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Research Article

**COMPARISON BETWEEN INJECTION SCLETHERAPY AND  
RUBBER BAND LIGATION IN THE TREATMENT OF SECOND  
DEGREE HEMORRHOIDS**<sup>1</sup>Dr. Muhammad Nauman, <sup>2</sup> Dr. Sheroze Ullah Khan, <sup>3</sup> Dr. Afak Yousaf Chaudary<sup>1</sup>Sheikh Zayed Medical College Rahim Yar Khan, Pakistan<sup>2</sup>Rawalpindi Medical College Rawalpindi, Pakistan<sup>3</sup>Abbottabad International Medical College Abbottabad, Pakistan**Abstract:**

**Objective:** The aim of this study is to make a comparison between the efficiency of (RBL) Rubber Band Ligation & (IST) injections Sclerotherapy for treatment of second degree haemorrhoids for improvement in (SS score) i.e. symptoms severity score in (OPD) patients.

**Study Design:** It was a study of (randomized controlled trial).

**Place and Duration of Study:** The research was done in the surgical (OPD) of Mayo Hospital Lahore in the duration from 15 Oct, 2017 to 10 Apr, 2018.

**Material and Methods:** 116 patients having symptoms of second degree haemorrhoids were classified in 2 groups randomly as (RBL) & (IST) and 58 subjects in each group respectively. A baseline (symptoms severity score) was recorded for every patient. Both the groups were treated accordingly as (RBL) group treated with RBL and (IST) with the same IST. Results were all about relief of symptoms and improvement in SS score.

**Results:** The baseline SS score in (RBL) was  $(4.67 \pm 2.01)$  and minimized to final average SS score of  $(1.34 \pm 0.96)$ . The baseline SS score in (IST) group was found  $(4.31 \pm 2.13)$  & it was minimized to final average SS score of  $(1.6 \pm 0.97)$ . The patients who have complete recovery & controlled bleeding in (RBL) group was 44 at 75.95 percent and this number was 32 at 55.1 percent in (IST) group after 2 weeks.

**Conclusion:** (RBL) i.e. Rubber band ligation has better results of patient than (IST) i.e. injections sclerotherapy for treating (second degree haemorrhoids).

**Keywords:** Symptoms severity score, rubber band ligation, internal haemorrhoids, Sclerotherapy.

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**INTRODUCTION:**

Haemorrhoids is the most popular conditions which

is affecting every age group & is a large part of surgical (OPD) i.e. out-patient department. There are 4 groups of haemorrhoids: first degree is just bleeding, second degree is prolapsing but reduced automatically, third degree is prolapsing, stay & they are minimized manually and fourth degree is permanently prolapsed [1]. Dealing with haemorrhoids differs from mere dietary variations to the surgical haemorrhoidectomy because most patients are hesitant for operation in our society, so they choose for conservative treatment. There could be many reasons like, fear of pain, economical, shame or to save them from hospitalization. For treatment of 1<sup>st</sup> & 2<sup>nd</sup> degree haemorrhoids, traditional therapies be following: hydrotherapy, lifestyle changes & changing diet. To prove it effective, it all need good compliance by the patient [2].

In case of traditional haemorrhoid therapy failure, other out-patient treatment choices could be bipolar coagulation, cryotherapy, injection sclerotherapy IST, rubber band ligation RBL & infra-red coagulation [3]. For dealing 2<sup>nd</sup> degree of haemorrhoids, (IST) & (RBL) are two usually employed office methods. The oldest non-surgical treatment for early haemorrhoids is (IST). In this method, a sclerosing agent is injected sub-mucosal. It causes fibrosis around vessels of the internal haemorrhoidal plexus in order to demolish & make them shrink to get thrombosed [4]. The 1<sup>st</sup> description of (RBL) was made by Blaisdell in (1958) & then in (1963) for banding, a special gun was developed by Barron [5]. The method of (RBL) includes, a haemorrhoidal tissue (1-2) cm long above the dentate line is gripped. It is then pulled in a barrel of elastic band applicator & an elastic band is dragged on it. The process of necrosis is done in tissue distal to elastic band & then excess mucosa in the (upper anal canal) is detached. It is painless procedure and need no anaesthesia or hospitalization [6].

(IST) & (RBL) are cost effective, easy and office-based procedures. To avoid the fear of surgery, it is necessary to adopt non operative outpatient haemorrhoids treatment to ensure less morbidity, early return to work & unnecessary hospitalization. The degree of prolapse decides the grading of haemorrhoids which then shows the suitable technique for treatment. The 4 degrees of haemorrhoids are as follows: haemorrhoids of first degree are just visible, second degree are prolapsing with defecation yet come back spontaneously third are lesions prolapse & they need replacement manually and fourth degree have prolapsed in (anal canal) in spite of efforts to minimize them [9, 10].

Internal haemorrhoids can have following options for treatment: laser surgery, scalpel surgery, cryosurgery, injection sclerotherapy, infrared coagulation, radiofrequency coagulation, direct current coagulation or electro-coagulation, rubber Band ligation [11]. For advanced fourth degree of haemorrhoids, surgery is usually reserved & performed after patient's admission to hospital. Less painful is laser surgery but its verification is not easy to verify [12]. Due to prolonged discharge & profuse, Cryotherapy is not mostly used. Its complications are sphincter injury & excessive sloughing, poor outcomes and continence issues [13]. A disposable probe unit is used by radiofrequency coagulation along with electrical current passing among 2 flat electrodes as +ve & -ve bring into line at tip. A producer ensures that all the haemorrhoids available can be dealt in one time while this is linked with extreme pain & bleeding.

The outcomes of (Harmonic scalpel haemorrhoidectomy) has proven far good [14]. The technique of (Infrared coagulator) has been accepted largely for curing outpatient of internal first, second & a few third degree haemorrhoids. It is claimed by some authors as best treatment but the issue is only 1 section of haemorrhoids is possible to treat on one visit. The patients usually face 2 to 4 areas for treatment but have to come many times after 1-month time for controlling all their issues. The research was made to contrast outcomes of (IST) with (RBL) aiming to devise an efficient office-based method for treating twenty (haemorrhoids) in our scenario.

#### **MATERIAL & METHODS:**

Research was based on (randomized control trial) in which allocation was simple random, parallel assignment for intervention model & single blind method was employed for masking. The research was done in surgical (OPD) of Mayo Hospital Lahore in the duration from 15 Oct, 2017 to 10 Apr, 2018. A total of 116 cases of second haemorrhoids were included using non-probability sampling method. These were classified in 2 groups (RBL) & (IST) using random technique and 58 patients were in every group after taking informed consent. Both men & women of age greater than and above twenty years from all ethnic classes of Pakistan were included. The patients were presenting having bleeding per-rectum & having or not all the related symptoms as pruritis-ani, discharge, pain & mucosal prolapse. The patients were included being identified on proctoscopy findings & history as engorged anal cushions and visible bleeding.

Following were excluded from research: pregnant

ladies, on anticoagulants, bleeding diathesis, anal fissure & (perianal abscess). Every patient was briefed about procedure & related complications. Based on history, (SS) score was observed on presentation. The level of haemorrhoids was ensured on (anoproctoscopy) in each subject. Depending on computer-generated table having simple random, patients were classified in 2 groups as (RBL) & (IST). In (RBL) group, rubber band ligation was conducted & (IST) was performed in (IST) patient group being an (OPD) method. Every patient was placed in knee elbow position in (RBL) group. Both (Elise's tissue forceps) & (Barron's Gun) were employed to apply (rubber band) on base of every haemorrhoid. Having diagnosed the position, anoproctoscopy & degree of haemorrhoids, the haemorrhoidal tissue was grabbed using (Elise's tissue forceps) by (Barron's Gun). At the insensitive region over dentate line, a rubber band was placed.

Every patient of (IST) was told the method & placed in same position as (RBL) without any bowl preparation. In almond Oil, 5 % phenol was filled in a syringe having twenty-gauge spinal needle & fully oiled proctoscopy was then injected softly in rectum. The obturator was taken out & proctoscopy gradually taken back until (pedicle of haemorrhoid) to be injected was seen. Over dentate line, pointer of syringe was inserted in (sub-mucosal plane) of pedicle. To avoid any (intravascular injection), suction with needle was performed. Ensuring suitable placing of needle in (sub-mucosal plane), a (3 - 5 ml) solution was given to every pile in one setting and at a time, not more than 2 haemorrhoids were inserted. Oozing of solution after needle, was stopped using local pressure having (gauze pack) & forceps for a time of (2 - 3 minutes).

The issues of heaviness & occasional wish to defecate after injection were briefed to patients and advised not to try to defecate & strain for further one day. They were observed for thirty minutes for complications as bleeding & pain. To observe for bleeding, repeat anoproctoscopy was performed. A follow-up on 15<sup>th</sup> day was done & betterment (SS) score was found. In a form, personal data of patients was noted like degree of improvement, final SS score, presenting complaints, any complications, finding on rectal & general physical examination, initial SS score and the procedure done.

(IBM) of (SPSS) i.e. statistical package for social sciences of version 21.0 was used analysis. Frequency & percentage were guessed for the categorical variables as examination findings & complaints of patients. For all quantitative variables as age, standard deviation and mean were measured. Frequency was measured in both groups for categorical variables as SS score, gender & efficacy. The categorical values as efficacy were compared by employing (chi-square test) &  $p < 0.05$  was noted as significant.

### RESULTS:

In table-1, demographic data is shown and difference of age in both groups has no significance because patients were taken in random way in (RBL) & (IST) group. In table-2, a contrast of variables as symptoms, age & time of treatment didn't show any significant change among 2 groups and  $p > 0.05$ . The time was classified in 3 groups for making calculations consistent. For (ano-proctoscopy), nine at 15.5 percent patients have visible bleeding in (RBL) group as contrast to only six at 10.3 percent in (IST) group.

**Table-I:** Demographic data and symptoms duration

Groups	Mean $\pm$ SD (Age) (Years)	Mean $\pm$ SD (Duration of symptoms) (Months)	M:F
RBL	43.13 $\pm$ 10.38	6.84 $\pm$ 4.46	4.8:1
IST	44.16 $\pm$ 14.23	6.15 $\pm$ 4.62	8.6:1

Almost 52 at 89.6 percent & 49 at 84.5 percent subjects have not any bleeding shown in (IST) and (RBL) respectively as p-value was 0.563. While in (RBL) thirteen at 22.4 percent, 34 at 58.6 percent & eleven at 18.9 percent subjects were observed to have 1, 2 & 3 (visible haemorrhoids) respectively. In (IST) 17 at 29.3 percent, 28 at 48.3 percent & 13 at 22.4 percent subjects have 1, 2 & 3 (visible haemorrhoids) respectively and p was found 0.05.

**Table-II:** Frequency and percentage of variables among groups

Group variables	Value	Group RBL (n=58)	Group IST (n=58)	p-value
Age group	1	6 (10.3%)	8 (13.8%)	0.324
	2	28 (48.3%)	22 (37.9%)	(>0.05)
	3	19 (32.7%)	25 (43.1%)	
	4	5 (8.6%)	3 (5.2%)	
Symptoms	Bleeding PR Only	32 (55.2%)	37 (63.8%)	0.814
	Mucosal Prolapse	4 (6.9%)	3 (5.2%)	(>0.05)
	Bleeding with Pruritis Ani	9 (15.5%)	10 (17.2%)	
	Bleeding with Pain	8 (13.8%)	4 (6.9%)	
	Discharge per rectum	5 (8.6%)	4 (6.9%)	
Duration	<6 Months	31 (53.4%)	38 (65.5%)	0.584
	6-12 Months	26 (44.8%)	17 (29.3%)	(>0.05)
	>12 Months	1 (1.7%)	3 (5.2%)	

The figure depicts contrast of initial & fifteenth post-procedure day SS score of both groups. In terms of immediate (post-operative complications) no difference in both groups was observed. Only three patients at 5.2 percent of (RBL) and 4 at 6.9 percent from (IST) group have felt mild pain as VAS 1- 3 &  $p > 0.05$ . Just one patient in (IST) at 1.7 percent as VAS 4 – 6 &  $p \geq 0.05$  and 3 patients in (RBL) at 5.2 percent have moderate pain. Severe pain was experienced by two patients as one at 1.7 percent in RBL & one at 1.7 percent in IST group experienced severe pain and VAS was found (7-10). To relieve it, (mefanemic acid i.e. ponstan) 500 mg was used three times a day till the time the pain relieved.

**Table-III:** Symptomatic relief at 15th post-operative day

Variable	RBL (32)	IST (37)	p-value
Control of bleeding	25 (78.1%)	27 (73.0%)	0.005
	7 (21.9%)	10 (27.0%)	(<0.05)
Prolapse and discharge reduction	n=4	n=3	
	3 (75.0%)	2 (66.6%)	0.809
	1 (25.0%)	1 (33.3%)	(>0.05)
Recovered	n=58	n=58	0.005
	44 (75.9%)	32 (55.1%)	(>0.05)

Moreover, 52 at 9 percent from (IST) and 51 at 8.8 percent patients from (RBL) never complained pain immediately after thirty minutes as  $p \geq 0.05$ . Only 2 at 3.4 percent in (RBL) have seen bleeding in contrast to three at 5.2 percent in (IST) as  $p \geq 0.05$ . Just 1 patient had (vasovagal shock) as  $p \geq 0.05$  & it was treated using (intra-venous crystalloid) 0.9 percent (NaCl 1000 ml) infusion at sixty drops per minute until the patient recovered and no patient of (RBL) showed such complication.

In IST group, 32 patients at 55.1 percent had no bleeding (PR) after fifteen days as compared to 48 patients at 82.8 percent in RBL as ( $p$ -value 0.005). 14 at 54.8 percent in IST group needed repetition of method in contrast to RBL in which just six patients at 3.4 percent needed repetition as  $p$ -value < 0.05. Slippage of ligature was major reason of repetition &

bleeding in (RBL). The symptomatic recovery was achieved by overall 44 at 82.1 percent in RBL & 32 at 61.3 percent in IST as  $p$ -value less than 0.05.

After two weeks of follow-up, average SS score calculated has shown more clear advancement in (RBL) group as in table-3 and also bleeding control was significant. The patients having complete

recovery and bleeding control were 44 at 75.95 percent in RBL while in IST, 32 at 55.1 percent have it after two weeks as in table-5. The reduction in (mucosal prolapse) found more in (RBL) as table-5. Bleeding & pain were main complications in (RBL). Overall improvement in SS score & slippage of ligature was more in (RBL) as compare to IST. After two weeks of follow-up, SS score of RBL better improved and it was clear from baseline SS score of  $(4.67 \pm 2.01)$  towards final average SS score of  $(1.34 \pm 0.96)$ . IST showed this improvement less significant as observed in outcomes from baseline SS score of  $(4.31 \pm 2.13)$  towards final average SS score of  $(1.6 \pm 0.97)$  as in table-3. Out of both these, RBL is better option for (second degree haemorrhoids).

### DISCUSSION:

About fifty percent population above 50 years' age are affected of haemorrhoids in many forms in the world as every human has (haemorrhoidal tissue) which serves the role of flatus continence [7]. The main symptoms are pain, prolapsing tissue, fullness after defecation & bleeding. Lower GI pathology & cancer can be reason of bleeding which should be completely assessed by colonoscopy [7]. Mostly, simple, swift & efficient treatment may be provided in health centre or an out-patient clinic. The main idea to understand feasibility of (outpatient treatment) must be that there are no (sensory nerve fibres) over dentate line (pectinate) in anus that locates at (squamo-mucosal junction) [8]. Over this line, (internal haemorrhoids) come which can be dealt not using any anaesthetic. Below this line, (external haemorrhoids) grow which are finely sensitive [8]. For (symptomatic internal haemorrhoids), the RBL is most beneficial treating method. Other than conventional (Barron apparatus) number of newer changes are introduced in this method. Synchronous ligation & suction ligation for haemorrhoids with changed anoscope with employing (videoscopic anoscope) are some innovations which assisted in gaining much good outcomes [15].

One issue which continues to disturb all proctologists is (post ligation pain) & inconvenience linked with (rubber band ligation). Though, (Benzoni E et al) never observed any big problem in their series [16]. In its study material there are few complications as gas gangrene, tetanus, pelvic cellulitis & fatal haemorrhage but luckily we never found any such in our research. An old technique haemorrhoids treatment is non-surgically by (IST) which is less boring & effective procedure [17]. Occasional complications found were (necrotizing fasciitis of perineal region), liver abscess and (life-threatening retro-peritoneal sepsis).

Suppiah has found (phenol induced chemical hepatitis) from (injection sclerotherapy) [18]. Injection sclerotherapy complications as 82 percent were urological found in a survey conducted in England [19]. Injection sclerotherapy, in spite of all complications is mostly used non-surgical technique of haemorrhoids treatment due to its ease of use & efficiency. Outcomes of our research shows that fixation methods of (RBL) and (IST) done are effective for treating second degree haemorrhoids. In IST group, 32 at 41.1 percent and 44 at 57.9 percent in (RBL) were recovered at 15th post procedure day. No complication was found in both groups except (ligature slip) 7 / 58 at 12.1 in (RBL) with enhanced number of bleeding seen for which major reason was a little hold by the (rubber band). In this research, haemorrhoids were banded in 1 session using (Barron's method). In this study, Watson described that applying multiple band is more effective for all subjects for whom bleeding was main symptom before (RBL). So it gave satisfactory control of (haemorrhoidal disease) in many patients [20].

(RBL) was better in comparative study than (IST) in second degree haemorrhoids [21]. A research by Majid A & fellows showed (RBL) as treatment of choice for second haemorrhoids having success of 76 percent treatment rate [22]. The outcomes show clear benefit of (RBL) in cases as 57.9 percent in (RBL) & 41.1 percent in (IST) group. In national researches Aftab found a response rate to (IST) as 63 percent for first degree & 60 for second (degree haemorrhoids) [23]. But Mahmood observed rate of 95 percent of first degree & sixty percent of second (degree haemorrhoids) [24]. Another person Saleem observed rate of 95 percent for first degree & second degree as 60 percent for second (degree haemorrhoids) [25]. Moreover, Oliver found this treatment as short as four years after follow-up & just 28 percent remained symptom- free [26]. Modern methods for (outpatient treatment) of internal haemorrhoids are found good as they are fast & painless [27]. Subjects lose less time from work with lesser complications & treatment rates are higher.

### CONCLUSION:

Finally, (RBL) is an easy to apply, non-invasive & cost-effective along with controlled region of necrosis. It has low chances of after-procedure infection compared to (IST) which is invasive method. Finally, (out-patient RBL) must be taken as a fine choice for treating second (degree haemorrhoids).

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