Rubber Band Ligation as Effective Treatment Modality in Second Degree Haemorrhoids

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Abstract:
In the present modern age, the majority of people are suffering from haemorrhoids. Mithyaahara- Vihara (faulty food habits and improper sedentary lifestyle) has increased its incidence. Haemorrhoidectomy either open or closed is an invasive procedure for the treatment of hemorrhoids. A noninvasive measure for the treatment of second degree haemorrhoids is Rubber Band Ligation. In this procedure hemorrhoids are tied off at its base with rubber bands to cutting off blood flow resulting in necrosis of the haemorrhoidal stump. It relies on the principle of mucosal fixation. In the present clinical study Rubber Band, Ligation was done in randomly selected 15 patients of either sex with Second degree haemorrhoids. The duration of the trial was of 15 days, with a follow-up of 4 weeks. The total effect of therapy was assessed based on Clinical and Postoperative criteria. The significance of the treatment was determined by Statistical analysis. The significance level was p<0.05 for all values. Rubber Band Ligation has the advantages of no requirement of anesthesia, minimal hospitalization, and less postoperative pain. Hence after clinical study, it can be concluded that Rubber Band Ligation is a timely accepted effective modality to treat symptomatic second degree haemorrhoids. Through a non-invasive approach, it cures second degree haemorrhoids without disturbing normal haemorrhoidal cushion.

Key words: Rubber band ligation, Haemorrhoids, Non-Invasive.

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Introduction:

Haemorrhoids are dilated veins within the anal canal in subepithelial region formed by the radicals of the superior, middle and inferior rectal veins. [8] Rubber band ligation is a procedure in which the hemorrhoids are tied off at its base with tight rubber bands. These bands cut off the blood supply of the pile masses resulting in necrosis and ultimately fall off of the same resulting in a less painful procedure. Dilated plexus of superior haemorrhoidal vein in relation to anal canal is called as haemorrhoids. [9] Internal haemorrhoid is within anal canal and internal to anal orifice. It usually commences at anorectal ring and ends at the dentate line. [10] There are 4 degrees of hameorrhoids. In second degree haemorrhoid pile massed prolapse and reduces spontaneously in anal canal. There are several types of treatment available for internal haemorrhoids ex-Injection treatment, Rubber band ligations, Manual dilatation and operative treatment (Formal Haemorrhoidectomy). [11] Rubber band ligation is comparatively noninvasive measure for haemorrhoidal treatment. In 1958, Blaisdell originally proposed and practiced this method. The principal of the method is to apply a rubber band ligature through proctoscope to the mucosal covered part of the internal haemorrhoid. Over period of 7 to 10 days this elastic band gradually cuts through the tissue and the pile sloughs off spontaneously. [12] No anaesthetic is required for rubber band ligation. Barron (1963) claimed that it was a virtually painless maneuver as a rule. [13]

Materials and Methods:
Written informed consent was taken from randomly selected 15 patients of either sex with internal second degree haemorrhoids from opd. Patients excluded from the study were those not willing to undergo a trial or not ready to give informed consent, age less than 20 and more than 65 years, having uncontrolled systemic disorders like–diabetes mellitus, uncontrolled hypertension, ischaemic heart diseases, severe anemia, tuberculosis, human immuno deficiency virus infection & acquired immune deficiency syndrome and hepatitis B/C positive, ulcerative colitis, pregnancy, with any type of endocrinal disorders with evidence of malignancy. Clinical findings in each case were recorded in properly designed proforma. The study design was open, randomized, and prospective. The duration of the trial was 15 days with a follow up of 4 weeks.
Technique of Rubber Band Ligation in Haemorrhoids:
As per routine bowel preparation along with the local operative field Preoperative measures were done by cleaning, shaving, and painting. The procedure was done without anesthesia. In the Lithotomy position after draping for the revelation of Haemorrhoidal masses, Proctoscope with an external light source was passed through the anal canal. Two rubber bands were loaded on the inner tube. After loading of rubber bands loading part removed and the outer tube of the ligating part was worn over the inner tube exposing the tip of the inner tube protruded out. Thereafter, the handling part was further connected with a tube of the suction machine. The tip of the inner tube of the rubber band ligation gun was placed directly over the mucosal part of the prominent pile mass. Special care was taken to place a ligator at least 1 cm. above the pectinate line. Thereafter, by using the right thumb the hole of the handling part was occluded and pressure with foot suction applied. At the suction pressure of about 25mm, the thumb was removed from the hole of the ligation part. Due to the release of suction pressure, the sliding of the outer tube of the handling part occurred. It caused the sucking of internal haemorrhoidal mass in the inner tube and slipping of rubber bands over the base of internal haemorrhoids. The resulting mass of strangulated tissue was about 1cm in diameter and the colour of the pile mass changed from pink to dark violet. The same procedure was done for other pile masses. After removal of the proctoscope a sterile pad was given [14]. As shown in the Fig. 1, Fig.2, Fig.3 and Fig.4 technique of rubber band ligation has been applied on the patient.

Table-1: Effect of Rubber band ligation on Clinical Criterions -

<table>
<thead>
<tr>
<th>S. N</th>
<th>Parameters</th>
<th>n</th>
<th>Mean</th>
<th>D</th>
<th>%ag e Relief</th>
<th>SD ±</th>
<th>SE±</th>
<th>t</th>
<th>p</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Proctorrhagia</td>
<td>15</td>
<td>1.8</td>
<td>0.4</td>
<td>0.1</td>
<td>0.6</td>
<td>0.1</td>
<td>8.57</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>2.</td>
<td>Prolapse</td>
<td>15</td>
<td>2.4</td>
<td>0.8</td>
<td>0.1</td>
<td>0.2</td>
<td>0.0</td>
<td>31.</td>
<td>&lt;0.001</td>
<td>HS</td>
</tr>
<tr>
<td>3.</td>
<td>Pain</td>
<td>15</td>
<td>0.2</td>
<td>0.0</td>
<td>0.20</td>
<td>0.4</td>
<td>0.1</td>
<td>1.8</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>4.</td>
<td>Discharge per anum</td>
<td>15</td>
<td>0.8</td>
<td>0.4</td>
<td>0.33</td>
<td>0.4</td>
<td>0.1</td>
<td>2.6</td>
<td>&lt;0.05</td>
<td>S</td>
</tr>
<tr>
<td>5.</td>
<td>Heaviness in Ano-rectal region</td>
<td>15</td>
<td>0.7</td>
<td>0.3</td>
<td>0.40</td>
<td>0.5</td>
<td>0.1</td>
<td>3.0</td>
<td>&gt;0.001</td>
<td>MS</td>
</tr>
</tbody>
</table>

In above shown table n is the representative of no. of sample, BT – Before Treatment, AT – After treatment, d – difference, SD – Standard Deviation, SE- Standard Error, t - calculated difference represented in units of standard error, p - estimated probability of rejecting the null hypothesis, HS – Highly significant, NS – nonsignificant, MS - Moderately significant (All
the values are average values of 15 patients). As shown in above table the values clearly indicate the efficacy of the rubber band ligation methods on the set of patients.

Clinical images:

![Image](https://example.com/image1.png)

**Fig- 1: Revelation of haemorrhoidal Masses**

![Image](https://example.com/image2.png)

**Fig -2: Lodging of the band over gun**

![Image](https://example.com/image3.png)

**Fig- 3: Occlusion of Hole of Handling Part**

![Image](https://example.com/image4.png)

**Fig -4: Colour Changed after Ligation**

**Postoperative Management:**
A hot sitz bath, Bulk evacuant, and light diet were advised. Triphala Guggulu was given postoperatively to reduce pain and inflammation. The patient was advised not to strain during defecation. Daily *Jatyadi Taila matra vasti* was done.

**Mechanism of Action of Rubber Band Ligation:**
The mechanism of action is simply mechanical, clear, and easy. Rubber Band Ligation relies on the principle of Mucosal Fixation and reduction of bulk of pile masses by complete or partial excision. The mucosa and the submucosal vascular cushions were fixed to the underlying muscle coat by creating scarring after full-thickness ulceration. Perivascular fibrosis ultimately produced in the submucosal plane also prevents engorgement of vessels, prolapse of sub-mucosal vascular cushion & reduces bleeding. The strangulated small haemorrhoidal tissue mass being about 1 cm held in elastic ligature results in the formation of a smaller wound by rapid falling out of pile mass. Application of Rubber bands over the base of the haemorrhoidal tissue causes pressure effects over the base and ischaemic changes in the distal part of the haemorrhoidal tissue which ultimately falls out after complete necrosis of the concerned haemorrhoidal mass. Thus
Rubber band ligation acts without disturbing normal haemorrhoidal cushion.

It can be explained in following manner.

Rubber bands applied over the base of the haemorrhoidal tissue
\[ \downarrow \]
Pressure effects over the base
\[ \downarrow \]
Ischaemic changes in the distal part of the haemorrhoidal tissue
\[ \downarrow \]
Necrosis of haemorrhoidal mass
\[ \downarrow \]
Falling out of pile mass

Results & Analysis:

Criteria for assessment: The following criteria was used for assessment of result.

1. **Proctorrhagia**
   - Grade 0 - No bleeding
   - Grade 1 - Mild bleeding (2 to 5 drops/24 hr)
   - Grade 2 - Moderate bleeding (6 to 10 drops/24 hr)
   - Grade 3 - Severe bleeding (>12 drops/24 hr)

2. **Prolapse**
   - Grade 0 - No prolapse
   - Grade 1 - Only at time of defaecation
   - Grade 2 - Prolapses at time of defaecation and spontaneously reducible after defaecation
   - Grade 3 - Prolapses but digitally reducible
   - Grade 4 - Irreducible, remain prolapsed out

3. **Discharge P/A**
   - Grade 0 - None
   - Grade 1 - Mild (2 to 5 drops/24 hr)
   - Grade 2 - Moderate (6 to 10 drops/24 hr)
   - Grade 3 - Severe (>12 drops/24 hr)

4. **Pain**
   - Grade 0 - No pain
   - Grade 1 - Mild pain
   - Grade 2 - Moderate pain
   - Grade 3 - Severe pain

5. **Heaviness in ano-rectal region**
   - Grade 0 - None
   - Grade 1 - Mild (only during defecation)
   - Grade 2 - Moderate (In sitting posture)
   - Grade 3 - Severe (even in standing posture)

Postoperative criteria of assessment – Results after Rubber band ligation were assessed according to following criteria:

1. **Postoperative pain**: (recorded on days 1 and 15 after operation).
   - Grade 0 - No pain
   - Grade 1 - Mild pain
   - Grade 2 - Moderate pain
   - Grade 3 - Severe pain

2. **Time taken for Falling out of pile mass**:
   - Grade 0 - <5 days
   - Grade 1 - 5-7 days
   - Grade 2 - 7-10 days
   - Grade 3 - >10 days
3. Healing time after Falling out of pile mass.
   - Grade 0: Wound healing after 5 days of Falling out of pile mass
   - Grade 1: Wound healing after 7 days of Falling out of pile mass
   - Grade 2: Wound healing after 10 days of Falling out of pile mass
   - Grade 3: Wound healing after 12 days of Falling out of pile mass
   - Grade 4: Wound healing after 14 days of Falling out of pile mass

4. Postoperative urinary complaints:
   - Grade 0: No
   - Grade 1: Dysuria
   - Grade 2: Retention

5. Wound infection:
   - Grade 0: Absent
   - Grade 1: Present

6. Anal incontinence:
   - Grade 0: Absent
   - Grade 1: Present

7. Anal stenosis:
   - Grade 0: Absent
   - Grade 1: Present

8. Hospital stay (In days):
   - Grade 0: No hospital stay
   - Grade 1: 1-2 days
   - Grade 2: 5-7 days
   - Grade 3: >7 days

Criteria for assessing the total effect of therapy:
- Grade 0: Deteriorated (Aggravation of the sign and symptoms)
- Grade 1: Unchanged
- Grade 2: Improved (Less than 50% relief in complaints, no healing of the wound)
- Grade 3: Markedly Improved (More than 50% relief in complaints and wound healing)
- Grade 4: Cured (More than 80% relief in complaints, complete healing of the wound)

Results of clinical study:
1. Proctorrhagia – Percentage age relief in was 77.7% and results were highly significant.
2. Prolapse – Percentage age relief was 66.6% and the results were highly significant.
3. Pain – Percentage age relief was 100% and nonsignificant.
4. Discharge per anum – Percentage age relief was 41.75% (p < 0.05) and significant only.
5. Heaviness in the anorectal region – Percentage age relief was 54.97% with minimal significance.

Study of Postoperative criteria:
1. Postoperative pain (1st day) – Mean score was 0.53.
2. Postoperative pain (15th day) - Mean score was 0.00.
3. Time taken for falling out of pile mass – Mean score was 0.26. Rubber band ligation took less duration to shed off the pile masses.
4. Healing time after falling out of pile mass – Mean score was 0.80. Statistically difference in healing time
after falling out of pile mass was significantly less after RBL.
5. Postoperative urinary complaints – Mean score was 0.13. Statistically, the difference in postoperative urinary complaints on 1st day was more compared to pain on the 15th postoperative day. No patient complained of postoperative urinary complaints on the 15th postoperative day.
6. Wound infection – Mean score was 0.06.
7. Anal incontinence - None of the patients developed anal incontinence.
8. Anal stenosis - This complication was not encountered.
9. Hospital stay – Mean hospital stay was 1.4 days. It indicates that patients after Rubber band ligation required a comparatively less hospital stay.
10. Type of anesthesia – In all the 15 patients RBL was done without any anesthesia.

**Total Effect of Therapy:**
According to the total effect of therapy 60% of patients were cured (>80% relief in complaints, complete healing of the wound), while 40% of patient were markedly improved (50% relief in complaints, more than 50% of the wound healing).

**Discussions:**
Rubber band ligation is useful in small haemorrhoidal masses of up to 2nd degree. It causes ischemic necrosis of the pile masses. Application of Rubber bands over the base of the haemorrhoidal tissue causes pressure effects over the base and ischaemic changes in the distal part of the haemorrhoidal tissue which ultimately fall out after complete necrosis of the concerned haemorrhoidal mass. Small tissue mass held in elastic ligature resulted in immediate complete ischemia resulting in rapid falling out of pile mass. Rubber band ligation is a comparatively painless procedure pre and postoperatively. Ligation of internal hemorrhoids was done 1 cm. above the dentate line at the base of hemorrhoids, which is pain insensitive mucosa due to autonomic innervation. Mild pain was experienced only due to multiple ligations conducted on the same day. Patients underwent Rubber band ligation without any anesthetic requirement. As an OPD procedure with the less hospital stay patients can be discharged on the same day. Anal incontinence was also not reported in any patient. Jatyadi Taila matra vasti also results in soothing the area by relieving Rukshata and shotha by virtue of its Snigdha, Shodhan and soothing properties. Jatyadi Taila is Kushthaghna and Krimighna(Ingredient - Haridra (Curcuma longa Linn.), Karanja (Pongamia pinnata L. Pierre.) to check wound infection. It promotes wound healing and control bacterial growth. Jatyadi taila is very effective in postoperative patient of Rubber band ligation.

**Conclusion:**
The study concluded that Rubber band ligation is an effective treatment for complete relief from the symptoms for second degree haemorrhoids. Rubber band ligation has the advantages of minimum hospitalization, less pain, cost-
effectiveness, and very useful in early internal hemorrhoids.

**Limitation of study:**
The sample size should be larger, which may give much sharper results. Follow-up of patients of Rubber Band Ligation could have been longer than 04 weeks for having better scientific and clinical results.

**Consent of patients:**
After initial counseling, patients were given the informed consent proforma both in English and Hindi. Patients willing to get registered for the study were asked to return the form after putting signatures of the subject and attendant or family member. Written informed consent of patient as well as attendant was obtained.

**References:**


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