted that 80.0% patients in endoscopic injection sclerotherapy group had mild pain; whereas 69.3% patients in endoscopic rubber band ligation had moderate to severe pain. Using the effect sizes noted in this study, considering the level of significance to be 5%, power to be 80% (or 20% type II error), and attrition rate (non-response rate) to be 10%, the minimum required sample size was rounded off to be 40 per group – a total sample of 80 patients with 95% confidence. We used nonprobability sampling – convenience/purposive sampling technique – complete enumeration of patients undergoing either sclerotherapy or rubber band ligation in accordance with prespecified inclusion and exclusion criteria. The patients were divided into two groups: Group A received sclerotherapy, while Group B underwent rubber band ligation. For those in Group A, the procedure involved positioning the patient laterally. A 2% Lox jelly was applied as an anaesthetic agent. During a proctoscopic examination, the hemorrhoidal swelling was identified, and a 3% Polidocanol sclerosing agent was injected using a 23-gauge needle. Similarly, for patients in Group B, they were positioned laterally, and 2% Lox jelly was applied as an anaesthetic agent. The hemorrhoidal swelling was identified during the proctoscopic examination, and a rubber band was applied using a Baron's band applicator to achieve ligation of the hemorrhoidal swelling. The data collected from patients who underwent sclerotherapy was recorded, focusing on post-operative pain levels (using visual analogue scale (VAS) scores), rate of recurrence, and post-operative complications (including bleeding per rectum, retention of urine, anal stricture, and anal incontinence) in comparison to those who received rubber band ligation. A purpose pre-designed, semi structured, pretested questionnaire was used to document the findings.

Statistical analysis: The data obtained was manually entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) v23. All the categorical variables were summarised using frequencies and percentages. Continuous variables were summarized using mean (standard deviation) and/or median (interquartile range) (based on the results of data normality, tested using Kolmogorov–Smirnov test and the Shapiro–Wilk test). To test for statistical significance, Chi square test or Fisher exact test (for categorical variables) and independent “t” test or Mann Whitney U

test (for continuous variables) was used. Statistical significance was considered at p value less than 0.05.

Results

A total of 80 patients with symptomatic grade II haemorrhoids were enrolled – 40 patients in Group A undergoing sclerotherapy, and 40 patients in Group B undergoing rubber band ligation. The mean (SD) age of the patients was 45.1 years (8.9) – 44.3 years (8.1) in Group A and 45.8 years (9.7) in Group B. Majority of the patients in Group A (65.0%) and Group B (72.5%) were between 30 and 50 years of age. The test of association showed that the study groups did not vary significantly by age ($p>0.05$). Of the 40 patients in Group A, 80.0% were males; and of the 40 patients in Group B, 85.0% were males ($p>0.05$). Based on presenting symptoms, the results showed that in Group A, 70.0% patients had bleeding per rectum, 60.0% had mass per rectum, 70.0% had straining at defecation, 37.5% had painful defecation, 50.0% had constipation, 27.5% had discharge per rectum, and 22.5% had anal irritation. In Group B, 77.5% had bleeding per rectum, 65.0% had mass per rectum, 70.0% had straining at defecation, 52.5% had painful defecation, 47.5% had constipation, 22.5% had discharge per rectum, and 17.5% had anal irritation ($p>0.05$). The mean (SD) duration of symptoms among patients in Group A was 12.7 months (11.4) with a median (IQR) of 10.2 months (1.0 to 23.0); and that in Group B was 12.3 months (10.9), with a median (IQR) of 11.3 months (1.0 to 22.0). Importantly, the study groups did not vary significantly by duration of symptoms ($p>0.05$). In Group A, 47.5% patients had haemorrhoids in left lateral position, 30.0% had in right posterior, and 22.5% had in right anterior position. In Group B, 52.5% patients had haemorrhoids in left lateral, 27.5% in right posterior, and 20.0% patients had haemorrhoids in right anterior position. The test of association showed that the study groups did not vary significantly by position for haemorrhoids ($p>0.05$).

The mean (SD) pain scores and their p-values were as follows. On Day 1, Group A had a mean score of 8.7 (0.8) and Group B had 8.8 (0.8), with a p-value of 0.578. By Day 3, Group A's mean score was 7.3 (0.3) and Group B's was 8.3 (0.7), with a p-value of <0.001 , indicating statistical significance. At Week 1, the mean scores were 6.3 (0.5) for Group A and 7.0 (0.6) for Group B, with a p-value of <0.001 . At Week 2, Group A had a mean score



of 4.8 (0.6) and Group B had 5.5 (0.4), with a p-value of <0.001. At Month 1, the mean scores were 3.0 (0.5) for Group A and 3.5 (0.8) for Group B, with a p-value of 0.001. By Month 3, Group A had a mean score of 1.0 (0.1) and Group B had 2.1 (0.6), with a p-value of <0.001.

The recurrence rate among patients in Group A was 15.0% and that among patients in Group B was 10.0%. The test of association showed that the study groups did not vary significantly by recurrence rates ($p>0.05$). The study assessed the incidence of per rectal bleeding in Group A and Group B. On Day 1, per rectal bleeding was observed in 22 participants (55.0%) in Group A and 12 participants (30.0%) in Group B, with a p-value of 0.023, indicating statistical significance. By Day 3, the incidence decreased to 47.5% in Group A and 20.0% in Group B, with a p-value of 0.009, also statistically significant. At Week 1, 27.5% in Group A and 7.5% in Group B reported per rectal bleeding, with a p-value of 0.018, showing statistical significance. By Week 2, the incidence further decreased to 15.0% in Group A and 5.0% in Group B, with a p-value of 0.136, which was not statistically significant. At Month 1, 5.0% in Group A and none (0.0%) in Group B reported per rectal bleeding ($p>0.05$). By Month 3, no participants (0.0%) in either group reported per rectal bleeding ($p>0.05$).

The results showed that 10.0% patients in Group A and 7.5% patients in Group B had retention of urine ($p>0.05$). Also, 5.0% patients in Group A and 2.5% patients in Group B had anal strictures – the difference between the study groups was not found to be statistically significant ($p>0.05$). Similarly, it was found that 5.0% patients in Group A and 5.0% patients in Group B had anal incontinence – the difference between the study groups was not found to be statistically significant ($p>0.05$).

Discussion

The present study compared the outcomes of two commonly used treatments for grade II haemorrhoids: sclerotherapy and rubber band ligation. The demographic and clinical characteristics of the patients, as well as the presenting symptoms and duration of symptoms, were analysed to determine if any significant differences existed between the two groups. The mean age of patients in this study was 45.1 years, with no significant difference between the two groups ($p>0.05$). This finding

is consistent with the typical age range for haemorrhoid patients, as haemorrhoids are most prevalent among adults aged 45 to 65 years (Johanson & Sonnenberg, 1990).(20) The distribution of age within the groups, with the majority being between 30 and 50 years, reflects the common age of onset for grade II haemorrhoids (Sun et al., 2020).(21) Gender distribution showed a higher prevalence of male patients in both groups, which aligns with previous research indicating a male predominance in haemorrhoid cases (Garg et al., 2017).(22) The lack of significant gender variation between the groups ($p>0.05$) suggests that gender does not influence the choice of treatment modality between sclerotherapy and rubber band ligation.

The most common presenting symptom in both groups was bleeding per rectum, reported by 70.0% of patients in Group A and 77.5% in Group B. This symptom is a primary indication for treatment in grade II haemorrhoids (Mott et al., 2018).(23) Other symptoms such as mass per rectum, straining at defecation, painful defecation, constipation, discharge per rectum, and anal irritation were similarly distributed between the groups. These findings are in line with the typical clinical presentation of haemorrhoids, which often includes bleeding, prolapse, and pain (Riss et al., 2012).(24) The similarity in the presenting symptoms between the two groups ($p>0.05$) suggests that both sclerotherapy and rubber band ligation are considered appropriate treatments for a similar clinical profile of haemorrhoid patients.(25) This supports the notion that the choice between these two treatments can be based on other factors such as patient preference, physician recommendation, and resource availability rather than on differences in presenting symptoms. The mean duration of symptoms was comparable between the two groups, with Group A at 12.7 months and Group B at 12.3 months ($p>0.05$). This similarity indicates that the chronicity of haemorrhoid symptoms was consistent across the treatment groups. Previous studies have shown that chronic symptoms are a key factor influencing the decision to seek treatment for haemorrhoids (Sheikh et al., 2020).(26) The comparable duration of symptoms in both groups underscores the need for effective treatment options that provide long-term relief.(27)

The mean pulse rate, systolic blood pressure (SBP), and diastolic blood pressure (DBP) were similar between the



two groups, with no statistically significant differences ($p > 0.05$). These findings suggest that the baseline cardiovascular status of patients in both groups was comparable, indicating no pre-procedural physiological bias towards either treatment modality (Seyfried et al., 2021).(28) The positional distribution of haemorrhoids observed during per rectal examination showed that in Group A, 47.5% had haemorrhoids in the left lateral position, 30.0% in the right posterior, and 22.5% in the right anterior. In Group B, 52.5% had haemorrhoids in the left lateral, 27.5% in the right posterior, and 20.0% in the right anterior positions. The lack of significant variation between groups ($p > 0.05$) indicates that the anatomical location of haemorrhoids does not influence the choice between sclerotherapy and rubber band ligation, aligning with the findings of Templeton et al. (1983) who reported similar positional distributions in haemorrhoid patients undergoing different treatment modalities.(29)

Pain assessment over time revealed significant differences between the two treatment modalities. On Day 1, pain scores were similar between Group A (8.7 ± 0.8) and Group B (8.8 ± 0.8) with no statistical significance ($p = 0.578$). However, by Day 3, Group A reported significantly lower pain scores (7.3 ± 0.3) compared to Group B (8.3 ± 0.7) with a p -value of < 0.001 . This trend continued over the subsequent weeks and months, with Group A consistently reporting lower pain scores at Week 1 (6.3 ± 0.5 vs. 7.0 ± 0.6), Week 2 (4.8 ± 0.6 vs. 5.5 ± 0.4), Month 1 (3.0 ± 0.5 vs. 3.5 ± 0.8), and Month 3 (1.0 ± 0.1 vs. 2.1 ± 0.6), all with p -values < 0.001 except for Month 1 ($p = 0.001$). The initial comparable pain scores can be attributed to the immediate post-procedural discomfort inherent to both treatments (MacRae & McLeod, 1995).(25) However, the significantly lower pain scores in Group A (sclerotherapy) from Day 3 onwards suggest that sclerotherapy might be associated with a faster reduction in pain compared to rubber band ligation. This aligns with findings from other studies, such as He et al. (2023),(30) which reported that sclerotherapy often results in less postoperative pain due to its less invasive nature compared to the mechanical strangulation caused by rubber band ligation.(18, 30, 31)

The incidence of per rectal bleeding was higher in Group A (sclerotherapy) than in Group B (rubber band ligation)

on Day 1 (55.0% vs. 30.0%, $p = 0.023$), Day 3 (47.5% vs. 20.0%, $p = 0.009$), and Week 1 (27.5% vs. 7.5%, $p = 0.018$), all of which were statistically significant. By Week 2, the incidence of per rectal bleeding reduced in both groups, with 15.0% in Group A and 5.0% in Group B ($p = 0.136$), which was not statistically significant. By Month 1, the incidence was 5.0% in Group A and 0.0% in Group B ($p = 0.556$), and by Month 3, no bleeding was reported in either group. The higher initial incidence of per rectal bleeding in the sclerotherapy group could be due to the chemical irritation and subsequent sloughing of the mucosa following the injection of sclerosants (Acheson et al., 2010).(32) Conversely, rubber band ligation mechanically occludes the blood flow, which might result in a more immediate cessation of bleeding but could also contribute to higher pain scores initially.(33-35) The findings from this study have significant clinical implications for the management of grade II haemorrhoids. The choice of treatment modality can be guided by the patient's pain tolerance and the need for rapid symptom relief. For patients prioritizing faster pain reduction and can tolerate some initial bleeding, sclerotherapy might be the preferred option. On the other hand, for those who seek to minimize bleeding post-procedure, rubber band ligation might be more suitable despite the initially higher pain levels.

The recurrence rate was 15.0% in Group A (sclerotherapy) and 10.0% in Group B (rubber band ligation), with no statistically significant difference between the groups ($p > 0.05$). Recurrence rates are crucial for evaluating the long-term efficacy of haemorrhoid treatments. Studies have shown that recurrence can occur due to incomplete eradication of hemorrhoidal tissue or new hemorrhoidal growth (Brown et al., 2013).(36) The slightly higher recurrence rate in the sclerotherapy group might be related to the nature of the procedure, which relies on the inflammatory response to sclerosing agents. Although effective, this method may not always achieve complete resolution compared to the more definitive mechanical intervention of rubber band ligation (Shanmugam et al., 2005).(35) Retention of urine occurred in 10.0% of patients in Group A and 7.5% in Group B, with no significant difference ($p > 0.05$). Urinary retention is a recognized complication following anorectal procedures, often attributed to postoperative pain and opioid use, which can inhibit bladder function (Grass et al., 2017).(37) The similar rates between the



two groups suggest that both procedures carry a comparable risk of urinary retention, highlighting the need for vigilant postoperative monitoring and management of pain and urinary function. Anal strictures were observed in 5.0% of patients in Group A and 2.5% in Group B, with no significant difference ($p>0.05$). Anal strictures can result from fibrotic healing processes following interventions that cause tissue trauma (Nyström et al., 2010).(38) The low incidence and lack of significant difference between the groups indicate that both treatments have a relatively low risk of causing strictures. This finding is consistent with other studies that have reported low rates of strictures following minimally invasive hemorrhoidal treatments (MacRae & McLeod, 1995).(25) Anal incontinence was reported in 5.0% of patients in both groups, with no significant difference ($p>0.05$). Anal incontinence can be a distressing complication, affecting patients' quality of life. It may result from damage to the anal sphincter or nerves during the procedure (Johanson et al., 1990).(20) The identical rates of incontinence between the two groups suggest that both sclerotherapy and rubber band ligation carry similar risks, underscoring the importance of careful procedural technique to minimize this risk. The findings of this study have important clinical implications for the management of grade II haemorrhoids. Both sclerotherapy and rubber band ligation demonstrate comparable outcomes in terms of recurrence, urinary retention, anal strictures, and incontinence. The choice of treatment may therefore depend on other factors, such as patient preference, pain tolerance, and specific clinical considerations.

Limitations

The limitations of the present study includes short follow-up period, single-centre study design limiting the external validity of the findings, lack of blinding may have led to observer bias, limited assessment of quality of life, and no consideration of cost-effectiveness.

Conclusion

The findings suggest that both sclerotherapy and rubber band ligation are effective treatments, each with its own set of advantages and limitations. Throughout the study period, both procedures demonstrated similar safety profiles in terms of complication rates such as anal strictures, anal incontinence, and retention of urine.

However, there were significant differences observed in pain scores and rates of postoperative bleeding between the two groups. Sclerotherapy resulted in lower pain scores and rubber band ligation had reduced incidence of early postoperative bleeding compared to sclerotherapy. Moreover, the study highlights the importance of individualizing treatment decisions based on patient preferences, symptom severity, and procedural outcomes.

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Table 1: Baseline characteristics of the study groups

		Group A N = 40	Group B N = 40	Total N = 80	p value
		n (%)	n (%)	n (%)	
Age (in years) Mean (SD)		44.3 (8.1)	45.8 (9.7)	45.1 (8.9)	0.504
Age (in years)	≤30	4 (10.0)	3 (7.5)	7 (8.8)	0.768
	30 to 50	26 (65.0)	29 (72.5)	55 (68.8)	
	>50	10 (25.0)	8 (20.0)	18 (22.4)	
Gender	Male	32 (80.0)	34 (85.0)	66 (82.5)	0.556
	Female	8 (20.0)	6 (15.0)	14 (17.5)	
Presenting symptoms (the numbers are not mutually exclusive)	Bleeding per rectum	28 (70.0)	31 (77.5)	59 (73.8)	0.932
	Mass per rectum	24 (60.0)	26 (65.0)	50 (62.5)	
	Straining at defecation	28 (70.0)	28 (70.0)	56 (70.0)	
	Painful defecation	15 (37.5)	21 (52.5)	36 (45.0)	
	Constipation	20 (50.0)	19 (47.5)	39 (48.8)	
	Discharge per rectum	11 (27.5)	9 (22.5)	20 (25.0)	
	Anal irritation	9 (22.5)	7 (17.5)	16 (20.0)	
Symptom duration (in months) Mean (SD)		12.7 (11.4)	12.3 (10.9)	12.5 (11.2)	0.873
Pulse rate Mean (SD)		86.7 (8.1)	87.3 (9.4)	87.0 (8.8)	0.761
Systolic BP Mean (SD)		135.5 (14.5)	136.1 (13.2)	135.8 (13.9)	0.847
Diastolic BP Mean (SD)		87.2 (6.1)	87.4 (5.7)	87.3 (11.8)	0.880
Position	Left lateral	19 (47.5)	21 (52.5)	40 (50.0)	0.904
	Right posterior	12 (30.0)	11 (27.5)	23 (28.8)	
	Right anterior	9 (22.5)	8 (20.0)	17 (21.2)	
*Statistically significant at p<0.05 SD, Standard deviation					

Table 2: Comparison of study groups, by visual analogue scale (VAS) scores

		Group A N = 40	Group B N = 40	Total N = 80	p value
		Mean (SD)	Mean (SD)	Mean (SD)	
	Day 1	8.7 (0.8)	8.8 (0.8)	8.8 (0.8)	0.578



Pain scores (VAS)	Day 3	7.3 (0.3)	8.3 (0.7)	7.8 (0.5)	<0.001*
	Week 1	6.3 (0.5)	7.0 (0.6)	6.7 (0.6)	<0.001*
	Week 2	4.8 (0.6)	5.5 (0.4)	5.2 (0.5)	<0.001*
	Month 1	3.0 (0.5)	3.5 (0.8)	3.3 (0.7)	0.001*
	Month 3	1.0 (0.1)	2.1 (0.6)	1.6 (0.4)	<0.001*

*Statistically significant at p<0.05
VAS, Visual analogue scale

Table 3: Comparison of study groups, by rate of recurrence and post-operative complications

		Group A N = 40	Group B N = 40	Total N = 80	p value
		n (%)	n (%)	n (%)	
Recurrence	Present	6 (15.0)	4 (10.0)	10 (12.5)	0.499
	Absent	34 (85.0)	36 (90.0)	70 (87.5)	
Per rectal bleeding	Day 1	22 (55.0)	12 (30.0)	34 (42.5)	0.023*
	Day 3	19 (47.5)	8 (20.0)	27 (33.8)	0.009*
	Week 1	11 (27.5)	3 (7.5)	14 (17.5)	0.018*
	Week 2	6 (15.0)	2 (5.0)	8 (10.0)	0.136
	Month 1	2 (5.0)	0 (0.0)	2 (2.5)	0.556
	Month 3	0 (0.0)	0 (0.0)	0 (0.0)	1.000
Retention of urine	Present	4 (10.0)	3 (7.5)	7 (8.8)	0.692
	Absent	36 (90.0)	37 (92.5)	73 (91.2)	
Anal stricture	Present	2 (5.0)	1 (2.5)	3 (3.8)	0.556
	Absent	38 (95.0)	39 (97.5)	77 (96.2)	
Anal incontinence	Present	2 (5.0)	2 (5.0)	4 (5.0)	1.000
	Absent	38 (95.0)	38 (95.0)	76 (95.0)	

*Statistically significant at p<0.05

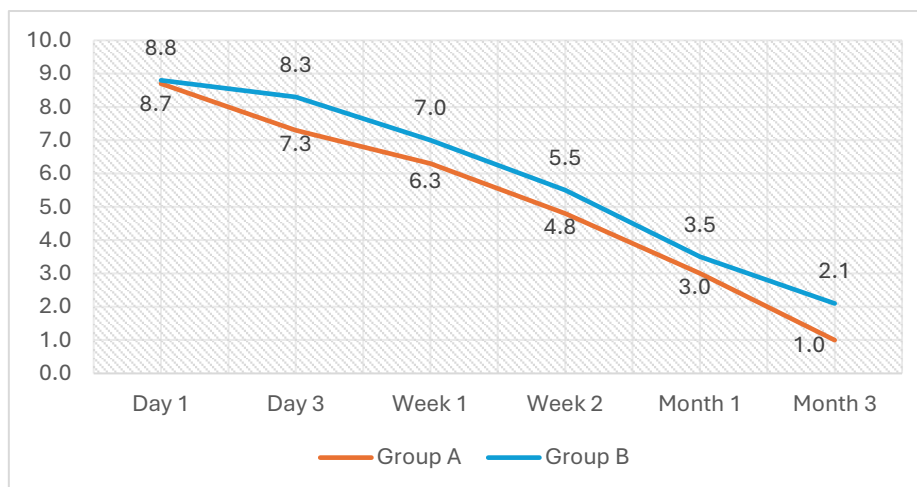


Figure 1: Comparison of study groups, by visual analogue scale (VAS) scores