



A COMPARATIVE STUDY COMPARING THE OUTCOME OF INJECTION SCLEROTHERAPY VS RUBBER BAND LIGATION VS SUTURE LIGATION WITHOUT DOPPLER GUIDANCE IN TREATMENT OF SYMPTOMATIC GRADE II AND III HEMORRHOIDS

General Surgery

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ABSTRACT

Background: Ambulatory treatments for hemorrhoids include injection sclerotherapy, rubber band ligation, cryosurgery, infrared coagulation, and transanal hemorrhoidal ligation with or without doppler guidance. In general, the lower the grade, the more likely an office-based procedure will be successful. **Aims And Objectives:** To compare the clinical outcome related to treatment of grade II and III haemorrhoid by Injection Sclerotherapy vs. Rubber band ligation vs. Suture ligation without doppler guidance. **Methodology:** An analytical prospective comparative study was done on 90 patients presenting with symptomatic grade two and grade three hemorrhoids in the outpatient department as well as emergency admissions in Department of General Surgery, Swaroop rani Nehru hospital, MLN Medical College, Prayagraj over a period of one year from November 2019 to November 2020. **Result:** There was no significant difference in the various treatment groups with respect to clinical outcome, recurrence and recovery. **Conclusion:-** In the present study all the three procedures were found to be very effective outpatient procedures for management of symptomatic 2nd and 3rd degree hemorrhoids.

KEYWORDS

INTRODUCTION

Hemorrhoids are one of the most common afflictions of human being and have been defined differently over the years from over simplified definition of varicosities of haemorrhoidal plexus to the more recent study describing them as specialized highly vascular "cushions" of discrete masses of thick submucosa, containing blood vessels, smooth muscles, elastic and connective tissue which may slide down due to breakage of collagen and anchoring supporting connective tissue causing symptoms like prolapse, bleeding, pain etc. Hemorrhoids developing above the dentate line are internal. They are painless because they are viscerally innervated. External hemorrhoids develop below the dentate line and can become painful when swollen. The extent of prolapse of internal hemorrhoids can be graded from I to IV, which guides effective treatment.

First degree: Veins of anal canal increase in number and size, and they bleed on defecation

Second degree: Hemorrhoids prolapsed outside anal canal but reduce spontaneously

Third degree: Hemorrhoids protrude outside anal canal and require manual reduction

Fourth degree: Irreducible hemorrhoids that remain constantly prolapsed

Ambulatory treatments for hemorrhoids include injection sclerotherapy, rubber band ligation, cryosurgery, infrared coagulation, and transanal hemorrhoidal ligation with or without doppler guidance. In general, the lower the grade, the more likely an office-based procedure will be successful, whereas recurring and grade III or IV hemorrhoids are more amenable to excisional haemorrhoidectomy. (Mott et al)(1)

In sclerotherapy, a sclerosing agent or hardening agent is injected submucosally into the base of the haemorrhoid. This is thought to induce a local inflammatory reaction shrinking the haemorrhoidal mass and causing fixation of the mucosa to the underlying muscle. It is best suited for grade 1 & 2 hemorrhoids with bleeding as the principal complaint. Recurrence rate is 15% and repeated injections are difficult due to the fibrosis. Band ligation of the haemorrhoid leads to obliteration of the vessel feeding the haemorrhoid which in turn, leads to ulceration and sloughing, with subsequent healing over a period of weeks. Rubber band ligation produces fixations of mucosa by causing ulceration rather than a simple sub mucosal inflammation. Dearterialization of hemorrhoids, either with suture ligation, hemorrhoidal artery ligation (HAL/THD) along with mucopexy for prolapsing hemorrhoids has been studied & found to be safe & effective minimally invasive outpatient treatment for symptomatic hemorrhoids. (Brown et al 2016)(2)

AIMS AND OBJECTIVES

To compare the clinical outcome related to treatment of grade II and III haemorrhoid by Injection Sclerotherapy vs. Rubber band ligation vs. Suture ligation without doppler guidance with respect to following variables:-

- pain
- bleeding per rectum
- discharge
- anal stenosis
- incontinence

METHODOLOGY

An analytical prospective comparative study was done on 90 patients presenting with symptomatic grade two and grade three hemorrhoids in the outpatient department as well as emergency admissions in Department of General Surgery, Swaroop rani Nehru hospital, MLN Medical College, Prayagraj over a period of one year from November 2019 to November 2020. They were divided into three groups of 30 patients each on random basis as follows:-

Distribution of patients according to Treatment Modality

S.NO.	GROUP	NO. OF PATIENTS(n)	TREATMENT
1.	A	30	INJECTION SCLEROTHERAPY
2.	B	30	RUBBER BAND LIGATION
3.	C	30	SUTURE LIGATION WITHOUT DOPPLER GUIDANCE

INCLUSION CRITERIA:- 1) Those patients who are willing to participate in the study. 2) All diagnosed patients of grade II and III hemorrhoids with symptoms 3) Patients in the age group of 20 to 80 4) Patients with coexisting medical disorders like DM/HTN/TB/thyroid illness etc. 5) Patients with anal fissure and bleeding diathesis.

EXCLUSION CRITERIA:- 1) Immunocompromised Patients 2) Pregnant Females 3) Patients with active infections (ischioanal abscess and perianal abscess), etc. 4) Patients with malignancy, prolapse, grade IV hemorrhoids, fistula in ano, complicated hemorrhoids (thrombosed) etc

Written and informed consent was taken from all patients prior to carrying out any study related. All patients were immunised against tetanus toxoid on admission and 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 any of the groups. Local anaesthesia was given for patients in all the groups. No

sedation was used in either group.

INJECTION SCLEROTHERAPY

After patient been put in Sims position, anoscope was introduced and the haemorrhoidal tissue visualized. 3 ml of sodium tetradecyl sulfate was injected in the perivascular space around each haemorrhoid.

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.

SUTURE LIGATION

the hemorrhoid pedicle was transfixed and ligated with 2-0 vicryl on round body needle in order to occlude the superior hemorrhoidal vessel as they enter the internal hemorrhoids.

All patients were discharged after the procedure (day care surgery). Follow-up was at day 2 weeks, 1 month and 3 months postoperatively. Data was converted into variables and entered into SPSS-13. Chi square tests and t-tests were used to find out statistical difference between the groups. P value of < 0.05 was considered as statistically significant and highly significant if P < 0.001.

RESULTS

Table No. 1: Distribution of the Patients According to Clinical Presentation

A) Bleeding Per rectum

Association Between Type of Treatment and Symptom: Bleeding PR (n = 90)

Symptoms: Bleeding PR	Type of Treatment				Chi-Squared Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Present	13 (43.3%)	12 (40.0%)	12 (40.0%)	37 (41.1%)	0.092	0.955
Absent	17 (56.7%)	18 (60.0%)	18 (60.0%)	53 (58.9%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Symptoms: Bleeding PR ($\chi^2 = 0.092$, p = 0.955).

B) Altered bowel habits

Association Between Type of Treatment and Symptoms: Altered bowel habits (n = 90)

Symptoms: Constipation	Type of Treatment				Fisher's Exact Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Present	2 (6.7%)	4 (13.3%)	3 (10.0%)	9 (10.0%)	0.741	0.905
Absent	28 (93.3%)	26 (86.7%)	27 (90.0%)	81 (90.0%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Symptoms: Constipation ($\chi^2 = 0.741$, p = 0.905)

C) Painful Defecation

Association Between Type of Treatment and Symptoms: Painful Defecation (n = 90)

Symptoms: Painful Defecation	Type of Treatment				Chi-Squared Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Present	6 (20.0%)	8 (26.7%)	5 (16.7%)	19 (21.1%)	0.934	0.627
Absent	24 (80.0%)	22 (73.3%)	25 (83.3%)	71 (78.9%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

Symptoms: Discharge	Type of Treatment				Fisher's Exact Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Present	2 (6.7%)	2 (6.7%)	4 (13.3%)	8 (8.9%)	1.098	0.722
Absent	28 (93.3%)	28 (93.3%)	26 (86.7%)	82 (91.1%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Symptoms: Painful Defecation ($\chi^2 = 0.934$, p = 0.627).

D) Discharge

Association Between Type of Treatment and Symptoms: Discharge (n = 90)

Symptoms: Discharge	Type of Treatment				Fisher's Exact Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Present	2 (6.7%)	2 (6.7%)	4 (13.3%)	8 (8.9%)	1.098	0.722
Absent	28 (93.3%)	28 (93.3%)	26 (86.7%)	82 (91.1%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Symptoms: Discharge ($\chi^2 = 1.098$, p = 0.722).

E) Pruritis

Association Between Type of Treatment and Symptoms: Pruritis (n = 90)

Symptoms: Pruritis	Type of Treatment				Fisher's Exact Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Present	2 (6.7%)	1 (3.3%)	4 (13.3%)	7 (7.8%)	2.169	0.493
Absent	28 (93.3%)	29 (96.7%)	26 (86.7%)	83 (92.2%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Symptoms: Pruritis ($\chi^2 = 2.169$, p = 0.493).

Table No. 2: Distribution of the Patients According to Post-Operative Outcome (n = 90)

Post-Operative Outcome	No. Of Patients	Percentage
Pain	68	75.55%
Bleeding PR	12	13.3%
Discharge	10	11.1%
Anal Stenosis	0	0%
Anal Incontinence	0	0%
Total	90	100.0%

In our study, majority of the patients, 75.55% (n = 68) had pain in the Post-Operative period, 13.3% (n = 12) of the patients had immediate /delayed complaint of bleeding per rectum in the post-operative period, 11.1% (n = 10) of the patients had discharge as the main post op complication. None of the patients had anal stenosis and anal incontinence as a post-operative complication.

Table No. 3: Association Between Type of Treatment and Post-Operative Outcome (n = 90)

Post-Operative Outcome	Type of Treatment				Fisher's Exact Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Pain	23 (76.7%)	21 (70.0%)	24 (80.0%)	68 (75.55%)	4.781	0.838
Bleeding PR	4 (13.3%)	4 (13.3%)	4 (13.3%)	12 (13.3%)		
Discharge	3 (10.0%)	5 (16.7%)	2 (6.7%)	10 (11.1%)		

Anal Stenosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Anal Incontinence	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Post-Operative Outcome ($\chi^2 = 4.781, p = 0.838$).

Table No. 4: Distribution of the Patients According to Recovery (n = 90)

Recovery	No. Of Patients	Percentage
Complete	70	77.8%
Partial	20	22.2%
Total	90	100.0%

Including all the three study groups, 77.8% (n = 70) patients recovered completely while 22.2% (n = 20) patients were recovered partially

Table No. 5: Association Between Type of Treatment and Recovery (n = 90)

Recovery	Type of Treatment				Chi-Squared Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Complete	26 (86.7%)	20 (66.7%)	24 (80.0%)	70 (77.8%)	3.600	0.165
Partial	4 (13.3%)	10 (33.3%)	6 (20.0%)	20 (22.2%)		
Total	30 (100.0%)	30 (100.0%)	30 (100.0%)	90 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Recovery ($\chi^2 = 3.600, p = 0.165$).

Table No. 6: Distribution of the Patients According to Recurrence (n = 80)

Recurrence	No. Of Patients	Percentage
Present	14	17.5%
Absent	66	82.5%
Total	80	100.0%

*10 patients were lost to follow up.

In our study, patients were followed up on 7th day, 14th day, 1st month and 3rd month of the procedure and 17.5% (n = 14) of the patients had recurrence of same or lower grade of hemorrhoids while 82.5% (n = 66) of the patients showed no recurrence of the hemorrhoids on follow up. In the present study, 10 patients were lost to follow up.

Table No. 7: Association Between Type of Treatment and Recurrence (n = 80)

Recurrence	Type of Treatment				Fisher's Exact Test	
	Sclerotherapy	Rubber Band Ligation	Suture Ligation	Total	χ^2	P Value
Present	7 (25.9%)	5 (19.2%)	2 (7.4%)	14 (17.5%)	3.287	0.200
Absent	20 (74.1%)	21 (80.8%)	25 (92.6%)	66 (82.5%)		
Total	27 (100.0%)	26 (100.0%)	27 (100.0%)	80 (100.0%)		

There was no significant difference between the various groups in terms of distribution of Recurrence ($\chi^2 = 3.287, p = 0.200$).

DISCUSSION

• CLINICAL PRESENTATION OF THE PATIENTS

Contrary to our study, *Saxena P et al(3)* reported the symptom of bleeding per rectum in 100% of the patients, *Govardhan et al(4)* also had majority of patients with symptoms of bleeding per rectum in his study group. *Ambrose et al(5)* had 84.2% patients with the symptoms of bleeding per rectum. *Rahul P et al(6)* reported the symptom of bleeding per rectum in 96.8% of the patients and *Ali et al(7)* in 85% of the patients.

Saxena P et al(3) reported altered bowel habits in 28.12% of the patients while *Govardhan et al(4)* and *Ambrose et al(5)* found constipation in quite few of their patients in the study. *Rahul et al(6)* reported constipation in 33.3% of the patients and *Ali et al(7)* in 22.5% of the patients.

Our study was in accordance to the study done by *Saxena P et al(3)* who found painful defecation in 32.81% of the patients. *Govardhan et al(4)* also found painful defecation as a major symptom in his study. *Rahul et al(6)* reported painful defecation in 16.2% patients while *Ali et al(7)* in 12.5% of the patients

In the study done by *Saxena P et al(3)* discharge was found in 21.87% patients and pruritis in 12.5% of the patients while discharge and pruritis was found in majority of the patients in the study by *Ambrose et al(5)*. In the study by *Rahul et al(6)* pruritis was found in 5.2% of the patients and in the study by *Ali et al(7)* pruritis was found in 12.5% of the patients.

• POST OPERATIVE COMPLICATIONS, RECOVERY AND RECURRENCE

Haemorrhoids is one of the oldest diseases suffered by mankind, though most of the time not life threatening still it causes significant discomfort. Though different modalities of treatment are recommended for first & second-degree internal haemorrhoids, search for a simple, outpatient based, convenient cost-effective treatment still continues. The present study was done to compare the effectiveness of rubber band ligation, sclerotherapy and suture ligation in the treatment of 2nd & 3rd degree internal haemorrhoids.

Post-operative pain is a complication which is less in rubber band ligation as compared to injection sclerotherapy and suture ligation. Post-operative bleeding per rectum as a complication was equally seen in all the three procedures. Anal stenosis and anal incontinence are rare complications which was not seen with any of the procedures in our study.

Post-operative recovery rate was highest in the injection sclerotherapy group followed by rubber band ligation and suture ligation. Recurrence rate was highest in the injection sclerotherapy procedure.

CONCLUSION

In the present study all the three procedures were found to be very effective outpatient procedures for management of symptomatic 2nd and 3rd degree hemorrhoids. All had simple technique, did not need expertise or too much skill, no need of anaesthesia, no pre procedure elaborate work up, no expensive equipment, day care surgery, similar efficacy, equally effective in symptomatic relief, less time consuming, less post-operative complication, have early resumption to work & were cost effective.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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