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### Efficacy of band ligation in preventing post operative complications for grade III haemorrhoids

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#### Abstract

**Background:** Several factors have been attributed to the cause of haemorrhoids of which diet and lifestyle forms the predominant factors, in addition to increased intra-abdominal pressure. Haemorrhoids are treated surgically by haemorrhoidectomy although the comprehensive management involves diet and life style modification. This study was carried out to compare the efficacy of band ligation and standard haemorrhoidectomy in terms of post-operative complications

**Methods:** This randomized controlled trial was carried out among 50 patients, equally randomized into experiment (band ligation) and control (haemorrhoidectomy) groups. A structured interview schedule was used to obtain data regarding the complications during the follow up period at immediate, one month, three months and six months.

**Results:** On comparing the post-operative complications, during all the follow up periods, complications were higher among the haemorrhoidectomy group (100%) compared to band ligation group. The association was statistically significant. (P value < 0.0001).

**Conclusion:** Considering the non-invasiveness of the procedure and minimal complications, band ligation may be implemented as a standard protocol in the management of grade III haemorrhoids.

**Keywords:** Band ligation, constipation, bleeding in ANO, Haemorrhoids, haemorrhoidectomy

#### Introduction

Haemorrhoids is a common gastro intestinal problem resulting due to swollen blood vessels in and around the anus and rectum. Haemorrhoids causes blood loss during the passage of stools and is often associated with pain and itching. Haemorrhoids occur due to the swelling of the venous plexus situated around the rectum and anus. The veins undergo swelling and thereby they get stretched and thinned out. When the person passes stools the veins are irritated due to the nervous excitement. Haemorrhoids often recur in individuals, thereby significantly impacting the quality of life of the individual due to blood loss and impacting the daily activities of the affected individual.

Haemorrhoids is one of the leading diagnosis in the outpatient departments worldwide. It accounts for approximately 3 million cases in the United States, corresponding to 4.4% of the population. In India, studies have shown that about 50% of the population suffer from haemorrhoids at some point of time in their life and approximately 5% of the population suffer from haemorrhoids at any given point of time [1, 2]. Several factors have been attributed to the cause of haemorrhoids of which diet and lifestyle forms the predominant factors. In addition, various other contributing factors including elevated intra-abdominal pressure, especially in pregnancy and straining due to weak supporting muscles in the lower pelvic region are important factors. Any activity which put the pressure on the intra- abdominal system results in haemorrhoids. In tropical countries like in India, consuming a vegetarian diet which is loaded with high fibre usually protects from the haemorrhoids. Haemorrhoids are treated surgically by haemorrhoidectomy although the comprehensive management involves diet and life style modification. A permanent cure is achieved by invasive and non-invasive surgical procedures like haemorrhoidectomy, sclerotherapy, band ligation method, etc. Certain other procedures like infrared coagulation and Doppler guided artery ligation are also explored for the management of haemorrhoids. Haemorrhoidectomy has been standard treatment which has been in place a for a several decades. It involves the resection of the entire haemorrhoid plexus along with the tissue followed by ligation of the arteries [3]. Although it is a complete procedure, it is an invasive

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technique involving longer duration of hospital stay and is associated with serious complication including pain and bleeding. Several alternative non-invasive office procedures have been attempted to replace the haemorrhoidectomy including band ligation, sclerotherapy, and infrared coagulation. These procedures have improved the quality of life of the patient following the procedure and also minimised the recurrence rate and the duration of hospital stay. These office procedures have also documented significant success rates up to 80% and are therefore, effective and safe alternatives for haemorrhoidectomy [4].

### Objectives

This study was carried out to compare the efficacy of band ligation and standard haemorrhoidectomy in terms of post-operative complications.

### Methods

#### Study setting and participants

This study was carried out as a randomised controlled trial among patients who were diagnosed with grade three haemorrhoids in the outpatient clinic of Department of General Surgery of our tertiary teaching institution were taken up for a study. The study was carried out for a period of two years between October 2017 and 2019.

#### Sample size and sampling technique

All the patients who were admitted with grade III haemorrhoids during the study period were selected for this study. A total of 50 patients were selected. The participants were selected for the study by purposive sampling.

#### Selection criteria

All adult patients who presented with Grade III haemorrhoids were included in the study. Patients with other anorectal conditions like fistula, sinus, fissure, stricture or abscess were excluded. Presence of other co-morbid conditions like hypertension or bleeding diathesis were also excluded. History of previous surgery/ endoscopic treatment for haemorrhoids and presence of rectal prolapse were also excluded.

#### Ethical approval and informed consent

Approval was obtained from the Institutional Ethics Committee prior to the commencement of the study. Each participant was explained in detailed about the study and informed consent was obtained prior to the data collection.

#### Randomization

The study consisted of two groups- the experimental group which underwent rubber band ligation, and the control group which consisted standard treatment, haemorrhoidectomy. The participants were equally distributed to both the groups by randomisation. Randomisation was carried out using computer generated random numbers.

#### Data collection

The experimental group underwent Milligan- Morgan Method of band ligation while the control group underwent standard haemorrhoidectomy. Postoperatively, sitz bath, antibiotics, laxatives, analgesics, local applications are given. A structured interview schedule was used to collect data regarding the demographic characteristics, dietary factors and symptom complex. The participants were randomly taken up for rubber band ligation or haemorrhoidectomy. Post operatively, the

participants were followed up at interval of one, three and six months to evaluate the presence of complications, such as pain, bleeding and constipation.

### Data analysis

Data was entered and analysed using SPSS version 21 software. The prevalence of complications and symptomatology were expressed as percentages. The comparison between both the experimental and control group were carried out by chi square test. A  $p$  value  $< 0.05$  was considered statistically significant.

### Results

This study was carried out among 50 participants who were diagnosed with grade III haemorrhoids among which 25 underwent rubber band ligation and 25 underwent haemorrhoidectomy. Majority of the participants belong to the age group of 35 – 50 years (42%) followed by 55 - 60 years (30%). Majority of the participants were males (13%) (Table 1)

The post operative complications were assessed during immediate post- operative period, after one, three and six months. In the immediate post- operative period, pain and bleeding were the most common complaints (40%). Pain was predominantly present in the participant group who underwent band ligation (32%) while bleeding was the most common complication among haemorrhoidectomy group (20%). (Table 2) During the one month post operative period the most common complication observed was pain (28%) among those who underwent band ligation (36%) while among the haemorrhoidectomy group pain and bleeding were present in 40% of the participants. During the three months post operative period pain was the most common complication (14%) among both the groups. Among the participants who underwent haemorrhoidectomy pain, bleeding and constipation was present in 16%. At 6 months post operative period the most common complication was pain and constipation (12%). No complication were seen in the band ligation group (100%). (Table 2)

On comparing the post operative complications, during the immediate post operative period, complications were higher among the haemorrhoidectomy group (100%) compared to band ligation group (44%) the association was statistically significant. (Chi square =19.4,  $P$  value  $< 0.0001$ ). (Table 3)

During the one month post operative period complications were higher among the haemorrhoidectomy group (92%) compare to the band ligation group (36%).The association was statistically significant ( $P$  value  $< 0.0001$ ). (Table 4)

During the three months post operative period, the complications were present among the haemorrhoidectomy group (60%) compared to the band ligation group (4%). The association was statistically significant ( $P$  value  $< 0.0001$ ). (Table 5)

During the six months postoperative period there were absolutely no complications in the banding group (100%) compared to haemorrhoidectomy (68%). The observed difference was statistically significant ( $P$  value  $< 0.005$ ). (Table 6).

### Discussion

This study was carried out among 50 patients who were diagnosed with grade III haemorrhoids in the Outpatient Department of General Surgery in our tertiary care hospital. Majority of the participants were aged between 35 to 50 years and were males. In a study done by Gagloo M.A. majority of the participants were males (70%) and mean age of participants was 43.5 years, similar to our study [5]. Our study was also comparable in terms of the background characteristics with

study done by Brown SR. *et al* where the mean age of the participants 49 years and males predominantly participated in that study [6].

In this study, the complications following the intervention in both the groups were analysed immediately post operative period, at 1 month, 3 months, 6 months following the post operative period. It was observed that complications in the immediate post-operative period was higher in the haemorrhoidectomy group compared to the band ligation group. With 32% of the participants presenting with the pain in the immediate post operative period, 12% of the participants in the haemorrhoidectomy group presented with pain during the immediate post operative period the observed difference was statistically significant (p value < 0.001).

During the further follow up periods of 1 month, 3 months and 6 months the present study showed a significant drop in the incidence of complications in the band ligation group compared to haemorrhoidectomy group. At one month, the number of participants without any complications in the band ligation group was 64% as compare to 8% in the haemorrhoidectomy group. This percentage further increased to 96% in the band ligation group at 3 months follow up and 100% to 6 months follow up. However even at 6 months post-operative period only 68% of the participants in the haemorrhoidectomy group did not have any complication. The observed differences at each level of

follow up period was statistically significant between band ligation group and haemorrhoidectomy group. Our study results were comparable with studies done Izadpanah A *et al* were patients who underwent haemorrhoidectomy had increased rates of post operative pain compared to band ligation procedure [7]. In a study done by Nikam V *et al* where band ligation was used as a treatment of choice for grade II and III haemorrhoids, it was observed that success rate during the immediate post operative period was 21% for grade 3 haemorrhoids, similar to our study. [8] At longer duration of follow up at 6 weeks, it was observed that recurrence and complications were reduced to as low as 30%, similar to our study and after 9 weeks of follow up the success rate was found to be as high as 68.3% which is comparable our study. In comparative study done by Gagloo M.A. *et al* band ligation showed improvement in 78% of the cases for grade 3 haemorrhoids, which was similar to our study [5].

**Table 1:** Age and sex distribution

Age (in years)	Males N(%)	Females N(%)	Total
<35	5 (16.7)	7(35)	12(24)
35-50	10(33.3)	11(55)	21(42)
50-65	13(43.3)	2(10)	15(30)
>65	2(6.7)	0(0)	2(4)
Total	30(60)	20(40)	50 (100)

**Table 2:** Complications following the surgery among both the groups

S. No	Timeline	Complications	Banding		Haemorrhoidectomy	
			N	%	N	%
1	Immediate	No complications	14	56	0	0
		Pain	8	32	3	12
		Bleeding	0	0	5	20
		Pain and bleeding	3	12	17	68
2	1 month	No complications	16	64	2	8
		Pain	9	36	5	20
		Bleeding	0	0	2	8
		Pain and bleeding	0	0	10	40
		Pain, and bleeding constipation	0	0	6	24
3	3 months	No complications	24	96	10	40
		Pain	1	4	6	24
		Bleeding	0	0	3	12
		Pain and bleeding	0	0	2	8
		Pain, and bleeding constipation	0	0	4	16
4	6 months	No complications	25	100	17	68
		Constipation	0	0	1	4
		Pain and constipation	0	0	6	24
		Pain, and bleeding	0	0	1	4
		constipation				

**Table 3:** Comparison of complications between experiment and control groups- Immediate post-operative period

S. No	Group	N	Complications	
			Present	Absent
1	Band ligation	25	11(44)	14(56)
2	Hemorrhoidectomy	25	25(100)	0(0)
			Chi sq =19.4	P value =0.0001

**Table 4:** Comparison of complications between experiment and control groups- one-month postoperative period

S. No	Group	N	Complications	
			Present	Absent
1	Band ligation	25	9(36)	16(64)
2	Hemorrhoidectomy	25	23(92)	2(8)
			Chi sq =17.01	P value = 0.0001

**Table 5:** Comparison of complications between experiment and control groups- three months post-operative period

S. No	Group	N	Complications	
			Present	Absent
1	Band ligation	25	1(4)	24(96)
2	Hemorrhoidectomy	25	15(60)	10(40)
			Chi sq =18.01	P value = 0.0001

**Table 6:** Comparison of complications between experiment and control groups- 6 months post operative period

1	Band ligation	25	0(0)	25(100)
2	Hemorrhoidectomy	25	8(32)	17(68)
			Chi sq =9.5	P value =0.002

### Conclusion

Haemorrhoids, although a minor outpatient ailment causes huge socioeconomic burden and physiological complications. Since it is commonly seen among middle aged adults, it is important to consider a therapeutic management which is non-invasive, involving shorter hospital stay and speedy recovery. In comparison with the standard procedure which is haemorrhoidectomy, rubber band ligation has been proven to demonstrate better effectiveness and minimized recurrence rates, especially for grade III haemorrhoids. Although there are several other non-invasive techniques like infrared coagulation, etc, they are deemed suitable only for minor and grade I & II haemorrhoids. Our study has demonstrated the negligible incidence of post-operative complications, thereby providing scope for choosing rubber band ligation as a first line management of choice for up to grade III haemorrhoids.

### Declaration

Conflict of interest – nil

Funding- nil

Ethical approval – obtained

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