

Rubber Band Ligation versus Injection Sclerotherapy for the Management of Grade I and Grade II Haemorrhoids: A Prospective Interventional Study

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ABSTRACT

Introduction: Several approaches are available for treating haemorrhoids, ranging from conservative in-office procedures to more invasive surgeries. Rubber Band Ligation (RBL) and Injection Sclerotherapy (SCL) are two widely used, minimally invasive techniques that can be performed in an office setting. While both methods relieve symptoms and enhance patients' quality of life, they vary in mechanisms, techniques, and outcomes. Despite their popularity, there is limited comparative research on their efficacy, safety, and patient satisfaction.

Aim: To compare RBL and SCL regarding post-procedural pain, bleeding, relief of symptoms, and recurrence.

Materials and Methods: A prospective interventional study was conducted at Sri Ramachandra Institute of Higher Education and Research, Chennai, from July 2019 to July 2021. A total of 60 patients over the age of 18 years, with grade I or II haemorrhoids, undergoing RBL or injection SCL were included. Patients were recruited by convenience sampling and allocated alternately, i.e., RBL (n=30) or SCL (n=30), and systematically compared in terms of post procedural pain, bleeding, relief of symptoms, and recurrence. Data was analysed using IBM SPSS version

23.0 statistics software. The t-tests and Chi-square tests were applied and p-value of <0.05 was considered significant.

Results: The mean pain score immediately post-procedure (30 minutes) was 2.6 and 1.7 in the RBL and SCL groups, respectively, $p=0.024$. The same trend was reported on day zero and mean pain score was significantly lower in the SCL group (0.37) as compared to the RBL group (0.93), $p=0.008$. In the first week, 53.3% of the RBL group presented with bleeding as compared to 20% of the SCL group, $p=0.007$. Patients in the RBL group reported better relief of symptoms (i.e., pain, bleeding, pruritus, sensation of mass per rectum) than patients in the SCL group, 93.3%, and 83.3%, respectively, though this data was not statistically significant. The RBL group had one recurrence (3.3%) and the SCL group had three recurrences (10%).

Conclusion: The SCL group outperformed the RBL group regarding pain and bleeding in the first week post-procedure. However, clinically the pain experience was similar for both groups. While data beyond the first week was not statistically significant, SCL remains a safe and effective treatment for early haemorrhoids.

Keywords: Haemorrhoidectomy, Outpatient, Proctology

INTRODUCTION

Haemorrhoids are submucosal vascular cushions of the anorectum that maintain anal continence and are normally located in the left lateral (3 o'clock), right posterior (7 o'clock), and right anterior (11 o'clock) positions. Haemorrhoidal disease is stratified by grades of prolapse, which is evaluated clinically via a proctoscopic examination. Grade I haemorrhoids may be seen protruding into the lumen but remain above the dentate line. Grade II haemorrhoids protrude beyond the dentate line on straining but reduce spontaneously thereafter. These are early or low-grade haemorrhoids. Whereas, grade III haemorrhoids require manual reduction and grade IV haemorrhoids cannot be reduced and may become strangulated. These are considered high-grade or complicated haemorrhoids [1].

Little data is reporting the current prevalence of haemorrhoidal disease. However, an article from South Korea reported prevalence of 14.4% [2] and up to 39% in Austria [3]. In the United States, haemorrhoids result in 2.5 million annual outpatient visits [4]. The commonest presenting complaint is painless haematochezia during defecation, which worsens on straining, sometimes with accompanying tissue prolapse [5]. Haemorrhoids, especially external haemorrhoids, produce acute pain and a palpable lump in the perianal region if they undergo thrombosis. Internal haemorrhoids usually cause pain if they become strangulated [1].

Detailed history taking and clinical examination usher clinicians towards a definitive diagnosis of haemorrhoidal disease. Possibilities of upper and lower gastrointestinal diseases, like inflammatory bowel disease or colorectal cancer, must be excluded first via endoscopic evaluation [1]. Asymptomatic haemorrhoids are not to be treated.

Symptomatic patients with low-grade haemorrhoids are initially managed conservatively. Six to eight weeks of recommended daily intake of 20-30 grams of insoluble fibre and around two litres of water is required to see a noticeable improvement [6,7]. An active, healthy lifestyle is encouraged and patients are advised to not strain and spend over five minutes on the toilet. Topical analgesics (lidocaine), steroid ointments, phlebotonics, antispasmodic agents (nitroglycerin), and sitz baths are prescribed to treat symptoms of pain, swelling, dermatitis, sphincter spasm, and bleeding [8].

Grade I and II symptomatic internal haemorrhoids that do not improve with six to eight weeks of conservative management can be treated by in-office procedures. RBL, injection SCL, and infrared coagulation are the most popularly performed outpatient procedures. The bottom line of all the aforementioned therapies is the sloughing of haemorrhoids, followed by scarring of the mucosa, which would thereby fix it to the underlying anorectal muscular sphincter complex [8]. The choice of therapy depends upon local availability, technical expertise, and patient factors.

Grades I to III haemorrhoids are preferably treated by RBL, despite it being associated with greater pain, as it is more effective and requires fewer sessions when compared to injection SCL and infrared coagulation [9]. Injection SCL is recommended for patients who are on anticoagulant or antiplatelet therapy, are immunocompromised, or have portal hypertension, as its mechanism of action is a caustic local reaction that causes fibrosis and shrinkage of the haemorrhoids. In such patients, RBL is contraindicated due to an increased risk of delayed bleeding as it involves producing ischaemia and necrosis, followed by an ulcer that heals over several weeks [8]. Some external haemorrhoids may be excised in the office if patients present early on. Surgery is reserved for low-grade haemorrhoids refractory to in-office procedures, high-grade haemorrhoids, and haemorrhoids with complications [10]. This study takes a close comparative look at patient outcomes of injection SCL and RBL.

MATERIALS AND METHODS

A prospective interventional study was done in the general surgery outpatient clinics of Sri Ramachandra Institute of Higher Education and Research from July 2019 to July 2021. This study was commenced with the approval of the Institutional Research Ethics Committee of Sri Ramachandra Institute of Higher Education and Research (approval ID: CSP-MED/19/JUN/53/62). All patients provided an informed written consent detailing the purpose, procedure, and potential risks and benefits of this research.

Based on the research by Ammanagi AS and Mathew T [11] as reference, a minimum sample size of 18 per interventional group was calculated. Therefore, a minimum total sample size of 36 was recommended to yield a confidence interval of 95% and a power of 80% in our study.

Patients were recruited by convenience sampling and allocated alternately based on preference, i.e., RBL or SCL. To improve the study's strength, 30 patients were included in each interventional group during data collection, beyond the minimum requirement of 18 samples per group. Ultimately, the total sample size of 60 was reached.

Inclusion and Exclusion criteria: Patients over 18 years of age with grade I or II haemorrhoids were included. Grade III or IV haemorrhoids, inflammatory bowel disease, malignancy, and history of previous anal surgeries comprised the exclusion criteria.

Study Procedure

A thorough history taking involving age, gender, comorbidities, and presenting complaints was done. Patients were then subjected to a digital rectal and proctoscopic examination. For patients with multiple haemorrhoids, no more than two haemorrhoidal columns were treated to reduce patient discomfort and risk of necrosis.

Injection Sclerotherapy (SCL): Patients were placed in left lateral position. After local application of 2% lidocaine jelly, a full length proctoscope was introduced and the haemorrhoidal mass was identified. A 2-3 mL of sodium tetradecyl sulphate was injected into the submucosa at the base of the haemorrhoidal mass. Care was taken at all times to remain above the dentate line.

Rubber Band Ligation (RBL): Patients were placed in left lateral position. After local application of 2% lidocaine jelly, a full length proctoscope was introduced and the haemorrhoidal mass was held using an atraumatic grasper. A tight rubber band was placed at the base of the pedicle using a band applicator. Care was taken at all times to remain above the dentate line.

Patients' pain was closely monitored and recorded 30 minutes after the procedure. Pain was reassessed at the end of day zero, one, and two via a detailed telephonic communication. Pain scores were recorded based on the numeric pain rating scale [12]. Bleeding, relief of symptoms, and recurrence were noted and compared between both interventional groups at the 1st, 2nd, 4th, and 6th weeks.

STATISTICAL ANALYSIS

Collected data was analysed using the IBM SPSS version 23.0 software. Statistical frequency analysis was done for descriptive data. Percentage analysis was done for categorical variables. Mean and standard deviation were used for continuous variables. To find the significant difference between continuous variables, t-test was done. To determine the significance in categorical data, the Chi-square test was used. A p-value of <0.05 was considered significant.

RESULTS

The minimum age in this study was 23 years and maximum was 74 years. Majority of the patients were between 31-50 years of age in both groups. There was no statistically significant difference in age and gender distribution amongst the two interventional groups [Table/Fig-1-3].

Variable	Procedure	n	Mean	SD	t-value	p-value
Age	RBL	30	45.18	13.23	0.896	0.374
	SCL	30	48.43	14.97		

[Table/Fig-1]: Mean age of both interventional groups.

Age (years)		RBL	SCL	Total	χ ² value	p-value
21-30	n	3	4	7	2.496	0.777
	%	10	13.3	11.7		
31-40	n	9	8	17		
	%	30	26.7	28.3		
41-50	n	9	5	14		
	%	30	16.7	23.3		
51-60	n	4	4	8		
	%	13.3	13.3	13.3		
61-70	n	4	7	11		
	%	13.3	23.3	18.3		
71-80	n	1	2	3		
	%	3.3	6.7	5		
Total	n	30	30	60		
	%	100	100	100		

[Table/Fig-2]: Statistical analysis of age distribution amongst both interventional groups.

Gender		RBL	SCL	Total	χ ² value	p-value
Female	n	14	13	27	0.067	0.795
	%	46.7	43.3	45		
Male	n	16	17	33		
	%	53.3	56.7	55		
Total	n	30	30	60		
	%	100	100	100		

[Table/Fig-3]: Statistical analysis of gender distribution amongst both interventional groups.

Distribution of symptomology, i.e., constipation, pruritus, and grades of haemorrhoids (according to Goligher classification [13]), were comparable and did not show any statistical significant difference [Table/Fig-4-6].

Post procedural pain: The mean pain score in the RBL group was 2.6 and 1.7 in the SCL group, p=0.024 [Table/Fig-7].

Pain assessment on day zero, one, and two: On day zero, the SCL group reported a statistically significant lower mean pain score than the RBL group, 0.37 and 0.93, respectively, p=0.008 [Table/Fig-8,9].

In the first week, 53.3% of the RBL group reported bleeding as compared to 20% of the SCL group, p=0.007 [Table/Fig-10]. The data from the subsequent weeks was not statistically significant.

Constipation		RBL	SCL	Total	χ^2 value	p-value
Absent	n	14	12	26	0.271	0.602
	%	46.7	40	43.3		
Present	n	16	18	34		
	%	53.3	60	56.7		
Total	n	30	30	60		
	%	100	100	100		

[Table/Fig-4]: Presence of constipation in both interventional groups.

Pruritus		RBL	SCL	Total	χ^2 value	p-value
Absent	n	25	26	51	0.131	1
	%	83.3	86.7	85		
Present	n	5	4	9		
	%	16.7	13.3	15		
Total	n	30	30	60		
	%	100	100	100		

[Table/Fig-5]: Presence of pruritus in both interventional groups.

Grade of haemorrhoids		RBL	SCL	Total	χ^2 value	p-value
Grade I	n	12	10	22	0.287	0.592
	%	40	33.3	36.7		
Grade II	n	18	20	38		
	%	60	66.7	63.3		
Total	n	30	30	60		
	%	100	100	100		

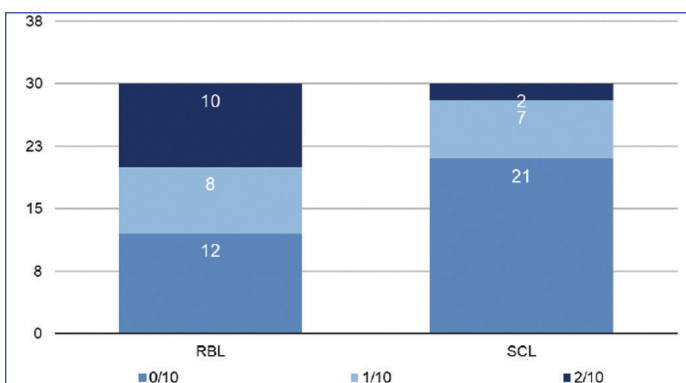
[Table/Fig-6]: Grade of haemorrhoids in both interventional groups.

	Procedure	n	Mean	SD	Z value	p-value
Post procedural pain (30 min)	RBL	30	2.6	1.7	2.259	0.024
	SCL	30	1.7	1.2		

[Table/Fig-7]: Statistical analysis of post procedural pain by interventional group.

Post procedure day	Procedure	N	Mean	SD	Z value	p-value
Day 0	RBL	30	0.93	0.868	2.661	0.008
	SCL	30	0.37	0.615		
Day 1	RBL	30	0.33	0.711	1.603	0.109
	SCL	30	0.07	0.254		
Day 2	RBL	30	0.23	0.626	1.435	0.151
	SCL	30	0.03	0.183		

[Table/Fig-8]: Statistical analysis of pain scores on post procedure day zero, one, and two.



[Table/Fig-9]: Comparison of pain score on day zero by interventional group.

Relief of symptoms: A 93.3% of the RBL group reported relief of symptoms as compared to 83.3% of the SCL group, $p=0.424$ [Table/Fig-11].

One out of the 30 patients that underwent RBL experienced recurrence. Three out of the 30 patients that underwent SCL reported recurrence, (10%) [Table/Fig-12].

Post procedure week	Bleeding	RBL	SCL	Total	χ^2 value	p-value
1 st week	Absent	n	14	24	7.177	0.007
		%	46.7	80		
	Present	n	16	6		
		%	53.3	20		
2 nd week	Absent	n	28	25	1.456	0.424
		%	93.3	83.3		
	Present	n	2	5		
		%	6.7	16.7		
4 th week	Absent	n	26	27	0.162	1
		%	86.7	90		
	Present	n	4	3		
		%	13.3	10		
6 th week	Absent	n	28	26	0.741	0.671
		%	93.3	86.7		
	Present	n	2	4		
		%	6.7	13.3		

[Table/Fig-10]: Statistical analysis of bleeding in both interventional groups.

Relief of symptoms	RBL	SCL	Total	χ^2 value	p-value
Absent	n	2	5	1.456	0.424
	%	6.7	16.7		
Present	n	28	25		
	%	93.3	83.3		

[Table/Fig-11]: Statistical analysis of relief of symptoms in both interventional groups.

Recurrence	RBL	SCL	Total	χ^2 value	p-value
Absent	n	29	27	1.017	0.612
	%	96.7	90		
Present	n	1	3		
	%	3.3	10		

[Table/Fig-12]: Statistical analysis of recurrence in both interventional groups.

Refractory to in office management: Both the RBL and SCL groups each had one patient that had symptoms refractory to their respective intervention, i.e., persistent bleeding from first to sixth week. These findings were not statistically significant, $p=1$.

DISCUSSION

According to a quality analysis of patient information on haemorrhoids by Yeung T and D'Souza N, the internet is host to varying information regarding haemorrhoids and its management. Many websites are sponsored privately and solicit alternative treatments. Generally, only 14% of the websites offer high quality information on treatment options in the management of haemorrhoids [14]. Moreover, due to the socially sensitive nature of this affliction, patients tend to resort to self-diagnosis via the internet and are misguided in their self-treatment. Hence, often when patients seek medical advice for symptomatic haemorrhoids, their disease has relatively progressed.

Current evidence based literature and the growing pool of research related to in office procedures is as large as it is heterogeneous [15,16]. MacRae HM and McLeod RS attributed due consideration to the pain faced by patients post haemorrhoidectomy and formed the recommendation of reserving surgery for cases refractory to RBL despite its superior response [9]. RBL subsequently proved to be a safe and effective modality by Iyer VS et al., in long-term outcomes [17]. Analogously, numerous studies have since been done suggesting that RBL offers better outcomes than SCL, but with greater associated pain [18,19].

Furthermore, some studies have shown no significant difference in RBL and SCL in terms of effectiveness in treating haemorrhoids

[19,20]. In fact, in the Netherlands, the THROS trial is an ongoing multicentre randomised controlled trial conducted by van Oostendorp JY et al. They are investigating the potential non inferiority of SCL to RBL in the treatment of grades I and II haemorrhoids in terms of patient outcomes, experience, complications, and recurrence [21]. In the immediate aftermath of the procedure, i.e., after 30 minutes, patients who underwent RBL reported a mean score of 2.6 and patients who underwent SCL reported a mean score of 1.7, $p=0.024$. With statistically significant results to support our claim, SCL was associated with lower immediate post procedural pain. Our results reiterated the findings of Awan SL et al., that also showed higher pain associated with RBL as compared to SCL [22].

Fundamentally, though our results showed statistical significance in favour of SCL in post procedural pain, we did not see a valuable clinical difference in the two interventional groups. The difference was less than one point on the numeric pain rating scale at all assessment points in time. The authors believe this subtle increase is attributed to the discomfort caused by the foreign body induced ischaemia and necrosis in RBLs. Watson N et al., reported that pain peaked four hours after an RBL procedure [23]. On the contrary, Awad AE et al., found SCL to be associated with higher pain when compared to RBL [24] likely due to the caustic sclerosant action.

Post procedural rectal bleeding was compared amongst both interventional groups in the first, second, fourth, and sixth week. Approximately 53% of the RBL group reported bleeding as compared to 20% of the SCL group, $p=0.007$. The bleeding is due to the eschar formation and sloughing of the haemorrhoidal pedicle in RBL. It was found to be self-limiting and no patient required hospitalisation. Similar results have been reported by Awan SL et al., who found 56% of their RBL group versus 26% of their SCL group experienced rectal bleeding in the initial 24 hours post procedure, and 30% of their RBL group versus 3% of their SCL group experienced rectal bleeding during the first week after the procedure [22]. Bleeding after SCL is rare [19]. In fact, SCL is preferable in patients with a higher bleeding risk due to lack of eschar formation [25].

The American Society of Colon and Rectal Surgeons clinical practice guidelines for the management of haemorrhoids released in May 2024 considers RBL to be the most effective nonsurgical management [10]. One study has shown RBL to be cost-effective as well [26]. Although infamously associated with greater pain up front, RBL is the choice of management when trying to achieve long-term relief in the least number of sessions. This precedence may be challenged by a study which showed that SCL is associated with a lower pain score, a lesser complication rate, and even a lower incidence of recurrence [18]. Additional studies have presented data suggesting that SCL is associated with low complication rates, and a 95.6% ($N=183$) success rate in symptom resolution at the one year mark [27,28]. From the above data, we can extrapolate that it could be a better option than RBL in select patients with early haemorrhoids.

Overall, this study design was cost-effective and replicable. The primary investigators were able to directly scrutinise the therapeutic effects of both interventions. We attempted to quantify and assess pain despite the highly subjective nature of the perception of pain.

Limitation(s)

The use of the numeric pain rating scale in our study may have invited a degree of reporting bias to our results. Alternatively, the use of the visual analogue scale could have averted said reporting bias but potentially at the cost of an observer bias. Within the scope of this study, there were entailed time constraints hindering the long-term follow-up of these patients, i.e., beyond six weeks. Follow-up of patients up to a year is valuable to accurately determine their healing, lifestyle habits, and potential recurrences. Non-randomisation and

thereby potential selection bias were additional lacunae in this study design.

CONCLUSION(S)

Ultimately, the SCL group performed better than the RBL group in terms of pain and bleeding in the first week after the procedure. However, despite statistical significance in favour of SCL, the postprocedural pain experience was nearly equivocal for patients of both interventional groups clinically speaking. Nonetheless, future studies may reveal SCL to be comparable, if not superior, to RBL in the management of early haemorrhoids.

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