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Comparative study between rubber band ligation versus injection sclerotherapy in second degree Haemorrhoids

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Abstract

Objective: The aim of this study was to compare between rubber band ligation and injection sclerotherapy in patients with second degree haemorrhoids.

Background: Haemorrhoids are common surgical problem throughout the world which affects quality of life and leads to significant pain and discomfort. Various modalities are available as treatment options for haemorrhoids. Injection sclerotherapy and rubber band ligation are in use for the treatment of early haemorrhoids (1st and 2nd degree)

Study Designs: The study was designed as a prospective randomized study.

Place and Duration of Study: The study was conducted in Indira Gandhi medical college and hospital, Puducherry from January 2019 to August 2019.

Patients and Methods: A total of 72 patients with second degree haemorrhoids were divided into two groups. In group A, there were 36 patients who were subjected to rubber band ligation and in group B there were 36 patients in whom injection sclerotherapy was done. Patients were followed up at 3 months following surgery to assess the incidence of pain, bleeding per rectum, recurrence.

Results: At 3 month follow up, pain during defaecation was significantly lower in Group A (rubber band ligation) compared to Group B (injection sclerotherapy) with no significance in other complications.

Conclusion: Rubber band ligation is superior to injection sclerotherapy in treating patients with second degree haemorrhoids.

Keywords: Haemorrhoids, rubber band ligation, injection sclerotherapy

Introduction

Haemorrhoids is a very common surgical problem which can occur at any age and affect both males and females ^[1]. Peak age is between 35-65 years and there is reduced incidence thereafter ^[2]. Haemorrhoids are anal cushions composed of arterioles venules and arterio venous communications ^[3, 4]. The cause of haemorrhoids is unclear but there is increased incidence in western population due to their high refined diet compared to Asians ^[5]. Patients with haemorrhoids present with symptoms like bleeding per rectum, pain during defecation, itching prolapse and perianal soiling ^[1]. Haemorrhoids is classified according to their size into four degree. While surgery is treatment of choice for grade 3 and grade 4 haemorrhoids, conservative approach can be used to treat second degree haemorrhoids. Surgical procedure of choice for higher degree haemorrhoids is milligan morgan method which is open haemorrhoidectomy ^[6]. For second degree haemorrhoids various conservative treatments are available to date. Among these rubberband ligation and injection sclerotherapy are quite easy and readily available procedures ^[7].

In this trial we evaluate the effectiveness and various complications of rubber band ligation and injection sclerotherapy in the treatment of second degree haemorrhoids.

Aims and objectives

The aim of this study is to compare the effectiveness, advantages and disadvantages of rubber band ligation versus injection sclerotherapy for patients with second degree haemorrhoids.

Types of Intervention:

- a) Rubber band ligation.
- b) Injection sclerotherapy

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Types of Outcome Measures

1. Type of anesthesia
2. Post operative pain
3. Post operative bleeding per rectum
4. Post op retention of urine
5. Post op anal incontinence
6. Recurrence of haemorrhoids at 3 months
7. Cost of procedure.

Materials and method:

1. The Study was conducted in the Dept. of General Surgery - Indira Gandhi Medical College and hospital, Pondicherry from January 2019 to august 2019
2. Patients will be selected from those admitted to Department of General Surgery, Indira Gandhi medical college and hospitals for second degree haemorrhoids.

Inclusion Criteria

- a) Patients of any age and sex.
- b) Patients with second degree haemorrhoids.
- c) Patient willing to give informed consent.

Exclusion Criteria

- a) Patients with external haemorrhoids
- b) Infected internal haemorrhoids
- c) Internal haemorrhoids with thrombus
- d) Associated perianal fistula fissure.

Sample Size

Number of patients to be studied are 72
 Statistical Analysis of my study will be by standard- 't' test, chi-square method.

Methodology

Total of 72 patients admitted to our hospital with second degree haemorrhoids according to Nivatvongs' classification [8] were exclusively studied in this prospective study. They were divided into Group A (36) who underwent rubberband ligation and Group B (36) who underwent injection sclerotherapy based on odd and even admissions. Patient characteristics, anaesthesia, complications encountered, outcome and followup were studied in detail. Data collected will be subjected to compare between the above mentioned two techniques.

Preoperative Preparation: All patients were immunised against tetanus toxoid on admission. All patients in both group were given saline enema on the evening before the day of surgery and early morning on the day of surgery. Entire bowel preparation was not done in both groups.

Anaesthesia: Local anaesthesia was given for patients in both groups. No sedation was used in either group.

Operative Procedure

Rubber band ligation: After the patient been put in Sims position, anoscope was introduced and the haemorrhoidal tissue visualized. With a disposable suction haemorrhoidal ligator, two rubber bands were applied at the level of vascular pedicle. This

procedure was repeated for all quadrants and the anoscope was withdrawn once the rings were in position.

Injection sclerotherapy: After patient been put in Sims position, anoscope was introduced and the haemorrhoidal tissue visualized. With use of Gabriel syringe, the sclerosant ATLA (aluminium potassium sulphate and tannic acid) was injected submucosally into each pile site [9].

All patients were discharged after the procedure (day care surgery). Patients in each group were followed up at 1, 4 and 12 weeks after the procedure for evaluation of occurrence of symptoms like bleeding, pain, itching. Assessment of post operative pain was done by using a 10 cm VAS scale. A score of seven and above were considered significant post operative pain.

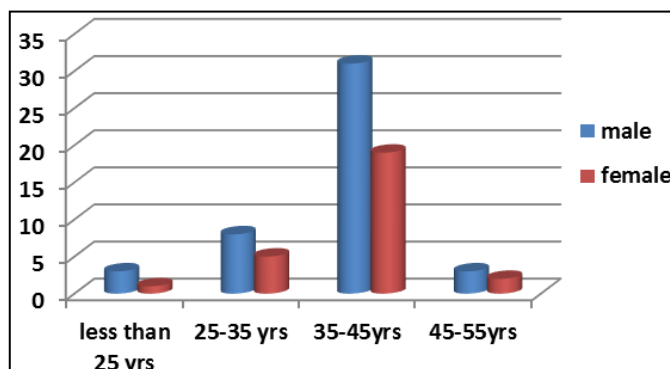
Observation

Seventy two patients with second degree haemorrhoids were taken up for study at the Indira Gandhi Medical College and Hospitals, puducherry during the period of January 2019 and August 2019. Those cases were admitted to the Department of Surgery and following were observed.

Below 25 years there were 3 males and 1 female, between 25 - 35 years there were 8 males and 5 females, between 35 - 45 years there were 31 males and 19 females, between age 45 to 55 there were 3 males and 2 females. In this study, the peak age incidence of haemorrhoids was between 35 - 45 years. Out of 72 cases under study 62% were males and 38% were females, incidence of 1.6: 1 (M:F) showing male predominance. Table 1 and graph 1 shows age and sex distribution among both groups.

Table 1: Age and Sex Distribution (original)

Age in yrs	Male	Percentage	Female	Percentage	Total	Percentage
< 25 yrs	3	4.2%	1	1.3%	4	5.5%
25-35yrs	8	11.1%	5	6.9%	13	18.1%
35-45yrs	31	43%	19	26.5%	50	69.4%
45- 55 yrs	3	4.2%	2	2.8%	5	7%
Total	45	62.5%	27	37.5%	72	100%

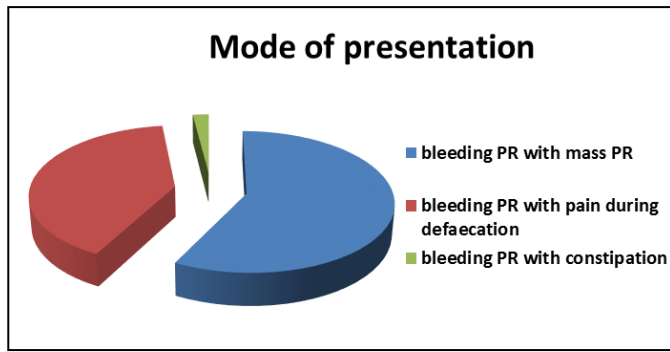


Graph 1: Age and sex distribution

Most of the patients presented with bleeding per rectum with mass per rectum (40). Other symptoms were bleeding with painful defaecation (28), bleeding with constipation (4). Table 2 and graph 2 shows mode of presentation.

Table 2: Mode of presentation (original)

Symptoms	Number of patients	Percentage
Bleeding per rectum with mass per rectum	40	55.5%
Bleeding per rectum with painful defaecation	28	38.9%
Bleeding per rectum and constipation	4	5.6%



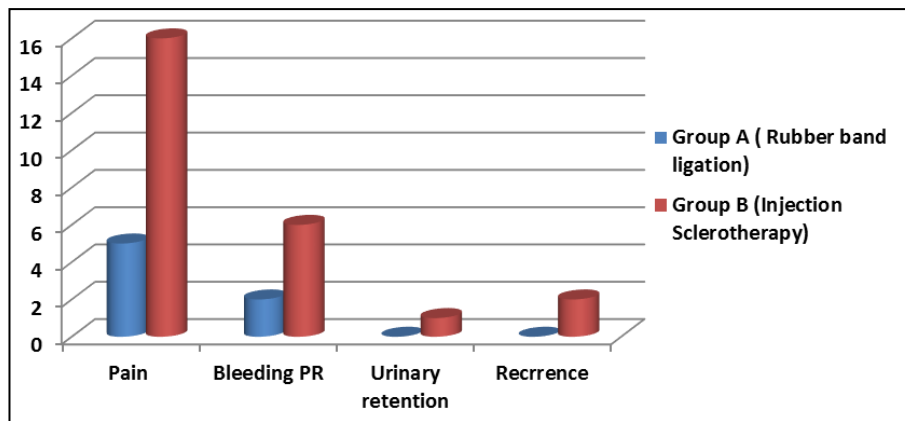
Graph 2: Mode of presentation:

72 patients were divided into two groups. Group A (36 pts) underwent Rubber band ligation and in patients in Group B (36 pts) injection sclerotherapy was given. Local anaesthesia was used in all 72 patients. operative time varied between 15 to 20

min. Patients were discharged after the procedure and were followed up at 1 week, 4 weeks and 12 weeks post procedure. At 12 weeks follow up, five parameters were compared. These are pain during defecation, bleeding per rectum, urinary retention, anal incontinence and recurrence at 3 month post op. Pain was evaluated based on visual analogic scale (VAS) in cm with range of 0 -10. A score of 7 and more was considered significant. Significant pain at 12 weeks were observed in 5 patients in Group A as compared to 16 patients in group B. Bleeding per rectum was observed in 2 patients in Group A and 6 patients in Group B. Urinary retention was observed in 0 patients in Group A and 1 patient in Group B. Anal incontinence was not observed in any patient in either group. There was no recurrence in Group A as compared to 2 patients with recurrence in group B. Table 3 and graph 3 shows post operative complications at 3 month follow up in both groups.

Table 3: Follow up at 12 weeks

Parameters	Group A (n=36) Rubber band ligation	Group B (n=36) Injection sclerotherapy	P value
Pain during defecation	5	16	0.004 (Significant)
Bleeding per rectum	2	6	0.13
Urinary retention	0	1	0.98
Anal incontinence	0	0	-
Recurrence at 12 weeks	0	2	0.56



Graph 3: Follow up at 12 weeks

The total cost for rubber band ligation in Group A was around 800 rupees and in group B it was around 1200 rupees who underwent injection sclerotherapy.

Discussion

In our study, we have conducted a randomised controlled trial in Department of General Surgery, IGMCRI, Puducherry from January 2019 to august 2019 among 72 patients with second degree haemorrhoids and have compared these two methods in terms of post operative pain, bleeding per rectum, urinary retention and recurrence at 12 weeks.

According to the observation based on table 1 and Graph 1, the peak age incidence of second degree haemorrhoids was observed between 35 - 45 years. A total of 45 males and 27 females were considered for study and the male-to-female ratio in this study is 1.6:1. In the study conducted by jehan *et al* peak age of haemorrhoids was 3rd to 4th decade [10]. In the study conducted by Mohan *et al* showed higher incidence of haemorrhoids in male [11].

All the 72 patients underwent either procedure under local

anaesthesia in our Institution.

In our present study the most common presenting symptom was bleeding per rectum with mass per rectum (55%) followed by pain during defaecation. In the study conducted by Steinberg *et al*, bleeding per rectum was the main presenting complaint in patients with haemorrhoids [12].

In our study, at 12 week follow up patients in Group A (rubber band ligation) had significantly lower incidence of pain compared to patients in Group B (injection sclerotherapy). There was no significant difference between two groups in other complications like bleeding per rectum, anal urinary retention and recurrence at 12 weeks follow up. In a meta analysis conducted by MacRae *et al* concluded that injection sclerotherapy was less effective than rubber band ligation [13]. In another study by Bayer *et al*, it was reported that rubber band ligation is more effective than other treatment methods [14].

Summary

72 cases of second degree of haemorrhoids were subjected to either Rubber band ligation or Injection sclerotherapy at

Department of Surgery, Indira Gandhi Medical College and Hospital from January 2019 to August 2019. Patients were divided into two groups 36 each. After thorough investigation and pre-procedure preparation, patients were subjected for procedure.

In our study, the male-to-female ratio was 1.6: 1 with male predominance. The peak age incidence in our study was between 35 - 45 yrs. Most common presentation was bleeding per rectum with mass per rectum. At 12 week follow up there was significant lower incidence of pain in Group A (rubber band ligation) compared to group B (injection sclerotherapy).

Conclusion

The study ends with the conclusion that Rubber band ligation is definitely better option than injection sclerotherapy for second degree haemorrhoids.

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