INJECTION SCLEROTHERAPY VERSUS RUBBER BAND LIGATION FOR SECOND DEGREE HEMORRHOIDS

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ABSTRACT

Objective: To compare the efficacy of injections Sclerotherapy (IST) and rubber band ligation (RBL) for the treatment of 2nd degree haemorrhoids in terms of improvement in symptoms severity score (SS score) in OPD patients.

Study Design: Randomized controlled trial.

Place and Duration of Study: It was conducted in surgical OPD of CMH Kohat, from 15th October 2010 to 10th April 2011

Material and Methods: A total of 116 patients with symptomatic 2nd degree haemorrhoids were randomly divided into two groups, RBL and IST (58 patients each) respectively and a baseline symptoms severity score was noted for each patient. Patients in RBL group were treated with RBL while in IST group were treated with IST. The outcome measures were relief of symptoms and improvement in SS score.

Results: In RBL group, baseline SS score was 4.67 ± 2.01 which reduced to final mean SS score of 1.34 ± 0.96 whereas in IST group the baseline SS score was of 4.31 ± 2.13 which reduced to a final mean SS score of 1.6 ± 0.97. 44 (75.95%) patients had complete recovery and control of bleeding in RBL group; whereas in IST group 32 (55.1%) of the patients had this response by the end of two weeks.

Conclusion: Rubber band ligation was found to have better patient outcomes as compared to injections sclerotherapy in treatment of 2nd degree hemorrhoids.

Keywords: Internal hemorrhoids, Rubber band ligation, Sclerotherapy, Symptoms severity score.

INTRODUCTION

Hemorrhoids is one of the commonest conditions affecting all age groups and makes the bulk of any surgical out-patient department (OPD). Haemorrhoids are classified into four groups i.e. 1st degree (only bleeding), 2nd degree (prolapse but reduce automatically), 3rd degree (prolapse and stay, they are reduced manually) and 4th degree (permanently prolapsed)[1].

The spectrum of management of haemorrhoids varies from just dietary changes to surgical haemorrhoidectomy. Majority of the patients in our society opt for conservative treatment as they are reluctant for operation. The reason may be economical, shame, fear of pain or to avoid hospitalization. Conservative therapies for the treatment of 1st and 2nd degree haemorrhoids may include changing the diet, lifestyle changes, and hydrotherapy, which require a good patient compliance to be effective[2]. When conservative haemorrhoid therapy is ineffective, there are various other out-patient treatment options available for haemorrhoids like; injection sclerotherapy (IST), rubber band ligation (RBL), cryotherapy, infra-red coagulation (very expensive) and bipolar coagulation[3].

IST and RBL are the two most commonly adapted office procedures for the treatment of 2nd degree haemorrhoids. IST has been one of the oldest non surgical treatments for early haemorrhoids in which a sclerosing agent is injected sub-mucosally causing fibrosis around the vessels of internal haemorrhoidal plexus, to obliterate and cause them to shrink and get thrombosed[4].

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RBL was first described by Blaisdell in 1958 and Barron in 1963 developed a special gun device for banding[5]. RBL is a procedure in which haemorrhoidal tissue 1-2cm above dentate line is grasped, pulled into the barrel of an elastic band applicator and a small elastic band is slipped over it. The tissue distal to elastic band under goes necrosis and excess mucosa in upper anal canal is removed. It is simple and almost painless procedure requiring no local or general anaesthesia and has no need of hospitalization or time off work[6].

Both IST and RBL are office-based procedures, easy to do and are cost effective. In a set-up like ours, where people are very much apprehensive about surgery, it becomes imperative to adopt non-operative outpatient and short methods of treatment for haemorrhoids to avoid unnecessary hospitalization, less morbidity and early return to work.

A set of symptoms is present in every patient who presents to OPD with haemorrhoids. Haemorrhoids are graded by the degree of prolapse, and this grading determines the most appropriate methods of treatment. 1st degree haemorrhoids are merely visible, 2nd degree haemorrhoids prolapse with defecation but return spontaneously, 3rd lesions prolapse and require manual replacement, and 4th degree remain prolapsed out of the anal canal despite attempts to reduce them[9,10]. The treatment choices for internal haemorrhoids include infrared coagulation, radiofrequency coagulation, electro-coagulation or direct current coagulation, rubber band ligation, injection sclerotherapy, cryo-surgery, scalpel surgery,and Laser surgery[11].

Surgery is generally reserved for advanced 4th degree haemorrhoids and is most often done after admitting the patient to hospital. Laser surgery is said to be less painful, but thishas proved difficult to verify[12]. Cryotherapy is also of little use because of the profuse and prolonged discharge, the complications suchas excessive sloughing and sphincter injury, continence problemsand the poor results[13].

The radiofrequency coagulation unit uses a disposable probe with an electrical current flowing between two flat electrodes (positive and negative) aligned at the tip. Although the manufacturer claims that all haemorrhoids present can be treated in a single session, but it is associated with excessive pain and bleeding. Harmonic scalpel haemorrhoidectomy has proven better results instead[14].

Infrared coagulator is being accepted widely for outpatient treatment of internal 1st degree and 2nd degree haemorrhoids and some 3rd degree haemorrhoids; some authors have claimed it the best treatment, but only one sectionof the haemorrhoids is treated per visit. Patients generallyhave two to four areas that need treatment and so, have to return several times at monthly intervals until all have been controlled.

This study was designed to compare the results of IST with RBL with an aim to adopt an effective office based procedure for treatment of 20 hemorrhoids in our set up.

MATERIAL AND METHODS

The study was a randomized control trial where allocation was random, intervention model with parallel assignment and masking was ensured by single blind method. It was conducted in out patient department (OPD) of General Surgery department, Combined Military Hospital (CMH), Kohat from september 2010 to march 2011 after obtaining permission from Hospital Ethics Committee. One hundred and sixteen cases of 2nd Haemorrhoids were selected by consecutive non probability sampling technique and were divided into two groups RBL and IST by random allocation, placing 58 patients in each group, written informed consent was obtained from all the patients.

Male and female patients of more than 20 years and above, representing all ethnic groups and areas of Pakistan presenting with bleeding per rectum with or without associated symptoms like mucosal prolapse, discharge, pruritis ani and pain as well having being diagnosed on history and proctoscopy findings like visible bleeding

and engorged anal cushions were included in the study.

Patients having bleeding diathesis, or on anticoagulants, having anal fissure and/or peri-anal abscess, pregnant ladies or having any other advanced disease were excluded from the study.

The procedure and its associated complications were explained to each patient in detail. SS score was noted at the time of presentation on the basis of history. Degree of haemorrhoids was ascertained on anoprocto-scopy in all patients. They were divided into two groups RBL and IST based on computer generated table of random numbers. Rubber band ligation was done in RBL group and IST was done in IST group patient asan OPD procedure.

In RBL group, each 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. After anoproctoscopy and proper identification of position and degree of haemorrhoids, haemorrhoidal tissue was grasped with Elise's tissue forceps through Barron's Gun and rubber band was placed at insensitive area above the dentate line. In IST group, each Patient was briefed about the procedure and placed in knee elbow position. No bowl preparation was done. Five percent phenol in almond Oil was taken in a disposable syringe with 20 gauge spinal needle and a well lubricated proctoscope was inserted gently into the rectum. Obturator was removed and proctoscope slowly withdrawn till the pedicle of the haemorrhoid to be injected became visible. Needle of the syringe was inserted into the submucosal plane of the pedicle above the dentate line. Suction with the needle was done to rule out any possibility of intravascular injection. After confirmation of proper placement of needle in submucosal plane, 3-5 ml of the solution was injected into each pile in a single setting. No more than two haemorrhoids were injected at a time. After the withdrawal of the needle, oozing of the solution was stopped by applying local pressure with a gauze pack and forceps for 2-3 minutes which also helped in controlling the bleeding from injection site.

Patients were informed about the heaviness and occasionally desire to defecate after the injection. Post injection patients were advised not to try to defecate for next 24 hours. They were also advised not to strain and to contact the doctor in case of any problem in relation to treatment.

Patients in both groups were observed for 30 minutes for immediate complications like pain and bleeding. Repeat anoproctoscopy was done to look for bleeding if necessitated in these patients. Patients were then followed up on 15th post procedure day and improvement in SS score was noted. The improvement in SS score was noted.

Patient's personal data, presenting complaints, findings on general physical and rectal examination, initial SS score, procedure done, any complications, final SS score and degree of improvement were noted on Performa.

Statistical Analysis

All the data collected was entered in IBM statistical package for social sciences (SPSS) version 21.0. Relevant descriptive statistics i.e. frequency and percentage were estimated for categorical variables like; presenting complaints and examination findings. Mean and standard deviation was calculated for quantitative variables like age. Categorical variables like gender, SS score and efficacy in both groups, frequency was used. Comparison of categorical values like efficacy was done using chi-square test and *p*-value less than 0.05 was taken as significant.

RESULTS

Demographic data is summarized in table-I. The difference of age in the two groups has no statistical significance as the patients were randomly subjected to either RBL or IST group.

Table-II shows comparison of grouped variable e.g. age, symptoms and duration didn't show any statistical significant difference between two groups (*p*-value>0.05). Duration was grouped into three groups to make calculation more consistent.

On ano-proctoscopy, 9 (15.5%) patients showed visible bleeding in RBL group as compared to 6 (10.3%) patients in IST group. About 49 (84.5%) and 52 (89.6%) patients showed no visible bleeding in RBL and IST group respectively (*p*-value 0.563). Whereas in RBL group, 13 (22.4%), 34 (58.6%) and 11 (18.9%) patients were found to have one, two and three visible haemorrhoids respectively. While in IST group, 17 (29.3%), 28 (48.3%) and 13 (22.4%) patients had one, two and three visible haemorrhoids respectively. A *p*-value was 0.05. Figure shows the comparison of baseline SS score versus SS score on 15th post procedure day of both the groups.

Regarding immediate post operative complications, there was no statistically significant difference among RBL and IST group. Four patients (6.9%) of IST group and 3 patients (5.2%) of RBL group experienced mild pain (VAS 1-3) (*p*-value>0.05). Three patients in RBL (5.2%) and 1 patient in IST (1.7%) had Moderate Pain

Table-I: Demographic data and symptoms duration.

Groups	n	Mean ± SD (Age) (Years)	Mean ± SD (Duration of symptoms) (Months)	M:F
RBL	n=58	43.13 ± 10.38	6.84 ± 4.46	4.8:1
IST	n=58	44.16 ± 14.23	6.15 ± 4.62	8.6:1

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

Group variables	Value	Group		*p*-value
		RBL (n=58)	IST (n=58)	
Age group	1	6 (10.3%)	8 (13.8%)	0.324 (>0.05)
	2	28 (48.3%)	22 (37.9%)	
	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 (>0.05)
	Mucosal Prolapse	4 (6.9%)	3 (5.2%)	
	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 (>0.05)
	6-12 Months	26 (44.8%)	17 (29.3%)	
	>12 Months	1 (1.7%)	3 (5.2%)	

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

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

Note: Percentage is within group

(VAS 4-6) (*p*-value≥0.05). Only 2 patients, 1 (1.7%) of RBL and 1 (1.7%) of IST group experienced severe pain (7-10 on VAS), for which mefanemic acid (Ponstan) 500mg was given thrice daily till it relieved. Fifty one patients (8.8%) undergoing RBL and 52 patients (9.0%) undergoing IST did not complain any pain immediately 30 minutes after the procedure (*p*-value≥0.05). Two (3.4%) patients in RBL group had visible bleeding as compared to 3 (5.2%) patients of IST group (*p*-value≥0.05). Only one patient had vasovagal shock (*p*-value≥0.05) that was treated with intravenous crystalloid (0.9% NaCl) 1000 ml infusion at the rate of 60 drops/minute till he recovered. No patient in RBL group experienced this complication.

Fourty eight (82.8%) patients of RBL group had no bleeding PR by the end of 15 days as compared to 32 (55.1%) patients in IST group, *p*-value 0.005. Fourteen (54.8%) patients in IST group required repetition of procedure as compared to RBL, group in which only 6 patient (3.4%) required repetition of procedure (*p*-value <0.05). Main reason of repetition and bleeding in RBL group was slippage of ligature. Overall 44 (82.1%) in RBL group and 32 (61.3%) in IST group achieved symptomatic recovery (*p*-value <0.05). Mean symptoms severity score measured at the end of 2 weeks follow up showed more significant improvement in RBL group (table-III).

It is evident from above mentioned inferences that control of bleeding was significant in RBL group. Moreover 44 (75.95%) patients had complete recovery and control of bleeding in RBL group; whereas in IST group 32 (55.1%) of the patients had this response by the end of 2 weeks (table-V). Mucosal prolapse reduction was also more with RBL (table-V). Pain as well as bleeding was a major complication in RBL group. Slippage of ligature, again, is more in RBL group. But overall improvement in symptoms severity score was better in RBL group as compared to IST group.

By the end of 2nd week of follow up, the improvement in SS score of RBL was significant; from a baseline SS score of 4.67 ± 2.01 to a final mean SS score of 1.34 ± 0.96. In contrast to this, in IST group this improvement was less significant as shown in results, from baseline SS score of 4.31 ± 2.13 to a final mean SS score of 1.6 ± 0.97 (table-III).

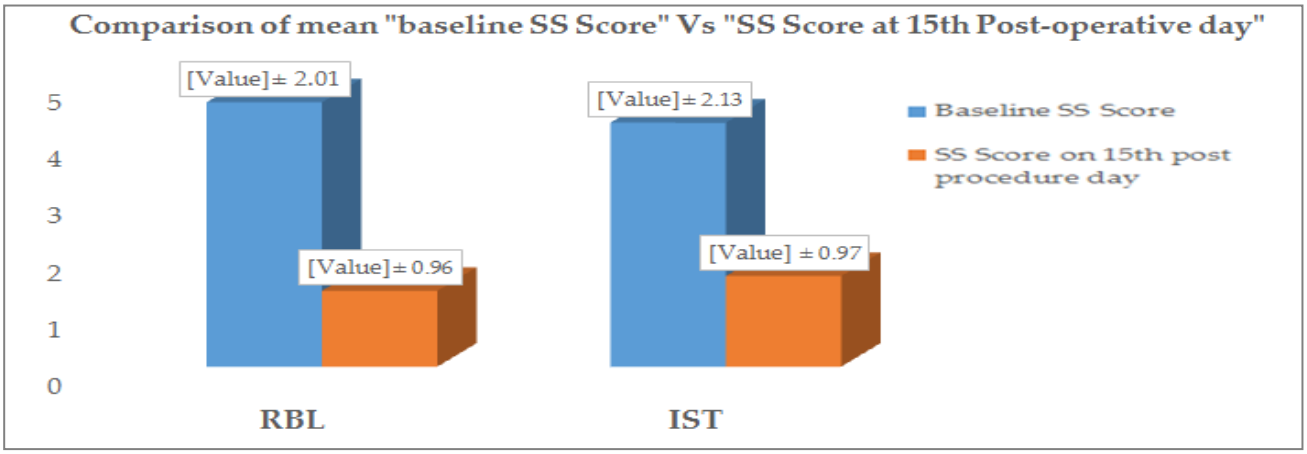

Figure: The graph shows significant improvement in SS score in RBL group on 15th post procedure day down from 4.67 ± 2.01 to 1.34 ± 0.96 as compared to that of IST group which improved from 4.31 ± 2.13 to 1.6 ± 0.97 only.

Thus RBL is a better choice for 2nd degree haemorrhoids, if one has to choose between IST and RBL.

DISCUSSION

Almost 50% of the population over the age of 50 has been complaining of haemorrhoids in various forms worldwide, since haemorrhoidal tissue is present in every human being, serving

the normal function of flatus continence[7]. Bleeding, prolapsing tissue, fullness after defecation, and pain are the major symptoms. Bleeding can be due to some form of lower GI pathology or even cancer and must be thoroughly evaluated by colonoscopy[7]. In most cases, however, swift, simple, and effective treatment can be given in an out patient clinic or a health centre. The key to understanding the feasibility of outpatient treatment is that there are no sensorynerve fibres above the dentate (pectinate) line in the anus,which is at the squamo-mucosal junction[8]. Internal haemorrhoidsarise above this line, so they can be treated without an anaesthetic. External haemorrhoids develop below the dentate line and are exquisitely sensitive[8].

RBL is considered to be an effective treatment for symptomatic internal haemo-rrhoids. A part from conventional Barron apparatus; many new useful modifications have been introduced in the procedure. Suction ligation, synchronous ligation of all the haemorrhoids with a modified anoscope and using a videoscopic anoscope are a few of such innovations that have helped achieve still better results[15]. However, despite all of these modifications, one problem that persists and continues to bother proctologists is the post-ligation pain and discomfort associated with rubber band ligation although Benzoni E et al didn't find any major complication in their series[16]. In literature some serious complications like fatal haemorrhage, pelvic cellulitis, tetanus and gas gangrene but fortunately we didn't encounter any of these in our study.

Another very older method of treating haemorrhoids non-surgically is by IST. It is very effective and a less tedious procedure[17], but is not free from complications which can be serious sometimes. Rare complications reported were liver abscess, life threatening retro-peritoneal sepsis, and necrotizing fascitis of the perineal region. Phenol induced chemical hepatitis from injection sclerotherapy has been reported by Suppiah[18]. In a survey in UK, it's been observed that among the complications associated with injection sclerotherapy, 82% were urological[19]. Despite all these associated complications, injection sclerotherapy, because of its ease of use and effectiveness, is the widely used nonsurgical method of treating haemorrhoids. In our study, by the grace of Allah Almighty none of such grave complication occurred.

The results of this study indicate that the fixation methods of RBL or IST performed are encouragingly effective in the treatment of 2nd degree haemorrhoids. Forty four (57.9%) in RBL Group and 32 (41.1%) in IST Group were completely recovered at 15th day of treatment in our study. Neither RBL nor IST was associated with any significant complication except ligature slip 7/58 (12.1%) in RBL group and increased number of visible bleeding; main cause for both these complication is little hold by rubber band. Otherwise, cure rate is comparable with the data in literature. In our study haemorrhoids were banded in single session with Barron's method. Watson stated in his study that application of multiple rather than single band may prove more effective in those patients for whom bleeding was the predominant symptom prior to RBL thus getting satisfactory control of haemorrhoidal disease in large series of patients[20]. Comparative studies regarding the efficacy of RBL and IST have shown that RBL was better than IST in 2nd degree haemorrhoids[21]. A local study conducted by Majid A and colleagues have concluded RBL as the treatment of choice for 2° Haemorrhoids with achievement of 76% cure rate[22]. Our results also indicate a significant advantage of RBL in such cases (57.9% in RBL group and 41.1% in IST group).

Among the national studies, Aftab has found a response rate to IST of 63% for 1st degree and 60% for 2nd degree haemorrhoids[23], while Mahmood has observed a rate of 95% for the 1st degree and 60% for 2nd degree haemorrhois[24], while Saleem has observed a rate of 95% for the 1st degree and 60% for 2nd degree haemorrhoids[25]. Oliver has found this cure to be short lived and at 4 years of follow up, only 28% of his patients

remained symptom free[26]. The clear advantages of the modern methods for outpatient treatment of internal haemorrhoids are that they are quick and relatively painless[27]. Patients lose little if any time from work, the complications are minor, and the cure rates are high.

CONCLUSION

This study proved that RBL is an easy to apply, cost-effective, non-invasive with controlled area of necrosis and has got less chances of post procedure infection as compared to IST being an invasive technique. It is therefore concluded that out-patient RBL should be considered as the treatment of choice for the treatment of 2nd degree haemorrhoids.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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