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A PROSPECTIVE EVALUATION OF RUBBER BAND LIGATION, SCLEROTHERAPY AND COMBINED METHOD OF THESE TWO PROCEDURES IN MANAGEMENT OF HAEMORRHOIDS:An INTERIM RESULT ANALYSIS.

General Surgery

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ABSTRACT

Aim of this study is to compare among the non open surgical techniques for the management of haemorrhoids. It includes rubber band ligation, sclerotherapy and combined procedure of these two. These procedures are simple and do not require too much skill, anaesthesia, pre operative work up, expensive equipments and no need of bed rest. A prospective study done on 90 symptomatic patients of 1st and 2nd degree internal haemorrhoids was done at a tertiary care hospital with an age distribution of the patients from 31years to 80 years. The patients were divided into three groups consisting of 30 each and were analysed. It was found that combined method was the best in comparison to individual procedures.

KEYWORDS

non open surgical technique, rubber band, sclerotherapy, combined, haemorrhoids

INTRODUCTION–

Haemorrhoid is the one of the oldest disease suffered by the mankind1. For centuries the human race has been plagued by it, but it is impossible to give an accurate figure for their prevalence. Haemorrhoids have plagued humans since they attained the erect posture. The word _Haemorrhoid' is derived from Greek word Haemorrhoids, meaning flowing of blood (haem=blood, rhoos= flowing). The word _piles' comes from Latin word pila meaning a pill or ball. To be accurate, we should call the disease as piles when the patient complains of a swelling and _haemorrhoids' when he or she complains of bleeding1. It is one of the commonest diseases too2. It is found in almost 50% of the people over the age of fifty, who suffer from the disease in some or other form3. Haemorrhoids are normal anatomical structure4. They are known to play part in continence of flatus and faeces, protection of under lying muscle during defecation and in complete closure of anal canal after defecation5. Haemorrhoids are dilated veins occurring in relation to the anus6. It may be external or internal6, i.e. external or internal to dentate line. Most earliest and principal symptoms are bright red painless bleeding6.

Despite a long medical history of identification and treatment, haemorrhoids still pose a challenge to the medical fraternity in terms of satisfactory cure. There has been a long search for the best method of treatment. A wide variety of technique is now currently available for treatment of early haemorrhoids. Enthusiastic reports of success with injection Sclerotherapy and Rubber band ligation have been made. However, increasing modalities of treatment suggested for dealing with haemorrhoid signifies to the lack of universal satisfaction with those currently available methods. Most common modalities of treating early haemorrhoids are injection sclerotherapy and rubber band ligation7. The common consensus is that injection sclerotheapy is ideal for 1st degree internal haemorrhoids and early 2nd degree haemorrhoids while banding is successful in treating large 2nd degree haemorrhoids. These procedures can be performed in the outpatient clinics, with minimum resources and are cost effective7. Thus less invasive methods of treatment such as sclerotherapy and rubber band ligation are widely performed8. The combination of sclerotherapy and rubber band ligation retains all the advantages of both methods as it does not require preparation of either the patient or the bowel,can be applied to outpatients and can be performed immediately at the time of diagnosis9.

In a previous study done by Kanellos et al in March 2003 it was concluded that combination of sclerotherapy and rubber band ligation was significantly more efficient than sclerotherapy own8.

Study conducted by Chew SS et al showed that combined triple sclerotherapy and rubber band ligation is an effective treatment for early hemorrhoids and incomplete mucosal prolapse, with low rates of recurrence, complications, and hemorrhoidectomy10.

In a study conducted by Choi J, Freeman JB, Touchette J et al11 showed that addition of sclerotherapy in conventional rubber band ligation has the advantages of exciting a greater inflammatory reaction between mucosa and sub-mucosa and preventing premature slipping of the band.

Another study conducted by D. Kazantzidou and E. Christoforidis et al12 , it was found that after combined treatment of rubber band ligation and sclerotherapy results were considered excellent in >70% of patient The aim of present study is to compare which modality of treatment is more successful for treating 1st & 2nd degree haemorrhoid and whether combined application of sclerotherapy and rubber band ligation is more effective over separate application of either sclerotherapy or rubber band ligation for the treatment of 1st & 2nd degree haemorrhoid.

METHODOLOGY –

A prospective study of 90 patients willing to be treated with symptoms of 1st and 2nd degree haemorrhoids done at our hospital, a tertiary care hospital with an age distribution of sample is from 31 to 80 years. They were then divided into three groups and distributed for treatment under sclerotherapy, rubber band ligation and a combination of these two.Ethical clearance was obtained from the institutional ethical committee before preceding for the study.

Student's independent samples t test was applied to compare normally distributed numerical variables between groups; unpaired proportions were compared by Chi sqaure test or Fischer's exact test .

RESULTS AND ANALYSIS-

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 20.0.1and GraphPad Prism version 5. Data have been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. The median and the interquartile range have been stated for numerical variables that are not normally distributed. Student's independent sample's t-test was applied to compare normally distributed numerical variables between groups; Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate.

Explicit expressions that can be used to carry out various t-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a t-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test.

Once a t value is determined, a *p*-value can be found using a table of values from Student's t-distribution. If the calculated *p*-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis.

p-value ≤ 0.05 was considered for statistically significant.

In the present prospective study the following data for clinical studies was obtained from R.G.Kar MCH. Ninety (90) patients of symptomatic 1st&2nd degree internal haemorrhoid who wanted to be treated were chosen during the period.

TABLE 1: Showing distribution of age, sex and grade of haemorrhoid.

AGE (range)	Frequency (percentage)	SEX		GRADE	
		Male	Female	1st degree	2nd degree
31-40	12 (13.33%)	10 (16.9%)	2 (6.3%)	8 (40%)	4 (5.7%)
41-50	16 (17.77%)	10 (16.9%)	6 (19.35%)	8 (40%)	8 (11.4%)
51-60	23 (25.55%)	13 (22%)	10 (32.2%)	4 (20%)	19 (27.1%)
61-70	26 (28.88%)	18 (30.5%)	8 (25.8)	-	26 (37.14%)
71-80	13 (14.44%)	8 (13.5%)	5 (16.1%)	-	13 (18%)
	90 (100%)	59 (100%)	31 (100%)	20 (100%)	70 (100%)

In the present study the maximum number of patients was seen between the age group of 61-70 years while minimum age group was recorded between the 31-40 years and maximum age group was recorded between the 71-80 years.

Out of 90 patients 59 were male and 31 were female. There was male preponderance (65.6%) of cases and maximum number of patients presented with 2nd degree haemorrhoid (77.8%).

All 1st degree haemorrhoid cases (20) were treated by sclerotherapy whereas out of of remaining (70) 2nd degree haemorrhoid cases, 30 patients each received combined therapy and rubber band ligation and 10 patients got sclerotherapy.

Association between symptoms and control in all three groups:

Rectal bleeding was controlled in 25 patients (83.3%) in combined group whereas 15 patients (50%) in rubber band ligation group & 10 patients (40%) in sclerotherapy group. The difference of percentage in three groups was statistically significant (P=0.0001). So it was concluded that in combined group there was better control of rectal bleeding in compare to rubber band ligation group and sclerotherapy group.

Rectal discharge was controlled in 10 patients (33.3%) in combined treatment group and 4 patients (20%) in each rubber band ligation group & sclerotherapy group. Though it was not statistically significant but combined treatment was superior in controlling the rectal discharge.

Out of 30 patients who received combined treatment, control of mucosal prolapse occurred in 22 patients (73.3%) . Mucosal prolapse was controlled in 12 patients (40%) of rubber band ligation treatment and only 1 patient of sclerotherapy treatment. The difference of percentage in three groups was statistically significant (P=0.0002). So it was concluded that in combined group there was better control of mucosal prolapse in compare to rubber band ligation group and sclerotherapy group.

On follow up it was noted that recurrence of haemorrhoid had ocurred in only 2 patients (6.7%) treated with combined treatment whereas it occurred in 6 patients (20%) in case of rubber band ligation treatment and in 12 patients (40%) in case of sclerotherapy treatment. The difference of percentage in three groups was statistically significant (P=0.0076). So it was concluded that in combined group there was better control of recurrence of hemmorrhoid in compare to rubber band ligation group and sclerotherapy group.

TABLE 2: Showing overall review of the percentage of cases controlled

TREATMENT	CONTROL OF RECTAL BLEEDING (P=0.0001, Chi-square= 22.7143, Statistically significant)	CONTROL OF RECTAL DISCHARGE (P=0.2583, Chi-square =5.2954, Statistically not significant)	CONTROL OF MUCOSAL PROLAPSE (P=0.0002, Chi-square=8.9143, Statistically significant)	RECURRENCE OF HAEMORRHOIDS (P=0.0076, Chi-square=9.7714, Statistically significant)	NUMBER OF CASES
COMBINED THERAPY	25 50%	10 45.5%	22 62.8%	2 10%	30
SCLEROTHERAPY	10 20%	6 27.28%	1 2.8%	12 60%	30
RUBBER BAND LIGATION	15 30%	6 27.28%	12 34.28%	6 30%	30
ROW %	50 (100%) 55.6%	22 (100%) 24.45%	35 (100%) 38.9%	20 (100%) 22.23%	90

Out of the total cases, control of rectal bleeding was seen in 55.6% cases. Control of rectal discharge in 24.45% and control of prolapse in 38.9%. Recurrence was seen in 22.23% of the cases with least recurrence being in the group with combined therapy.

DISCUSSION-

Popularity of minimally invasive sutureless technique for the treatment of haemorrhoids is increasing due to its safety and effectiveness. Patients were made ambulatory as day cases.It is better as no need of surgical expertise,anaesthesia,pre operative work up,prolong bed rest,expensive instruments. It is safe and effective and with minimal or no blood loss.

Age distribution- A study published by Robert A. Ganz et al13 showed that peak incidence of symptomatic disease seems to be between the ages of 45–65 years & development of hemorrhoids before the age of 20 is unusual. Our study group was from 31 to 80 years of age. In our study mean age of the patient receiving rubber band ligation and combined treatment is 54.6 years and 58.4 years Sex distribution- Our study male predominance with a ratio of M:F=66:34 was seen in comparision to Ruffinhood et al14 who showed a 75:25 male:female ratio.

Distribution of clinical grading- In this study 2nd degree haemorrhoids were 77.8% rest were 1st degree. There was 2nd degree haemorrhoid of 64.2% in Di Giorgio A et al15, 47.5% in Iyer VS et al16 , 26.4% each in M. P. Singh et al17 and Choi J et al18.

Symptoms and sign- Principal presenting symptom is bleeding per rectum(90%). Next was mucosal prolapse and rectal discharge. The principal presenting symptom in most studies was bleeding per rectum

; 90.8% in seen in Iyer VS et al16, 80% in Choi J et al18, 58.3% in Di Giorgio A et al 15, 90% in Ali SA et al19 , 68.8% in M. P. Singh et al17,97% in Murie et al20, 88% in Arabi et al21, 62% in David Marshman's study22 and 91% in David Steinberg et al23. Next frequent symoptom prolapse was seen in 47.5% in Iyer VS et al16 , 26.4% in M. P. Singh et al17, 26% in of Choi J et al18 , 64.2% of Di Giorgio A et al15, 36% in Murie et al20, 55% in Arabi et al21, 20% in David Marshman study22 and 64% David Steinberg et al23.

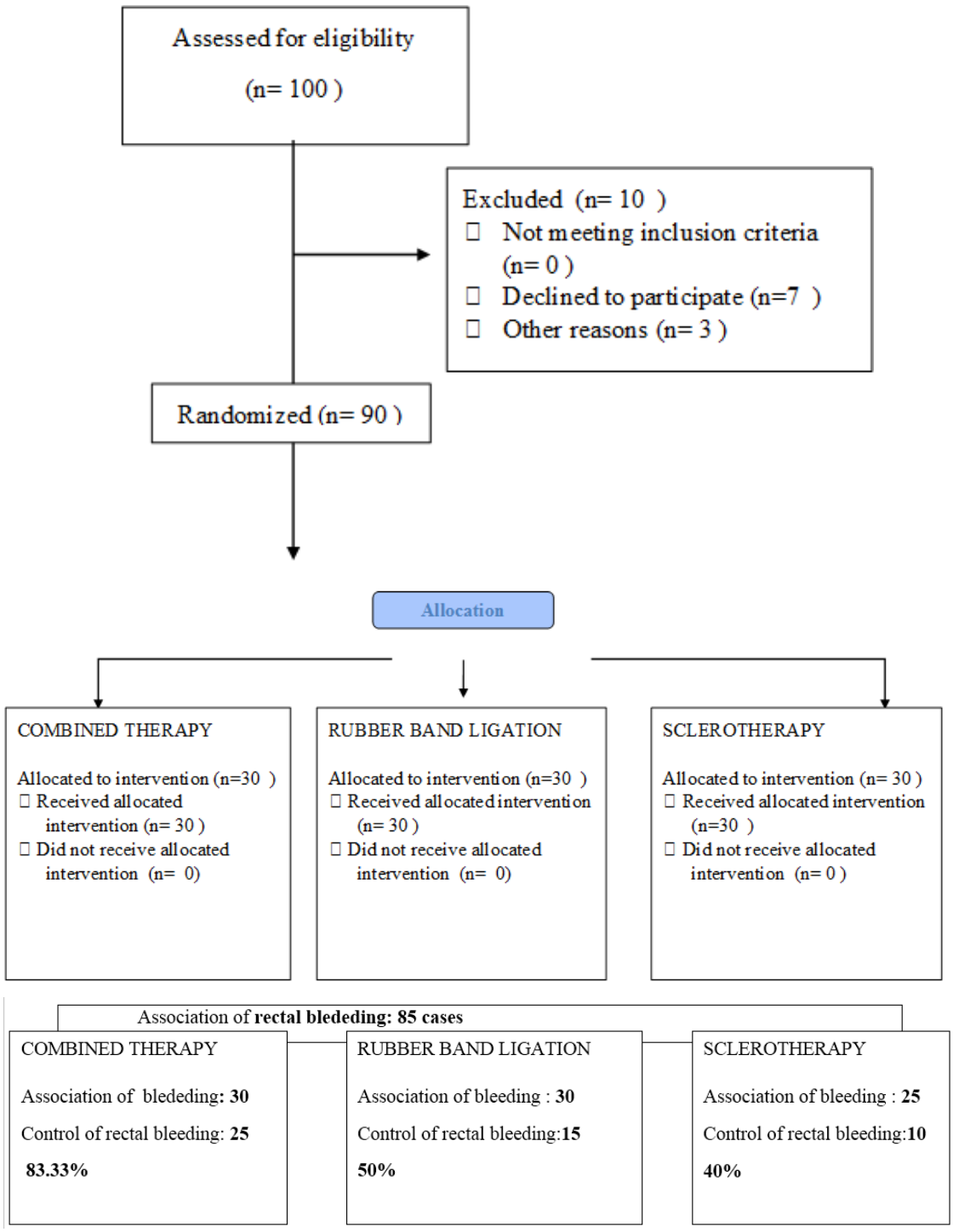
Outcome and procedure-

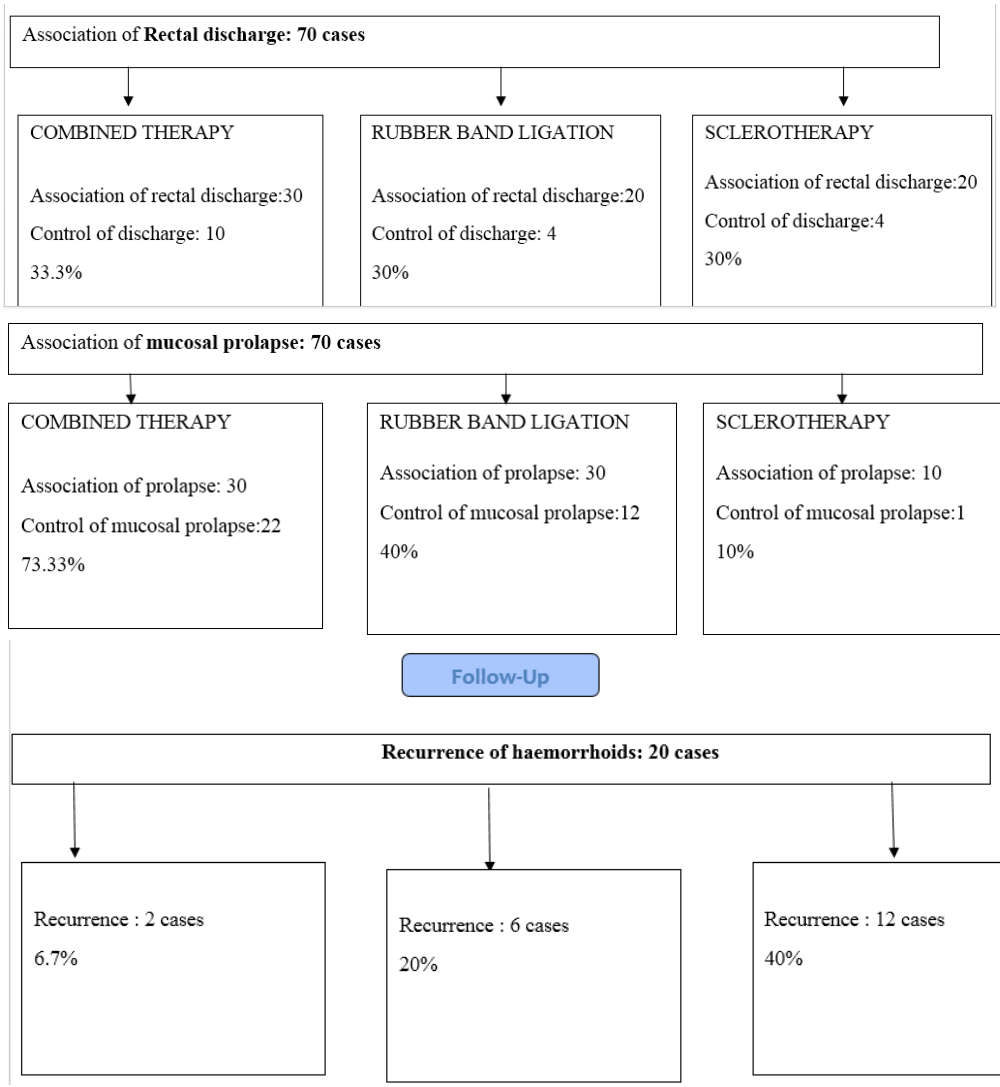
After comparing between the outcome of those procedures, it was seen that there was statistical significance in better control of rectal prolapse (P=0.0002), rectal bleeding(P=0.0001) and recurrence of haemorrhoids (P=0.0076) in combined group in comparison to rubber band ligation and sclerotherapy

CONCLUSION-

Minimally invasive procedures are better as no need of too much expertise,anaesthesia,pre operative work up,prolong bed rest,exp ensive instruments. It is safe and effective and with minimal or no blood loss. Combined therapy is most effective for symptomatic hemorrrhoids and rarely requires hemorrhoidectomy further. Recurrence is also less in combined therapy and it is effective for control of bleeding, rectal discharge, mucosal prolapse too. Hence the study shows that combined therapy of sclerotherapy and rubber band ligation is much better than the individual procedures.

CONSORT FLOW CHART SHOWING RANDOMIZATION AND ALLOACATION OF CASES





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