

## A COMPARATIVE STUDY OF RUBBER BAND LIGATION AND SCLEROTHERAPY IN PATIENTS WITH SECOND DEGREE HAEMORRHOIDS

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### ABSTRACT

#### BACKGROUND

Haemorrhoids are an extremely common surgical condition of anorectal area. With the available non-surgical approaches for haemorrhoids like infrared coagulation, bipolar diathermy, direct current therapy, cryotherapy, etc. the number of haemorrhoidectomies performed has decreased significantly over time.<sup>12</sup> Rubber band ligation and injection sclerotherapy have become the mainstays of outpatient treatment for patients presenting with grade 1 to 2 haemorrhoids.

#### MATERIALS AND METHODS

The study was carried out between November 2016 and October 2017 over a period of twelve months. A total of 142 patients with second degree haemorrhoids who consented to participate in the study were included. A detailed history was obtained with emphasis on symptoms, occupation and dietary habits. All patients underwent digital rectal examination and proctoscopy. In sclerotherapy group, with the patient in left lateral position, 3 to 5 ml of 5% phenol in groundnut oil was injected into a point above the main mass of haemorrhoid into the sub mucosa, till elevation and pallor of the mucosa was seen. Similarly, in rubber band ligation group one rubber band was applied on each haemorrhoidal bundle on rectal mucosa. Patients were followed up at intervals of 3 weeks, 6 weeks and 9 weeks. At each followup, symptoms of bleeding, prolapse, discomfort, discharge, pruritus / irritation were assessed. Intraoperative pain during the treatment was assessed on a visual analogue scale (VAS) ranging from 1 to 10 with 1 indicating no pain and 10 the worst pain. If the patient was still symptomatic, further treatment given up to a maximum of three times. Patients failing to respond after these three visits for treatment were considered as treatment failure and surgery advised.

#### RESULTS

In comparison of rubber band ligation and sclerotherapy, we found out that all the symptoms of haemorrhoids showed improvement over the course of 9 weeks in both treatment groups. Significantly more number of patients in the Rubber band ligation group had excellent symptomatic relief on patient assessment when compared to sclerotherapy group. Shrinkage of haemorrhoids was also significantly less in sclerotherapy group as compared to rubber band ligation group.

#### CONCLUSION

It was therefore seen that sclerotherapy is slower to give symptomatic relief of bleeding and prolapse compared to rubber band ligation.

#### KEYWORDS

Haemorrhoid, Sclerotherapy, Rubber Band Ligation, Bleeding, Pain.

**HOW TO CITE THIS ARTICLE:** Selvaraj V, Balakrishnan U. A comparative study of rubber band ligation and sclerotherapy in patients with second degree haemorrhoids. J. Evid. Based Med. Healthc. 2018; 5(16), 1366-1370. DOI: 10.18410/jebmh/2018/284

#### BACKGROUND

Haemorrhoids are an extremely common surgical condition of anorectal area. Very few people do not suffer from symptoms of haemorrhoids, and only few reports to their doctor before having resorted to self-medication with proprietary preparations.<sup>1</sup> Hyams and Philpot<sup>2</sup> reported that about one in four of those over 30 years had some degree

of haemorrhoids. Similar prevalence rates have been noticed by several authors.

In both western and Indian studies.<sup>3-5</sup> The common ano-rectal complaints from the patients suffer from haemorrhoidal disease include bleeding, protrusion, discharge, discomfort. Theories like organic obstruction to the venous return from the superior haemorrhoidal veins, heredity factors, anatomical and physiological factors, bowel and dietary factors,<sup>6-8</sup> vascular cushions,<sup>9</sup> internal anal sphincter dysfunction<sup>10,11</sup> and anal corpus cavernosum have been proposed. With the available non-surgical approaches for haemorrhoids like infrared coagulation, bipolar diathermy, direct current therapy, cryotherapy, etc. the number of haemorrhoidectomies performed has decreased significantly over time.<sup>12</sup> Rubber band ligation and injection sclerotherapy have become the mainstays of outpatient

*Financial or Other, Competing Interest: None.*

*Submission 22-03-2018, Peer Review 25-03-2018,*

*Acceptance 10-04-2018, Published 11-04-2018.*

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*DOI: 10.18410/jebmh/2018/284*



treatment for patients presenting with grade 1 to 2 haemorrhoids.

#### *Incidence*

According to Johansson et al. prevalence of haemorrhoids is quite common in Western World, with a reported 10 million people suffering from this affliction and a corresponding prevalence rate of 4.4% in USA.<sup>3</sup> Hyams and Philpot et al. reported that about one in four of those over 30 years had some degree of haemorrhoids.<sup>1</sup> Distribution is most commonly the right anterior, right posterior and left lateral positions; however, many variations can exist, especially if accessory haemorrhoids occupy the areas in between.

*Classification-* Depending on the degree

*First Degree-* Haemorrhoids leads to bleeding at the time of defecation and on physical examination are seen to bulge and sometimes actually bleed.

*Second Degree-* Haemorrhoids protrude or bulge out of the anal canal during defecation and spontaneously return to their proper position.

*Third Degree-* Haemorrhoids prolapse and require digital replacement.

*Fourth Degree-* haemorrhoids are incapable of digital reduction. The symptoms of haemorrhoids are bleeding, prolapse, discharge, anal irritation and Symptoms of secondary anaemia.

#### *Complications*

Prolapse and thrombosis are complications which may affect all the haemorrhoids present in a particular patient or may be confined to one or two.<sup>14</sup>

#### *Treatment*

'To tie; stab; to stretch; perchance to Freeze"<sup>13</sup> A wide range of treatment options starting from medical measures such as local medications, to ambulatory treatments such as sclerotherapy and banding, to surgical options in form of a variety of haemorrhoidectomies are available. Recent developments include cryotherapy and stapler haemorrhoidectomies.

#### *Expectant or Medical Treatment<sup>4</sup>*

Medical measures include aperients or advice regarding high roughage diet to overcome habitual constipation and local medical treatment with various kinds of ointments and suppositories. Keighley et al. in his prospective trial of minor surgical procedures and high fiber diet for haemorrhoids, reported symptomatic relief in 37% of patients treated by high roughage diet alone at the end of 12 months.<sup>15</sup>

#### *Local Medical Treatment*

##### *Injection Treatment<sup>16</sup>*

The injection when given into the submucous areolar tissue in which the haemorrhoidal veins lie produces an inflammatory reaction and fibrous tissue forms. This surrounds and constricts the veins (and arteries) in the submucosae. The fibrosis may also increase the fixation of

the pile or to the underlying muscular coat and in that way it may reduce the amount of prolapse.

#### *Indications<sup>17</sup>*

1. Most second degree internal haemorrhoids which are relatively small, prolonged relief are seen before further injections are required. The larger they are and the more they approach third degree cases, the poorer becomes the prospects with injections.

#### *Contraindication*

1. External piles or lower, skin covered components of large internal piles must never be injected as it produces severe pain.

#### *Complications<sup>18</sup>*

1. Necrosis and formation of injection ulcers.  
2. Submucous abscess, haematuria or prostatic abscess due to deep injection of right anterior haemorrhoid, stricture and encroachment of lumen, paraffinoma are all rarely encountered complications.

#### *Rubber Band Ligation*

The operation was developed by Barron (1964) as a modification of an outpatient ligation method originally proposed and practiced by Blasdel (1958).<sup>19,20</sup>

#### *Rationale*

The principle of the method is to apply a rubber ring ligation through a proctoscope, to the mucosal - covered part of the internal pile. Over a period of 7 to 10 days this elastic band gradually cuts through the tissue and the pile sloughs off immediately.<sup>21</sup>

#### *Disadvantages and Complications*

The main disadvantage of this method is that it does play a role in removal of the skin - covered component of the pile or an associated skin tag, which in patients with large piles, may be of considerable size and troublesome.

1. Incidence of pain has been reported as varying from 6.66% to 29.97% in the clinical trials of rubber band ligation.<sup>22,23</sup>
2. Delayed Pain- A sensation of fullness and pressure follows banding and sometimes this sensation intensifies over 24 to 48 hours but settles soon after 59.
3. Bleeding
4. Thrombosis
5. Anal fissure
6. Slippage
7. Sepsis

#### *Aim of the Study*

To compare the efficiency of sclerotherapy and rubber band ligation in the treatment of second degree haemorrhoids in our institution. The study was carried out between November 2015 and October 2016 over a period of twelve months.

**MATERIALS AND METHODS**

*Inclusion Criteria*

A total of 142 patients with second degree haemorrhoids who consented to participate in the study and who did not have any other associated anorectal lesions were included in the study.

*Exclusion Criteria*

Seven patients developed thrombosed haemorrhoids and five patients subsequently lost to follow up, hence they were excluded from the study leaving 130 patients who formed the study groups.

*Methods*

A detailed history was obtained with emphasis on symptoms occupation and dietary habits. All patients underwent digital rectal examination and proctoscopy. Patients were then assigned to two treatment groups i.e. sclerotherapy or rubber band ligation group consecutively by block randomization.

In sclerotherapy group, with the patient in left lateral position, 3 to 5 ml of 5% phenol in groundnut oil was injected into a point above the main mass of haemorrhoid into the sub mucosa, till elevation and pallor of the mucosa was seen. Similarly in rubber band ligation group one rubber band was applied on each haemorrhoidal bundle on rectal mucosa. Patients were followed up at intervals of 3 weeks, 6 weeks and 9 weeks. At each followup symptoms of bleeding, prolapse, discomfort, discharge, pruritus / irritation were assessed. Proctoscopic findings with regard to grade of haemorrhoids and any treatment associated complications were also noted. Their response to treatment on follow up visits was assessed and termed 'complete' when all haemorrhoids disappeared or incomplete when any residual haemorrhoids were found. Patients were asked to assess degree of symptomatic relief on a 4 point scale as follows:

*Excellent*

Patients who became completely asymptomatic.

*Better*

Patients who had improvement of symptoms.

*Same*

Patients who had persistence of symptoms without any improvement

*Worse*

Patients whose symptoms worsened after treatment. Intraoperative pain during the treatment was assessed on a visual analogue scale (VAS) ranging from 1 to 10 with 1 indicating no pain and 10 the worst pain.

**RESULTS**

Out of 130 patients in our study, 65 patients were randomized to sclerotherapy and 65 patients to rubber band ligation.

Sl. No.	Symptom	Fully Resolved	Improved
1	Recurrent thrombosis	100%	-
2	Pain	71%	14%
3	Bleeding	88%	8%
4	Protrusion	92%	4%

**Table 1**

Group	No. of Patients	Percentage (%)
Sclerotherapy	65	50.00
Rubber band ligation	65	50.00
<b>Total</b>	<b>130</b>	<b>100.00</b>

**Table 2**

Age (Years)	Frequency	Percentage (%)
21-30	20	15.38
31-40	21	16.15
41-50	40	30.76
51-60	26	20.00
61-70	21	16.18
71-80	2	1.53
<b>Total</b>	<b>130</b>	<b>100.00</b>

**Table 3**

Occupation	Total No. of Patients	Percentage (%)
Manual labourers	53	40.77
Predominantly standing	37	28.46
Predominantly sitting	40	30.77
<b>Total</b>	<b>130</b>	<b>100.00</b>

**Table 4**

Bowel Habits	Total No. of Patients	Percentage (%)
Normal	44	33.84
Diarrhoea	0	0
Constipation	86	66.16
<b>Total</b>	<b>130</b>	<b>100.00</b>

**Table 5**

Presenting Symptoms	Total No. of Patients	Percentage (%)
Bleeding	112	86.15
Prolapsed	93	71.53
Discomfort	26	20.00
Discharge	18	13.84
Pruritus/irritation	33	25.38

**Table 6**

**DISCUSSION**

Our study had patients with age ranging from 18 years to 73 years with the highest frequency between 41-50 years. There were 102 men (78.46%) and 28 women (21.54%) in our study. Keighley et al. found similar sex distribution with 154 men and 62 women in his study.<sup>24</sup> 30.77% patients in our study had occupation involving predominantly sitting throughout the day, 28.46% worked mainly standing and 40.77% were manual labourers.

In our study, 67.69% of patients were in the habit of taking predominantly vegetarian diet, 42.31% with low fibre content and 17.69% with high fibre content. Another 32.30% were taking predominantly nonvegetarian diet, 21.54% with high fibre and 11.53% with low fibre.

In the present study of ours, there was evidence of 66.16% of patients having constipation and 33.84% of patients had normal bowel habits. We found that bleeding per rectum was the predominant symptom (86.15%) followed by prolapse (71.53%), pruritus/irritation (23.38%), Discomfort (20%) and discharge (13.84%).

#### *Responses at 3 Weeks Follow up*

Patients who received sclerotherapy were found to have significantly higher persistence of bleeding and prolapse at 3 weeks when compared to rubber band ligation group. 'p' value for bleeding was 0.02 and for prolapse was 0.015 respectively.

Significantly more number of patients in the Rubber band ligation group had excellent symptomatic relief on patient assessment when compared to sclerotherapy group ( $p' = 0.04$ ). Shrinkage of haemorrhoids was also significantly less in sclerotherapy group as compared to rubber band ligation group ( $p = 0.026$ ).

#### *Responses at the End of 6 Weeks Follow up*

At 6 weeks post treatment, bleeding and prolapse persisted in 11.47% and 51.02% of patients in sclerotherapy group, other symptoms like discomfort, discharge and pruritus / irritation persisted in 13.51% patients in the sclerotherapy group. There was statistically significant difference in improvement of symptoms between the treatment groups ( $p=0.02$ ).

After completion of 6 weeks follow up, complete response was seen in 46.15% of patients in sclerotherapy and 64.62% patients in rubber band ligation group. Rubber band ligation shows significantly better clinical response as compared to sclerotherapy ( $p' \text{ value} = 0.022$ ).

#### *Responses at the End of 9 Weeks Follow up*

At the end of 9 weeks follow up, only one patient in rubber band ligation had persistence of bleeding and other symptoms like discharge, discomfort, pruritus/irritation, compared to 5 patients in sclerotherapy group. Prolapse however persisted in 16 in sclerotherapy and 4 in rubber band ligation group. There was a significant difference in persistence of symptoms in the two groups at 9 weeks.

Patient assessment of treatment showed that significantly more patients felt better relief with rubber band ligation compared to sclerotherapy ( $p=0.032$ ).

The observed clinical response was complete in only 61.54% and 81.54% in sclerotherapy and rubber band ligation group respectively. This response was significantly lower in sclerotherapy group compared to rubber band ligation group ( $p = 0.023$ ).

## CONCLUSION

In both rubber band ligation and sclerotherapy, we found out that all the symptoms of haemorrhoids showed improvement over the course of 9 weeks. Due to the slower improvement of bleeding in patients with sclerotherapy group compared to rubber band ligation, patients with significant bleeding due to haemorrhoids maybe better treated by rubber band ligation to give quicker relief. However, patients in both groups had excellent symptomatic relief even in the presence of prolapse, hence complete disappearance of prolapse is not a prerequisite for symptomatic relief. Both the modalities were not found to have significant effect on treating prolapse, hence patients with prolapse as the main presenting symptom may have surgery as an initial treatment option.

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