

## RUBBER BAND LIGATION VS INJECTION SCLEROTHERAPY IN OFFICE MANAGEMENT OF 1ST & 2ND DEGREE HEMORRHOIDS

Muhammad Yousaf Shah, Ahmed Khan Chaudhry, Wajahat Ali Nadeem

5 Mountain Field Ambulance, \*Combined Military Hospital Rawalpindi, \*\*4 Mountain Field Ambulance

### ABSTRACT

**Objectives:** To compare the effectiveness and complications of Rubber Band Ligation (RBL) with Injection Sclerotherapy (IST) in the treatment of 1st degree and 2nd degree hemorrhoids.

**Study Design:** Randomized Controlled Trial.

**Place and Duration of Study:** CMH Rawalpindi, from 1<sup>st</sup> Feb to 30 Sep 2007.

**Subjects and Methods:** A total of 120 patients were selected for study. 60 patients with 1st degree haemorrhoids were placed in group I and 60 patients with 2nd degree haemorrhoids were placed in group II. These patients were then randomly divided into two sub-groups 'A' and 'B' through Random Allocation by Table of Random Numbers. Group 'IA' had 30 patients of 1st degree haemorrhoids and group 'IIA' had 30 patients of 2nd degree haemorrhoids. Similarly group 'IB' had 30 patients of 1st degree haemorrhoids and group 'IIB' had 30 patients of 2nd degree haemorrhoids. Then groups 'IA' & 'IIA' were subjected to RBL and Groups 'IB' & 'IIB' were subjected to IST. The outcome measures were relief of symptoms, recurrence rate and complications.

**Results:** Male to female ratio was 11:1. Among patients subjected to RBL, 58.3% were from age group 2 (31-50 yrs) with mean age  $42.90 \pm 11.74$  yrs and mean duration of symptoms was  $6.24 + 4.91$  months. Among patients subjected to IST, 55% were from age group 2 (31-50 yrs) with mean age  $45.62 \pm 12.49$  yrs and mean duration of symptoms was  $7.03 + 4.76$  months. Important immediate complication was pain, but majority of patient were pain free. In group IA 36.7% patients had slippage of ligature but none of the patients undergoing IST developed Prostatitis. Visible bleeding was the main complication in group 'IA' 4th week ( $p < 0.05$ ). Response to IST among 1st degree haemorrhoids was significant at 4th week i.e. 90%, as compared to RBL, i.e. 63.3% ( $p < 0.05$ ).

**Conclusion:** IST is treatment of choice for 1st degree haemorrhoids, but for 2nd degree haemorrhoids, both RBL and IST are equally effective.

**Keywords:**

### INTRODUCTION

Haemorrhoids are dilated veins occurring in relation to anal canal. They are necessary for full continence. They can be internal or external being above or below dentate line respectively, in the anal canal. They are more common when intra-abdominal pressure is raised, e.g. obesity, constipation and pregnancy. Classically, they occur at 3, 7 and 11 o'clock position with patient in Lithotomy position. Symptoms of haemorrhoids are: bright red painless bleeding, mucus discharge, mucosal prolapse, pruritis and sometimes only pain. Haemorrhoids are 1<sup>o</sup> (only bleed), 2<sup>o</sup> (prolapse but return automatically), 3<sup>o</sup>

4<sup>o</sup> (permanently prolapsed)<sup>1-3</sup>. All haemorrhoids bleed but are classified into types according to the degree of prolapse<sup>4</sup>. They produce symptoms only when complicated.

Ten million people complain of haemorrhoids in USA annually, with a prevalence rate of 4.4%. Peak age is 35-65 years. They are rare before 20 years of age<sup>5</sup>. The treatment of haemorrhoids has changed in recent years with a tendency to avoid operation. At some centres in the west, office management is in >95% cases<sup>6</sup>.

Most of the patients in our society are reluctant for operation and opt for conservative treatment. The reason may be social, economical, fear of pain or desire to have no hospitalisation<sup>7</sup>. Conservative therapies in the treatment of haemorrhoids include diet, lifestyle changes and hydrotherapy, which require a high degree of

**Correspondence:** Major Muhammad Yousaf Shah, Dept of Surgery, 05 Mtn Fd Amb,  
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(prolapse and stay reduced on reduction) or

patient compliance to be effective. When conservative haemorrhoid therapy is ineffective, many physicians may choose from various other outpatient treatment options like; Injection Sclerotherapy (IST), Rubber Band Ligation (RBL), Cryosurgery, Infra-red Photocoagulation, Bipolar Coagulation and LASAR Technique<sup>8</sup>. Each of the above mentioned option can be safely performed as an outpatient procedure<sup>9</sup>. If a non-surgical approach fails, the patient is often referred to a surgeon<sup>10</sup>.

Both IST and RBL are easy to apply, readily available and easily learnt procedures. In IST sub-mucosal fibrosis is produced around the vessels of internal haemorrhoidal plexus, to obliterate and cause them to shrink. Complications include aching pain, bleeding, injection ulcers, sub-mucosal abscess, haematuria and prostatic abscess<sup>4</sup>. In RBL a band is applied around haemorrhoids by a gun that causes ischemic necrosis of haemorrhoids, causing them to slough away in one or two weeks. It is simple, almost painless, requiring no local or general anaesthesia and has no need of hospitalization or time off work<sup>4</sup>.

IST is relatively cheap and requires one clinician to administer it. This has contributed to its popularity for treating 1<sup>o</sup> and 2<sup>o</sup> haemorrhoids in the UK. However, in terms of efficacy of treatment, IST and photocoagulation are similar<sup>11,12</sup> and both have been shown to be less effective than RBL in controlling symptoms and long-term outcome<sup>13</sup>. A meta-analysis of published randomised controlled trials has not shown a significant difference in the incidence of complications following RBL and IST (including haemorrhage), although RBL was significantly more painful<sup>14</sup>.

In a set-up like ours, where people are very much apprehensive of surgery, it becomes imperative to adopt non-operative outpatient and short methods of treatment for haemorrhoids because they can not afford unnecessary hospitalisation and want less morbidity and early return to work, so making IST and RBL the best suited choice for

outpatient treatment of haemorrhoids.

## PATIENTS AND METHODS

Out of all patients with symptomatic 1<sup>st</sup> and 2<sup>nd</sup> degree haemorrhoids, presenting at Out Patient Department (OPD) of General Surgery, Combined Military Hospital (CMH), Rawalpindi, from 1<sup>st</sup> February 2007 to 30<sup>th</sup> September 2007, 120 patients were selected for study. Sixty patients with 1<sup>st</sup> degree haemorrhoids were placed in group I and 60 patients with 2<sup>nd</sup> degree haemorrhoids were placed in group II.

After complete history and physical examination, degree of haemorrhoids was ascertained by anoproctoscopy. These patients were then randomly divided into two sub-groups 'A' and 'B' through Random Allocation by Table of Random Numbers. Group 'IA' had 30 patients of 1<sup>st</sup> degree haemorrhoids and group 'IIA' had 30 patients of 2<sup>nd</sup> degree haemorrhoids. Similarly group 'IB' had 30 patients of 1<sup>st</sup> degree haemorrhoids and group 'IIB' had 30 patients of 2<sup>nd</sup> degree haemorrhoids. Informed consent, willingness and voluntary participation of the subjects were obtained.

Rubber Band Ligation (RBL) was done in groups 'IA' and 'IIA' and Injection Sclerotherapy (IST) was done in groups 'IB' and 'IIB'. Both procedures were done in OPD setting. In groups 'IA' and 'IIA', every patient was briefed about the procedure and placed in knee elbow position. Barron's Gun and Elise's tissue forceps were used to apply the Rubber Band at the base of each haemorrhoid, above the *Dentate line*. In groups 'IB' and 'IIB', after thorough brief about the procedure, every patient was placed in knee elbow position and the base of each haemorrhoid was identified. A solution of 3-5ml of 5% phenol in Almond oil was injected into the base of pedicle with a disposable syringe, with bevel of the Lumber Puncture needle directed towards rectal wall.

Following procedure, in both groups, patients were observed for 30 minutes for immediate complications like pain, bleeding and vasovagal shock; patients were asked to rate the pain on a Pain Scale of 1-10. The pain was graded as mild (1-3), moderate (4-6) and

severe (7-10). After that they were followed up at 1st and 4th week and anoproctoscopy was done to take an account of late complications, degree of improvement and need for repetition of procedure.

Patient's bio-data, presenting complaints, findings on examination, procedure done, need for sigmoidoscopy, immediate complications, complications at 1st and 4th week of procedure and degree of improvement were noted on Proforma attached as Annex 'A'.

Statistical Package for Social Sciences (SPSS) version 10 was used to analyse data. Relevant descriptive statistics were used to describe the data. Frequency and percentage were calculated for qualitative variables while mean and standard deviation (SD) were calculated for quantitative variables. Independent sample t-test was used to compare quantitative variables while Chi square test was applied to compare qualitative variables between the groups.  $p$ -value  $<0.05$  was considered as significant.

## RESULTS

Among 120 patients, 110 (91.67%) were males and 10 (8.33%) were females. Male to female ratio was 11:1. Details are as in table 1.

There was no statistical difference between groups with regard to 'presenting complaints', 'duration of symptoms', 'number of haemorrhoids on examination' and bleeding PR was the leading symptom.

At 30 minutes of procedure: Only 2 patients, 1 from group 'IIA' and 1 from group 'IIB' had severe pain (7-10 on VAS), for which Mefenamic Acid (Ponstan) 500mg was given thrice daily till relieved (Table 2).

At 1 Week: At the end of 1<sup>st</sup> week, as shown in table 3, 74.1% patients in group 'IA' and 85.7% patients in Group 'IB' achieved symptomatic relief from bleeding. Out of 4 patients with mucosal prolapse in group 'IA', 3 patients showed reduction in prolapse. In group 'IB' 2 out of 3 patients showed reduction, while in group 'IIB' 1 out of 2 patients showed mucosal reduction. On anoproctoscopy at 1 week, it was evident that

bleeding has increased only in patients treated with RBL (Fig 1).

In group IA 36.7% patients faced failure of procedure due to slippage of ligature. This number was very less in group 'IIA' where only 3.3% patients faced this complication. On contrary, none of the patient in groups 'IB' and 'IIB' developed Prostatitis.

At 4th Week (Table 3, 4): Symptomatic stoppage of bleeding was significant in group 'IB'. No doubt, there was a marked response in group 'IIB', but it was statistically insignificant ( $p$  Value  $>0.05$ ). Bleeding recurrence was a significant complication in group 'IA' where 37% had visible bleeding as compared to 10.7% in group 'IB' ( $p$  Value  $<0.05$ ).

At the end of 4 week follow up, out of 9 patients with complaint of mucosal prolapse at presentation, 6 were cured, all of them had 1<sup>st</sup> degree haemorrhoids. Thirteen patients in Group 'IA' and 2 patients in group 'IB' required repetition of procedure ( $p$  Value  $<0.05$ ). Main cause of repetition and bleeding in group 'IA' was slippage of ligature in 1<sup>st</sup> degree haemorrhoids. Overall 63.3% in group 'IA' and 90% in group 'IB' achieved symptomatic recovery ( $p$  Value  $<0.05$ ). Patient recovery was equal in groups 'IIA' and 'IIB' i.e. 90% ( $p > 0.05$ ).

It is evident from these results that stoppage of bleeding in 1<sup>st</sup> degree haemorrhoids is significantly more with IST. Response in 2<sup>nd</sup> degree haemorrhoids is same with either treatment. Mucosal prolapse reduction is more with RBL. Pain and recurrence of bleeding is a major complication with RBL in 1<sup>st</sup> degree haemorrhoids. Slippage of ligature, again, is more with RBL. Thus IST is a better choice for treatment of 1<sup>st</sup> degree haemorrhoids and there is no statistical difference between RBL and IST for treatment of 2<sup>nd</sup> degree haemorrhoids.

## DISCUSSION

Haemorrhoids are one of the most common complaints affecting in various forms almost 50% of people over the age of 50<sup>15</sup>.

**Table 1: Demographic Description**

Grouped Variable	Value	Group 'IA' (n=30)	Group 'IB' (n=30)	p Value	Group 'IIA' (n=30)	Group 'IIB' (n=30)	p Value
Age Group	< 30 years	1 (3.3%)	4 (13.3%)	0.376 (>0.05)	7 (23.3%)	2 (6.7%)	0.169 (>0.05)
	31 – 50 years	20 (66.7%)	17 (56.7%)		15 (50%)	16 (53.3%)	
	51 – 70 years	9 (30%)	8 (26.7%)		8 (26.7%)	10 (33.3%)	
	> 70 years	-	1 (3.3%)		-	2 (6.7%)	
Mean Age	In years $\pm$ SD	45.13 $\pm$ 11.72	44.30 $\pm$ 11.36	0.781	40.67 $\pm$ 11.51	46.93 $\pm$ 13.59	0.059
Duration	In Months $\pm$ SD	7.02 $\pm$ 5.92	7.27 $\pm$ 3.68	0.845	5.46 $\pm$ 3.56	6.80 $\pm$ 5.69	0.280
Gender	Male	28 (93.3%)	27 (90%)	0.640 (>0.05)	27 (90%)	28 (93.3%)	0.640 (>0.05)
	Female	2 (6.7%)	3 (10%)		3 (10%)	2 (6.7%)	
Presenting Complaint	Bleeding PR	25 (83.3%)	26 (86.7%)	0.695 (>0.05)	26 (86.7%)	27 (90%)	0.360 (>0.05)
	Mucosal Prolapse	3 (10%)	2 (6.7%)		-	1 (3.3%)	
	Bleeding with Pruritis Ani	-	1 (3.3%)		2 (6.7%)	-	
	Bleeding with Pain	1 (3.3%)	-		2 (6.7%)	1 (3.3%)	
	Bleeding with Prolapse	1 (3.3%)	1 (3.3%)		-	1 (3.3%)	
No of Hemorrhoids	One	15 (50%)	11 (36.7%)	0.277 (>0.05)	17 (56.7%)	12 (40%)	0.334 (>0.05)
	Two	11 (36.7%)	17 (56.7%)		12 (40%)	15 (50%)	
	Three	4 (13.3%)	2 (6.7%)		1 (3.3%)	3 (10%)	

Note: Percentage is within Groups.

**Table 2: At 30 minutes of Procedure**

Variable	Value	Group 'IA' (n=30)	Group 'IB' (n=30)	p Value	Group 'IIA' (n=30)	Group 'IIB' (n=30)	p Value
Pain	Mild (1-3)	3 (10%)	4 (13.3%)	0.921 (> 0.05)	4 (13.3%)	5 (16.7%)	0.769 (> 0.05)
	Moderate (4-6)	3 (10%)	3 (10%)		3 (10%)	1 (3.3%)	
	Severe (7-10)	-	-		1 (3.3%)	1 (3.3%)	
	No Pain	24 (80%)	23 (76.7%)		22 (73.3%)	23 (76.7%)	
Vasovagal Shock	No	29 (96.7%)	30 (100%)	0.313 (> 0.05)	30 (100%)	29 (96.7%)	0.313 (> 0.05)
	Yes	1 (3.3%)	-		-	1 (3.3%)	

**Table 3: Symptomatic Relief at 1<sup>st</sup> and 4<sup>th</sup> Week**

Variable	Value	Group 'IA'	Group 'IB'	p Value	Group 'IIA'	Group 'IIB'	p Value
Stoppage of Bleeding at 1 <sup>st</sup> Week	Yes	20 (74.1%)	24 (85.7%)	0.281 (> 0.05)	28 (93.3%)	26 (89.7%)	0.612 (> 0.05)
	No	7 (25.9%)	4 (14.3%)		2 (6.7%)	3 (10.3%)	
Stoppage of Bleeding at 4 <sup>th</sup> Week	Yes	17 (63%)	25 (89.3%)	0.022 (< 0.05)	27 (90%)	27 (93.1%)	0.669 (> 0.05)
	No	10 (37%)	3 (10.7%)		3 (10%)	2 (6.9%)	

Note: Percentage is within Groups.

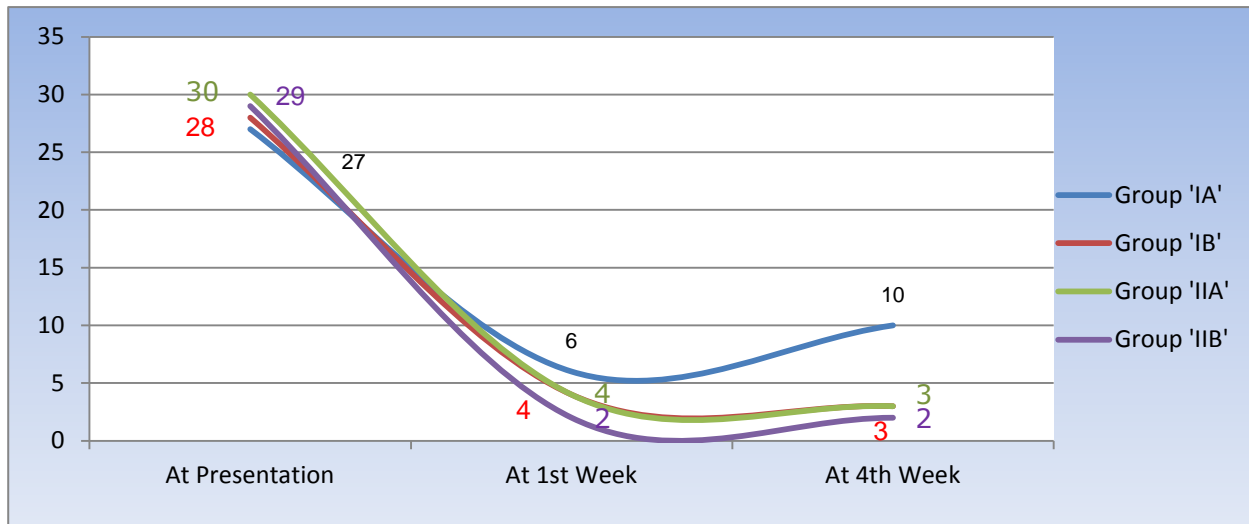
RBL is considered to be an effective treatment for symptomatic internal haemorrhoids<sup>16</sup>. Since its introduction by Barron, many new useful modifications have been introduced in the procedure. Suction ligation<sup>17</sup>, synchronous ligation<sup>18</sup> of all the

haemorrhoids with a modified anoscope<sup>19</sup> and using a videoscopic anoscope<sup>20</sup> are a few of such innovations that have helped achieve still better results. However, post-ligation pain and discomfort associated with RBL is the main problem.

**Table 4: Outcome at 4<sup>th</sup> week**

Variable	Value	Group 'IA'	Group 'IB'	p Value	Group 'IIA'	Group 'IIB'	p Value
Need of Repetition	Yes	13 (43.3%)	2 (6.7%)	0.001 ( $< 0.05$ )	2 (6.7%)	2 (6.7%)	1.000 ( $> 0.05$ )
	No	17 (56.7%)	28 (93.3%)		28 (93.3%)	28 (93.3%)	
Recovered	Yes	19 (63.3%)	27 (90%)	0.015 ( $< 0.05$ )	27 (90%)	27 (90%)	1.000 ( $> 0.05$ )
	No	11 (36.7%)	3 (10%)		3 (10%)	3 (10%)	

Note: Percentage is within Groups.



**Figure: Patients with visible bleeding on Anoproctoscopy**

Injection sclerotherapy is an older method of treating haemorrhoids non-surgically. It is very effective and a less tedious procedure but is not free from complications which can be serious sometimes. Rare complications reported were liver abscess<sup>21</sup>, life threatening retroperitoneal sepsis<sup>22</sup> from UK, and necrotizing fasciitis of the perineal region from India<sup>23</sup>. Phenol induced chemical hepatitis from injection sclerotherapy has been reported by Suppiah<sup>24</sup>. In a survey conducted by Al-Ghnamien and his colleagues in UK, among the complications associated with injection sclerotherapy, 82% were urological<sup>25</sup>. Despite all these associated complications, injection sclerotherapy, because of its ease of use and effectiveness, is the widely used nonsurgical method of treating haemorrhoids. Fortunately, in our study none of such complications occurred.

Short-term results of this study indicate that the fixation methods of RBL or IST

performed on an outpatient basis are encouragingly effective in the treatment of 2<sup>o</sup> haemorrhoids as 90% were completely recovered at 4<sup>th</sup> week of treatment with either treatment. Neither RBL nor IST was associated with any significant complication except ligature slip (36.7% with 1<sup>o</sup> haemorrhoids and 3.3% with 2<sup>o</sup> haemorrhoids) and increased number of visible bleeding in the 4<sup>th</sup> week (37% with 1<sup>o</sup> haemorrhoids); main cause for both these complication is little hold by rubber band in 1<sup>o</sup> haemorrhoids due to less tissue in 1<sup>o</sup> haemorrhoids. Otherwise, cure rate is comparable with the data in literature. During a five year follow-up period, Oueidat et al achieved 81.2% of success with RBL alone<sup>37</sup>. In another study, Di Giorgio et al reported that RBL enabled satisfactory control of haemorrhoidal disease in large series of patients<sup>38</sup>. Comparative studies regarding the efficacy of RBL and IST have shown that RBL was better than IST in 2<sup>o</sup> haemorrhoids<sup>39,40</sup>. Some studies like; Gartell et al<sup>41</sup> and Greca et

al<sup>42</sup> have concluded RBL as the treatment of choice for 2<sup>o</sup> Haemorrhoids. But our results indicate no significant advantage of RBL in such cases.

IST was equally effective in both 1<sup>o</sup> as well as 2<sup>o</sup> haemorrhoids achieving 90% cure rate each, at the end of 4<sup>th</sup> week. In comparison to 90% cure rate with IST for 1<sup>o</sup> or 2<sup>o</sup> haemorrhoids in our study, Verma et al. from Hong Kong have found early cure rate of 84% with IST for 1<sup>o</sup> haemorrhoids<sup>43</sup>. Among the national studies, Aftab has found a response rate to IST of 63% for 1<sup>o</sup> and 60% for 2<sup>o</sup> haemorrhoids<sup>44</sup>, while Saleem has observed a rate of 95% for the 1<sup>o</sup> and 60% for 2<sup>o</sup> haemorrhoids<sup>45</sup>. Rabau states a cure rate of 85-90% at one year of follow up but Santos and his co-workers from UK have found this cure to be short lived and at 4 years of follow up, only 28% of his patients remained symptom free<sup>46</sup>.

The clear advantages of the modern methods for outpatient treatment of internal haemorrhoids are that they are quick and relatively painless. Patients lose little if any time from work, the complications are minor and the cure rates are high<sup>47</sup>.

## CONCLUSION

Aforementioned results show that, "For the treatment of 1<sup>o</sup> haemorrhoids, office based IST is the treatment of choice and for the treatment of 2<sup>o</sup> haemorrhoids, there is no statistical difference between RBL and IST".

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