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Original Article

A COMPARISON OF TWO DIFFERENT TREATMENT MODALITIES FOR THE MANAGEMENT OF HAEMORRHOIDS

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ABSTRACT

Introduction: Hemorrhoids are common surgical problem all over the world. Various modalities for the treatment of haemorrhoids are available. Injection sclerotherapy and rubber band ligation are two non-surgical procedures to treat first and second degree haemorrhoids.

Objectives: To compare the two options of sclerotherapy and rubber band ligation in the cases of early second-degree haemorrhoids

Study Design: Prospective Comparative Study

Setting: A multicenter study conducted at Taluka Hospital Matiari, Bhittai General Hospital, Hyderabad and Department of Surgery, Liaquat University Hospital.

Duration of Study: January 2009 to December 2010.

Material and Methods: Hundred patients of either sex, aged 20–60 years with second degree internal haemorrhoids were included and associated fissure or fistula in ano, Cryptitis or proctitis were excluded. Fifty patients in injection sclerotherapy (Group A) and fifty patients in rubber band ligation (Group B) were randomized through envelope technique after taking informed consent. Routine investigations were performed. Data was recorded on a proforma including age, sex, presenting complaints, number of sessions and post-operative complications (within 30 minutes). SPSS-10.0 was used for analysis.

Results: Significant number of patients of group-B than group-A (38% vs. 78%, p<0.001) complained post treatment pain. Two (4%) patients of group-A and 7 (14%) patients of group-B had severe pain. Bleeding after the procedure in group-A was reported by 11 (22%) patients of group-A and 10 (20%) patients of group-B. Prostatitis was found in only one patients of group-A while fissure in ANO was found only in one patient of group-B. Post treatment complications were insignificant (p = 0.366) between two groups.

Conclusion: Injection sclerotherapy being treatment of choice as post treatment complaints are comparatively less.

Key Words: Haemorrhoids, injection sclerotherapy, rubber band ligation, early complication.

INTRODUCTION

Haemorrhoids are one of the commonest diseases. [1] It is found in almost 50% of the people over the age of fifty, who suffer from the disease in some or other form. [2] Haemorrhoids are normal anatomical structure[3-4]. 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 defecation. Haemorrhoids that prolapsed on defecation but return or need to be replaced manually and then stay reduced are called second degree haemorrhoids. [5] Injection sclerotherapy and rubber band ligation are two common non-surgical interventional procedures to treat first (1st) and second (2nd) degree haemorrhoids. These procedures can be performed in the outpatient clinics, with minimum resources and are cost effective.[6] Thus; less invasive methods of treatment such as sclerotherapy and rubber band ligation are widely performed. [7]

Surgical treatment is documentarily proven even 4000 years back.[8] Ligation and excision being used by Hippocrates. [9] But now over 90% of haemorrhoids are manageable by non-operative method and less than 10% required haemorrhoidectomy. [10] Injection sclerotherapy alone or in combination with rubber band ligation is recommended by many authors for the treatment of both first and second degree haemorrhoids. [11] The common post procedural complaint was anal discomfort, proctalgia and soiling. All of these complaints alleviated within a week after treatment without requiring further management.[12]

MATERIAL AND METHODS

Study Design: Prospective Comparative Study
Setting: A multicenter study conducted at Taluka Hospital Matiari, Bhittai General Hospital, Hyderabad and Department of Surgery, Liaquat University Hospital.
Duration of Study: January 2009 to December 2010.
Sample Size: Total number of patient is hundred. Fifty patients in injection Sclerotherapy (Group A) and fifty patients in rubber band ligation (Group B).
Sampling Technique: Non probability, purposive sampling technique
Sample Selection:

Inclusion Criteria:
- Either sex
- Age range 20 years – 60 years
- Complaints
  - o Pain
  - o Bleeding P/R
  - o Pruritus
  - o Prolapse
    - Second degree internal haemorrhoids

Exclusion Criteria:
- Internoexternal haemorrhoids
- Third degree haemorrhoids
- Associated with fissure in ano or fistula in ano
- Cryptitis or proctitis
- Patients who refuse to sign the informed consent.

Data Collection Procedure:
The data was collected on a proforma. The patients were randomized into study groups. The informed consent was taken before any procedure. Since both the treatment options were established for the disease and there were no unknown risks in any option so there was no specific ethical problem.

RESULTS

All patients had early second degree haemorrhoids. There were 70 (70%) male and 30 (30%) female patients (male to female ratio of 2.3:1). In sclerotherapy (Group A) males were 28 (56%) and females were 22 (44%) (Male to female ratio of 1.3:1). In rubber band ligation (Group B) males were 42 (84%) and females were 8 (16%) (Male to female ratio of 5.3:1). There was significant difference of sex distribution between two groups.
Average age of group-A was computed 40.98 ± 8.50 and of group-B was 39.97 ± 8.33. Statistically insignificant difference of means between group-A and group-B (t = 0.60, d.f=98, p = 0.575) was observed) Table I
Prolapse was reported by all 100 patients (100%) of the study.

TABLE-1
COMPARISON OF AGE DISTRIBUTION:

Age	Group-A (n = 50)	Group-B (n = 50)
20-25 years	2 (4)	3 (6)
26-30 years	4 (8)	3 (6)
31-35 years	6 (12)	8 (16)
36-40 years	11 (22)	12 (24)
41-45 years	12 (24)	10 (20)
46-50 years	10 (20)	11 (22)
51-55 years	2 (4)	1 (2)
56-60 years	3 (6)	2 (4)
Mean ± SD	40.98 ± 8.50	39.97 ± 8.33

Statistically insignificant difference of means between group-A and group-B (t = 0.60, d.f=98, p = 0.575)

TABLE-2
COMPARISON OF PRESENTING SYMPTOMS BETWEEN TWO GROUPS:

Symptom	Group-A (n = 50)	Group-B (n = 50)	P-value
Prolapse	50 (100)	50 (100)	0.999
Bleeding	45 (90)	45 (90)	0.999
Pain	41 (82)	41 (82)	0.999
Pruritus	33 (66)*	22 (44)	0.027
Constipation	20 (40)	13 (26)	0.137

Significant high proportion at p < 0.05

TABLE-3
DURATION OF SYMPTOMS:
n = 100

DURATION OF SYMPTOMS	NUMBER OF PATIENTS	PERCENTAGE
3 MONTHS OR LESS	7	7
3-6 MONTHS	12	12
6 MONTHS TO 1 YEAR	32	32
1-2 YEARS	24	24
2-5 YEARS	13	13
5-10 YEARS	12	12

Bleeding was reported by 90 patients (90%), as 45 (90%) patients in each group. Pain was reported by 82 patients (82%), as 41 (82%) patients in each group. Pruritis was figured 55 patients (55%), as 33 (66%) in group-A and 22 (44%) patients in group-B and this difference of proportions was statistically significant (p = 0.027). Constipation was reported by 33 (66%) patients; however the difference of proportions in group-A and group-B of the patients with constipation was insignificant (40% vs. 26%, p = 0.137) (Table-2).

The most frequent of duration of the symptoms was 6 months to 1 year that was reported by 32% patients. Mean duration of symptoms was 2.11 ± 2.20 (Mean ± SD). Maximum duration was 10 years (Table-3).

Number of haemorrhoids per patients was evaluated. Five (10%) patients of group-A and 11 (22%) patients of group-B had single haemorrhoid, 16 (32%) patients of group-A and 13 (26%) patients of group-B had two haemorrhoids and 29 (58%) patients of group-A and 26 (52%) patients of group-B had three haemorrhoids. The number of haemorrhoids per patient was statistically insignificant between two groups.

In our study of 100 patients haemorrhoids were present at their classical position (3,7 and 11 o'clock) in only 55 patients (55%). In other 45 patients (45%) haemorrhoids were present at non-classical positions.

During observation of early complications recorded within 30 minutes, total 19 (38%) patients of group-A and 39 (78%) patients of group-B complained pain after the procedure. Ten (20%) patients of group-A and 26 (52%) patients of group-B had mild (VAS: 1-3) pain, 7 (14%) patients of group-A and 6 (12%) patients of group-B had moderate (VAS: 4-6) pain and 2 (4%) patients of group-A and 7 (14%) patients of group-B had severe pain. This data revealed significantly high (p<0.001) proportion of patients with pain / discomfort who underwent band ligation than whom underwent injection sclerotherapy.

Complained of bleeding after the procedure in group-A was reported by 11 (22%) patients of group-A and 10 (20%) patients of group-B. Prostatitis was found in only one patients of group-A while fissure in ANO was found only in one patient of group-B. Post treatment complications were found statistically insignificant (p = 0.366) between two groups.

The analgesic requirement in group-A (injection sclerotherapy) only in 19 patients (38%) while in group B (rubber band ligation) the analgesics required in 39 patients (78%).

DISCUSSION:

Hundred patients included in which 50 in injection sclerotherapy (group A) and 50 in rubber band ligation (group B). Our main aim was determination of efficacy, safety and cost effectiveness between two groups and also determination of incidence of common complication between two methods.

Out of hundred patients, 70 (70%) male and 30 (30%) female patients (male to female ratio of 2.3:1). In sclerotherapy (Group A) males were 28 (56%) and females were 22 (44%) (Male to female ratio of 1.3:1). In rubber band ligation (Group B) males were 42 (84%) and females were 8 (16%) (Male to female ratio of 5.3:1).

The age ranged from 20 to 60 years. The highest incidence was from 31-50 years. 80 patients (80%) were found in this age group.

Effect on prolapse in injection sclerotherapy group (Group A) is 41 patients (82%) showed improvement in prolapse at 4 week. But at 6 month follow-up, there was recurrence in some patients at that time 32 patients (64 %) stated improvement. In rubber band ligation group (Group B) improvement was present in 48 patients (96 %) at 4 week and in 47 patients (94 %) at 6 month. Effect on bleeding in group A was 40 patients (88.9 %) showed improvement at 4 week and at 6 months 34 patients (75.55 %) improved. While at 4 week in group B, 44 patients (97.77 %) improved and at 6 month result was 43 patients (95.55 %).

In group A, the improvement in pain at four week was 35 patients (85.36 %) and finally 32 patients (78.04 %) at 6 month. In group B, at 4 week the improvement in pain was 40 patients (97.56 %) and at 6 month improvement was 38 patients (92.68 %).

The difference in results of pain in group A and group B at four week and at 6 month are statistically significant.

Pain after rubber band ligation occurs more often than previously recognized. It is suggested that informed consent be obtained before rubber band ligation and that patients should be given the opportunity to delay treatment if they so wish. [13-14]

Although, rubber band ligation demonstrated greater long term efficacy, it was associated with the significantly higher incidence of post treatment. [15-16]

The improvement in pruritis at 4 week in group A was 30 patients (90.90 %) and at 6 months 28 patients (84.84 %) finally improved. And in group B 21 patients (95.45 %) at 4 week and 20 patients (90.90 %) at 6 month was noted.

In our study overall result of symptoms of prolapse, bleeding pain and pruritus in group A at four week was 86.39 % and at 6 month was 74.55 %.

In group B the final result was at four week 96.83 % and at 6 month 93.67 %.

Many authors claim that banding can be done in one session [17,18] which is safe and economical. It is also effective in patients with haemorrhoids and bleeding disorders and haemorrhoids with portal hypertension. [19]

Studies of Murie et al [20] and Poen at al [21] have shown rubber band ligation as effective as haemorrhoidectomy. It was necessary to evaluate the intensity of pain and discomfort after the treatment to accept or to reject the treatment.

The pain and discomfort in group A felt by 19 patients, in which two had severe pain that managed by injection Diclofenac sodium 75 mg i/m, and others managed by tablet Paracetamol 500 mg 8 hourly or tablet Diclofenac sodium 50 mg two times daily.

In group B pain and discomfort felt by 39 patients, mild to moderate pain treated by oral analgesics example tablet Paracetamol 500 mg 8 hourly or tablet Diclofenac sodium 50 mg two times daily. Rest of 7 patients had severe pain that treated by injection Diclofenac sodium 75 mg i/m.

Tablet Metronidazole 400 mg 8 hourly and 0.2% glycerol trinitrate (GTN) ointment were added in post procedure treatment to lesser the pain after banding or sclerotherapy.

Minor bleeding was present in group A in 11 patients and in group B 10 patients. All patients treated by reassurance. In this study there was no severe bleeding found.

One patient developed prostatitis after injection sclerotherapy, that patient was treated conservatively by Antibiotic tablet Ciprofloxacin 500 mg two times daily and analgesic tablet Diclofenac sodium 50 mg two times daily and a sodium citrate solution two table spoon three times daily.

After banding one patient develop acute anal fissure, that patient advised sitz bath and 0.2% glycerol trinitrate ointment three times daily for two weeks.

CONCLUSION:

Injection Sclerotherapy was found more effective than band ligation for the treatment of early second degree haemorrhoids as rate of non-compliance and post treatment complications were comparative low in this procedure. Injection Sclerotherapy in a non-invasive and cost effective method in this way. Further, large scale sample experiments are required to reach more precise results regarding the use of both treatments.

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