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Research Article

COMPARISON BETWEEN INJECTION SCLEROTHERAPY AND RUBBER BAND LIGATION IN THE TREATMENT OF SECOND DEGREE HEMORRHOIDS

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Objective: The aim of this study is to make a comparison between the efficacy of (RBL) Rubber Band Ligation & (IST) Injection Sclerotherapy for treatment of second degree hemorrhoids 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 hemorrhoids 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. (RBL) group treated with Rubber Band Ligation and (IST) with the same Injection Sclerotherapy. Results were all about relief of symptoms and improvement in SS score.

Results: The baseline SS score in (RBL) was (4.67 ± 2.01) and minimized to final average SS score of (1.34 ± 0.96) . The baseline SS score in (IST) 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 (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 in patients as compared to (IST) i.e. injection sclerotherapy for treating second degree hemorrhoids.

Keywords: Symptoms Severity Score, Rubber Band Ligation, Internal Hemorrhoids, Sclerotherapy.

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INTRODUCTION:

Hemorrhoids 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 hemorrhoids: 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 hemorrhoids differs from mere dietary variations to the surgical hemorrhoidectomy 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 hemorrhoids, 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 hemorrhoid 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 hemorrhoids, (IST) & (RBL) are the two most commonly employed office methods. The oldest non-surgical treatment for early hemorrhoids 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 (RBL) was made by Blaisdell in (1958) & then in (1963) for banding, a special gun was developed by Barron [5]. In (RBL), 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 hemorrhoids treatment to ensure less morbidity, early return to work & unnecessary hospitalization. The degree of prolapse decides the grading of hemorrhoids which then shows the suitable technique for treatment. The 4 degrees of hemorrhoids are as follows: hemorrhoids 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 hemorrhoids 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 hemorrhoids, 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 hemorrhoids available can be dealt with at the same time while this is linked with extreme pain & bleeding.

The outcomes of Harmonic scalpel hemorrhoidectomy 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 hemorrhoids in Outpatient department. It is claimed by some authors as the best treatment but the issue is only 1 section of hemorrhoids 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 (hemorrhoids) 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 degree hemorrhoids 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 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 (anoproctoscopy) 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, anoproctoscopy & 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 (RBL) 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 hemorrhoid) 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 hemorrhoids 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, anoproctoscopy 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.

(IBM) of (SPSS) i.e. statistical package for social sciences version 21.0 was used for analysis. Frequency & percentage were calculated 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 did not have any bleeding shown in (IST) and (RBL) respectively as p-value was 0.563. While in (RBL) 13 at 22.4 percent, 34 at 58.6 percent & 11 at 18.9 percent subjects were observed to have 1, 2 & 3 (visible hemorrhoids) respectively. In (IST) 17 at 29.3 percent, 28 at 48.3 percent & 13 at 22.4 percent subjects have 1, 2 & 3 (visible hemorrhoids) 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, (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 percent from (IST) and 51 at 87.9 percent patients from (RBL) did not complaint of pain immediately after thirty minutes as $p \geq 0.05$. Only 2 at 3.4 percent in (RBL) experienced 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 6 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 showed 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) was more evident in (RBL) as shown in table-5. Bleeding & pain were main complications in (RBL).

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verall 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) 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 hemorrhoids).

DISCUSSION:

About 50 percent of the population above 50 years of age are affected by hemorrhoids 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 [7]. 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) [8]. Over this line, (internal hemorrhoids) are present which can be dealt with, without using any anaesthetic. Below this line, (external hemorrhoids) are present which are very sensitive [8]. For (symptomatic internal hemorrhoids), the (RBL) 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 hemorrhoids with changed anoscope employing (videoscopic 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 hemorrhoid treatment is non-surgically by (IST) which is less tedious & very 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]. 82 percent of the Injection sclerotherapy complications were of urological nature found in a survey conducted in England [19]. Injection sclerotherapy, in spite of all complications is the mostly commonly used non-surgical technique of hemorrhoids treatment due to its ease of use & efficiency. Outcomes of our research shows that fixation methods of (RBL) and (IST) done properly are effective for treating second degree hemorrhoids. 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 an ineffective grip of the (rubber band). In this research, hemorrhoids were banded in 1 session using (Barron's method). In his 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 (hemorrhoidal disease) in many patients [20].

(RBL) was better in comparative study than (IST) in second degree hemorrhoids [21]. A research by Majid A & fellows showed (RBL) as treatment of choice for second degree hemorrhoids having success rate of 76 percent treatment [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 percent for (Second degree hemorrhoids) [23]. But Mahmood observed rate of 95 percent of (First degree) & sixty percent of (Second degree hemorrhoids) [24]. Another research by Saleem observed rate of 95 percent for (First degree) & 60 percent for (Second degree hemorrhoids) [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 hemorrhoids 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 treatment method with controlled region of necrosis. It has low chances of after-procedure infection compared to (IST) which is an invasive method. Finally, we conclude that outpatient (RBL) must be considered the better choice

for treating (Second degree hemorrhoids) as compared to (IST).

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