

Comparison of Effectiveness of Injection Sclerotherapy and Rubber Band Ligation for Second-Degree Hemorrhoids

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ABSTRACT

Objective To compare the effectiveness of injection sclerotherapy (IST) and rubber band ligation (RBL) for second-degree hemorrhoids.

Study design Comparative study.

Place & Duration of study Surgical Unit 3, Civil Hospital Karachi, from August 2020 to February 2021.

Methodology A total of 162 patients with the diagnosis of second degree hemorrhoids were included. They were randomly assigned into two groups of 81 patients each. In group I, 5% phenol in almond oil was used for sclerotherapy and in group R, rubber band ligation was performed. In a single sitting only two hemorrhoids were injected. Rubber bands were applied to all the hemorrhoids in single sitting by using Barron's gun. Effectiveness was labelled when no bleeding per rectum and prolapse of hemorrhoids occurred. Data were entered into SPSS version 20. The success of the two groups was compared by using Chi-square test. A p-value of <0.05 was taken as significant.

Results The mean age of the patients was 43.64±11.27 year. There were 97 (59.9%) male and 65 (40.1%) female patients. Baseline characteristics were comparable between the two groups. Injection sclerotherapy was effective in 66.7% (54/81) of the patients while rubber band ligation was effective in 81.5% (66/81) of the patients. This was statistically significant in favor of rubber band group (p=0.03).

Conclusion The outcome of rubber band ligation procedure was superior to the injection sclerotherapy group. It was found safe with low complication rate.

Key words Hemorrhoids, Injection sclerotherapy, Rubber band ligation.

INTRODUCTION:

Hemorrhoids is a common anorectal condition which is identified as the symptomatic dilatation of the anal cushions and their distal displacement.¹ The tissue that holds the vascular cushions in the anal canal

get weakens thus causing the veins to become enlarged and the cushions to protrude.² Prevalence of the disease is thought to be 4.4% in general population.³ This condition usually starts with per rectal bleeding followed by prolapse and, if left untreated, thrombosis of the veins.⁴ Hemorrhoids are usually diagnosed on the basis of clinical examination.⁵ Hemorrhoids are divided in to four grades according to the degree of prolapse. There are multiple treatment modalities used to treat this condition that include sclerotherapy, rubber band ligation, cryosurgery, conventional and stapled hemorrhoidectomy.⁶

Surgery is considered to be superior in terms of

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complete cure. However, many patients opt for non-operative management.⁷ Non operative management of first and 2nd-degree hemorrhoids include changing dietary habits, lifestyle modifications and avoiding straining at defecation.⁸ Different out-patient therapeutic methods are available for the hemorrhoids once conservative therapy is unsuccessful, like injection sclerotherapy and rubber band ligation. These are usually recommended in early uncomplicated stages of hemorrhoids and are done as day care cases.^{9,10} Both therapies are been reported to be effective.^{3,11} This study was conducted to compare the outcome of the two commonly employed techniques, IST and RBL, for evidence based decision making.

METHODOLOGY:

This comparative study was conducted at Surgical Unit-3 of Civil Hospital Karachi from August 2019 to February 2020. The sample size was n=162 with 81 participants in both the groups. The sample size estimation was achieved through the use of the OpenEpi software version 3.0. where, Alpha=5%, Power of the test 1- beta=80, an anticipated population proportion with hemorrhoids who underwent injections sclerotherapy was I=55.1% while those who underwent rubber band ligation was R=75.9%.¹²

Patients of hepatitis B, C or HIV infection, anal fissure or fistula, malignancy, congestive cardiac failure, chronic liver disease, COPD and stroke were excluded from the study.

They were randomly allocated using sealed opaque envelop bearing group I - patients who underwent injections sclerotherapy and group R - patients who underwent rubber band ligation. Departmental approval was obtained for this study. Patients were informed about the type of study design and allocation into each group. Both the surgical interventions are accepted method of treatment.

INJECTION SCLEROTHERAPY GROUP I:

Patients were informed about the method and placed in the left lateral position. After proctoscopy, the obturator was removed, a disposable syringe with a spinal needle of 20-gauge, filled with 5% phenol in almond oil was inserted into the pedicle in submucosal plane above the dental line. In one session, at the base of each hemorrhoid, around 3 to 5ml of the sclerosing agent was injected. Only two hemorrhoids were injected at one time. Patients were counseled about feeling of heaviness and tenesmus after the procedure.

RUBBER BAND LIGATION GROUP R::

In RBL (R group), each patient was counseled about the procedure. Barron's gun was used for the application the rubber band at the level of pedicle of the hemorrhoids. After proctoscopy, hemorrhoidal tissue was grasped with tissue forceps through Barron's gun and rubber band was placed. Patients were asked to visit on the 15th post-procedure day and asked about the resolution of symptoms; bleeding and prolapse of hemorrhoids.

Effectiveness was assessed by the resolution of the symptoms (bleeding and prolapse of hemorrhoids) and regression of hemorrhoidal tissue on proctoscopic examination on 15th post-procedure day.

The quantitative variables of age and duration of surgery were analyzed using SPSS Version 20 by calculating the mean and standard deviations. For the qualitative variables like gender, diabetes mellitus type II (FBS >126mg/dl/ 02 hr. RBS >200mg/dl), hypertension (systolic BP 140 mmHg/diastolic BP 90 mmHg), smoking status (history), BMI and efficacy, frequencies and percentages were measured. The success of the two groups was compared by using Chi-square test. A p-value of <0.05 was taken as significant.

RESULTS:

There were 81 patients in each group. The mean age of the patients was 43.64±11.27 year. There were 97 (59.9%) male and 65 (40.1%) female patients. Of the total 49 males were in group I and 32 in group R while 48 females were in group I and 33 in group R. More than 50% of the patients had diabetes mellitus, 46.3% were hypertensive and 32.1% smokers. Baseline characteristics of the study participants are given in table I. Effectiveness of the intervention in both the groups is given in table II. The difference was statistically significant (p=0.03) in favor of group R.

DISCUSSION:

Hemorrhoids are one of the common anorectal pathologies. It is quite prevalent in Pakistan however, many patients are reluctant to either disclose the symptoms, get examined or seek treatment. They prefer to avoid surgery till no option is left. There is a great fear of pain following surgery and hospitalization. In this study rubber band ligation and injection sclerotherapy were offered to patients with second degree hemorrhoids. Both the procedures are extensively practiced. They are reported as quick, simple, affordable procedures with high patient compliance and satisfaction.¹³

Table I: Baseline Characteristics of the Study Participants

Variables	Group I n=81		Group R n=81	
	Mean (n)	Standard. Deviation (±)	Mean (n)	Standard. Deviation (±)
Age (Years)	42.93	11.25	44.35	11.32
Weight (Kg)	73.89	15.97	71.96	17.10
Height (cm)	161.93	10.26	162.07	9.75
BMI (Kg/m ²)	28.23	6.24	27.42	6.15
Duration of surgery (minutes)	4.81	1.73	5.54	1.59

Table II: Comparison of Effectiveness of Intervention Between the Groups

Effectiveness of The Intervention	Group I n=81	Group R n=81	Total	p- Value
Yes	54 (66.7%)	66 (81.5%)	120	0.03
No	27(33.3%)	15 (18.5%)	42	

Chi-Square =4.629

The male gender predominance in our study is well correlated with the reported literature.¹⁴ However, Lee performed rubber band ligation for higher number of female cases.¹⁵ Many researchers suggest that banding can be performed in one session. We follows the same protocol and performed single session of band ligation dealing with all the hemorrhoids. RBL is regarded as an efficient conservative technique, but many patients have discomfort for several days after the procedure.¹⁶ IST is similarly effective, but it is not free from occasional serious complications such as retroperitoneal sepsis, perianal abscess, necrotizing fasciitis of the perineal region and at times severe urological damages.^{17,18}

In a meta-analysis of 23 clinical trials evaluating treatment for internal hemorrhoids it was concluded that sclerotherapy is less efficient than all other modalities of treatment.¹⁹ Another review compared sclerotherapy, rubber band ligation, and infrared coagulation and concluded that rubber band ligation is an effective treatment.²⁰ Our study shows high efficacy of 81.5% with rubber band ligation. In a study it was found that band ligation is not only a simple and non-invasive technique for the treatment of hemorrhoids, but also cost-effective, with less postoperative infection rate.²¹ It is advised that in cases of first and second-degree hemorrhoids, RBL must be regarded as the method of choice.²² We concur with these observations.

CONCLUSION:

Rubber band ligation was found superior to injection

sclerotherapy in its effectiveness for the treatment of second degree hemorrhoids.

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Jahanzaib Babar: Conception, study design and data collection.

Maria Ahmed: Interpretation and data analysis.

Hina Khan: Critical revision of article.

Khursheed Ahmed Samo: Final approval of the article.

All authors approved final version of the manuscript.

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