

## ORIGINAL ARTICLE

## COMPARISON BETWEEN INJECTION SCLEROTHERAPY AND RUBBER BAND LIGATION FOR FIRST AND SECOND DEGREE HAEMORRHOIDS

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**Background:** For first and second degree haemorrhoids, the preferred outpatient treatments are injection sclerotherapy or rubber band ligation of the haemorrhoids. The aims of this study were to compare postoperative pain, postoperative and delayed bleeding after injection sclerotherapy and rubber band ligation of first and second degree haemorrhoids. **Methods:** From January 2016 to January 2017, 60 patients were alternately allocated to undergo either injection sclerotherapy (group A) or rubber band ligation of the haemorrhoids (group B). Pain sores, and frequency of early and delayed per-rectal bleeding were compared between the two groups. **Results:** Postoperative pain was present in 9 patients (30%) in sclerotherapy group and 15 patients (50%) in rubber band ligation group. Per-rectal bleeding was more common in rubber band ligation group (56% vs 26%;  $p=0.018$ ). Delayed bleeding was more common in rubber band ligation group (30% vs. 3%;  $p=0.0006$ ). **Conclusion:** Injection sclerotherapy of first and second degree haemorrhoids is associated with fewer complaints of pain and per-rectal bleeding, both early and delayed.

**Keywords:** Haemorrhoids, sclerotherapy, rubber band ligation, pain, bleeding

Pak J Physiol 2017;13(2):15–8

## INTRODUCTION

The word haemorrhoid is derived from Greek (haema=blood, rhos=flow) adjective Haemorrhoids.<sup>1</sup> The deterioration of the supporting tissue to the vascular cushions in the anal canal results in venous distension, erosion bleeding and thrombosis of these cushions: a condition a commonly call as hemorrhoids.<sup>2</sup> There are four grades of haemorrhoids according to degree of prolapsed. Surgical options aiming to treat haemorrhoids include clot removal, rubber band ligation (RBL), cryosurgery, injection sclerotherapy, infrared and bipolar electrocoagulation probe (BICAP) coagulations, conventional haemorrhoidectomy and stapled hemorrhoidopexy.<sup>3,4</sup>

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. About 77% of the time the haemorrhoids do not return.<sup>5,6</sup> 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.<sup>7</sup>

Injection sclerotherapy and band ligation are effective therapies to treat first and second degree haemorrhoids with success rates of 77% and 86% respectively.<sup>6,7</sup> Rubber band ligation is recommended as the initial mode of therapy for first to third degree hemorrhoids.<sup>1,2</sup> Although formal haemorrhoidectomy should show better response rates, it is associated with more complications and pain than rubber band ligation, thus should be reserved for patients who fail to respond to rubber band ligation.<sup>8,9</sup>

Various studies have been conducted on this aspect in west and in India but unfortunately, very limited work has been done on this topic in local setup in last 5 years.<sup>10-12</sup> This study aimed to find which procedure among sclerotherapy and rubber band ligation is a better option for treatment of first and second degree haemorrhoids.

## METHODOLOGY

It was a quasi experimental study. The study was conducted at Department of Surgery, Abbas Institute of Medical Sciences Muzaffarabad. The study was carried out over one year duration, from January 2016 to January 2017. There were a total of 60 cases, 30 patients were enrolled in the injection sclerotherapy group and 30 in the band ligation group. Patients of first and second degree haemorrhoids irrespective of age and gender were included in the study and those who had received any prior treatment for first and second degree haemorrhoids, unwilling patients, patients of third and fourth degree haemorrhoids and patients taking analgesics in any form for other illnesses like arthritis were excluded from the study. After approval from Hospital Ethical Committee, a well-understood informed consent was taken from each patient recruited in the study. Patient's profile including name, age and gender were recorded on pre-tested proforma. Detailed history and physical examinations were carried out on each patient and were recorded on the proforma. Digital rectal examination and proctoscopy findings were noted and diagnosis of first and second degree haemorrhoids were made and recorded on the proforma. Blood complete picture and urine examination were done for each patient. Patients were divided into two groups at random; Group A underwent injection sclerotherapy,

and Group B had rubber band ligation. Both procedures were performed in the outdoor clinics.

In injection sclerotherapy, 3 ml of mixed solution of Ethanalamine+almond oil was injected in the perivascular space around each haemorrhoid. In rubber band ligation, one rubber band was applied at the base of each haemorrhoid. No anaesthesia or pain killer were given during the procedure. Patients were retained in outpatient department for 1 hour and were given proforma for pain scoring after 1 hour. Patient was sent home after prescribing Co-trimoxazole 500 mg twice daily for 5 days, Metronidazole 400 mg thrice daily for 5 days and Povidone-iodine sits bath twice daily for 5 days.

No strenuous exercise or weight lifting was allowed for 7 days during postoperative period. Patient was re-examined after 24 hours for presence or absence of visible postoperative bleeding. Patients were advised to report on 7<sup>th</sup> postoperative day for delayed bleeding.

Data was converted into variables and entered into SPSS-13. Mean and standard deviation were calculated for age. Frequencies were calculated for postoperative pain, bleeding, and delayed bleeding after injection sclerotherapy or band ligation. Chi-square test was used to compare the frequencies of postoperative pain, bleeding, and delayed bleeding for Group A and B, and  $p \leq 0.05$  was considered statistically significant.

## RESULTS

The mean age of the participants in this study was  $40.6 \pm 9$  years. The youngest patient was 21 years old while the oldest was 62 years old. In Group A, the mean age was  $40.4 \pm 9.4$  years and in Group B, the mean age was  $40.9 \pm 9.2$  years. The independent samples *t*-test showed no statistically significant differences between the two groups ( $p=0.847$ ). Among all 60 participants, 36 (60%) were males while the rest 24 (40%) were female patients. In group A there were 19 males (63%) and 11 females (37%) while in group B there were 17 males (56%) and 13 females (44%). (Table-1).

**Table-1: Comparison of age, gender and haemoglobin of patients in two groups (Mean±SD)**

Characteristics	Group A	Group B
Age, (Year)	40.4±9.4	40.9±9.2
Male	19 (63%)	17 (56%)
Female	11 (37%)	13 (44%)
Haemoglobin, g/dL	11.2±1.0*	11.9±1.1*

\* $p=0.01$

Among all the participants, 15 (25%) had complaints of per rectal bleeding without mention of prolapsed while 45 (75%) has bleeding accompanied by complaints of something coming out of the anus. On proctoscopic examination, 14 patients (23%) had first degree haemorrhoids while 46 patients (77%) had second degree haemorrhoids (Table-2).

**Table-2: Frequency of 1<sup>st</sup> and 2<sup>nd</sup> degree haemorrhoids in patients**

Proctoscopic Findings	N	%
1 <sup>st</sup> degree haemorrhoids	14	23
2 <sup>nd</sup> degree haemorrhoids	46	77

Postoperative pain was present in 9 patients (30%) in group A (injection sclerotherapy) and was complained of by 15 patients (50%) in group B (Rubber Band Ligation). The frequency of complaints on Wong-Baker pain rating score is shown in Table-3.

**Table-3: The grading of post operative pain according to the Wong Baker scale [n (%)]**

	Group A	Group B
No Pain	21 (70)	15 (50)
Pain present but does not limit activities	7 (23.33)	5 (16.66)
Mild pain, annoying	0 (0)	6 (20.00)
Can do most of the activities, rest pain	1 (3.33)	1 (3.33)
Nagging pain, uncomfortable, troublesome	0 (0)	2 (6.66)
Intense, dreadful, horrible pain	1 (3.33)	1 (3.33)

In group A, 8 patients (26%) complained of per-rectal bleeding in the first 24 hours after sclerotherapy procedure while in group B, 17 patients (56%) had the same complaint. There was a statistically significant difference between the frequency of postoperative bleeding between the two groups ( $p=0.018$ ; OR 1.96 [95% CI 1.05–3.67]), (Table-4).

**Table-4: Frequency of postoperative rectal bleeding**

Procedure	Bleeding	No Bleeding
Sclerotherapy	8	22
Band Ligation	17	13

Delayed bleeding, occurring from 24 hours post-procedure to 7 days post-procedure, was present in 1 patient (3%) in group A and 9 patients (30%) in group B. The difference in frequency of delayed bleeding between the two groups was statistically significant ( $p=0.006$ ; OR 5.8, 95% CI 0.89–37.7).

## DISCUSSION

The present study aimed to find out the frequency of early complaints of patients undergoing sclerotherapy or rubber band ligation of first or second degree haemorrhoids. Patients undergoing rubber band ligation more frequently complained of post-procedure pain and bleeding as compared to patients who underwent injection sclerotherapy of haemorrhoids. Haemorrhoids can occur in all ages, gender and socioeconomic status.

Our study showed high male proportion. Shamim *et al*<sup>12</sup> from Karachi also showed male predominance of 74.88%. Various other authors in our population show male predominance in haemorrhoid patients.<sup>12-14</sup> However, western literature showed an equal or mixed male or female predominance pattern in haemorrhoid disease.<sup>15-17</sup> This could be due to different hospital setup, social, cultural, and food values. Haemorrhoids are a common problem in general

population with an estimated 5–30% of adults suffering from.<sup>18</sup> It is, hence, imperative that evaluation of the early side-effect profile of the two most common outpatient procedures for the management of first and second degree haemorrhoids —injection sclerotherapy and rubber band ligation, be evaluated in a local cohort of patients.

Studies on direct quantitative comparison of frequency of pain between patients undergoing sclerotherapy and band ligation of 1<sup>st</sup> and 2<sup>nd</sup> degree haemorrhoids are rare. The present study compared the results of sclerotherapy with band ligation for which direct comparison was possible. The results of this study indicate that pain to some degree is experienced during the first postoperative hour by half of the patients undergoing rubber band ligation of haemorrhoids. In most of the patients experiencing pain in this group, the degree of discomfort varied from mild to moderate, and only one patient experienced intense pain and required analgesics. This observed frequency of pain is in conformation with the findings of Watson *et al*<sup>19</sup> who observed that at 4 hours after banding, 55% patients complained of some degree of pain. Although the frequency is significantly higher than that seen in local series of patients undergoing banding which have noted 6–20% patients complaining of pain, most of these studies, unlike this study, did not include discomfort felt by the patient while noting the frequency of pain.<sup>13,20,21</sup> This study employed a 1–10 pain scoring scale and zero for no pain. For comparative purposes every patient scoring more than zero was summarily classified as having pain, hence, the larger number of patients complaining of discomfort and pain.

When the frequency of patients complaining of pain following the procedure was compared among the two groups, there was a significant difference in the number of patients having this complaint (50% in RBL, and 30% in sclerotherapy). Hence, sclerotherapy less frequently causes pain and discomfort in the first hour following the procedure when compared with rubber band ligation.

Early postoperative per-rectal bleeding, within the first 24 hours following the procedure was noted in 56% patients in the group which underwent rubber band ligation. This conforms to Watson *et al*<sup>19</sup> who found that 65% patients complained of per-rectal bleeding on the day following operation. In the case series by Bhutta *et al*<sup>20</sup> and Dilawaiz *et al*<sup>21</sup> only 6–12% patients complained of per-rectal bleeding immediately following the procedure. Those studies also carried out banding as an outpatient procedure, however, limitations in follow-up of the patients probably accounted for the fewer patients who came back with complaints of per-rectal bleeding. As compared to the frequency of patients in the rubber band ligation group,

significantly fewer patients undergoing sclerotherapy had complaints of early bleeding. Only 26% patients, almost a half of the patients in the RBL group experiencing per-rectal bleeding, complained of such problem. Lesser instrumentation and damage to the mucosa of the upper anal canal during the submucosal injection of sclerosant<sup>22</sup> probably accounts for the lesser frequency of early bleeding seen in patients undergoing injection sclerotherapy.

A similar pattern was also seen for delayed bleeding, defined in this study as bleeding occurring from 24 hours till one week following the procedure. In the injection sclerotherapy group, only 1 patient complained of per-rectal bleeding after a week while in the rubber band ligation group, 3 patients still had these complaints. According to Chaleoykitti<sup>23</sup> these patients would be better benefited by applications of multiple instead of single bands as this is known to influence outcome in banding procedures. A recent study from Faisalabad<sup>24</sup> showed that 60% of patients developed mild to moderate bleeding in first postoperative week. Bernal *et al*<sup>17</sup> showed that 32% of the patients referred pain after ligation and 13.81% of cases were operated due to persistent rectal bleeding or haemorrhoidal prolapse.<sup>17</sup>

As the results of this study show, rubber band ligation is associated with more frequent complaints of pain and both early and delayed bleeding. This has been shown in meta-analyses, comparing various modes of treatment of haemorrhoids<sup>25,26</sup>, however, this procedure is preferred over sclerotherapy because it provides a more definitive and long lasting treatment of haemorrhoids and without the risks of surgery such as haemorrhoidectomy or stapled hemorrhoidopexy.<sup>18</sup> Greca *et al*<sup>27</sup> showed that 15% patients required re-treatment following rubber band injection sclerotherapy as compared to only 5% patients who underwent rubber band ligation. Other authors have also concluded that despite a higher frequency of post-operative complications, but owing to its significantly better long term results, rubber band ligation is preferred over injection sclerotherapy for outpatient treatment of first and second degree hemorrhoids.<sup>28</sup>

## CONCLUSION

Injection sclerotherapy of first and second degree haemorrhoids is associated with fewer complaints of pain and per-rectal bleeding, both early and delayed. Need exists for exploring the long-term outcome of these procedures in local cohorts of patients so that the risk of short-term complications can be weighed against long-term benefit from these interventions.

## LIMITATIONS

The results from this study do not conform well to literature from Pakistan and this difference should be

further explored using standardized questionnaires and study at multiple centres simultaneously.

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Received: 28 May 2017

Reviewed: 12 Jun 2017

Accepted: 18 Jun 2017