SCLEROTHERAPY VERSUS RUBBER BAND LIGATION;
COMPARATIVE STUDY OF EFFICACY AND COMPLIANCE IN THE TREATMENT OF UNCOMPLICATED SECOND DEGREE HAEMORRHOIDS

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ABSTRACT…Objective: To compare the outcome of two different procedures of non operative treatment of uncomplicated second degree hemorrhoids in terms of efficacy and patients compliance. **Study Design:** Prospective interventional. Controlled Phase II clinical trial. **Setting & Duration:** Surgical Unit DHQ (Teaching) Hospital Rawalpindi from 10th September 2004 to 20th May 2006. **Methodology:** Regardless of age and sex, first hundred patients attending the out patients department of surgical unit, DHQ(Teaching) Hospital , Rawalpindi with uncomplicated second degree hemorrhoids after informed consent were enrolled in the trial. Patients were divided into two treatment groups A&B with 50 patients in each by random draw sampling. Patients in Group A were subjected to injection sclerotherapy (SCL) whereas of Group B, Rubber band ligation (RBL) was performed. **Results:** One hundred patients of mean age of 42.24 years with uncomplicated second degree hemorrhoids with standard deviation of + 13.63 years were enrolled in this study. Out of total one hundred patients, 62 were male and 38 were female. The major indications of treatment were bleeding per rectum and prolapse. Patients in Group A were subjected to Injection sclerotherapy (SCL) and of Group B , Rubber band ligation (RBL) was performed. In Group A , 28 patients (56%) were symptoms free after 4-6 weeks with single session of SCL , 16 patients (32%) required additional second session at eight week and 6 patients (12%) required third session at 12 weeks respectively due to persistence of symptoms. In Group B , 44 patients (88%) were symptom free after four weeks with single session of RBL, while 6 patients (12%) required second session at 10 weeks to become symptom free. At 12 month follow-up 46 patients (92%) remain symptomfree and 4 patients (8%) had recurrence of symptoms in Group A and rubber band ligation was performed. All the patients of Group B (RBL) remained symptom free. (P value=0.041). **Conclusions:** Rubber band ligation is a safe, effective, economical non operative treatment option for second degree uncomplicated hemorrhoids with good patients compliance.

Key words: Bleeding Per Rectum, Hemorrhoids , Band ligation, Sclerotherapy

INTRODUCTION

Hemorrhoids means blood flowing (Greek: Haema= Blood and Rhoos =flowing). Hemorrhoids have plagued human kind since the dawn of history. It is an ancient disease that is carried through the civilization. Hemorrhoids have been treated by Surgeons for centuries. Therapies for the topical treatment of hemorrhoids dates back to Egyptian papyri 1700 BC. The first surgical treatment was described in the Hippocratic Treatises of 460 BC, and suggested transfixing them with a needle and tying them with a very thick and large woolen[1]. During the early times insertion of suppositories and application of leeches were tried. Despite centuries of treating the condition, its precise etiology is unclear and a definitive treatment has yet to be established. It is a condition with a variety of symptoms and spectrum of severity.

Hemorrhoids affect between 4.4 and 36.4% of the general population[2]. Only in the last 30 years anatomical[3] and histological studies have been used to characterize their anatomy and etiology[2]. This has led to resurgence in interest in the condition, associated with the development of a number of novel treatments. Nevertheless, the surgical management of hemorrhoids is often based more on anecdote than science. Many myths continue to perpetuate in both lay and professional circles.

The vascular anatomy of the anal cushions inspired many of the original theories of hemorrhoid etiology. The suggestion that a local increase in pressure caused by venous dilatation within the anal cushions, was initially favored[4]. It appeared to explain the known associations between pregnancy and hemorrhoids, constipation and straining as an etiology[5].

Prior to work in 1975, the rich plexus of blood vessels in the anal sub mucosa was thought to form a continuous ring of erectile tissue around the anal canal. This was the first to introduce the concept of 'anal cushions', usually 3

in number, found in the left lateral, right anterior, right posterior (Classical 3, 7, 11 O' clock position)[3]. The bulk of the anal cushions sits above the dentate line. They are therefore lined with relatively insensate mucosa. Between this and internal sphincter lies the sub mucosal layer, consisting of vascular, muscular and connective tissue elements. This layer is thought to be central to the understanding of both etiology and the treatment of hemorrhoid. Below and continuous with the sub mucosa is the inferior haemorrhoidal plexus. At the anal verge, this can become engorged in continuity with the internal plexus, giving and external component to the hemorrhoid. A careful distinction between prolapsing internal hemorrhoids, and external hemorrhoids and their skin tag remnants may have implications for the choice of treatment.

The surgical procedures like open or closed Hemorrhoidectomy require hospital admission and are usually performed under general anesthesia. Taking in to account the different complications that can occur with hemorrhoidectomy it is important to know the simple and better technique to have better results regarding morbidity and satisfaction of the patients in our circumstances.
The present study was conducted with an intention to compare the outcome of two different techniques of conservative treatment of uncomplicated second degree hemorrhoid and develop a consensus over single best treatment option for the uncomplicated second degree hemorrhoids. Sclerotherapy is injection of sclerosing agent at the site of the hemorrhoid which is 5% Phenol in almond oil, and ligation means application of an elastic rubber band on the pedicle of a hemorrhoid.

MATERIAL & METHODS

This study was carried out at the Out patient department of Surgical unit of District Headquarters (DHQ) Teaching Hospital, Rawalpindi. DHQ (Teaching) Hospital is a 357 bedded . tertiary care, teaching hospital affiliated with Rawalpindi Medical College Rawalpindi. It is the main referral center for the patients from all Basic / Rural Health centers/ Tehsil Headquarters Hospitals of Rawalpindi Division. Surgical Unit has 75 beds with on take OPD 6 days a week, and round the clock emergency cover throughout the year. There are three operation days per week with four operation tables with separate operating facility for minimal access laparoscopic and Endo-urology procedures.

This was a prospective controlled Phase-II trial, conducted over a period of 01 year and 08 months and 11 days from 10th September 2004 to 20th May 2006. Regardless of the age and sex , first hundred patients attending the out patients department of surgical unit with uncomplicated second degree hemorrhoids on examination were enrolled in the trial after their informed consent. The patients were divided into two treatment groups A & B with Fifty patients in each group by simple random draw method. Patients with complicated hemorrhoids e.g. complete prolapsed, strangulated, thrombosed, ulcerated, gangrenous , fibrotic and with suppuration were excluded from study. Patients with hemorrhoids associated with other pathology like Anal fissure , Fistula and malignancy , bleeding per rectum due to chronic liver disease were also excluded from the trial.

Diagnosis was established on clinical grounds by digital rectal examination, proctoscopy. Sigmoidoscopy was performed in selected patients to exclude the possibility of other causes of rectal bleeding. Patients with uncomplicated 2nd degree hemorrhoids were offered these treatment options. Informed consent was obtained from all the patients deemed eligible for inclusion in the study after an explanation of nature of disease , treatment options and risks involved. Patients were advised to empty the bowel before the application of injection sclerotherapy or elastic rubber band.

Patients in Group-A were subjected to injection sclerotherapy (SCL) of all three primary hemorrhoids at one sitting. 5% Phenol in Almond oil was used as sclerosing agent and 3-5 ml was injected at each site with Gebriel's Syringe. Similarly elastic rubber band ligation (RBL) of all three primary hemorrhoids was performed with Hemorrhoidal Gun (Barron's Band applicator) in Group-B patients in single session. Patients were advised to remain recumbent for 15-20 minutes and sent home with the advice to take Tablet Ibuprofen 400mg in case pain and discomfort and stool softener to avoid constipation. They were instructed not to defecate if

possible , and should micturate in standing position for at least 12-16 hours. Patients were called after fortnight and examined in out- patient department followed by out-door visit at monthly interval for a year. The data was collected on a Performa. The data collected was entered and analyzed using SPSS Software version 10. Mean & + Standard deviation were calculated for age. Frequency & percentage was determined for healing by single session or repeats treatment sessions for both the groups and was compared using Chi-square test. P-value was derived for each variable and a P- value of < 0.05 was considered statistically significant.

RESULTS

The study population presented with in age range of 15-73 years with mean age 42.24 years with standard deviation of + 13.63 years. Shown in Table I.

Table I: Showing the age range, mean and Standard Deviation of the study groups.

Group	Mean	Number	Standard Deviation
Injection sclerotherapy (SCL)	39.94	50	14.41
Rubber Band Ligation (RBL)	44.54	50	12.54
Total	42.24	100	13.63

Out of total 100 patients 62 were male and 38 were female. Gender distribution of study groups is shown in Table II (P=0.680).

Table-II. Gender distribution in study groups.

Group	Male	Female	Total
Injection sclerotherapy (SCL)	30	20	50
Rubber Band Ligation (RBL)	32	18	50
Total	62	38	100

Presenting complaints of the patients in study group are shown in Table III. The major indications for treatment were bleeding per rectum and prolapsed hemorrhoids. The majority of the patients reported with two or more symptoms with no significant difference among the study groups. (P=0.590).

Table-III. Showing presenting complaints with number of patients in each group

Presenting symptoms	Sclerotherapy Group	Band ligation group	Total patients
Rectal bleeding	06	06	12
Prolapsed	-	01	01
Perianal irritation & discomfort	02	-	02
Bleeding and prolapse	30	34	64
All above symptoms	11	08	19
Prolapse & irritation	01	01	02

The frequency and site of hemorrhoids in both the study groups are shown in Table-IV. The site of hemorrhoids and frequency of patients under went SCL & RBL were one (N=1), two (n=14), three (n=35), and one (n=5), two (n=15), and three (n=30) respectively in Group –A and B. No correlation was found between the number of sites injected or bands placed and the degree of subsequent pain or bleeding.(p=0.621).

Table-IV. Showing, the Site of hemorrhoid and number of patients in study group

Examination findings	Sclerotherapy group	Band ligation group	Total
3 O' Clock	-	01	01
11 O' Clock	01	04	05
3 & 7 O' Clock	05	04	09
3 & 11 O' Clock	06	07	13
7 & 11 O' Clock	03	04	07
3,7,11 O' Clock	35	30	65
Total	50	50	100

In Group-A , 28 (56%) patients were symptoms free after 4-6 weeks with single session of SCL, 16 patients (32%) required additional second session at eight weeks and

06 patients (12%) required third session at 12 weeks respectively duo to persistence of symptoms.

In Group-B, 44 patients (88%) were symptoms free after four weeks with single session of RBL, while 06 patients (12%) required second session at 10 weeks to become symptom free.

Overall 72% (n=72) patients were symptoms free after single session and 22% (n=22) and 06 patients (n=06) required an additional second and third sessions respectively to become symptom free as shown in Table-V with P-value of 0.001, which is highly significant.

Table-V. Showing efficacy of SCL & RBL treatment

Shifted to other treatment modality	SCL	RBL	Total
Not shifted	46	50	96
Shifted to band ligation from SCL	04	-	04
Total	50	50	100

Most of the patients were able to return to their usual daily activities on the next post procedure day. All the patients completed their follow-up regularly for 12 months.

After 12 months follow-up 46 patients (92%) remained symptom free and 04 patients (08%) had recurrence of symptoms in Group-A and RBL was done in these patients, while all the 50 patients (100%) of Group-B remained symptom free.(P-value=0.041), that is also significant, represented in Table-VI.

DISCUSSION

This was a prospective, unblended, controlled Phase-II clinical trial on the efficacy in terms of healing of second degree hemorrhoids and patients compliance in terms of follow-up and convenience with Sclerotherapy (SCL) and Rubber band ligation.(RBL). Hemorrhoids are very common problem of our society and patients are usually reluctant to undergo surgery because of shyness to show their private body parts, fear of pain of operation, and hospitalization. Non- operative treatment modalities are being preferred by patients. Rubber band ligation of hemorrhoid and injection sclerotherapy are now two commonly practiced non operative treatment modalities available for selected cases of hemorrhoids. These procedures are carried out in the out patient department without need of admitting the patient. These procedures are easy , rapid, and cost effective and has good compliance of the patients.

As for as , application sessions of rubber band ligation of hemorrhoids is concerned , many authors claim that banding can be done in one session[7]. In our study we also did single session of band ligation in 44 (88%) cases, where as in 06 patients (12%) required two sessions. None of our patient complained of pain due to care full selection of insensate mucosa. Mild to moderate / pain discomfort can be managed by injection of one ml of 2% lignicaine in each hemorrhoid mass[8]. Rubber band ligation can be complicated with slippage of bands , reactive or secondary hemorrhage., urinary retention[9], peri anal abscess and peri anal fistula[10]. In our study we did not face these complications. Rubber band ligation of hemorrhoids may be complicated with more disastrous

Table-VI. Outcome of rubber band ligation "A comparative review of six studies'

Study	Year	No. of Patients	Follow-up	%age Cured / Improved
Zafar A21	2002	100	01 Year	82%
Komorozas VA26	2000	500	02 Years	88%
Aftab ML22	1995	71	03 Months	88%
Oueidet DM23	1994	148	18 Months	81%
Adamth-waite DN24	1983	52	02 Years	98%
Murie JA25	1980	100	01 Year	80%

complications as mentioned in the literature like hemorrhage[11], pelvic cellulitis[12], tetanus[13] and gas gangrene[14].

Komorozos reported a recurrence rate of 11.9% after 2 years follow-up while walker et al has reported recurrence rate of 27% at 1 year[15], and Savioz has reported recurrence rate of 23% after 5 years follow-up[16] where as, in our study we did not find recurrence after rubber band ligation at one year follow-up. Mattana et al, have reported a low recurrence rate of 9% in patients with normal bowel habits , when compared with constipated patients whose symptoms recurred in 85% cases[17].

Many trials have been conducted, comparing rubber band ligation with Hemorrhoidectomy[18], Sclerotherapy, Cryotherapy, and infrared coagulation. A prospective clinical trial has shown that rubber band ligation abolished or improved prolapse and bleeding as effectively as Hemorrhoidectomy. Mac Rae HM, McLeod RS , have reported in their study that rubber band ligation is superior to sclerotherapy and infrared coagulation[19].

A comparative study of the non surgical methods of treating hemorrhoids with follow-up up to 12 months has been reported by Johnson, he concluded that the results were the same irrespective of methods used[20]. Alemdaroglu and Ulualp[20] found long term results with rubber band ligation were satisfactory in 93.3% cases. They have concluded that a single session of rubber band ligation is an effective and valuable alternate to Hemorrhoidectomy in selected patients.

The results of our study are comparable with National and International literature. (Table VI) Although we have a small study, we also conclude that the rubber band ligation in uncomplicated first and second degree hemorrhoids is an effective and superior non operative option. However we followed-up patients for one year, we suggest more studies with larger sample size and long follow-up to further evaluate the long term efficacy of the procedure.

CONCLUSIONS

The aim of out patients management of hemorrhoids is to provide a convenient, safe, effective and economical, and acceptable method of treating hemorrhoids. This study shows that rubber band ligation of hemorrhoids fulfill most of these criteria and we recommend that rubber band ligation should be the treatment of choice for uncomplicated second degree hemorrhoids.

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Misfortune tests friends, and detects enemies"

Richard M. Nixon