# **Research Paper Rubber Band Ligation Versus Medical Therapy For Treatment of Grade II-III Hemorrhoids**

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# ABSTRACT

**Background and Aim:** The most prevalent clinical proctological disorder is internal hemorrhoids. Surgical treatment is a common treatment strategy for this disease. However, due to its significant complications, non-invasive methods are usually more on the agenda. This study aimed to evaluate the treatment results of patients with internal hemorrhoids with rubber band ligation and medication treatment and their one-year follow-up.

Materials and Methods: The current randomized clinical trial was performed on 57 patients with rectal bleeding caused by grade II and III internal hemorrhoids. The patients were randomly divided into two groups of medication treatment and rubber band ligation. The medication treatment with anti-hemorrhoid cream was performed three times a day until complete management of bleeding. The rubber band ligation was performed for another group of patients, and the patients' need for re-ligation was assessed by monthly examination. Treatment outcomes, recurrence, and complications were compared between the two groups in a 12-month follow-up.

**Results:** In the medication treatment group, the Mean±SD duration of using anti-hemorrhoid cream for bleeding management was  $5.05\pm2.17$  days. In 83.2% of patients, bleeding was controlled well within 6-8 days. The Mean±SD recurrence rate of bleeding was reported  $53.3\pm1.94$  times in one year. There was an inverse relationship between patients' age and recurrence of bleeding (r= -0.78, P<0.001). In the other group treated with rubber band ligation, 25%, 29.6%, and 44.4% of patients required rubber band ligation once, twice, and three times, respectively. Three patients (11.11%) in the rubber band ligation group suffered from complications, including pain (two patients: 7.40%) and minor bleeding (1 patient: 3.70%).

**Conclusion:** Regarding the minor complications and the remarkable success of rubber band ligation in the eradication of grade II and III hemorrhoids, this method can be recommended as a selective approach of low to moderate hemorrhoids' treatment, especially treatment-resistant types.

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# 1. Introduction



emorrhoids are the most prevalent clinical proctological disorder in adults over 50. The exact prevalence of this disease is not available since only a small number of symptomatic patients refer to the clinics. However, it is estimated that up to 4% of normal people suffer from hem-

orrhoids which can negatively affect their quality of life [1]. Hemorrhoids occur in an equal proportion between men and women [2, 3].

The hemorrhoids plexus are natural vessels located in the anal canal, and besides maintaining the integrity of this canal, controlling feces and preventing sphincter damage during defecation. The inflammation and enlargement of these plexus lead to hemorrhoids. Various predisposing factors, including obesity, excessive pressure during defecation, prolonged standing, and food habits (low fiber diet, spicy foods, and alcohol consumption), affect the occurrence of this disease [4]. About four out of ten hemorrhoid patients have symptoms. Bleeding is the most common and generally the first complaint of patients, followed by symptoms such as local inflammation and protrusion of hemorrhoids. Mucus excretion and anal itching are later symptoms. Pain is not as common as other symptoms, and it is more common in complications of hemorrhoids, including edema, thrombosis, and strangulation [5].

Although definitive treatment for hemorrhoids is surgery, due to its significant complications, an operation is recommended only in severe cases or in cases not responding to conservative treatments. Therefore, conservative methods, such as medication treatment or outpatient procedures, such as rubber band ligation, cryotherapy, sclerotherapy, are preferred for low-grade hemorrhoids [6, 7].

Rubber band ligation is the most common outpatient method that restricts blood supply to hemorrhoid plexus and leads to ischemia within one to two weeks. Hence, fibrotic tissue remains without the risk of prolapse or other complications. Despite the speed and ease of rubber band ligation, special care should be taken to prevent ischemia of adjacent tissue and consequently severe pain [8].

On the other hand, some physicians prefer medication treatments for grade II and III hemorrhoids rather than more aggressive strategies [9]. The medication treatments are available in different forms, such as pills, suppositories, creams, etc. Analgesics and anti-inflammatory drugs are the main components of pharmacological therapies. Nitrates and calcium channel blockers are other medications used [10]. This study aimed to evaluate the outcomes of Rubber Band Ligation (RBL) and medication treatment on patients with grade II and III hemorrhoids.

# 2. Materials and Methods

#### Study population

The current clinical trial was performed to evaluate the response to medication treatment and RBL in patients with rectal bleeding caused by grade II and III hemorrhoids referred to Noor, Ali Asghar, and Al-Zahra hospitals in 2020.

The studies were conducted based on the Declaration of Helsinki. The study was approved by the Ethics Committee of Isfahan University of Medical Sciences. In addition, all study protocols were approved by the above institution. Accordingly, informed written consent was obtained from all participants before the intervention.

All patients with rectal bleeding caused by grade II internal hemorrhoids (hemorrhoids come out when forced but return spontaneously into the anal canal) and grade III (hemorrhoids come out of the anus by force but returns into the anal canal with a finger) participated in this study. Other causes of benign or malignant rectal bleeding (colorectal cancer, inflammatory bowel disease, dysentery, anal fistula, external hemorrhoids, etc.), coagulation problems, the use of antiplatelet or anticoagulants, liver cirrhosis, and high port pressure were defined as the exclusion criteria.

A convenience sampling method was performed for the study population until the desired number of patients was obtained. The patients were randomly assigned to RLB or medication groups.

The diagnosis of grade II /III hemorrhoids was made by examining the patients by a gastroenterologist.

#### **Medication treatment**

The first group was treated with topical anti-hemorrhoid cream containing hydrocortisone acetate (0.275 g), lidocaine (5 g), aluminum subacetate (3.5 g), and zinc oxide (18 g). The patients applied the cream to the hemorrhoid plexus three times a day until complete cessation of bleeding. At the end of treatment, patients were visited monthly by a specialist for one year.

# **Rubber Band Ligation (RBL)**

The second group was treated with rubber band ligation. After the patient's examination, he or she was placed in the knee-chest or lateral position. After smearing the anoscope with lidocaine gel and local anesthesia of the anus, the anoscope was entered the anal canal. Then a hemorrhoidectomy device (Storz, Germany) attached to suction was used to insert 1-2 elastic bands and close the hemorrhoid plexus. The patients are advised not to use suppositories or creams and to refer to the clinic immediately in the case of any complications, including pain or bleeding. Otherwise, the patients were reviewed and revisited monthly for one year. The need for RBL was reassessed at subsequent visits.

#### **Recommendations and follow-ups**

The patients in both groups were advised to eat soft and high-fiber diets, use laxatives, sit in a hot tub for a few minutes daily, shorten their toilet time, and defecate as soon as feeling the need to defecate. The patients were examined monthly for hemorrhoids plexus by a gastroenterologist. In addition, demographic information (age and sex), complications (bleeding and pain), and disease recurrence were completed by all patients.

#### **Ethical issues**

This research was conducted following the Declaration of Helsinki. The study was approved by the Ethics Committee of Isfahan University of Medical Sciences. In addition, all protocols of this study were approved by the above institution (IR.MED.MUI.REC.1400.239). Accordingly, informed written consent was obtained from all participants before any intervention. This study is part of the general dissertation of Mehrnegar Dehghan at this university. The study protocol has been approved by the Iranian Registry of Clinical Trials (# IRCT20191111045401N1; https://en.irct.ir/trial/43662).

#### Statistical analysis

The data were entered in SPSS software v. 26 (IBM Crop. 2019. IBM SPSS Statistics for Windows, NY, EUA). Descriptive data are presented as Mean±SD, frequency, and percentage. P<0.05 is considered significant.

## 3. Results

In this study, 57 patients with grade II /III hemorrhoids were undergoing either medication treatment (n=30) or RBL (n=27). The study population had a Mean±SD age

of 39.37±12.96 years and included 17 men (29.82%) and 40 women (70.17%).

The Mean±SD age of patients in the treatment group with RBL was 38.78±8.12 years, and the patients were mostly male (14 patients: 51.9%). The second group includes 24 women (90%) and 3 men (10%) with Mean±SD age of 42.11±9.66 years. The Mean±SD period of using anti-hemorrhoid cream for bleeding management was 5.05±2.17 days (range: 2 to 10 days). Bleeding was managed within 4-6 days in 30% of patients in the medication treatment group, and it was controlled in less than 4 days in 26.6% of cases after taking anti-hemorrhoids. Table 1 presents the bleeding management time in the studied patients.

The pain was not reported by the patients treated with medication. Table 2 presents the recurrence rate of bleeding. The Mean±SD recurrence rate of bleeding in patients treated with medication was  $3.53\pm1.94$  times during one year. In addition, there was an inverse correlation between patients' age and recurrence of bleeding in patients treated with anti-hemorrhoid cream (r=-0.78, P<0.001). The recurrence was not reported in any of the RBL patients.

Table 3 presents the RBL times required for the control of bleeding and the elimination of hemorrhoid plexus. Accordingly, the bleeding stopped in 25% of patients with a single RBL use. While bleeding stopped in 29.6% and 44.4% of patients treated by RBL two and three times, respectively. The complete control of bleeding was obtained in 70.4% and the hemorrhoid eradication in 29.6% of patients after a single RBL.

Three patients (11.11%) treated with rubber band ligation suffered from complications such as pain on the first day and minor bleeding two weeks after bandaging (1 patient: 3.70%). The patients undergoing medication treatment did not show any complications.

# 4. Discussion

In this study, 57 patients with grade II /III hemorrhagic hemorrhoids were treated with medication or RBL. The study results indicate that bleeding was well controlled in 56.6% of patients within 6 days of using anti-hemorrhoid creams, including zinc oxide, hydrocortisone, aluminum sub-acetate, and lidocaine. The bleeding in the RBL group was controlled up to 10 days after topical cream prescription. None of the patients undergoing medication treatment suffered from complications; however, the recurrence of bleeding was common and significant. Table 1. Period of using anti-hemorrhoid cream

Number of Days of Using Anti-hemorrhoid Cream to Stop the Bleeding	No.(%)
Less than 4 days	8(26.6)
4≤day<6	9(30.0)
6≤day<8	8(26.6)
8≤day<10	5(16.8)
>10 days	0(0)
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Table 2. Recurrence rate following the use of topical anti-hemorrhoid cream during one year after starting treatment

Recurrence of Bleeding	No.(%)
One time	1(3.3)
Two times	9(30.0)
Three times	8(26.7)
Four times	5(16.7)
Five times	2(6.7)
Six times	3(10.0)
Seven times	1(3.3)
Eight times	1(3.3)
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In the Zagriadskii et al. study, conservative medication treatment was evaluated in patients with varying degrees of hemorrhoids from grade I to IV. They assessed their patients over a short period of 5-7 days and then, after 25-30 days. Prolapse and rectal bleeding were significantly controlled in short-term evaluations, while edema and tissue pain did not resolve during that period. An interesting result of their study was the significant improvement in all parameters at the next visit [11]. Nevertheless, long-term topical treatment is not recommended due to the pain and tenderness [12].

Although the two study groups were recommended to follow the food habits and health protocols associated with hemorrhoids to reduce confounding variables, high-fiber diets, bathing, defecation as soon as needed, and shortening the duration of fecal excretion can improve symptoms regardless of the type of treatment performed [13, 14].

<b>RBL</b> Times	No.(%)		
	Number of Patients	Management of Bleeding	Eradication
One time	7(25.0)	19(70.4)	8(29.6)
Two times	8(29.6)	6(22.2)	8(29.6)
Three times	12(44.4)	2(7.4)	11(40.8)
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Table 3. Rubber Band Ligation (RBL) times

Therefore, the results of medication treatment and RBL are largely related to health and nutrition protocols.

On the other hand, in the current study, 44.4% of patients in the RBL group needed three times rubber band ligation to stop the bleeding. The bleeding stopped in more than 70% of patients with the first RBL, while subsequent ligations were performed to eradicate the hemorrhoids. The complications occurred in 11.11% of patients. The complications include pain and bleeding in 7.40% and 3.70% of patients, respectively.

Though RBL is one of the oldest outpatient treatments for mild to moderate hemorrhoids, it still retains its place as one of the best treatment techniques. Various studies have shown successful eradication of hemorrhoids in 56% to 91% of patients treated with RBL [15, 16]. In this study, 100% of patients with hemorrhoids were completely eradicated in the first year after treatment.

Komporozos et al. conducted a study to evaluate RBL in a large population, and 71.6% of patients required recurrent RBL. Moreover, 84.5% of their patients were asymptomatic at two-year follow-up [17].

In another study, Cocorullo et al. monitored patients for one year after RBL [18]. The recurrence of the disease was diagnosed in 10% to 18.3% of the subjects, while long-term follow-up of patients showed recurrence of the disease between 11% and 20% [18].

In 2015, Lohsiriwat et al. conducted a study in which recurrence after RBL was significantly lower than medication treatment [7]. The complete eradication of grade I to III internal hemorrhoids was possible in only 2-3 RBL sessions in this study [7]. The occurrence of complications after rubber band ligation is 3% to 18.8%, consistent with the current research [19-22].

We assume that the main reason for the complete eradication of hemorrhoids was the study of patients with grade II and III hemorrhoids; most other studies have evaluated RBL in patients with grade IV disease.

The pain and discomfort at the bandage site, especially in the first 48 hours, is the most prevalent complication of RBL [19, 23]. Another prevalent complication is bleeding in the first two weeks after bandaging. The removal of hemorrhoid necrotic tissue and local inflammation are the reasons for this bleeding that cannot be prevented at all times [24]. Other findings associated with RBL include perineal sepsis, pelvic abscess, Fournier's gangrene, liver abscess, tetanus, and bacterial endocarditis [25]. Fortunately, none of those mentioned above threatening complications were found in our patients.

## **5.** Conclusion

Regarding the negligible complications and significant success rate of RBL in eradicating grade II/ III hemorrhoids, this method can be recommended as the elective approach of treating low to moderate grade hemorrhoids, especially those resistant to medication treatments. Unfortunately, there is little desire to do RBL by the community. Therefore, medication treatment is still the first choice of physicians, and if they do not respond to treatment, the patients will undergo surgery. Thus, the need for more programs to improve the community's attitude toward the RBL is strongly felt.

#### **Study limitations**

The small sample size is the most prominent limitation of this study, and further evaluations in this field are highly recommended.

# **Ethical Considerations**

# Compliance with ethical guidelines

The authors fully considered ethical issues (including plagiarism, data fabrication, and duplication). This article has been registered with the trial protocol in the Iranian Registry of Clinical Trials (IRCT20191111045401N1; (Code: IR.MUI.MED.REC.1400.239).

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### Authors' contributions

Conceptualization and Supervision: Mehrnegar Dehghan and Azam Teimouri; Methodology: Azam Teimouri; Investigation, Writing – original draft, and Writing – review & editing: All authors; Data collection: Mehrnegar Dehghan; Data analysis: Mehrnegar Dehghan; Funding acquisition and Resources: Azam Teimouri.

## **Conflict of interest**

The authors declared no conflict of interest.

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