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Research Article

**A COMPARATIVE STUDY OF INJECTION SCLEROTHERAPY
AND RUBBER BAND LIGATION IN THE TREATMENT OF
SECOND-DEGREE HEMORRHOIDS**¹Dr Hafiz Muhammad Umer Farooq, ¹Dr Toqeer Abbas, ²Dr Ahmed Raza¹Services Hospital Lahore, ²Allied / DHQ Hospital Faisalabad.**Article Received:** October 2020**Accepted:** November 2020**Published:** December 2020**Abstract:**

Objective: A comparison between the efficacy of Rubber band ligation Rubber Band Ligation & (IST) Injection Sclerotherapy for treatment of second-degree haemorrhoids for improvement in SS score i.e., symptoms severity score in (OPD) patients.

Material and Methods: It was a randomized controlled trial study. This study was conducted at Services Hospital Lahore and the duration of this study was from October, 2019 to April, 2020. 116 patients having symptoms of second-degree haemorrhoids were classified into 2 groups randomly as RBL & IST with 58 subjects in each group respectively. A baseline symptoms severity score was recorded for every patient. Both the groups were treated accordingly i.e., Rubber band ligation group treated with Rubber Band Ligation and Injection Sclerotherapy with the same Injection Sclerotherapy. Results were all about relief of symptoms and improvement in SS score.

Results: The baseline SS score in Rubber band ligation was 4.67 ± 2.01 and minimized to final average SS score of (1.34 ± 0.96) . The baseline SS score in Injection Sclerotherapy group was found (4.31 ± 2.13) & it was minimized to final average SS score of (1.6 ± 0.97) . The patients who have complete recovery & controlled bleeding in Rubber band ligation group was 44 at 75.95 % and this number was 32 at 55.1 % in IST group after 2 weeks.

Conclusion: Rubber band ligation has better results in patients as compared to injection sclerotherapy for treating second degree haemorrhoids.

Keywords: Rubber Band Ligation, Internal Haemorrhoids, Sclerotherapy.

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INTRODUCTION:

Haemorrhoids is one of the most common 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 without spontaneous reduction & they are reduced 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 of surgical intervention in our society, so they choose conservative treatment. There could be many reasons like, fear of pain, financial issues, shame or to save them from hospitalization. For treatment of 1st & 2nd degree haemorrhoids, traditional therapies being followed are: Hydrotherapy, Lifestyle changes & Dietary Modifications. To prove their effectiveness, they all require 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 with 2nd degree haemorrhoid's, IST & RBL are the two most commonly employed office methods. The oldest non-surgical treatment for early haemorrhoid's is IST. In this method, a sclerosing agent is injected into the sub-mucosa. It causes fibrosis around the vessels of the internal hemorrhoidal plexus causing them to shrink as a result of thrombosis [4]. The 1st description of Rubber band ligation was made by Blaisdell in (1958) & then in (1963) for banding, a special gun was developed by Barron [5]. In Rubber band ligation, a hemorrhoidal 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 to it. The process of necrosis occurs in tissue distal to elastic band & then excess mucosa in the (upper anal canal) is detached. It is a painless procedure and does not require 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 haemorrhoid's treatment to ensure less morbidity, early return to work & unnecessary hospitalization [7,8]. The degree of prolapse decides the grading of haemorrhoid's which then shows the suitable technique for treatment. The 4 degrees of haemorrhoid's are as follows: haemorrhoids of First degree are just visible, second degree are prolapsing with defecation but are reduced spontaneously, third degree lesions are prolapsed & they require manual reduction while 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 haemorrhoid's, 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 bleeding, Cryotherapy is not mostly used. Its complications are sphincter injury & excessive sloughing, poor outcomes and continuation of symptoms [13]. A disposable probe unit is used in 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 haemorrhoid's available can be dealt with at the same time while this is linked with extreme pain & bleeding. The outcomes of Harmonic scalpel haemorrhoidectomy have proven to be very good [14]. The technique of Infrared coagulation has been accepted largely for curing internal first, second & a few third-degree haemorrhoid's in Outpatient department. It is claimed by some authors as the best treatment but the issue is only 1 section of haemorrhoid's is possible to be treated on one visit. The patients usually have 2 to 4 sites which require treatment but have to come to the outpatient department multiple times, with a gap of 1 month 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 second degree haemorrhoid's in our scenario.

MATERIAL & METHODS:

It was a randomized controlled trial study. This study was conducted at Services Hospital Lahore and the duration of this study was from October, 2019 to April, 2020. A total of 116 patients of second-degree haemorrhoid's were included using non-probability sampling method. They were distributed 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 presented having bleeding per-rectum & having all or some of the related symptoms as pruritis-ani, discharge, pain & mucosal prolapse. The patients being included were identified on proctoscopy findings & history of engorged anal cushions and visible bleeding. Following were excluded from the research: Pregnant ladies, Patients on anticoagulants, those with bleeding diathesis, anal fissure & perianal abscess. Every patient was briefed

about the procedure & related complications. Based on history, SS score was calculated on presentation. The level of haemorrhoids was ensured on a proctoscopy in each subject. Depending on computer-generated table having simple random allocation, patients were classified in 2 groups as RBL & IST. In RBL group, Rubber Band Ligation was conducted & Injection Sclerotherapy 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, a proctoscopy & degree of haemorrhoids, the haemorrhoidal tissue was grabbed using Elise's tissue forceps by Barron's Gun. At the insensitive region over the dentate line, a rubber band was placed.

Every patient of IST was told the method & placed in same position as Rubber band ligation without any bowel preparation. In almond Oil, 5 % phenol was filled in a syringe having twenty-gauge spinal needle & fully oiled proctoscope was then introduced softly into the rectum. The obturator was taken out & proctoscope 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 insertion, was

stopped using local pressure using 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 like bleeding and/or pain. To observe for bleeding, a proctoscopy was repeated. A follow-up on 15th day, after the procedure, was done and improvement in SS score was found. In a proforma, personal data of patients was noted like degree of improvement, final SS score, presenting complaints, any complications, findings on rectal & general physical examination, initial SS score and the procedure done. 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 proctoscopy, 9 at 15.5 % patients have visible bleeding in RBL group as contrast to only 6 at 10.3 % in Injection Sclerotherapy 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 % & 49 at 84.5 % subjects did not have any bleeding shown in IST and RBL respectively as p-value was 0.563. While in RBL 13 at 22.4 %, 34 at 58.6 % & 11 at 18.9 % subjects were observed to have 1, 2 & 3 visible haemorrhoid's respectively. In IST 17 at 29.3 %, 28 at 48.3 % & 13 at 22.4 % subjects have 1, 2 & 3 visible haemorrhoid's 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 % of RBL and 4 at 6.9 % from IST group have felt mild pain as VAS 1- 3 & $p > 0.05$. Just one patient in Injection Sclerotherapy at 1.7 % as

VAS 4 – 6 & $p \geq 0.05$ and 3 patients in RBL at 5.2 % have moderate pain. Severe pain was experienced by two patients as one at 1.7 % in RBL & one at 1.7 % in IST group experienced severe pain and VAS was found 7-10. To relieve it, mefenamic 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 89.6 % from Injection Sclerotherapy and 51 at 87.9 % patients from Rubber band ligation did not complaint of pain immediately after 30 minutes as $p \geq 0.05$. Only 2 at 3.4 % in Rubber band ligation experienced bleeding in contrast to three at 5.2 % in Injection Sclerotherapy 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 % NaCl 1000 ml infusion at 60 drops per minute until the patient recovered and no patient of RBL showed such complication.

In IST group, 32 patients at 55.1 % had no bleeding PR after 15 days as compared to 48 patients at 82.8 % in RBL as p -value 0.005. 14 at 54.8 % in IST group needed repetition of method in contrast to RBL in which just 6 patients at 3.4 % 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 % in RBL & 32 at 61.3 % in IST as p -value less than 0.05. After two weeks of follow-up, average SS score calculated showed more clear advancement in Rubber band ligation group as in table-3 and also

bleeding control was significant. The patients having complete recovery and bleeding control were 44 at 75.95 % in RBL while in IST, 32 at 55.1 % have it after two weeks as in table-5. The reduction in mucosal prolapse was more evident in Rubber band ligation as shown in 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 Rubber band ligation improved and it was clear from baseline SS score of 4.67 ± 2.01 towards final average SS score of 1.34 ± 0.96 . IST did not show as much improvement as observed in outcomes from baseline SS score of (4.31 ± 2.13) towards final average SS score of 1.6 ± 0.97 as in table-3. Out of both these, RBL was found to be the better option for Second degree haemorrhoids.

DISCUSSION:

About 50 % of the population above 50 years of age are affected by haemorrhoid's in many forms in the world as every human has hemorrhoidal tissue which serves a role in 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. Mostly, simple, swift & efficient treatment methods are more acceptable in health care centres 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 is located at squamo-mucosal junction. Over this line, internal haemorrhoids are present which can be dealt with, without using any anaesthetic. Below this line, external haemorrhoids are present which are very sensitive [8]. For symptomatic internal haemorrhoid's, the Rubber band ligation is the most beneficial treatment method. Other than conventional (Barron apparatus), a number of newer changes have been introduced in this method. Synchronous ligation & suction ligation for haemorrhoids with changed anoscope employing videoscope anoscope are some innovations which have assisted in gaining much better outcomes [15].

One issue which continues to disturb all proctologists is (post ligation pain) & inconvenience linked with rubber band ligation. Though, Benzoni E never observed any major problems in their series [16]. In its study material there are few complications as gas gangrene, tetanus, pelvic cellulitis & fatal haemorrhage but luckily, we never encountered any such complications in our research. An old technique of haemorrhoid treatment is non-surgically by Injection Sclerotherapy which is less tedious & very

effective procedure. 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 [8]. 82 % of the Injection sclerotherapy complications were of urological nature found in a survey conducted in England. Injection sclerotherapy, in spite of all complications is the mostly commonly used non-surgical technique of haemorrhoid's treatment due to its ease of use & efficiency. Outcomes of our research shows that fixation methods of Rubber band ligation and IST done properly are effective for treating second degree haemorrhoid's. In Injection Sclerotherapy group, 32 at 41.1 % and 44 at 57.9 % in Rubber band ligation were recovered at 15th post procedure day [7]. No complication was found in both groups except ligature slip 7 / 58 at 12.1 in Rubber band ligation with enhanced number of bleeding seen for which major reason was an ineffective grip of the Rubber band ligation. In this research, haemorrhoids were banded in 1 session using Barron's method. In his study, Watson described that applying multiple bands is more effective for all subjects for whom bleeding was main symptom before Rubber band ligation. So, it gave satisfactory control of hemorrhoidal disease in many patients.

Rubber band ligation was better in comparative study than IST in second degree haemorrhoids. A research by Majid A & fellows showed Rubber band ligation as treatment of choice for second degree haemorrhoid's having success rate of 76 % treatment [16]. The outcomes show clear benefit of Rubber band ligation in cases as 57.9 % in Rubber band ligation & 41.1 % in Injection Sclerotherapy group. In national researches Aftab found a response rate to IST as 63 % for First degree & 60 % for Second degree haemorrhoids. But Mahmood observed rate of 95 % of First degree & 60 % of Second-degree haemorrhoids. Another research by Saleem observed rate of 95 % for First degree & 60 % for Second degree haemorrhoids. Moreover, Oliver found this treatment as short as four years after follow-up & just 28 % remained symptom-free. Modern methods for outpatient treatment of internal haemorrhoid's are found good as they are fast & painless. Subjects lose less time from work with lesser complications & treatment rates are higher.

CONCLUSION:

Finally, Rubber band ligation is an easy to apply, non-invasive & cost-effective treatment method with controlled region of necrosis. It has low chances of after-procedure infection compared to Injection

Sclerotherapy which is an invasive method. Finally, we conclude that out-patient Rubber band ligation must be considered the better choice for treating Second degree haemorrhoids as compared to Injection Sclerotherapy.

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