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Rubber band ligation of hemorrhoids: is the procedure effective for the immunocompromised, hemophiliacs and pregnant women?

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Abstract

Background Rubber band ligation (RBL) is an effective, well-established, non-surgical option for symptomatic grade II-III hemorrhoid treatment. However, few reports exist about the benefit and risks of RBL in high-risk patients. We herein evaluated the effectiveness and safety of RBL in hemophiliac, human immunodeficiency virus (HIV)-positive and pregnant patients vs. other patients.

Methods We retrospectively evaluated the effectiveness of RBL, during the period 2001-2021, in 3 distinct patient categories deemed high-risk and thus not suitable for anesthesia and/or surgical management of their hemorrhoids: hemophiliacs, HIV-positive patients, and pregnant women. These were compared to matched controls, selected from our outpatient pool, who had no major comorbidities and who had opted for RBL as the primary method of treatment.

Results There were 3 study groups (44 with hemophilia, 29 HIV-positive patients, and 45 pregnant women) and controls respectively matched for grade, sex and age (2 for each one in the study groups). Hemophilia patients needed up to 6 RBL sessions for relief of symptoms (3.22 sessions/patient) compared to controls, who needed up to 4 sessions (1.88 sessions/patient, P<0.001); in the other 2 groups there was no difference. There were 3 minor complications: one minor bleeding in a hemophilia patient, a thrombosis in an HIV-positive patient, and severe rectal pain in a control patient. Patients were followed-up for at least 1 year.

Conclusion RBL is a safe and effective procedure in hemophiliacs, HIV-positive patients and pregnant women, with low complication rates for grade I-III hemorrhoids, similar to those in healthy matched controls.

Keywords Hemorrhoids, rubber band ligation, hemophilia, human immunodeficiency virus, pregnancy

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Introduction

Hemorrhoidal disease, one of the most common conditions of the perianal region, is defined as the symptomatic enlargement and/or distal displacement of the normal functional structures called anal cushions [1-3], at which point they begin to prolapse, bleed or become strangulated [4,5]. It is characterized by remarkably dilated, thin-walled vessels within the submucosal arteriovenous plexus, with absent or nearly-flat sphincter-like constriction of the vessels [6,7]. In 1980, Goligher classified internal hemorrhoids according to the severity of examination findings: grade I – bleeding only, without prolapse; grade II – prolapse that reduces spontaneously with or without bleeding; grade III – prolapse requiring manual reduction, with or without bleeding; and grade IV – irreducible prolapse of hemorrhoidal tissue [8-10].

Treatment choices include conservative, non-surgical and surgical options. Conservative management consists of diet and lifestyle modifications such as a high-fiber diet, increased water intake, avoidance of prolonged straining, and medical options with oral flavonoids and topical ointments. Office-based options include rubber band ligation (RBL), cryosurgery and infrared coagulation, among others. Surgical treatment is reserved mainly for patients in whom the conservative therapeutic approach has failed, or for patients with advanced disease (grade IV) [11,12].

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RBL is considered the most effective, painless, office-based option for grade I-III hemorrhoids, easily performed on an outpatient basis [4]. It consists of positioning elastic bands above the dentate line to strangulate the hemorrhoidal nodules, thus leaving an area where inflammation fixates the mucosa to the submucosa, preventing recurrence [13]. The Guidelines for hemorrhoidal disease from 2020 European Society of Coloproctology suggest it as a first-line treatment, since it is less invasive, has fewer and/or less serious reported complications, and is quicker and cheaper than other options [12]. However, it is of interest to focus on the authors' reference to "special situations", including inflammatory bowel disease, irradiation, immunodeficiency, pregnancy and coagulation disorders. In this specific section, the lack of satisfactory literature on the risks and effectiveness of RBL vs. surgery in such patients is emphasized.

We thus decided to retrospectively analyze the effectiveness of RBL in subgroups of our patients deemed as high-risk, and thus not suitable for general anesthesia and/or surgical management of their hemorrhoids, or denied such due to their underlying diseases or "conditions": hemophiliacs, human immunodeficiency virus (HIV)-positive patients, and pregnant women. For comparison purposes, each individual included in the treatment groups, was matched with 2 others (controls) recruited from our outpatient pool, who had no major comorbidities and had opted for RBL as the primary method of treatment.

Patients and methods

This was a retrospective, cohort, descriptive, single-center study based of the data of all adult patients (>18 years old) referred for RBL hemorrhoidal treatment during the period 2001-2021, after exclusion of: (i) grade IV, or acutely thrombosed, strangulated or prolapsed hemorrhoids; and (ii) patients with a background of inflammatory bowel disease, liver cirrhosis, systemic steroid use or active malignancy under chemotherapy. All included patients completed their treatment and the final result was assessed again at 3-month follow up in person, and then at 6-month and 12-month telephone follow up.

From this database of all the above subjects treated as outpatients in our Endoscopy Department between 2001-2021, 3 distinct patient categories were identified: hemophiliac patients, HIV-positive patients and pregnant women, to serve as separate study groups; 2 control subjects were then selected from the same database for each of the study group participants, matched for hemorrhoid grade, sex and age (within 5 years).

All patients had consented to their data being used for research purposes. As this is a descriptive retrospective study, no Ethics Committee approval was required.

RBL technique

All procedures were performed without any sedation. Initially, proctoscopy with local application of xylocaine was performed to assess the area and rule out other diseases of the anal canal. The ligature device (ShortShot® Saeed Hemorrhoidal Multi-Band Ligator, Cook Medical, IN 47402-0489, USA) was then inserted through the proctoscope, the position of the dentate line confirmed and an area 5-7 mm above the dentate line selected. The area of interest was suctioned into the transparent cap of the device, and the device detonated to release a single elastic band. A maximum of 4 bands were used in each session, but at different levels to avoid stricture. Banding sessions were repeated every 3 weeks, until there was complete eradication of hemorrhoids and resolution of clinical symptoms.

The total procedural duration was less than 10 min. Patients were observed for 1-2 h for immediate complications and then discharged, after being advised to maintain a high-fiber diet and remain well-hydrated, and instructed to use plain analgesia (such as paracetamol) if needed. A 24-h phone help line was also available in case of emergencies.

Statistical analysis

Age data are presented as median (range); numbers of patients are expressed as percentages. The chi-square analysis was used to determine whether a significant difference in the number of sessions was prominent within study groups and matched controls. SPSS Statistics for Windows software (Version 26.0. Armonk, NY: IBM Corp) was used.

Results

A total of 428 subjects from the database were found to be eligible for inclusion in the study, fulfilling the criteria mentioned above. Three study groups were then created from this cohort, based on the same comorbidity—the hemophilia group (44 cases, 10.28%) and the HIV patient group (29 cases, 6.77%)—or the same status of pregnancy (45 cases, 10.51%). Three control groups were then formed from the same cohort, each group having twice the number of subjects as the respective study group; the individuals were well matched to individual members of the study groups in respect of hemorrhoid grade, sex and age. Although not remarkable, it should be mentioned that the group of pregnant women exhibited a statistically significant difference in the ratio between the severity grades, with grade II predominating compared to the initial pool of patients (66.7% vs. 50.2%, P=0.029). In addition, 14 women (28 controls) were in the first trimester of pregnancy, 20 (40 controls) in the second, and 11 (22 controls) in the third. The demographic data and clinical characteristics of the study groups, as well as of the total 428 patients comprising the initial database, are presented in Table 1.

Analyzing the treatment parameters of the study groups we found that hemophiliac patients needed up to 6 sessions for eradication and relief of symptoms, more than controls, who needed up to 4 sessions; the 44 hemophilia patients underwent a total of 142 banding sessions (a mean of 3.22

Table 1 Demographic and clinical characteristics of the study groups

variables \ groups	Total patients (Initial Database) (n=428)	Study groups					
		Hemophilia (n=44)	Matched controls (n=88)	HIV-positive (n=29)	Matched controls (n=58)	Pregnancy (n=45)	Matched controls (n=90)
Age (years) median (range)	44 (23-77)	32 (23-59)	35 (25-56)	42 (26-71)	40 (28-72)	33 (23-39)	37 (25-42)
Sex M/F (Females %)	240/188 (43.92%)	25/19 (43.18%)	50/38 (43.18%)	(37.93%)	(37.93%)	0/45 (100%)	0/90 (100%)
Severity Grade 1 patients (%)	147 (34.4)	10 (22.7)	20 (22.7)	7 (24.1)	14 (24.1)	8 (17.8)*	16 (17.8)
Severity Grade 2 (patients)	215 (50.2)	29 (65.9)	58 (65.9)	17 (58.6)	34 (58.6)	30 (66.7)*	60 (66.7)
Severity Grade 3 (patients)	66 (15.4)	5 (11.4)	10 (11.4)	5 (17.2)	10 (17.2)	7 (15.6)	14 (15.6)

*P=0.029 in comparison with total group

sessions/patient), while the 88 controls had only 160 (a mean of 1.88 sessions/patient, P<0.001), despite controls being well-matched for disease severity, sex and age. However, it is of great interest to mention that such a significant difference between study patients and matched controls was not perceived in either of the other 2 groups: HIV-positive patients required a mean of 2.68 sessions vs. 2.53 for the matched controls (P=NS), and pregnant women 1.15 vs. 1.28 (P=NS), respectively. The treatment parameters in each study group are presented in Table 2.

Regarding major complications, only 3 were observed in our study groups: (i) one hemophiliac patient presented with rectal bleeding 7 days after the first banding. On proctoscopy the bleeding site was identified at the site of the previous banding; another rubber band was then applied, ensuring complete hemostasis and the patient was discharged 2 h later; no transfusion was required; (ii) One HIV-positive patient presented with severe anal pain 24 h after banding. Physical examination revealed the presence of a thrombosed external hemorrhoid, managed with incision and drainage under local anesthesia, with complete resolution of symptoms. Although this event was not directly related to any of the ligation sites, we include this complication in our data; and (iii) one young lady from the pregnancy control group experienced severe rectal pain a few hours after banding. Although on proctoscopy the band was well placed above the dentate line, she required opioids and eventually removal of the band for symptom control. Twelve more patients experienced pain that resolved with oral paracetamol: 4 and 2 in the hemophilia and control groups, respectively, and 3 and 3 in the HIV-positive and control groups.

Discussion

RBL as a treatment for internal hemorrhoids was first proposed by Bleisdell in 1958 and then adjusted to its current form by Barron in 1963 [11], to gradually replace the painful injection sclerotherapy. Since then, it has been established as a minimally invasive, painless, easily performed in-office, as well as cost-effective treatment modality for grade I-III piles [4,14], aimed at achieving resection of hemorrhoidal tissue with simultaneous fixation of the mucosa and correction of the prolapse [15,16].

The present study was based on data from a cohort of patients suffering from hemorrhoidal disease, treated with RBL in our department. The aim was to retrospectively assess the effectiveness and the risks of the procedure by analyzing the number of banding sessions needed and the complications that arose in 3 distinct study groups, i.e., hemophiliacs, HIV-positive patients and pregnant women, in relation to matched comparison groups. The patients in the study groups were deemed high-risk to receive general anesthesia (such as pregnant women) and/or surgical management of their hemorrhoids, or they refused to undergo general anesthesia because of their underlying diseases. From the same cohort of outpatients, 2 control subjects who had opted for RBL as a primary method of treatment, and who had no major comorbidities, were matched to each study group member according to disease severity (grade), sex, and age.

Hemophiliac patients were found to need almost twice the number of sessions (up to 6 sessions, mean 3.22) compared to the matched comparison group (up to 4 sessions, mean 1.81) for complete resolution of symptoms; this being mainly attributable to bleeding tendency, as a consequence of the impaired hemostasis mechanism, but also to the risk of secondary bleeding when the hemorrhoidal mucosa sloughed off at 7-14 days post-banding, leaving an ulcer with a blood vessel at its base [11]. To the best of our knowledge, there is no bibliography for such coagulation disorders, but only a small number of articles on patients receiving anticoagulants, for whom treatment cessation is generally recommended [9]. In a retrospective review of 364 patients undergoing RBL while on antithrombotic therapy, the authors reported only 6 severe bleedings requiring transfusion of blood products; if clopidogrel was not included, the risk of bleeding would be less than 0.5% [17]. In our series, we experienced only one case of minor bleeding, not requiring transfusion.

The story is totally different regarding HIV-positive patients; they mainly refused anesthesia/surgery for strictly personal,

Table 2 Treatment parameters of the study groups

groups / variables	Total patients (Initial Database) (n=428)	Study groups					
		Hemophilia (n=44)	Matched controls (n=88)	HIV-positive (n=29)	Matched controls (n=58)	Pregnancy (n=45)	Matched controls (n=90)
Session n: 1 patients (%)	163	10 (22.7)	34 (38.6)	4 (13.8)	3 (5.2)	38 (84.4)	66 (73.4)
Session n: 2 patients (%)	165	8 (18.2)	44 (50)	7 (24.1)	28 (48.3)	7 (15.6)	22 (24.4)
Session n: 3 patients (%)	60	8 (18.2)	6 (6.8)	12 (41.4)	21 (36.2)		2 (2.2)
Session n: 4 patients (%)	25	3 (6.8)	4 (4.5)	6 (20.7)	6 (10.3)		
Session n: 5 patients (%)	10	10 (22.7)					
Session n: 6 patients (%)	5	5 (11.4)					
Total number of sessions *	853	142	160	78	147	52	116
Mean number of sessions **	1.77	3.22	1.81	2.68	2.53	1.15	1.28
1-2 sessions patients (%)	328	18	78	11	31	45	88
>2 sessions patients (%)	100	26	10	18	27	0	2
Chi-square test		F=31.324	P<0.001	F=1.295	P=0.255	F=0.063	P=0.801

*number of sessions per patient multiplied by the number of patients needing n sessions

**number of sessions per group divided by the number of patients

psychosocial reasons, although the underlying disease raises no contraindication for surgery in the majority of cases. This is why this study group exhibited very similar effectiveness in symptom resolution, undergoing a mean of 2.68 sessions in relation to matched comparisons (2.53 sessions), the arbitrary but not statistically significant difference in the number of ligation sessions rather being attributed to possible anal sphincter laxity, allowing the hemorrhoids to protrude [18]. Some authors in the past considered these patients as being at increased risk of anorectal sepsis and poor tissue healing [19,20], thus advising adequate colonic preparation, although no evidence exists for antibiotic prophylaxis for RBL [16], or even for sclerotherapy, which is much more invasive and entails a higher risk for tissue necrosis [21]. Moore *et al* [16] reported 11 patients who underwent a median of 2 (range 1-4) RBLs per patient, without complication, including bleeding, severe pain, or pelvic infection.

The third study group of pregnant women is a totally different entity. The development or aggravation of hemorrhoidal disease during pregnancy is related to increased pressure in rectal veins caused by restriction of venous return by the enlarged uterus, as well as by pregnancy-related constipation—perhaps aggravated by hormonal factors such as progesterone—which tends to lower the strength of venous wall muscle [18]. For that young female group, it is understood from the beginning that general anesthesia is prohibited; moreover, hemorrhoids will often regress after delivery. Thus, a minimally invasive procedure such as RBL would be the gold standard. However, the European Society of Coloproctology Guidelines suggest, as expert opinion and not as evidence-based, that in pregnant and postpartum women conservative treatment (i.e., laxatives, topical treatments, phlebotonics, and analgesics) should be used. If a patient is thrombosed and unresponsive, surgical procedures to treat thrombosis can be considered [12]. Despite the guidelines, we effectively applied RBL in 45 pregnant women, in whom there was a statistically significant difference in the ratio between the severity of hemorrhoids, with grade II predominating in relation to the initial pool of patients (66.7% vs. 50.2%, P=0.029).

The number of bands used varies in the literature from 2 or 3 to 6 bands per session [13], while Fukuda *et al* [22] proposed, in a case series, a mean of 8 bands (range 4-14) placed per treatment session by retroflexed endoscopic vision, in order to reduce the number of sessions required. As we always placed a maximum of 4 bands/session, to avoid strictures, repeated sessions were required, particularly in hemophiliac patients (up to 6 vs. 4 in controls). The success rate of RBL ranged between 79% and 91.8% [13,23], while repeated banding sessions showed an efficacy of up to 94% [24]. In our series, all patients experienced successful eradication and remained asymptomatic for at least the 1-year follow up.

Several limitations could be attributed to our study. First and foremost, despite meticulous data collection and all attempts to eliminate bias, it remains a retrospective study. Second, we may have missed cases of asymptomatic recurrence that was not causing the patient any discomfort, as a significant part of the follow up was conducted over the phone, so no physical examination took place. Third, there may have been patients who developed later recurrences (after the 1-year follow-up period) and who, for whatever reason, chose either to manage their condition conservatively or to be further treated elsewhere.

In conclusion, the present retrospective analysis of 3 distinct patient categories, hemophiliacs, HIV-positive patients and pregnant women, revealed that RBL is a safe and effective procedure with low complication rates for grade I-III hemorrhoids for these patients. It is thus highly recommended as a management plan in high-risk patients not suitable or unwilling to undergo surgical intervention.

Summary Box

What is already known:

- Rubber band ligation (RBL) is considered the most effective, painless, non-surgical option for the treatment of grade I-III hemorrhoids, easily performed on an outpatient basis
- There is a lack of satisfactory literature on the risks and effectiveness of RBL vs. surgery in "special situations", including inflammatory bowel disease, irradiation, human immunodeficiency virus (HIV) infection, pregnancy, and coagulation disorders

What the new findings are:

- RBL (even when repeated sessions are needed) can offer a safe and effective management option, even in patients in whom it was previously considered a contraindication (such as hemophiliacs and HIV-positive patients)
- Hemophiliac patients were found to need almost twice the number of sessions compared to the matched comparison group for complete resolution of symptoms
- HIV-positive patients exhibited very similar effectiveness in symptom resolution in relation to matched comparisons
- We effectively applied RBL in 45 pregnant women, in whom there was a statistically significant difference in the ratio between the severity of hemorrhoids, with grade II predominating in relation to the initial pool of patients

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