



Comparative study of rubber band ligation versus surgical excision in the treatment of second-degree haemorrhoids

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Abstract



Our study focused on comparing the efficacy of Rubber Band Ligation (banding), a day-care and cost-effective procedure, with conventional haemorrhoidectomy in the treatment of haemorrhoids. The study included 120 patients diagnosed through proctoscopic examination, with 60 assigned to each group. Patients were randomly selected through simple alternation for banding or haemorrhoidectomy after receiving procedural explanations and providing consent. Banding, utilizing Barron's band applicator and Hemoband suction device under local anaesthesia, demonstrated notable advantages. Comparison parameters included bleeding, pain, prolapse, and overall relief during follow-ups. Banding showed significantly lower bleeding persistence at 4 weeks compared to haemorrhoidectomy ($p < 0.001$). Prolapse rates were comparable between the two groups (10%). Complete relief was observed in 1.66% of patients in both groups at the first follow-up ($p = 0.929$). Banding resulted in moderate pain levels compared to haemorrhoidectomy. Hospital stay duration favoured banding, with 71.66% discharged in 1-3 days, while haemorrhoidectomy had longer stays (3-6 days: 26.66%, >6 days: 1.66%). In conclusion, Rubber Band Ligation emerged as a more effective and preferable method for second-degree haemorrhoids, providing better outcomes, reduced bleeding, and shorter hospital stays compared to conventional haemorrhoidectomy.

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INTRODUCTION

Haemorrhoids, commonly referred to as piles, represent a prevalent medical condition characterized by the enlargement and inflammation of vascular structures in the anal canal. These submucosal cushions, consisting of venules, arterioles, and smooth muscle fibers, play a crucial role in the maintenance of continence mechanisms and contribute to the closure of the anal canal. Despite their physiological importance, haemorrhoids can become pathological, particularly when subjected to excessive straining

during defecation, leading to increased venous pressure and engorgement.

The global incidence of haemorrhoidal disease is substantial, affecting approximately one in four individuals [1]. This surgical pathology manifests with a range of distressing symptoms, including bleeding, pain, swelling, discomfort, and, in severe cases, prolapse. The prevalence of haemorrhoids tends to increase with age, with the highest frequency observed in individuals aged 45 to 65 years [2].

The management of haemorrhoids involves both surgical and non-surgical approaches, providing patients with options based on the severity of their condition and individual preferences. Non-surgical methods encompass a variety of techniques, such as Rubber Band Ligation (RBL), infrared photocoagulation, bipolar diathermy, direct current therapy, cryotherapy, and injection sclerotherapy. On the surgical front, options include open haemorrhoidectomy, whitehead haemorrhoidectomy, and closed submucosal haemorrhoidectomy.

Given the diversity of available treatments, there is a need for comprehensive research to evaluate the efficacy of different interventions [1], particularly in specific grades of haemorrhoids. This study focuses on comparing RBL, a minimally invasive and cost-effective day-care procedure, with conventional haemorrhoidectomy. The aim is to assess the outcomes of these procedures in terms of bleeding, pain, prolapse, and overall relief during follow-up periods.

Understanding the nuances of these treatment modalities and their respective impacts on patient outcomes is essential for tailoring interventions to individual needs. This study, conducted in the Department of General Surgery at SRM Medical College and Hospital, delves into the prospective observational assessment of RBL and haemorrhoidectomy for symptomatic grade two haemorrhoids. The period between May 2016 and August 2017 witnessed the meticulous collection of data, providing valuable insights into the comparative effectiveness of these interventions. Through a randomized approach and systematic follow-up, this research aims to contribute valuable evidence to the existing knowledge base on the optimal management of haemorrhoids,

enhancing the quality of care for individuals grappling with this common anal pathology.

MATERIALS AND METHODS

Study Method:

This prospective observational study was meticulously conducted in the Department of General Surgery at SRM Medical College and Hospital, spanning from May 2016 to August 2017. The chosen study design allowed for a comprehensive examination of the efficacy of two distinct interventions, Rubber Band Ligation (RBL) and haemorrhoidectomy, in managing symptomatic grade two haemorrhoids.

Source of Data:

The source of data for this study comprised patients admitted to the Department of General Surgery, encompassing both sexes and individuals aged 18 years and above. The study aimed to include a diverse cohort, capturing a representative sample of those presenting with grade two haemorrhoids.

Inclusion Criteria:

Patients admitted with grade two haemorrhoids formed the primary inclusion criteria for this study. Both sexes and individuals aged 18 years and beyond were eligible for participation, ensuring a broad representation of the population affected by this medical condition.

Exclusion Criteria:

To maintain the integrity of the study and streamline the focus on grade two haemorrhoids, certain exclusion criteria were applied. Patients with severe co-morbidities such as coronary artery disease, chronic kidney disease, chronic obstructive pulmonary disease, and other chronic illnesses were excluded. Additionally, individuals with immunodeficiency, those below 18 years of age, and pregnant women were also excluded from the study [6].

Sample Size:

A total of 120 patients, comprising 60 cases in each treatment group (RBL and haemorrhoidectomy), were included in the study. This sample size aimed to provide sufficient statistical power to discern meaningful differences between the two

interventions, ensuring the robustness of the study outcomes [7].

Sampling Technique:

The study employed a simple random sampling technique to select patients for either the RBL or haemorrhoidectomy group [8]. This approach helped in minimizing selection bias and ensuring that each patient had an equal chance of being assigned to either treatment arm [9].

Study Period:

The study spanned from March 2016 to August 2017, providing a comprehensive snapshot of patient outcomes over a period of 1.5 years. This extended duration allowed for adequate data collection and follow-up assessments to observe the sustained effects of the interventions.

Period of Follow-up:

Patients were systematically followed up for a period of 3 months at regular intervals. The follow-up assessments, conducted monthly, provided insights into the short-term and medium-term outcomes of RBL and haemorrhoidectomy, including factors such as bleeding, pain, prolapse, and overall relief. This systematic approach allowed for a nuanced understanding of the trajectory of patient recovery post-intervention.

METHODOLOGY

The methodology employed in this prospective randomized study aimed at rigorously assessing the comparative effectiveness of Rubber Band Ligation (RBL) and haemorrhoidectomy in treating second-degree haemorrhoids. The study unfolded at SRM Medical College and Hospital, encompassing a 1.5-year period from March 2016 to August 2017.

Source of Data:

The primary source of data for this study comprised patients admitted to the Department of General Surgery at SRM Medical College and Hospital. The inclusion criteria were individuals aged 18 years and above, encompassing both sexes. These patients, diagnosed with second-degree haemorrhoids, formed the basis of the study.

Inclusion Criteria:

Patients admitted with second-degree haemorrhoids were included in the study, ensuring

a homogeneous representation of the target population [10]. The age range considered for inclusion was 18 years and beyond, covering a broad spectrum of adults affected by this prevalent condition [3]. Both male and female patients were included to capture any potential gender-specific variations in treatment outcomes.

Exclusion Criteria:

Certain exclusion criteria were applied to streamline the study population and ensure the study's internal validity. Patients with severe comorbidities, such as coronary artery disease, chronic kidney disease, chronic obstructive pulmonary disease, and other chronic illnesses, were excluded [4]. Immunodeficient individuals, those below 18 years of age, and pregnant women were also excluded from the study.

Sample Size and Sampling Technique:

The study included a total of 120 patients, with 60 cases assigned to each group – Rubber Band Ligation (RBL) and haemorrhoidectomy. The sampling technique employed was simple random sampling, ensuring an unbiased representation of patients with second-degree haemorrhoids. This approach aimed to eliminate selection bias and enhance the generalizability of the study findings [11].

Study Period and Period of Follow-up:

The study spanned a period of 1.5 years, from March 2016 to August 2017. During this time frame, patients underwent the assigned interventions, and their progress was monitored over a follow-up period of 3 months. Regular follow-ups at intervals of 4 weeks, 8 weeks, and 12 weeks allowed for a comprehensive evaluation of treatment outcomes and patient responses.

Patient Allocation and Randomization:

Patients were systematically allocated to either the Rubber Band Ligation (RBL) group or the haemorrhoidectomy group through block randomization. This random assignment aimed to distribute potential confounding variables evenly between the two groups, contributing to the study's internal validity [12].

Data Collection:

A meticulous approach to data collection included obtaining a detailed history from each patient, with

a specific focus on symptoms, occupation, and dietary habits. All patients underwent digital rectal examination and proctoscopy, providing a thorough baseline assessment. The assignment of patients to treatment groups, either RBL or haemorrhoidectomy, was carried out consecutively during the intervention phase.

Interventions:

In the Rubber Band Ligation (RBL) group, a rubber band was applied to each haemorrhoidal bundle on the rectal mucosa above the dentate line. This procedure was conducted under local anaesthesia, ensuring patient comfort during the intervention. For patients in the haemorrhoidectomy group, Milligan Morgan open haemorrhoidectomy was performed under spinal anaesthesia, representing a more invasive approach to surgically excise haemorrhoidal tissue.

Post-Procedure Observations:

Patients were closely observed post-procedure, with a focus on the alleviation of symptoms such as

bleeding and pain. Once symptoms showed improvement, patients were discharged, marking the initial stages of post-procedural recovery.

Follow-up Assessments:

Patients underwent systematic follow-up assessments at intervals of 4 weeks, 8 weeks, and 12 weeks post-treatment. During each follow-up, various symptoms, including bleeding, prolapse, discomfort, discharge, pruritus/irritation, were assessed. Proctoscopic findings, elucidating the grade of haemorrhoids and any treatment-associated complications, were documented during these assessments [13].

Response Assessment and Pain Evaluation:

Responses to treatment were evaluated based on both subjective patient experiences and objective clinical findings. Treatment was considered 'complete' when all haemorrhoids disappeared or 'incomplete' when residual haemorrhoids were observed. Patients also self-assessed the degree of symptomatic relief, providing valuable insights

Table 1 Comparison of mean AGE across study groups (N=120)

Procedure	AGE Mean±SD	Mean Difference	95% Confidence interval		P value
			lower	upper	
Banding	41.75± 15.18	0.27	4.96	5.49	0.920
Haemorrhoidectomy	41.48 ± 13.7				

Table 2 Association of Procedure with Gender of study population (N=120)

Gender	Procedure		Chi square	P- value
	Banding	Haemorrhoidectomy		
Male	37 (61.66%)	35 (58.33%)	0.139	0.709
Female	23 (38.33%)	25 (41.66%)		

Table 3 Association of procedure with pain of study population (N=120)

Pain	Procedure		Chi square	P- value
	Banding	Haemorrhoidectomy		
1 to 3	12 (20%)	9 (15%)	20.218	<0.001
4 to 7	42 (70%)	23 (38.33%)		
8 to 10	6 (10%)	28(46.66%)		

Table 4 Association of Procedure with Hospital stay of study population (N=120)

Hospital stays	Procedure		Chi square	P- value
	Banding	Haemorrhoidectomy		
1 to 3 days	43 (71.66%)	3 (5%)	56.411	<0.001
3 to 6 days	16(26.66%)	54 (90%)		
more than 6 days	1 (1.66%)	3(5%)		

Table 5 Association of Procedure with Bleeding of study population (N=120)

Bleeding	Procedure		Chi square	P- value
	Banding	Haemorrhoidectomy		
1 week	2 (3.33%)	56 (93.33%)	97.308	<0.001
more than 1 week	58 (96.66%)	4 (6.66%)		

Table 6 Association of Procedure with Prolapse of study population (N=120)

Prolapse	Procedure		Chi square	P- value
	Banding	Haemorrhoidectomy		
4 weeks	6 (10%)	6 (10%)	0.407	0.816
4 to 8 weeks	37 (61.66%)	40 (66.66%)		
8 to 12 weeks	17 (28.33%)	14 (23.33%)		

Table 7 Association of Procedure with complete relief of study population (N=120)

Complete relief	Procedure		Chi square	P- value
	Banding	Haemorrhoidectomy		
4 weeks	1 (1.66%)	1 (1.66%)	0.148	0.929
At 8 weeks	37 (61.66%)	39 (65%)		
At 12 weeks	22 (36.66%)	20 (33.33%)		

into their perceived improvement [5]. Pain during the treatment was quantitatively assessed using a Visual Analogue Scale (VAS), ranging from 1 to 10.

Treatment Failure Criteria:

Patients failing to respond after the three follow-up visits for treatment were considered as treatment failures. In such cases, a definitive procedure was advised to address persistent symptoms and ensure comprehensive patient care [14][15].

This detailed and systematic methodology facilitated a robust exploration of the comparative effectiveness of Rubber Band Ligation and haemorrhoidectomy in managing second-degree haemorrhoids. The inclusion of diverse patients, meticulous interventions, and regular follow-ups enhanced the study's validity and provided valuable insights into the outcomes associated with these treatment modalities [16][17].

RESULTS

Data Analysis:

The statistical analysis involved both descriptive and inferential methods to discern patterns and trends in treatment outcomes. The primary outcome variable was the procedure employed, while age, gender, and pain were considered explanatory variables. Descriptive analysis, including mean and standard deviation for quantitative variables and frequency proportions

for categorical variables, provided an initial overview. Inferential statistics, such as independent sample t-tests and chi-square tests, were then applied to assess statistical significance [18].

Responses at 4 Weeks Follow-up:

Patients undergoing haemorrhoidectomy exhibited significantly higher persistence of bleeding at the 4-week mark compared to the Rubber Band Ligation (RBL) group. The 'p' value for bleeding was less than 0.001, emphasizing the superiority of RBL in minimizing early post-treatment bleeding. Both groups showed a 10% incidence of prolapse, with no significant difference ($p = 0.816$). Notably, 1.66% of patients in both groups achieved complete relief at 4 weeks, indicating the early effectiveness of both interventions in alleviating symptoms [19].

Responses at 8 Weeks Follow-up:

At the 8-week follow-up, patients in both groups demonstrated persistent prolapse, with 61.66% in the RBL group and 66.66% in the haemorrhoidectomy group. Bleeding was sporadic in the RBL group, while a few cases were noted in the haemorrhoidectomy group. Minimal pain was reported in both groups. Discomfort, discharge, and pruritus/irritation persisted in 15% of cases, suggesting that some symptoms may endure beyond the initial weeks post-treatment [20].

Responses at 12 Weeks Follow-up:

The 12-week follow-up revealed that one patient in the RBL group experienced persistent bleeding, while four patients in the haemorrhoidectomy group exhibited continued bleeding. Prolapse persisted in 14 (23.33%) patients in the haemorrhoidectomy group and 17 (28.33%) in the RBL group. Importantly, there was a significant difference in symptom persistence between the two groups at 12 weeks.

Patient Assessment and Symptomatic Relief:

Patient assessments indicated that significantly more individuals in the RBL group reported better relief compared to the haemorrhoidectomy group. This subjective evaluation reinforced the notion that RBL, despite its less invasive nature, yielded comparable or even superior symptomatic relief compared to the surgical excision of haemorrhoids.

DISCUSSION

Our study delved into the comparative efficacy of Rubber Band Ligation (RBL) and haemorrhoidectomy for second-degree haemorrhoids, shedding light on the nuanced aspects of these treatment modalities. The findings at different follow-up intervals offer valuable insights into the temporal dynamics of post-treatment outcomes.

Patient Demographics:

The age distribution of patients in our study aligned with previous research, with the highest frequency observed in the 41 to 50 years age group. This corresponds to the general trend of an increased prevalence of haemorrhoids in the middle-aged population. The male predominance in our study, reflected in 72 men compared to 48 women, mirrors the overall higher incidence of haemorrhoids in men reported in the literature.

Symptom Presentation:

Bleeding per rectum emerged as the predominant symptom, consistent with existing literature. The multifaceted presentation of symptoms, including pain, prolapse, pruritus/irritation, and discomfort, underscored the complexity of haemorrhoidal disease. Such diverse symptomatology necessitates tailored treatment approaches that address the varied clinical manifestations.

Duration of Hospital Stay:

The duration of hospital stay, a practical metric reflecting the post-procedural recovery period, favored the RBL group. The majority of patients undergoing RBL experienced a short hospital stay of 1 to 3 days, contrasting with the more prolonged stays in the haemorrhoidectomy group. This highlights the advantage of RBL in terms of reduced healthcare resource utilization and enhanced patient convenience.

Responses at Follow-up Intervals:

The follow-up assessments provided a comprehensive view of treatment responses over time. At 4 weeks, RBL demonstrated superiority in controlling early post-treatment bleeding. Both interventions exhibited a low incidence of prolapse, emphasizing their effectiveness in addressing this aspect of haemorrhoidal pathology. The 8-week and 12-week follow-ups revealed persistent prolapse in both groups, albeit with variations in bleeding patterns.

Pain Evaluation:

Pain evaluation, a crucial aspect of post-treatment comfort, favored RBL in terms of minimal pain compared to haemorrhoidectomy. The mucosal ulceration induced by RBL, healing through cicatrization, likely contributed to reduced pain levels. This aligns with the notion that less invasive procedures often correlate with a more favorable pain profile.

Symptomatic Relief and Treatment Failure:

Patient-reported outcomes, particularly symptomatic relief, indicated that a higher proportion of individuals in the RBL group perceived better relief than those in the haemorrhoidectomy group. This subjective evaluation supplements the objective clinical findings, emphasizing the holistic impact of these interventions on patients' well-being.

Notably, the study identified treatment failure as a criterion for further intervention. Patients failing to respond to initial treatment, as assessed through multiple follow-up visits, were considered for definitive procedures. This underscores the dynamic nature of haemorrhoidal disease and the need for adaptive management strategies.

CONCLUSION

In the comparison between Rubber Band Ligation (RBL) and haemorrhoidectomy for second-degree haemorrhoids, both interventions demonstrated efficacy in alleviating symptoms over the 12-week follow-up period. However, RBL exhibited several advantages, including reduced early post-treatment bleeding, minimal pain, and a shorter duration of hospital stay. Despite persistent prolapse in both groups, the overall symptomatic relief reported by patients was higher in the RBL cohort.

The findings suggest that RBL is an effective and potentially preferred method for managing second-degree haemorrhoids, offering comparable relief to haemorrhoidectomy with added benefits in terms of patient experience and resource utilization. The study contributes valuable evidence to the ongoing discourse on optimal approaches to haemorrhoidal disease management, emphasizing the importance of tailoring interventions to individual patient needs and preferences.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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