

Injection Sclerotherapy vs Rubber Band Ligation in the Management of Patients with 2nd Degree Haemorrhoids

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ABSTRACT:

Objective: To compare the efficacy of injection sclerotherapy and rubber band ligation in patients with 2nd degree haemorrhoids.

Study design & Setting: Prospective Observational study was conducted in PNS Shifa Karachi from 1st July 2018 to 31st March 2019.

Methodology: A total of 240 patients of both genders, known cases of 2nd degree haemorrhoids were included in the study. Patients with a known history of liver cirrhosis, previous history of haemorrhoidectomy, severe anaemia uncontrolled hypertension and patient requiring additional intervention post-procedure were excluded. Patients were randomized to either the injection sclerotherapy Group A or rubber band ligation Group B by lottery method. Final assessment was done at 6-months post-procedure regarding the effect of treatment on rectal bleeding.

Results: The age range in this study was from 18 to 65 years with a mean of 36.641±7.00 years in Group A while 35.700± 5.65 years in Group B. Mean BMI was 26.525±1.54 Kg/m² in Group A and 26.316±1.48 Kg/m² in Group B and duration of disease was 7.466±2.15 months in Group A and 7.883±1.78 months in Group B. Efficacy was seen in 87.5% patients in Group A as compared to 98.3% in Group B (p=0.001).

Conclusion: Rubber band ligation is more efficacious in the management of 2nd-degree haemorrhoids in terms of per-rectal bleeding from 3rd-week to 6 months post-application.

Keywords: Prolapsed haemorrhoids, Rubber ligation, Injection Sclerotherapy

How to cite this Article:

Raza Z, Jalil M, Khan WA, Rehman J, Abbas S, Mahmood S. Injection Sclerotherapy vs Rubber Band Ligation in the Management of Patients with 2nd Degree Haemorrhoids. J Bahria Uni Med Dental Coll. 2023;13(2):97-100 DOI: <https://doi.org/10.51985/JBUMDC2021038>

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INTRODUCTION:

Haemorrhoids are a frequently encountered condition in the

surgical outpatient department. As symptomatic haemorrhoids cause a sufficient reduction in quality of life. It is estimated that about 5% of the total population experience haemorrhoids once in their lifetimes and half of the patients in the fifth decade of life receive some haemorrhoid treatment, and nearly 10-20% of the individuals will require surgery¹. A poorly-developed healthcare system coupled with an unhealthy lifestyle and poor dietary habits put our population at an even higher risk for developing haemorrhoids, making it a significant problem². Haemorrhoids are symptomatic enlargement and abnormally downward displacement of anal cushions causing venous dilatation. Other pathologies include degenerative changes in supportive tissue within the anal cushions, vascular hyperplasia, and hyper perfusion of hemorrhoidal plexus³.

Patients present with complaints of itching, burning, protrusion of mass from the anus, bleeding, generalized weakness and constipation. Low-grade haemorrhoids are effectively treated with dietary and lifestyle modification, medical intervention⁴. Surgery is required high-grade or complicated haemorrhoids. Haemorrhoidectomy has been the mainstay of treatment, more recently other approaches have been employed including rubber band ligation (RBL), stapled haemorrhoidopexy, and Doppler-guided hemorrhoidal

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Received: 10-06-2021
Accepted: 01-02-2023

artery ligation⁵. Injection Sclerotherapy (IS) and rubber band ligation are the commonly performed procedures for 2nd-degree haemorrhoids.⁶

Jehan S. et.al in their randomized control study on 100 patients with 2nd-degree haemorrhoids concluded that in patients treated with injection sclerotherapy, 56% were symptoms free after 4 weeks, as compared to 88% after 4 weeks undergoing rubber band ligation. Whereas at 12-month follow-up, 92% remained symptom-free in the Injection sclerotherapy group, as compared to 100% in the rubber band ligation group⁷.

In a setup like ours, where people are very apprehensive of surgery, it becomes imperative to adopt non-operative, outpatient and short methods of treatment for haemorrhoids because of cost, hospitalization and morbidity associated with surgery. This brings Injection sclerotherapy and rubber band ligation is the best-suited choice for outpatient treatment of haemorrhoids. The goal of this study was to compare the efficacy of injection sclerotherapy and rubber band ligation.

METHODOLOGY:

A total of 240 patients of both genders, suffering from 2nd degree haemorrhoids with no improvement after dietary and lifestyle modifications were included in the study after obtaining approval from hospital ethical committee. Informed written consent was obtained from all participants. Patients with a known history of liver cirrhosis, previous history of haemorrhoidectomy, severe anaemia and uncontrolled hypertension were excluded. Patients were randomized to either the Injection sclerotherapy group (Group A) or rubber band ligation group (Group B) by lottery method. All procedures were performed by the same surgeon to exclude bias.

Subjects fulfilling the inclusion criteria a detailed clinical history concerning bleeding per rectum, painful defecation and dietary habits was recorded. A focused general physical exam was done in all. Each patient was subjected to local examination, proctoscopy was performed by the same surgeon to exclude observer bias. All the patients were given an enema in the evening and the morning before the procedure. After the procedure, all the patients were advised to report emergency department in case of any complication in the form of bleeding per rectum or prolapse. All patients were advised tab diclofenac 50mg thrice daily for 5 days. Post-operative bleeding up to 3 weeks is usually common and will not render the procedure non-efficacious. A final assessment was done at 6 months post-procedure regarding the effect of treatment on rectal bleeding. Those patients requiring additional treatment due to post-operative pain were excluded from the study. The Performa was filled for record-keeping.

Data Analysis: Data were evaluated and analysed using Statistical Program for Social Sciences (SPSS) version 23. Mean and Standard deviation was reported for quantitative

variables like age, BMI and duration of disease. Qualitative variables like gender and efficacy were measured in terms of frequency percentage. The results were presented using graphs and Pie charts. Categorical data were compared between the study groups using Chi-square and Quantitative data was compared by independent t-test. P < 0.05 was considered statistically significant.

RESULTS:

Out of the total 240 patients the age range in the study was from 18 to 65 years with a mean age of 36.641± 7.00 years in Group A while 35.700± 5.65 years in Group B. Mean BMI was 26.525±1.54 Kg/m² in Group A and 26.316±1.48 Kg/m² in Group B and duration of disease was 7.466±2.15 months in Group A and 7.883±1.78 months in Group B as shown in Table-I. Male gender was dominant in both groups as shown in Table II. Efficacy was seen in 87.5% of patients in Group A as compared to 98.3% in Group B (p=0.001) as shown in Table III. Stratification of efficacy in both groups concerning gender and duration of disease are shown in Table-IV, and V respectively.

Table 1: Means of patients according to age, BMI and duration of disease n=240

Demographics	Mean ±SD	Mean ±SD
	Group A (n=120)	Group B (120)
Age (yrs.)	36.64 ± 7.0	35.7 ± 5.6
BMI kg/m ²	26.53 ± 1.54	26.3 ± 1.48
Duration of disease	7.4 ± 2.12	7.88 ± 1.78

Table 2: Frequency and percentage of genders in both groups

Gender	Group A (n=120)	Group B (120)
Male	90(75%)	86(71.7%)
Female	30(25%)	34(28.3%)
Total	120 (100%)	120(100%)

Table 3: Comparison of efficacy in both groups

Efficacy	Group A (n=120)	Group B (120)	P value
Yes	105 (87.5%)	118 (98.3%)	0.001
No	15 (12.5%)	2 (1.7%)	
Total	120 (100%)	120(100%)	

Table 4: Stratification of efficacy with respect to gender in both groups

For male gender			
Efficacy			
Group	Yes	No	P value
A	79 (87.8%)	11 (12.2%)	0.003
B	85 (98.8%)	1 (1.2%)	
For Age 41-65 years			
Group	Yes	No	P value
A	26 (86.7%)	5 (15.2%)	0.122
B	33 (97.1%)	1 (2.9%)	

Table 5: stratification of efficacy with respect to duration of disease in both groups

For duration < 6 months			
Efficacy			
Group	Yes	No	P value
A	37 (94.9%)	111 (12.2%)	0.003
B	27 (100%)	0 (0%)	
For duration > 6 months			
Group	Yes	No	0.122
A	68 (84%)	13(16%)	
B	91 (97.8%)	2 (2.2%)	

DISCUSSION:

The present study aimed to find out the frequency of complications in patients undergoing sclerotherapy or rubber band ligation of first or second-degree haemorrhoids. Patients undergoing rubber band ligation more frequently complained of post-procedure pain and bleeding as compared to patients who underwent injection sclerotherapy. Haemorrhoids can occur in all ages, gender and socioeconomic status. Our study showed a high male proportion. Shamim et al from Karachi also showed a male predominance of 74.88%. Various other authors in our population show male predominance in haemorrhoid patients⁸⁻¹⁰. However, western literature showed an equal or mixed male or female predominance pattern in haemorrhoid disease¹¹⁻¹⁷. This could be due to different hospital setup, social, cultural values and eating habits. Haemorrhoids are a common problem in the general population with an estimated 5–30% of adults suffering from¹⁸. It is imperative that the early side-effect profile of the two most common outpatient procedures for the management of first and second-degree haemorrhoids injection sclerotherapy and rubber band ligation, be evaluated in a local cohort of patients. Studies on a direct quantitative comparison of the frequency of pain between patients undergoing sclerotherapy and band ligation of 2nd-degree haemorrhoids are rare. The present study compared the results of sclerotherapy with band ligation for which direct comparison was possible. The results of this study indicate that pain to some degree is experienced during the first postoperative hour by half of the patients undergoing rubber band ligation. In most of the patients experiencing pain in this group, the degree of discomfort varied from mild to moderate.

This observed frequency of pain is in conformation with the findings of Watson et al who observed that at 4 hours after banding, 55% of patients complained of some degree of pain¹⁹. Although the frequency is significantly higher than that seen in local series of patients undergoing banding which have noted 6–20% of patients complaining of pain, most of these studies, unlike this study, did not include discomfort felt by the patient while noting the frequency of pain²⁰. Early postoperative per-rectal bleeding, within the first 24 hours following the procedure was noted in 56% of

patients in the group which underwent rubber band ligation. This conforms to Watson et al who found that 65% of patients complained of per-rectal bleeding on the day following operation¹⁵. In the case series by Bhutta et al and Dilawaiz et al, only 6–12% of patients complained of per-rectal bleeding immediately following the procedure^{16,17}. Those studies also carried out banding as an outpatient procedure, however, limitations in the follow-up of the patients probably accounted for the fewer patients who came back with complaints of per-rectal bleeding. As compared to the frequency of patients in the rubber band ligation group, significantly fewer patients undergoing sclerotherapy had complaints of early bleeding. Only 26% of patients, almost half of the patients in the RBL group experiencing per-rectal bleeding, complained of such a problem. Lesser instrumentation and damage to the mucosa of the upper anal canal during the submucosal injection of sclerosant¹⁸ probably accounts for the lesser frequency of early bleeding seen in patients undergoing injection sclerotherapy. Efficacy was seen in 87.5% of patients in Group A as compared to 98.3% in Group B (p=0.001). Jehan S et al in their randomized control study on 100 patients with 2nd-degree haemorrhoids concluded that in patients treated with injection sclerotherapy, 56% were symptoms free after 4 weeks, as compared to 88% after 4 weeks undergoing rubber band ligation.

Also, at 12-month follow-up, 92% remained symptom-free in the Injection sclerotherapy group, as compared to 100% in the rubber band ligation group⁷.

According to Chaleoykitti these patients would be better benefited by applications of multiple instead of the single band as this is known to influence the outcome in banding procedures²⁰. A recent study from Faisalabad 22 showed that 60% of patients developed mild to moderate bleeding in the first postoperative week. Bernal et al showed that 32% of the patients suffered pain after ligation and 13.81% of cases were operated on due to persistent rectal bleeding or hemorrhoidal prolapse¹³. Rubber band ligation procedure is preferred over sclerotherapy because it provides a more definitive and long-lasting treatment of haemorrhoids and without the risks of surgery such as Haemorrhoidectomy or stapled haemorrhoidopexy¹⁴. Greca et al showed that 15% of patients required retreatment following rubber band injection sclerotherapy as compared to only

5% of patients who underwent rubber band ligation²¹. Other authors have also concluded that despite a higher frequency of post-operative complications, but owing to its significantly better long-term results, rubber band ligation is preferred over injection sclerotherapy for outpatient treatment of first- and second-degree haemorrhoids.²²

CONCLUSION:

In conclusion, rubber band ligation of second-degree haemorrhoids is associated with fewer complaints of per-rectal bleeding, from 03 weeks to 6 months

Authors Contribution:
Zahid Raza Article design, writer, data collection.
Muhammad Jalil: Intellectual supervision, design, proof reading.
Waseem Ahmad Khan: Intellectual supervision, design, proof reading.
Jehanzeb Rahman: data analysis, interpretation and supervision
Shahid Abbas: proof reading, data analysis, literature research
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