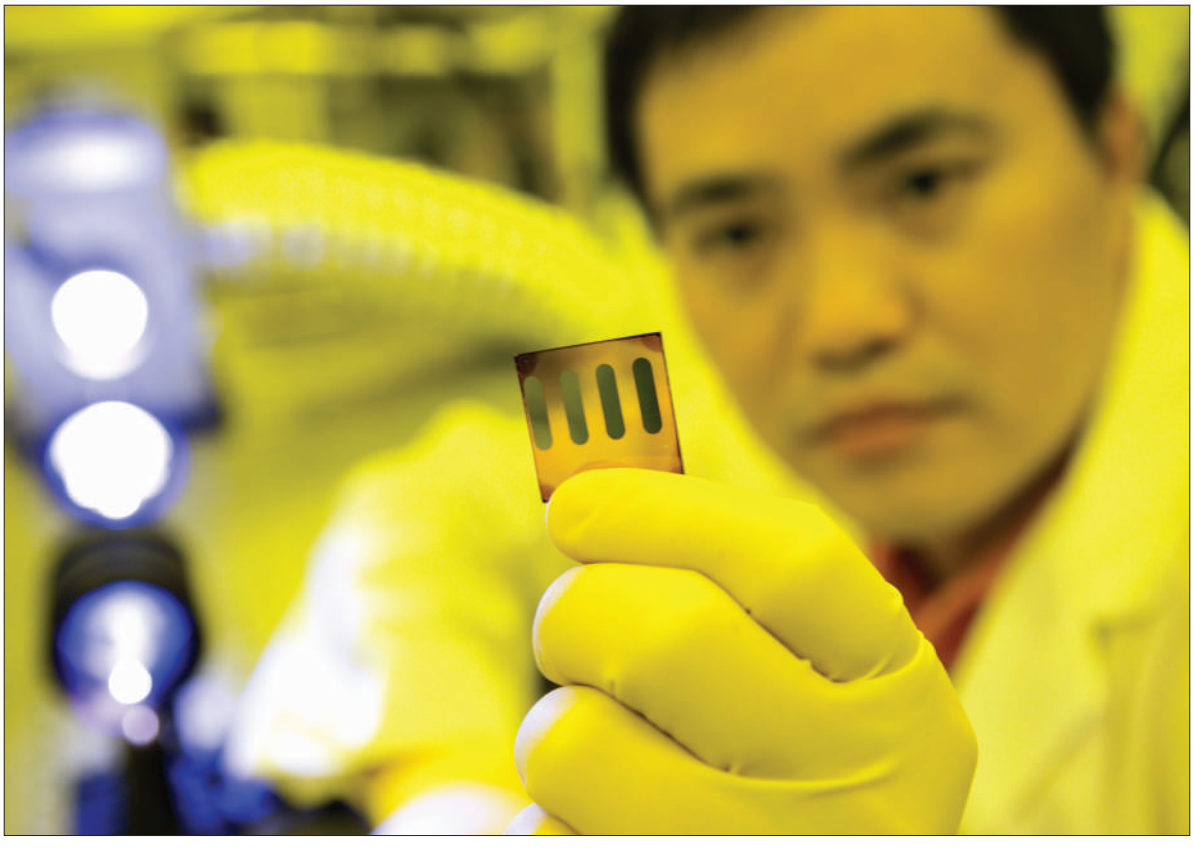

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# Research Article
# Rubber Band Ligation of Internal Hemorrhoids: A Study

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## Abstract

**Background and Objective:** Hemorrhoids are one of the most common gastrointestinal disorders affecting millions of people globally. The objective of this study was to study the efficacy of rubber band ligation (RBL) in the management of internal hemorrhoids. **Materials and Methods:** This was a prospective study conducted on 108 patients who were treated for grade 2 and 3 internal hemorrhoids and followed up for 3 years. **Results:** Pain and bleeding were the commonest complications. Twenty three patients (21.3%) had recurrence by 3 years. The 72 (66.7%) patients were satisfied with the treatment. **Conclusion:** Rubber band ligation (RBL) is a cost-effective, quick and safe outdoor procedure for symptomatic hemorrhoids, but the operator needs to be aware of the potential complications and associated morbidity.

Key words: Hemorrhoids, rubber band ligation, bleeding, pain, relapse, gastrointestinal disorder

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Competing Interest: The author has declared that no competing interest exists.

Data Availability: All relevant data are within the paper and its supporting information files.

## INTRODUCTION

Hemorrhoids are one of the most common gastrointestinal disorders and are defined as the symptomatic localized enlargement of the normal anal cushions[1,2]. Millions of people around the world are affected, creating a major medical and socioeconomic problem.

The exact pathophysiology of hemorrhoid development is poorly understood and multiple factors have been claimed to have a role in etiology including constipation and prolonged straining. Currently, the theory of sliding anal canal lining is widely accepted to explain this disorder. This theory proposes that hemorrhoids develop due to disintegration or deterioration of the supporting connective within the anal cushions[1,2].

The classification of hemorrhoids is generally done on the basis of their location and degree of prolapse. Internal hemorrhoids originate from the inferior hemorrhoidal venous plexus above the dentate line and are hence covered by insensate mucosa, whereas, external hemorrhoids are dilated venules of this plexus located below the dentate line and are covered with sensate squamous epithelium[2]. Internal Hemorrhoids are further graded based on their appearance and degree of prolapse, known as Goligher's classification[1,2] as shown in Table 1.

As far as the therapeutic management of hemorrhoids is concerned, it ranges from conservative approach by simple dietary and lifestyle modification to radical surgery, depending on degree and severity of symptoms. When bleeding or prolapse persists, in spite of conservative management, surgical or non-surgical intervention is required[3,4]. A wide range of options are available and newer modalities have been added over the recent decades.

Rubber band ligation (RBL) is considered one of the least invasive, non-surgical procedures for hemorrhoids that can be offered to the patient on outpatient or office level[5]. Studies have been conducted to study the efficacy and safety of RBL in comparison to other available modalities. Shanmugam *et al.*[6] conducted randomized controlled trials comparing rubber band ligation with excisional hemorrhoidectomy (EH) for symptomatic hemorrhoids and concluded that RBL can be adopted as the treatment of choice for second-degree hemorrhoids with similar results but without the adverse effects of EH and EH can be reserved for third-degree hemorrhoids or recurrence after RBL but at the cost of increased pain, higher complications and more time off work[6]. Brown *et al.*[7] Compared RBL to hemorrhoidal artery ligation (HAL) for the management of symptomatic second-degree and third-degree hemorrhoids in a multicentre, open-label, randomised controlled trial and found RBL preferable over HAL[7]. Filgate *et al.*[8] found RBL to be as effective as hemorrhoid energy therapy (HET) though the latter causes less pain.

Table 1: Grading of internal hemorrhoids

| Grades of Internal hemorrhoids | Description |
|---|---|
| 1-First degree hemorrhoids | The anal cushions bleed but do not prolapse |
| 2-Second degree hemorrhoids | The anal cushions prolapse through the anus on straining but reduce spontaneously |
| 3-Third degree hemorrhoids | The anal cushions prolapse through the anus on straining or exertion and require manual replacement into the anal canal |
| 4-Fourth degree hemorrhoids | The prolapse stays out at all times and is irreducible |

This study is aimed to evaluate the effectiveness of RBL conducted at office level, in respect to long term eradication of hemorrhoids, post-procedure complications and patient satisfaction.

## MATERIAL AND METHODS

The prospective study was conducted by enrolling 177 patients with 2nd and 3rd degree internal hemorrhoids for RBL in private sector summer clinics/office in Kashmir valley, India from March, 2006 to February, 2015 and followed up for 3 years after the procedure, 69 patients either did not report after first session or did not follow up after subsequent sessions and were excluded from the study at the time of compilation of results. Patients with a history of inflammatory bowel disease, associated anorectal pathology (anal fissure, fistula in ano), previous history of RBL, anticoagulant intake, features of acute thrombosis in hemorrhoids and large grade 4 hemorrhoids were excluded from the beginning. Referral to certified gastroenterologist for sigmoidoscopy and colonoscopy was made if the age and the presentation of the patients required so.

Results were derived on the basis of data related to 108 patients who followed up till the end of the study period. The outcomes were classified into three categories (a) No change-where the symptoms and grade of Hemorrhoids remained the same or worsened, (b) Better-where symptoms regressed though not completely relieved and the grade of hemorrhoids decreased by at least one Goligher's degree, (c) Relieved-where patients became asymptomatic and hemorrhoids got obliterated.

Procedure was explained to the patients and other possible options explained. The possible outcomes and complications of RBL were also explained in the light of the recent literature and formal consent sought. Proctoscopy was performed without sedation and the area to be ligated was identified. Barron hemorrhoidal ligator with a hemorrhoid-grasping forceps was used as ligature device.

The loading cone was screwed over the drum of the Barron hemorrhoidal ligator and a single rubber band was slipped to load the ligator. The hemorrhoid-grasping forceps was then passed through the drum of the ligator under vision of lighting device and the prominent hemorrhoid mass was grasped and pulled taut 7-10 mm above the dentate line followed by release of a single elastic band. During the procedure, the assistant held and maintained the position of the proctoscope, while the surgeon held the preloaded Barron band ligator with the grasping forceps. In a single session, 1 or 2 Hemorrhoids were banded and banding of 3 Hemorrhoids in single session was not undertaken to avoid any possibility of resultant anal stenosis. Post-procedure, the patients were advised Sitz bath and stool softeners.

Treatment was repeated at 3 weeks intervals until the hemorrhoids were obliterated or reduced by at least one Goligher's grade, with resolution of symptoms. Obliteration was defined as the absence of hemorrhoid mass projecting into the lumen or visible bleeding as confirmed by anoscopy. Patients were instructed to maintain a high fiber-diet and avoid constipation throughout the treatment period. A mobile phone number was provided to them for contact in case of any emergency.

Patients were followed up regularly for 3 years and the recurrences were treated by the option accepted by the patient after explanation of various possible options. At the end of the follow up period, patients were requested to give opinion if they were satisfied or otherwise, with the treatment.

**Statistical analysis:** Analyses of data were done with SPSS (Statistical Package for Social Sciences) for Windows version 11.5 and Microsoft Excel-2013 and the data were expressed as mean, range and numbers (with percentages). For the analyses, the significance level was set at p-value less than 0.05, with a confidence interval of 95%.

## RESULTS

The demography and the presenting features of 108 patients who participated in the study are shown in Table 2.

In these 108 patients, 29 (26.7%) had 3 hemorrhoids on presentation that were individually banded, 67 (62%) had 2 hemorrhoids and there was a single hemorrhoid in 12 (11.1%). The 68 (63%) patients required only a single session of banding, 29 (26.8%) required repeat banding of at least one hemorrhoid and 11 (10.2%) required 3rd session for banding of at least one hemorrhoid. Out of the 40 (37%) patients requiring repeat banding at 3 weekly follow-up, 22 had second degree and 18 had 3rd degree hemorrhoid at initial presentation.

The total procedure from the insertion of the proctoscope to the placement of bands took a mean time of 6 min (Range: 5-10 min) when a single hemorrhoid was banded and 9 min (Range: 7-15 min) when 2 Hemorrhoids were banded. The outcomes are as shown in Table 3.

Table 2: Demography and clinical presentation of patients

| Variables | Number | Percentage |
|---|---|---|
| Number of patients | 108 | |
| **Gender** | | |
| Male | 82 | 76.0 |
| Female | 26 | 24.0 |
| **Age (years)** | | |
| Mean | 34 | |
| Range (28-59) | - | - |
| **Symptoms** | | |
| Bleeding with stools | 44 | 40.7 |
| Prolapse (with/without itching, fecal soiling) | 11 | 10.2 |
| Bleeding and prolapse | 53 | 49.1 |
| **Degree of hemorrhoids** | | |
| Second degree | 87 | 80.5 |
| Third degree | 21 | 19.5 |

Table 3: Outcomes of RBL

| Complications/outcomes | Number | Percentage |
|---|---|---|
| **Pain (as assessed by visual analogue scale of 0-10** | | |
| 0 (No pain) | 69 | 63.9 |
| 1-4 (Mild pain) | 32 | 29.6 |
| 5-7 (Moderate pain) | 6 | 5.6 |
| 8-10 (Severe pain) | 1 | 0.9 |
| **Bleeding** | | |
| Minor (self-limiting) | 11 | 10.2 |
| Major (requiring hospitalization) | 1 | 0.9 |
| **Anal fissure** | | |
| Acute fissure | 1 | 0.9 |
| Chronic fissure | 3 | 2.7 |
| **Slippage/breakage of band** | | |
| During procedure | 4 | 3.6 |
| Within 24 h of the procedure | 1 | 0.9 |
| **Dizziness/fainting** | | |
| During procedure | 3 | 2.7 |
| Within 24 h of the procedure | 1 | 0.9 |
| **Urinary complications** | | |
| Acute retention requiring short term catheterization | 2 | 1.8 |
| **Recurrence** | | |
| At 1 year | 14 | 13.0 |
| At 2 years | 18 | 16.7 |
| At 3 years | 23 | 21.3 |
| **Satisfaction level** | | |
| Satisfied | 72 | 66.7 |
| Dissatisfied | 21 | 19.4 |
| Neutral/no opinion | 15 | 13.9 |

## DISCUSSION

Management options for internal hemorrhoids are diverse, increasing with time and ranging from conservative measures to a variety of office or operating room procedures, depending on the stage[2-4]. Rubber band ligation is one such non-operative treatment option that is widely used for management of second and third grade internal hemorrhoids[4-8].

In this study, bleeding per rectum and tissue prolapse, either solo or in combination, were the major presenting complaints in hemorrhoids. This corroborates with the literature[3,9]. Pain is not a significant feature of internal hemorrhoids and occurs in the setting of strangulation[9]. In this series, post-procedure discomfort was a significant adverse outcome. The 36% reported pain, though all except one had only mild pain (score 1-3/10) managed by oral analgesics. Only 1 patient has severe pain and that was due to faulty placement of band in small second degree hemorrhoid mass, having erroneously taken in sensitive skin distal to dentate line, the band was taken down and reapplied. There is an established teaching that rubber band be placed at least half a centimeter above dentate line to avoid placement into somatically innervated tissue[2]. Mild anal pain is reported in literature in at least 25-50% of patients, for the first 48 h after banding, sometimes associated with nausea, shaking, light headedness and retention of urine[10-11]. It is this issue of pain associated with RBL that newer modalities have been compared with in many studies[12-13]. Johanson and Rimm[13] undertook a comparative analysis of infrared coagulation, rubber band ligation (RBL) and injection sclerotherapy and found that RBL was associated with a significantly higher incidence of post treatment pain and that in contrast, infrared coagulation was associated with both fewer and less severe complications. The study thereby recommended that infrared coagulation may in fact be the optimal non-operative hemorrhoid treatment. Templeton *et al.*[14] in their study found that the incidence of side effects, particularly peri-procedure pain and discomfort, was significantly higher in those treated by rubber band ligation ($p<0.001$) and that factor appeared to be an appreciable deterrent to future patient compliance. The number of patients losing more than 24 h from work was higher after RBL than after infrared coagulation.

Other complications recorded in this study include bleeding, giddiness/syncope, band slippage and urinary retention. Bleeding was minor and self-limiting in 10.2% (n-11) of patients and only case who had bled after post procedure breakage of band required in-hospital care and surgical management of hemorrhage. Band slippage/breakage during procedure were managed by stat reapplication of band. On review of literature, the rates of complications following RBL, ranges[15,16] from 3-18.8%. The most common complications after RBL are pain and bleeding[17]. Besides bleeding and pain, there are many other common complications mentioned in literature and normally considered minor including band slippage vaso-vagal symptoms, priapism and difficulty in urination, anal fissure and chronic longitudinal ulcers[17-22]. Massive bleeding, thrombosed hemorrhoids, severe pain, urinary retention needing catheterization, pelvic sepsis, fistula and death are major adverse outcomes that have been less commonly reported by Albuquerque[17]. Wechter and Luna[18] reviewed 39 studies including 8060 patients submitted to RBL and revealed post-banding complications in 14% of the patients, in the form of severe pain in 5.8%, hemorrhage in 1.7%, infection in 0.05%, anal fissure and fistula in 0.4%.

Bleeding after RBL normally occurs after 10-14 days and is attributed to the sloughing of the banded hemorrhoids[20,21]. Patients taking anti-platelet and/or anti-coagulant medication are at a higher risk of secondary bleeding. There are cases of massive life-threatening hemorrhage following hemorrhoidal RBL in patients on aspirin[18] and clopidogrel[20]. It is hence routinely recommended that patients should stop this medication for at least 1 week prior to and 2 weeks post RBL[21]. The risk of the hemorrhoidal bleeding against the risk of thrombotic events must however be balanced[17].

In our series, there were no significant infection related complications though septic complications have been reported after RBL that include pelvic sepsis, Fournier's gangrene, liver abscess, tetanus and bacterial endocarditis. Deaths due to these septic complications have also been reported in literature[17]. The hypotheses presented to explain the possibility of septic complications is related to the transmural necrosis or slough following banding that facilitates the development of deep infection by migration of the bowel bacterial flora, which can spread to adjacent tissues[23-26].

Recurrence seen in this series was 13% at 1 year, 16.7% at 2 years and 21.3% at 3 years. This value is similar to the ones reported in literature. Vicente *et al.*[27] conducted a study involving 163 patients of hemorrhoids and concluded that the treatment was effective in 86% of patients after a mean follow-up of 32 months. Iyer *et al.*[28] studied the long-term outcome of rubber band ligation for symptomatic primary and recurrent internal hemorrhoids. In that series, success was obtained in 70.5% and failure in 29.5% of patients. Treatment of relapses with rubber band ligation resulted in success rates of 73.6, 61.4 and 65% for first, second and third recurrences, respectively.

Studies have been conducted to look into technical aspects of RBL whereby the complications may be reduced and relapses minimized. In this regard, studies worth mentioning include the ones that have found vacuum suction band ligation to be superior to traditional forceps ligation for the treatment of second-and third-degree hemorrhoids in terms of pain tolerance, amount of analgesia consumed and intra-procedure bleeding[27, 29,30].

In this series, 66.7% patients were satisfied with the treatment whereas 19.4% were not satisfied and 13.9% did not express their opinion as shown in Fig. 1. Watson *et al.*[31] in their series found that 59% were satisfied with their experience and only 57% of the patients surveyed would recommend the procedure to a friend. They found that patients experiencing pain, bleeding or vaso-vagal symptoms were significantly less likely to be satisfied with the procedure. In our series also, a similar trend can be found out. Watson *et al.*[31] further suggested that in order to improve the satisfaction levels, patients should be aware of the possible complications in order to make an informed decision as to whether to undergo the procedure and that surgeons should investigate ways of reducing the complications.

## CONCLUSION

This experience concludes that the Rubber band ligation (RBL) is a cost effective, quick and safe office based procedure for symptomatic hemorrhoids, but it is strongly stressed that the procedure not be deemed as trivial or complications-free. The aspect of safety is very important in general and for training centers in particular as RBL comes at the top of the list of procedures allowed to be conducted by trainee surgeons. The patients should be made aware of the possible adverse outcomes when the informed consent for the procedure is secured.

## SIGNIFICANT STATEMENT

This study validates the results of the earlier conducted institutional studies thereby endorsing the efficacy and safety of rubber band ligation for second degree and third degree internal hemorrhoids. And as the study is conducted in outpatient office settings with a long follow up of 3 years, the study would further encourage the management of hemorrhoids with this very cheap modality thereby favoring the patients in economically deprived regions, in an era where newer modalities involving high costs are fast occupying markets including healthcare facilities.

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