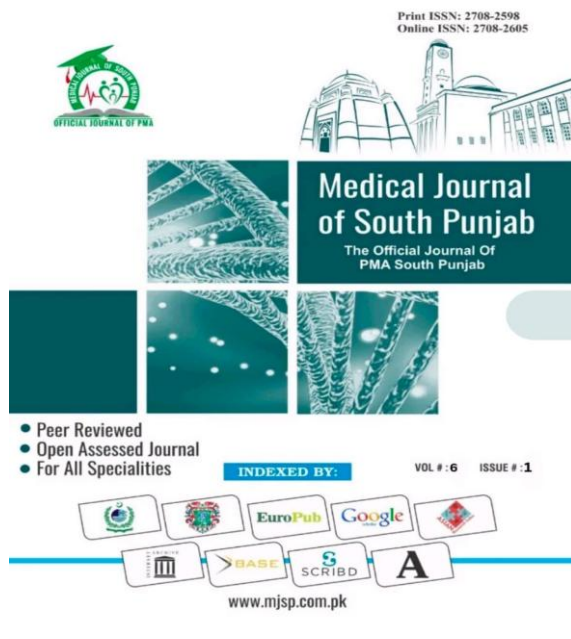


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Comparison of rubber band ligation and injection sclerotherapy for second degree hemorrhoids

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ABSTRACT

Objective: To compare the effectiveness of rubber band ligation (RBL) and sclerotherapy injection (SI) for 2nd degree hemorrhoids.

Methods: The study was conducted in the Department of General Surgery, Ibn-e-Siena Hospital, Multan, as a randomized controlled trial. It spanned a duration of six months following the approval of the study synopsis. The patients were randomly assigned to two groups (Group A and Group B) using the lottery method with sealed opaque envelopes. Group A consisted of patients who underwent hemorrhoidectomy using rubber band ligation, while Group B included those treated with injection sclerotherapy. All procedures were performed according to institutional protocols by consultant surgeons with a minimum of five years of post-fellowship experience.

Results: The mean age of rubber band ligation and Injection sclerotherapy was 49.95 ± 5.38 years and 47.66 ± 6.01 years, respectively. ($p=0.781$). There were 73.4% males and 26.6% females in Group rubber band ligation and 65.6% males and 34.4% females, in Group sclerotherapy. ($p=0.337$). There were 15.6% obese in Group rubber band ligation and 21.9% obese in Group sclerotherapy. The mean duration of symptoms of Group rubber band ligation and Group sclerotherapy was 5.37 ± 1.13 months, respectively. ($p=0.198$). Efficacy for Group rubber band ligation and Group sclerotherapy was 65.6% and 81.3%, respectively. ($p=0.035$).

Conclusion: Rubber band ligation has been demonstrated to be superior to injection sclerotherapy in terms of effectiveness for the treatment of second-degree hemorrhoids, offering better outcomes in symptom resolution, reduced recurrence rates, and overall patient satisfaction while maintaining a minimally invasive approach with fewer complications.

Keywords: Second degree hemorrhoids, Rubber band ligation, Sclerotherapy, Efficacy.

1. INTRODUCTION

Hemorrhoids are among the most common conditions affecting individuals across all age groups and constitute a significant proportion of cases seen in surgical outpatient departments¹. Hemorrhoids affect approximately 4–5% of the global population, although the condition is often underreported due to mild symptoms². Grade I hemorrhoids protrude into the anal canal without prolapse and may cause painless bleeding. Grade II hemorrhoids prolapse with defecation but spontaneously reduce. Grade III hemorrhoids also prolapse with defecation but require manual reduction. Grade IV hemorrhoids are irreducible and carry a risk of strangulation or thrombosis^{3,4}. Conservative treatment options for first- and second-degree hemorrhoids include dietary modifications, lifestyle changes, and hydrotherapy, all of which require good patient compliance to be effective⁵. If conservative management fails, alternative treatments such as injection sclerotherapy, rubber band ligation, cryotherapy, infrared coagulation (which is costly), and bipolar coagulation are available⁶.

Injection sclerotherapy (IST) and rubber band ligation (RBL) are two of the most commonly adopted office procedures for treating second-degree hemorrhoids⁷. IST, one of the oldest non-surgical treatments, involves injecting a sclerosing agent submucosally to induce fibrosis around the vessels of the internal hemorrhoidal plexus, leading to their shrinkage and thrombosis⁷. On the other hand, RBL involves grasping the hemorrhoidal tissue 1–2 cm above the dentate line and slipping a small elastic band over it. This procedure is simple, nearly painless, does not require local or general anesthesia, and typically eliminates the need for hospitalization or taking time off work⁸.

Both methods are minimally invasive, outpatient procedures with favorable safety profiles. However, they differ in their mechanisms of action, cost, patient comfort, and recurrence rates⁹. While RBL is associated with higher efficacy, it may result in more post-procedure discomfort compared to IST, which is generally better tolerated but may require repeated sessions to achieve comparable results¹⁰.

People are generally more apprehensive about surgery. We have planned this study to compare the efficacy of RBL versus IST primarily in terms of control of bleeding in patients with second degree hemorrhoids presenting at our local setting. The study results will be applicable by practicing surgeons of our setting, to opt more easy-to-do method of treatment which would also reduce hospital stay and associated morbidity.

2. METHODOLOGY

The study was conducted in the Department of General Surgery, Ibn-e-Siena Hospital, Multan, as a randomized controlled trial. Hospital ERB approved the study protocol. It spanned a duration of six months following the approval of the study synopsis.

The sample size was calculated using the WHO sample size calculator for hypothesis testing between two group proportions. The efficacy of rubber band ligation was taken as 75.95%⁸, while the efficacy of injection sclerotherapy was 55.1%⁸, 5% margin of error and a study power of 80%, the required sample size was determined to be 128 participants, with 64 patients in each group.

Patients aged 25 to 65 years of either gender, scheduled for surgery for second-degree hemorrhoids, were included in the study. Exclusion criteria comprised patients

with recurrent hemorrhoids, rectal carcinoma (as per medical records), and thrombosis of hemorrhoids (based on clinical examination). A total of 128 eligible patients planned for hemorrhoidectomy were enrolled after obtaining informed consent. Demographic and clinical data, including age, gender, obesity status, and duration of symptoms, were recorded.

The patients were randomly assigned to two groups (Group A and Group B) using the lottery method with sealed opaque envelopes. Group A consisted of patients who underwent hemorrhoidectomy using rubber band ligation, while Group B included those treated with injection sclerotherapy. All procedures were performed according to institutional protocols by consultant surgeons with a minimum of five years of post-fellowship experience. Anesthesia was administered in accordance with hospital guidelines. All patients were discharged the day after the procedure as per protocol, and weekly follow-ups were conducted postoperatively.

Efficacy, defined as the absence of pain, per rectal bleeding, and recurrence, was assessed during follow-ups by surgeons blinded to the treatment groups and uninvolved in the study. Data were recorded using a structured proforma.

SPSS version 27 was used for analysis, numerical data age and duration of symptoms were summarized as mean \pm standard deviation. Categorical variables such as gender, obesity, and efficacy were presented as frequencies and percentages. The chi-square test was applied to compare efficacy between the two groups, with a p-value of ≤ 0.05 considered statistically significant.

3. RESULTS

A total of 128 patients, who met the inclusion criteria, were included in this study. The 128 patients were equally divided into two groups, 64 in each, rubber band ligation group included patients in whom hemorrhoidectomy had done through rubber band ligation and injection sclerotherapy group included patients who undergone injection sclerotherapy.

Efficacy for Group I and Group II was 42 (65.6%) and 52 (81.3%), respectively. ($p=0.035$). (Figure. I).

Table-1: Demographic and Basic variables

Variable	Group I (Rubber band ligation)	Group II (Injection sclerotherapy)	Test of sig.
Age (years)	49.95 \pm 5.38	47.66 \pm 6.01	t=0.28, d.f=126, p=0.781
Gender			
Male	47 (73.4)	42 (65.6)	$\chi^2=0.92$, d.f=1, p=0.337
Female	17 (26.6)	22 (34.4)	
Obesity	10 (15.6)	14 (21.9)	$\chi^2=0.82$, d.f=1, p=0.365
Duration of symptoms (months)	6.09 \pm 1.32	5.37 \pm 1.13	t=-1.29, d.f=126, p=0.198
N (%), chi-square was applied. Mean \pm standard deviation, student t test was applied.			

Figure-1: Comparison of efficacy between the groups



The mean age of rubber band ligation and Injection sclerotherapy was 49.95 \pm 5.38 years and 47.66 \pm 6.01 years, respectively. ($p=0.781$).

There were 47 (73.4%) males and 17 (26.6%) females in Group I and 42 (65.6%) males and 22 (34.4%) females, in Group II. ($p=0.337$). There were 10 (15.6%) obese in Group I and 14 (21.9%) obese in Group II. The mean duration of symptoms of Group I and Group II was 5.37 ± 1.13 months, respectively. ($p=0.198$). (Table. No. 1).

4. DISCUSSION

The results are consistent with existing literature, which generally supports RBL as the preferred treatment for second-degree hemorrhoids due to its superior efficacy and long-term outcomes. Studies such as Gupta et al¹¹ have similarly concluded that RBL outperforms IS in terms of symptom resolution and recurrence prevention. However, IS remains a valuable option for patients who are pain-averse or unsuitable candidates for RBL.

The mean age of patients undergoing rubber band ligation was 49.95 ± 5.38 years, while for those receiving injection sclerotherapy, it was 47.66 ± 6.01 years. In contrast, Bhuiya et al¹² reported a higher upper age limit in their studies, with the age range extending from 70 to 85 years. Furthermore, Jehan et al¹³ observed that the age distribution in their study predominantly fell within the 3rd and 4th decades of life.

In the Rubber Band Ligation (RBL) group, there were 47 males (73.4%) and 17 females (26.6%), while in the Sclerotherapy Injection (SI) group, there were 42 males (65.6%) and 22 females (34.4%). These findings align with the male preponderance reported by Mohan et al¹⁴ who observed a higher proportion of male patients undergoing these procedures. However, Lee et al¹⁵ noted a slightly different trend, performing rubber band ligation in a more balanced ratio of male to female cases, which was 52:48, respectively. This suggests that while male dominance in such cases is commonly

observed, some variations exist based on study populations and geographical differences.

The efficacy rates for sclerotherapy injection (SI) and rubber band ligation (RBL) were 42 (65.6%) and 52 (81.3%), respectively, indicating a higher success rate with RBL. Comparative studies evaluating the efficacy of RBL and injection sclerotherapy (IST) have consistently demonstrated that RBL is more effective in treating second-degree hemorrhoids¹⁶. For instance, a local study conducted by Majid et al¹⁷ identified RBL as the treatment of choice for second-degree hemorrhoids, reporting a cure rate of 76%. These findings underscore the superior therapeutic outcomes of RBL over IST in managing this condition.

Nasir et al⁸ observed that rubber band ligation (RBL) is a simple, non-invasive, cost-effective outpatient procedure with minimal postoperative infections, making it more effective and favorable than sclerotherapy for treating hemorrhoids. In a study conducted by Babar et al¹⁸ demonstrated efficacy of sclerotherapy injection 66.7% and of RBL 81.5%. The difference in effectiveness between the two treatment methods was statistically significant, with a p-value of 0.03, indicating that rubber band ligation was more effective than injection sclerotherapy in this patient population.

Gartell et al¹⁹ compared the outcomes of RBL and injection sclerotherapy for outpatient hemorrhoids. They concluded that RBL is superior and should be the treatment of choice for first and second-degree hemorrhoids. AS et al conducted a similar study on 90 patients with second grade internal hemorrhoids. They observed that postoperative pain and bleeding per rectum was present in 42.9% and 22.2% in patients undergoing IST while 3.6% and 0% in patients undergoing RBL, respectively.²⁰

5. CONCLUSION

Rubber band ligation has been demonstrated to be superior to injection sclerotherapy in terms of effectiveness for the treatment of second-degree hemorrhoids, offering better outcomes in symptom resolution, reduced recurrence rates, and overall patient satisfaction while maintaining a minimally invasive approach with fewer complications.

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