

# Complication of Rubber Band Ligation in Second and Third Degree Haemorrhoids

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## ABSTRACT

**Introduction:** Haemorrhoids or piles are symptomatic anal cushions. They can be classified as 1<sup>st</sup> degree (only bleed), 2<sup>nd</sup> degree (prolapse but reduce automatically), 3<sup>rd</sup> degree (prolapse and requires manual reduction) and 4<sup>th</sup> degree (permanent prolapsed). Haemorrhoids can be managed either conservatively by regular sitz bath, dietary modifications and medications etc., or by minimal invasive procedures like Rubber Band Ligation (RBL), excising and whitehead haemorrhoidectomy. RBL is the most common non surgical and outpatient modality performed, as it is a safe, effective and easier to execute, it is being advised as an Outpatient Department (OPD) procedure.

**Aim:** To study the complications of RBL in 2<sup>nd</sup> and 3<sup>rd</sup> degree haemorrhoids.

**Materials and Methods:** The study was conducted as a prospective interventional study at Department of Surgery. The study population

consisted of 50 cases of second and third degree haemorrhoids, who underwent RBL as a outpatient procedure. Post-operative complication were studied. Statistical analysis was done using descriptive and inferential statistics through chi-square test. SPSS software 24.0 version and Graph Pad Prism 7.0 version were used in the analysis. Level of significance was considered as less than 0.05.

**Results:** Total 84% had 2<sup>nd</sup> degree haemorrhoids and 16% had 3<sup>rd</sup> degree haemorrhoids. The study showed an overall higher success rate (94%) of RBL procedure for 2<sup>nd</sup> and 3<sup>rd</sup> degree haemorrhoids; recurrence rate after RBL was 6% (3 patients), when followed-up for a period of 6 weeks The most common complication was pain (62%) followed by urinary retention (8%). The post RBL pain was significantly higher in the 2<sup>nd</sup> degree haemorrhoids.

**Conclusion:** RBL is an effective, safe outpatient procedure but the complications are more in 3<sup>rd</sup> degree when compared to 2<sup>nd</sup> degree haemorrhoids.

**Keywords:** Haemorrhoidectomy, Pelvic infection, Post RBL bleeding, Urinary retention

## INTRODUCTION

Haemorrhoids or piles are symptomatic anal cushions [1]. Degree of haemorrhoids can be classified as 1<sup>st</sup> degree (only bleed), 2<sup>nd</sup> degree (prolapse but reduce automatically), 3<sup>rd</sup> degree (prolapse and requires manual reduction) and 4<sup>th</sup> degree (permanent prolapsed). The approach in treatment of haemorrhoids has significantly changed in the past few decades [2].

Haemorrhoids can be managed either conservatively by regular sitz bath, dietary modifications and medications etc., or by minimal invasive procedures like RBL, sclerotherapy, cryotherapy, diathermy using bipolar, coagulation by Infrared rays or Laser, dilatation of anal region, ulroid and treatment with diode laser [3].

RBL is the most common non surgical and outpatient modality performed. As it is a safe, effective and easier to execute, it is being advised as an OPD procedure [3]. RBL was first described by Blaisdell in 1954. It was popularised by Barron in 1963 and now considered to be the most popular outpatient treatment for symptomatic internal haemorrhoids. RBL has low complication and is effective when compared to operative procedure. Recurrent internal haemorrhoids are also treated using RBL [4].

RBL is the most commonly used feasible, minimally invasive procedure, representing a balance between efficacy, pain and potential of complications [5] with success rate from 69 percent to 97 percent irrespective of the problems that are associated with surgical procedures [6]. The minor complications of RBL commonly consists of blood loss, pain, vasovagal reflex, slipping of the bands, urinary retention and long standing ulcers (vertical) [7]. Marshman D et al., found that the complication rate of RBL increases when multiple ligations are performed in one session [8]. The life threatening complication of RBL is pelvic sepsis.

At present there are two scenarios in context to RBL; one scenario shows minor complications whereas the other shows life threatening

complications. Hence, the present study was conducted to compare both major as well as minor complications of RBL in Indian population having second and third degree haemorrhoids simultaneously.

## MATERIALS AND METHODS

This prospective interventional study was conducted after the approval of the Ethical Committee (DMIMS (DU)/IEC/2017-18/6646), in the Department of Surgery, Jawaharlal Nehru Medical College, Deemed University, Sawangi (Meghe) from September 2017 to July 2019. Written consents were obtained from all the patients.

### Sample Size Calculation [9]

$$n = \frac{4pq}{L^2} = \frac{4 \times 88.6 \times 13.4}{9.959^2} = 46.80 \text{ (Thus, 50 patients, taken in this study)}$$

Where,

P=overall success rate (88.6%);

L=Allowable error (11.5% of p=9.959);

q=100-p (13.4)

The sample size was 50. All patients of 2<sup>nd</sup> and 3<sup>rd</sup> degree internal haemorrhoids were included in the study. Patients with 1<sup>st</sup> and 4<sup>th</sup> degree haemorrhoids, thrombosed haemorrhoids, inflammatory bowel disease, blood dyscrasia, haemorrhoids with rectal prolapsed and infected haemorrhoids were excluded.

Patients presenting with complaint of bleeding per rectum were thoroughly evaluated by complete physical examination, including per rectal examination and proctoscopy. The possible complications were explained and RBL was performed after taking informed consent. The base of the haemorrhoids was clearly visualised and band applied above the dentate line.

The details of procedure included proctoscopy to which pen torch was attached to provide illumination thereby displaying

haemorrhoids. Initially, the instrument was washed and treated with 2% glutaraldehyde solution for 20 minutes before using in each patient [10]. Each haemorrhoid trunk was then caught above the dentate line with a pre-loaded baron band ligator.

After procedure, patient was kept under observation for 6 hours for complaint of pain, bleeding and other complications like vasovagal reflex, urinary retention, slippage of band. Patient was also observed for pelvic infection. Patient was followed-up till 6 weeks for success and recurrence [9]. Pain was measured using Visual Analogue Scale (VAS). The minimum score was 0 and maximum score 6 in the study- 0: denoted no pain corresponding to VAS of 0 mm; 2-4: Mild pain corresponding to VAS of 1-40 mm; 6: Moderate pain corresponding to VAS of 41-60 mm; 8: Severe pain corresponding to VAS of 61-80 mm; and 10: Very severe Pain corresponding to VAS of 81-100 mm. Patients with severe and very severe pain were not taken into the study.

Success in a patient was defined as patient being completely asymptomatic for 6 weeks after the procedure with no evidence of haemorrhoids noted on proctoscopy whereas, recurrence was defined as symptomatic patients with evidence of haemorrhoids on proctoscopy 6 weeks after rubber band application [9].

The event of bleeding was controlled by using appropriate medicines Tranexamic acid 10 mg/kg body weight. Pain was controlled with appropriate medicines like Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) like Paracetamol 500 mg BD.

## STATISTICAL ANALYSIS

Statistical analysis was done by using descriptive and inferential statistics through chi-square test. SPSS software 24.0 version and Graph Pad Prism 7.0 version was used in the analysis. Level of significance was considered as less than 0.05.

## RESULTS

Maximum number of patients was seen between the age group of 41 to 50 years [Table/Fig-1]. Out of 50 patients 35 were males and 15 were females. Male:Female ratio was 2.3:1. Out of the 50 patients, 84% had 2<sup>nd</sup> degree haemorrhoids and 16% had 3<sup>rd</sup> degree haemorrhoids.

| Age group (Year) | No of patients           | Percentage |
|------------------|--------------------------|------------|
| ≤20              | 5                        | 10         |
| 21-30            | 6                        | 12         |
| 31-40            | 9                        | 18         |
| 41-50            | 12                       | 24         |
| 51-60            | 8                        | 16         |
| 61-70            | 6                        | 12         |
| 71-80            | 3                        | 6          |
| >80              | 1                        | 2          |
| Total            | 50                       | 100        |
| Mean±SD          | 45.50±17.71(16-86 years) |            |

[Table/Fig-1]: Age wise distribution of patients.  
SD: Standard deviation

## Complications in Patients after RBL

### a. Post RBL Bleeding

Out of 50 patients, bleeding was present in three patients at 6 weeks post-procedure. Out of the three patients, one (2%) patient had 2<sup>nd</sup> degree haemorrhoids and two (4%) patients had 3<sup>rd</sup> degree haemorrhoids ( $\chi^2=6.09$  and p-value=0.01).

### b. Pain after RBL

Pain after RBL was assessed by Visual Analogue Scale at 6 weeks post-procedure and given an appropriate scoring. The minimum

score was 0 and maximum score 6 [Table/Fig-2]. Post RBL the patients experience either no pain, mild pain or moderate pain.

| Pain score | Degree of haemorrhoids |                        | $\chi^2$ -value | p-value |
|------------|------------------------|------------------------|-----------------|---------|
|            | 2 <sup>nd</sup> degree | 3 <sup>rd</sup> degree |                 |         |
| 0          | 18 (36%)               | 1 (2%)                 | 10.52           | 0.014   |
| 2          | 1 (2%)                 | 1 (2%)                 |                 |         |
| 4          | 16 (32%)               | 1 (2%)                 |                 |         |
| 6          | 7 (14%)                | 5 (10%)                |                 |         |
| Total      | 42 (84%)               | 8 (16%)                |                 |         |

[Table/Fig-2]: Pain score according to degree of haemorrhoids.

## Other Complications after RBL

The most common complication seen was urinary retention and the incidence was same in patients with both 2<sup>nd</sup> and 3<sup>rd</sup> degree haemorrhoids. Out of 50 patients, none of the patients suffered from any pelvic infection [Table/Fig-3].

| Other complications |         | Degree of haemorrhoids |                        | $\chi^2$ -value | p-value |
|---------------------|---------|------------------------|------------------------|-----------------|---------|
|                     |         | 2 <sup>nd</sup> degree | 3 <sup>rd</sup> degree |                 |         |
| Urinary retention   | Present | 2 (4%)                 | 2 (4%)                 | 3.73            | 0.053   |
|                     | Absent  | 40 (80%)               | 6 (12%)                |                 |         |
| Slippage of band    | Present | 0 (0%)                 | 1 (2%)                 | -               | -       |
|                     | Absent  | 42 (84%)               | 7 (14%)                |                 |         |
| Vasovagal reflex    | Present | 0 (0%)                 | 0 (0%)                 | -               | -       |
|                     | Absent  | 42 (84%)               | 8 (16%)                |                 |         |

[Table/Fig-3]: Other complications according to degree of haemorrhoids.  
NS: Non-significant

## Treatment Modalities to Manage Complications

Most of the complications post RBL were managed conservatively, either by NSAID's like Paracetamol 500 mg BD, Tranexamic acid 10 mg/kg body weight given twice daily for 3 days and then SOS or by temporary Foley's catheterisation. Re-Banding was required only in 2% of the patients [Table/Fig-4].

| Treatment modalities   |              | Number of patients |
|--|--------------|--------------------|
| Medical Management for bleeding (Tranexamic acid 10 mg/kg body weight given twice daily for 3 days and then SOS) | Required     | 3 (6%)             |
|  | Not required | 47 (94%)           |
| Pain killer (NSAIDS: Paracetamol 500 mg BD)  | Present      | 11 (22%)           |
|  | Absent       | 39(78%)            |
| Catheterisation for urinary retention  | Present      | 4 (8%)             |
|  | Absent       | 46 (92%)           |
| Re-banding   | Present      | 1 (2%)             |
|  | Absent       | 49 (98%)           |

[Table/Fig-4]: Treatment modalities to manage complications.

## Outcome

Urinary retention is the inability to completely or partially empty the bladder and was recorded in 1<sup>st</sup> week after procedure. Vasovagal reflex is defined as sudden drop in the heart rate and blood pressure leading to fainting and was observed during the procedure. Slippage of band was assessed at 6 weeks post-procedure. Out of 50 patients, success rate of RBL was 94% (47 patients) and recurrence rate after RBL was 6% (3 patients), when followed-up for a period of 6 weeks.

## DISCUSSION

Various post RBL complication encountered by the patients in 2<sup>nd</sup> degree and 3<sup>rd</sup> degree haemorrhoids were studied. The most common complication experienced by the study population was pain (62%) which is consistent with many other studies as mentioned in [Table/Fig-5] [5,14-18]. Urinary retention (8%) is the second most common co complication experienced by the study

population as shown in [Table/Fig-5] [9,18]. There were no cases showing life threatening complications like vasovagal reflex [3,19] and pelvic infections [3] in the study as well as some other studies mentioned in [Table/Fig-5] [2,3,5,9,11-20].

|                                | Total patients | Post RBL bleed | Post RBL pain | Urinary retention | Slip-page of band | Vasovagal reflex | Pelvic infection |
|--------------------------------|----------------|----------------|---------------|-------------------|-------------------|------------------|------------------|
| Present study                  | 50             | 6%             | 62%           | 8%                | 2%                | 0%               | 0%               |
| El Nakeeb AM et al., [11]      | 750            | 4.13%          | -             | -                 | -                 | -                | -                |
| Aram FO [3]                    | 890            | -              | -             | -                 | -                 | 0.6%             | 0.1%             |
| Forlini A et al., [12]         | 206            | 2.4%           | -             | -                 | -                 | -                | -                |
| Hadi A et al., [13]            | 105            | 3.8%           | -             | -                 | -                 | -                | -                |
| Nikam V et al., [9]            | 60             | 16.6%          | -             | 6.7%              | -                 | -                | -                |
| Azizi R et al., [14]           | 60             | -              | 62%           | -                 | -                 | -                | -                |
| Watson NFS et al., [15]        | 183            | -              | 90%           | -                 | -                 | -                | -                |
| Hardwick RH and Durdey P, [16] | 52             | -              | 81%           | -                 | -                 | -                | -                |
| Kotzampassi K [5]              | 87             | -              | 31.2%         | -                 | -                 | -                | -                |
| Kumar N et al., [17]           | 98             | -              | 24.5%         | -                 | -                 | -                | -                |
| Khaliq T et al., [18]          | 56             | -              | 13%           | -                 | -                 | -                | -                |
| Chandra B et al., [19]         | 100            | -              | -             | 5%                | -                 | 0%               | -                |
| Ratan R and Rao PP, [2]        | 100            | -              | -             | -                 | 0%                | -                | -                |
| Bat L et al., [20]             | 512            | -              | -             | -                 | 1%                | -                | -                |

**[Table/Fig-5]:** Complications of Rubber Band Ligation seen in various studies [2,3,5,9,11-20].

Like many other studies [2,20], the present study also showed a higher success rate (94%) of RBL procedure for 2<sup>nd</sup> and 3<sup>rd</sup> degree haemorrhoids [Table/Fig-2] and lower recurrence (6%) of complications of RBL procedure for 2<sup>nd</sup> and 3<sup>rd</sup> degree haemorrhoids [Table/Fig-6] [2,20].

|                         | Success rate | Recurrence |
|-------------------------|--------------|------------|
| Present study           | 94%          | 6%         |
| Ratan R and Rao PP, [2] | 91%          | 9%         |
| Bat L et al., [20]      | 89%          | 11%        |

**[Table/Fig-6]:** Comparison of success rate of Rubber band ligation and recurrence of complications of Rubber band ligation [2,20].

## Limitation(s)

The follow-up period in this study was 6 weeks. The study was a single centre study and the sample size was less, hence might have an impact on the outcome of study.

## CONCLUSION(S)

Post RBL bleeding was more in third degree haemorrhoids. The success rate in this study was 94% at six weeks. To conclude, RBL is safe, outpatient procedure in second and third degree haemorrhoids with low rate of recurrence.

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