



Rubber band ligation of symptomatic hemorrhoids: an old solution to an everyday problem

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Abstract

Purpose The aim of this prospective study is to present the results of rubber band ligation (RBL) in 2635 consecutive patients with 2nd, 3rd, and 4th degree symptomatic hemorrhoids, the pain risk factors, and the applicability of the method in patients with liver cirrhosis and portal hypertension.

Methods A total of 1256 patients with 2nd, 1159 with 3rd, and 220 with 4th degree hemorrhoids were included in the study. Fifty-seven patients with hemorrhoids had liver cirrhosis and portal hypertension. RBL was performed using St Marks', McGinvey, and suction ligators. Single ligation was done in 178 patients, while 2457 patients had synchronous multiple ligations, in one (272), two (1289), and three (896 patients) sessions.

Results After the end of treatment, 86.8% of our patients were asymptomatic and 84.5% remained asymptomatic 2 years later. A total of 593 patients had complications. Thirty required hospitalization, while pain was the most frequent complication (16.16%). Multiple banding, young age, male sex, and external hemorrhoids were pain risk factors. RBL proved to be safe in 57 patients with coagulation disorders due to cirrhosis. Symptomatic recurrence was detected in 327 out of 2110 patients (15.49%), with repeat RBL in 219 cases and surgery in 108 cases.

Conclusion RBL is a safe, effective method for treating symptomatic 2nd and 3rd degree hemorrhoids. It can also be applied in selected cases of 4th degree hemorrhoids and patients with cirrhosis and portal hypertension.

Keywords Hemorrhoids · Rubber band ligation · Results · Treatment

Introduction

Hemorrhoids are normal cushions of vascular tissue in the anal canal. They are normal anatomical structures, which are thought to contribute to anal continence by forming a spongy bolster that cushions the anal canal and prevents damage to sphincters during defecation. Therefore, the presence per se of hemorrhoids is not an indication for treatment, which must be aimed at symptomatic relief and correction of anatomic deformity. These targets can be achieved by non-operative management as well as by surgical treatment.

Nowadays, non-operative methods constitute a valid alternative to surgical hemorrhoidectomy, aiming at hemorrhoidal tissue fixation, with or without tissue destruction (sclerotherapy, cryotherapy, phototherapy, BiCAP, laser, etc.), or at fixation with simultaneous resection of hemorrhoidal tissue (Rubber Band Ligation).

In 1954, Blaisdel invented the first hemorrhoid ligator, which was modified by Barron in 1962. Ever since then, RBL is widely used as an alternative method for the treatment of symptomatic hemorrhoids.

In this prospective study, we analyze the results of treatment for symptomatic hemorrhoids in 2635 patients with RBL on an outpatient basis.

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Methods

Two thousand six hundred and thirty-five consecutive patients with symptomatic hemorrhoids who were treated on an

outpatient basis in the rectal clinic are analyzed. The demographics and clinical records of these patients have been prospectively documented on a database.

Classification of hemorrhoids has been done according to the traditional Goligher's classification, based on bleeding and prolapse. The parameters that were evaluated included patient's symptoms, hemorrhoidal disease grade, the number of sessions needed, the number of hemorrhoid nodules ligated per session, results, and complications.

The time interval between sessions was 3 weeks and the patients were re-examined in a 2-month and a 2-year period after the end of treatment.

A total of 2635 number of patients with symptomatic hemorrhoidal disease were treated with RBL. One thousand six hundred and seventy-three of them were men (63.5%) and 962 women (36.5%), with a mean age of 49.4 years (SD 22.3) and age ranging from 19 to 96 years.

During their first visit, after their medical history was obtained, all the patients underwent detailed and complete physical examination including rectal digital examination and rigid rectoscopy.

The proportion of patients that suffered from second degree hemorrhoidal disease was 47.7% (1256/2635), from third degree 44% (1159/2635), and from fourth degree 8.3% (220/2635) (Table 1). External hemorrhoids coexisted in 738 patients (28%). Fifty-seven cirrhotic patients, 52 male and 5 female, with a mean age of 64±12.5 years (Child B and C) had symptomatic hemorrhoids. Eight of those patients had 2nd degree hemorrhoids, 35 had 3rd degree, and 14 had 4th degree hemorrhoids. All of them underwent banding of ≥2 piles in one session after previous correction of coagulation parameters (INR < 1.6).

The most common symptoms reported by our patients were rectal bleeding and hemorrhoid prolapse. Bleeding was the presenting symptom in 748 patients (28.4%), while 174 patients presented with prolapse only (6.6%) and 1713 (65%) with both bleeding and prolapse. In 67% of our patients, defecation problems coexisted. In 344 cases, patients' symptoms, medical history, and physical examination implied a different pathology from the colon. Further investigation with full colonoscopy or barium enema revealed other pathology, such as adenomas, hypertrophic polyps, and diverticula, while proctitis

was diagnosed in 162 (47%) of these patients. The treatment of the coexisting pathology preceded the ligation of hemorrhoids. Three patients were diagnosed with colorectal carcinoma and were excluded from the present material.

A fleet enema a few hours before the ligation and 500 mg of metronidazole per os just before the procedure were recommended. Orally administered metronidazole has been shown to improve postoperative pain [1]. Published results however have been somewhat variable and may either support or discourage the use of metronidazole [2, 3]. On the other hand, the use of metronidazole may prevent perianal infections after RBL.

Patients were placed in a left lateral position. An anoscope was inserted in the rectum to identify the dental line and the piles. Ligation was accomplished mainly by using the St. Marks' ligator (Seward or McGinvey), as well as a suction ligator, with application of two elastic bands around the base of each pile above the dental line. Finally, the anoscope was removed.

After the completion of the procedure, patients were informed about the progress of the treatment. Chemoprophylaxis with metronidazole (500mg 3) per os was continued for 24 h and high-residue diet, mild laxatives, common analgesics, and warm sitz baths were also recommended.

Whether the patients would proceed to another session or not depended on the results and the reported symptoms 3 weeks after the first session. The first follow-up evaluation was scheduled 8 weeks after the end of treatment and the results and early complications were recorded at that time.

All patients were scheduled for a follow-up appointment 2 years after the procedure.

Results were classified as cure or great improvement if the patient was asymptomatic after the end of treatment, as improvement if the symptoms had been minimized, and as failure when there was no improvement at all.

Statistical analysis was done by Student's *t*-test, chi-square test, Yates correction, and multiple regression analysis.

Results

Single ligation was performed in 178 patients (6.76%) while 2457 patients had 2 or more synchronous ligations requiring one (272 patients), two (1289 patients), or three (896 patients) sessions. Table 2 shows the number of sessions according to the hemorrhoidal degree.

Two months after the end of treatment, 2286 patients (86.7%) were cured or presented great improvement and 236 (8.95%) reported improvement, while in 113 patients (4.29%) the therapeutic approach failed (Table 3).

External hemorrhoids are clusters of vascular tissue below the dentate line covered with anoderm squamous epithelium.

Table 1 Degree of hemorrhoids in patients who underwent RBL

Hemorrhoid degree	Patients	
	<i>n</i>	%
1 st degree	0	0
2 nd degree	1256	47.7
3 rd degree	1159	44.0
4 th degree	220	8.3

Table 2 Number of RBL sessions according to the hemorrhoidal degree

RBL sessions	Degree of hemorrhoids			Total	%
	2 nd	3 rd	4 th		
Single ligation	159	19	-	178	6.8
2–3 piles' ligations					
1 session	68	164	40	272	10.3
2 sessions	821	439	29	1289	48.9
3 sessions	208	537	151	896	34
Total	1256	1159	220	2635	100

They are innervated by somatic nerves, which may produce pain. The presence of external hemorrhoids had no influence on the success rates of the method since 627 out of 738 (84.95%) patients with coexistent external hemorrhoids presented good results. This is a proportion comparable to 1659 out of 1897 (87.45%) patients with absence of external hemorrhoids ($\chi^2=0.177$, $p>0.05$ NS). The external component did not require any treatment, unless acute thrombosis occurred. In those cases, the clot was excised on emergency basis under local anesthesia.

Complications were recorded in 593 patients (22.5%) (Table 4).

Pain was the most common complication, affecting 426 patients (16.16%), followed by mild to significant bleeding, observed in 76 patients (2.88%) in a 2-week period after the procedure that was treated conservatively with local means such as anal spongostan or new ligation. It is worth mentioning that only 8 out of 2635 patients (0.3%) needed hospitalization due to bleeding.

Patients with two or more hemorrhoidal banding at the same session had greater discomfort and pain than those with single banding (402/2457 (16.36%) vs. 24/178 (13.48 %), respectively, $p < 0.05$).

Patients with coexistent external hemorrhoids presented with pain in a percentage higher than those without an external component (141/738 (19.1%) vs. 285/1897 (15.02%), $p < 0.05$).

Table 3 Early results of RBL in 2635 patients with symptomatic hemorrhoids according to hemorrhoidal degree

Results	Degree of hemorrhoids			Total	
	2 nd n (%)	3 rd n (%)	4 th n (%)	n	%
Very good	1193 (95)	1086 (93.7)	7 (3.2)	2286	86.8
Improvement	53 (4.2)	60 (5.2)	123 (55.9)	236	8.9
Failure	10 (0.8)	13 (1.1)	90 (40.9)	113	4.3
Total	1256 (100)	1159 (100)	220 (100)	2635	100

Table 4 Complications

Complications	Patients	
	n	%
Pain	426	16.16
Bleeding	76	2.88
Teinesmus	93	3.52
Thrombosis	38	1.44
Ulceration/fissure	24	0.91
Vagotomy	22	0.83
Fever	2	0.07
Perianal abscess	1	0.04
Perianal tissue necrosis	1	0.04

Multiple regression analysis showed that young age, male sex, and coexisting external hemorrhoids were significant risk factors for pain after RBL of symptomatic hemorrhoids.

Pain was usually treated conservatively with analgesics and warm sitz baths, and only in 47 cases (1.78%), we were forced to remove at least one elastic band.

Urgency and teinesmus were reported in 93 cases during the immediate postoperative period and vagotomy appeared in 22 patients, right after the procedure. In 38 cases, thrombosis of external hemorrhoids was detected as a consequence of the ligation of piles of the internal hemorrhoidal ring. Ulceration or fissure persistent for more than 3 weeks was detected in 24 patients. We detected only one perianal abscess as well as one more case of perianal necrosis in a male patient under chemotherapy for malignant lymphoma, who required surgical debridement.

Admission to the ward was necessary for 30 patients (1.14%). Specifically, 18 of the above were admitted for better pain control and eight for bleeding due to anticoagulant medication, anti-platelet factors, low platelet count, or haemophilia, while four patients with liver cirrhosis were preventively hospitalized.

Follow-up examinations were scheduled 2 months and 2 years after the procedure. From the total number of patients treated, 2484 (94.3%) came back for reassessment in 2 months and 2110 (80.08%) in 2 years. Table 5 shows the long-term results and follow-up of patients with RBL. Symptomatic recurrence was detected in 327 out of 2110 patients (15.49%), and repeat treatment was applied in all of them (repeat RBL treatment in 219/327 cases (66.9 %) and surgical hemorrhoidectomy in 108/327 cases (33.1%)).

Both recurrence and the need of surgical hemorrhoidectomy were related to the degree of hemorrhoids. In patients with 2nd and 3rd degree hemorrhoids, the recurrence rate was 5.3% (129/2415) and the need for surgery 1.9% (47/2415) versus 90% (198/220) recurrence rate and

Table 5 Long-term results of patients after RBL

Results	Patients	Re-examined	Asymptomatic	Symptomatic	Surgery	RBL
Very good	2286	1945	1783	162	47	115
Improvement	236	165	-	165	61	104
Failure	113	-	-	-	-	-
Total	2635	2110	1783	327	108	219

82.3% (181/220) need for surgery in patients with 4th degree hemorrhoids ($\chi^2=649.8, p=0.001$ and $\chi^2=87.32, p<0.001$).

Table 6 shows the influence of the degree of hemorrhoids on the long-term results.

Table 7 shows the results of RBL in cirrhotic patients. All of these patients were lost to follow-up 2 years later.

Discussion

RBL is one of the most widely used methods worldwide for the treatment of symptomatic hemorrhoids, which achieves resection of hemorrhoidal tissue with simultaneous fixation of the mucosa and correction of the prolapse.

The success rates of RBL range between 59 and 91% [4–14]. In our series, 86.8% (2286/2635) of the patients were asymptomatic after the end of the treatment and 84.5% (1783/2110) remained asymptomatic at 2-year follow-up. Two years after RBL, 162 out of 2286 patients with very good early results were symptomatic (7.08%). In 116 of them (71.6%), another session of ligation was performed, while in 47 patients (29.01%) conventional operation proved to be necessary. Symptomatic recurrence was detected in 327 out of 2110 patients who were re-examined (15.49%). All of them underwent repeat treatment (repeat RBL treatment in 219/327 cases and surgery in 108/327 cases). Previous studies reported symptomatic recurrence rate 11.04–20% 2 years after RBL [9, 15, 16], while Cocorullo et al. in a systematic review

in 2016 [17] reported a recurrence rate between 10 and 18.3% 12 months after RBL of symptomatic hemorrhoids.

Candidates for this method are patients with symptomatic 2nd and 3rd degree hemorrhoids, although some authors consider RBL also suitable for appropriately selected cases of advanced hemorrhoidal disease. In our study, the majority of cases had 2nd and 3rd degree hemorrhoids (47.7% and 44% respectively), while 220 cases (8.3%) with 4th degree hemorrhoids were also treated with this method. Early success rate of RBL for 2nd and 3rd degree hemorrhoids was 94.4%, without any difference between them ($p>0.05$), versus 3.2% for 4th degree hemorrhoids. The percentage of asymptomatic patients with 2nd and 3rd degree hemorrhoids remained equally high at 91.6% (1783/1945) 2 years after RBL.

On the contrary, the failure rate of the method was as high as 40.9% in patients with 4th degree hemorrhoids, although 55.9% of these patients had temporary symptomatic improvement after the treatment.

Two years after RBL, all patients with 4th degree hemorrhoids who presented at follow-up were symptomatic.

Several studies have described different rates of complications following RBL, ranging from 3 to 18.8% [6, 9, 16, 18].

In our series, complications were recorded in 593 patients (22.5%) and were mostly minor. It is worth noting that this number refers to complications recorded and not patients, as many of these complications, mainly pain, coexisted in the same patient. The relatively high rate of complications in our series, compared to that of other studies, probably reflects the different health status of patients and the fact that our study is a prospective one.

Table 6 Long-term results of patients with RBL according to the hemorrhoidal degree

Patients	Degree of hemorrhoids			Total n (%)
	2 nd n (%)	3 rd n (%)	4 th n (%)	
Pts who had RBL	1256	1159	220	2635
Pts lost at follow-up	259 (20.6)	227 (19.6)	39 (17.7)	525
Pts at follow-up	997 (79.4)	932 (80.4)	181 (82.3)	2110
Asymptomatic	941 (94.4)	842 (90.3)	-	1783
Symptomatic	56 (5.6)	90 (9.7)	181 (100)	327

Table 7 Early results of RBL in cirrhotic patients

Results	Degree of hemorrhoids			
	2 nd n (%)	3 rd n (%)	4 th n (%)	Total n (%)
Very good	7 (87.5%)	29 (88.8%)	- (-)	36 (63.2%)
Improvement	1 (12.5%)	4 (11.4%)	8 (57.1%)	13 (22.8%)
Failure	- (-)	2 (5.7%)	6 (42.9%)	8 (14%)
Total	8	35	14	57

As in most of the other series, pain is the most frequent complication of RBL. Some studies have reported mild anal pain and discomfort in at least 25–50% of patients for the first 48 h after banding [12, 19, 20], while other studies report rates between 2.3 and 15.9% [9, 15, 16, 21].

In our study, pain was the most common complication affecting 426 patients (16.16%). In most of the cases, the pain appeared immediately or a few hours after the procedure and lasted for less than 2–3 days. In our experience, pain occurred most frequently when the ligation was placed too low in the anal canal.

Patients with multiple hemorrhoidal banding at the same session had greater discomfort and pain compared to those with single banding (16.36% versus 13.48% respectively, $p < 0.05$). These results are in accordance with those of Lee et al. in 1994 [22] and Gehamy and Weakley in 1974 [23]. On the contrary, randomized prospective studies failed to show any relationship between the number of bands applied and the degree of pain [16, 24–26].

Patients with coexistent external hemorrhoids experienced pain in a percentage higher than those without an external component (19.1% versus 15.02%, $p < 0.05$).

Multiple regression analysis showed that young age, male sex, multiple banding, and coexistent external hemorrhoids were significant risk factors for pain after RBL of symptomatic hemorrhoids ($p < 0.05$).

Pain was usually treated conservatively with analgesics and warm sitz baths, while only in 47 cases (1.78%) we were forced to remove at least one elastic band.

Bleeding is a significant complication of RBL. It occurs after 10 to 14 days, probably due to the falloff in the hemorrhoidal nodules and local inflammation, and is unpreventable. Patients under anti-platelet and/or anticoagulant treatment, with low platelet count, and haemophilia are at higher risk of secondary bleeding [27–30]. Seizing antithrombotic medications, platelet transfusion, and replacement of the coagulation factor in deficiency may equalize the bleeding risk to that of patients without the aforementioned disorders.

Mild to significant bleeding was observed in 76 of our patients (2.88%) in a 2-week period after the procedure, which is no different from that previously reported (0.9–4.13%) [6, 15, 16]. It was treated conservatively by local means such as anal spongostan or new ligation. It is worth mentioning that only 8 out of 2635 patients (0.3%) needed hospitalization for bleeding.

Urgency and teinesmus were reported in 93 cases during the immediate postoperative period and vagotomy in 22 patients just after the procedure. In 38 cases, thrombosis of external hemorrhoids was detected as a consequence of the ligation of piles of the internal hemorrhoidal ring. Ulceration or fissure present for more than 3 weeks was detected in 24 patients. We detected only one perianal abscess as well as one more case of

perianal necrosis in a male patient under chemotherapy for malignant lymphoma, who required surgical debridement.

RBL for symptomatic hemorrhoid treatment in 57 patients with liver cirrhosis and portal hypertension was uneventful and only four of those patients were preventively hospitalized. The success rates in these patients were associated with the degree of hemorrhoids and were lower compared to those of non-cirrhotic patients (very good in 63.2% vs. 86.8% ($p < 0.05$), improvement in 22.8% vs. 8.9% ($p < 0.05$), and failure in 14% vs. 4.3% ($p > 0.05$) in cirrhotic versus non-cirrhotic patients, respectively). However, RBL is considered safe for these patients as the complication rates did not differ compared to those of non-cirrhotic patients.

Several infectious complications have been reported following RBL, including perianal sepsis, pelvic abscesses, Fournier's gangrene, liver abscesses, tetanus, and bacterial endocarditis [31–39]. These complications are very rare but frequently fatal, especially in immunosuppressed patients. Therefore, they require early recognition and immediate treatment [34, 40, 41].

Admission to the ward was necessary for 30 patients of our series (1.14%). Specifically, 18 were admitted for better pain control and eight for bleeding while four patients with liver cirrhosis were preventively hospitalized due to coagulation disturbances.

A meta-analysis [42] showed that 6.6–14.3% of patients undergoing RBL will require additional treatment due to symptomatic recurrence.

Symptomatic recurrence was detected in 327 out of 2110 patients (15.49%) with repeat treatment applied in all of them (repeat RBL treatment in 219/327 cases (66.9%) and surgical hemorrhoidectomy in 108/327 cases (33.1%)).

Both recurrence and the need for surgical hemorrhoidectomy were related to the degree of hemorrhoids. In patients with 2nd and 3rd degree hemorrhoids, the recurrence rate was 5.3% (129/2415) and the need for surgery 1.9% (47/2415), versus 90% (198/220) recurrence rate and 82.3% (181/220) need for surgery in patients with 4th degree hemorrhoids ($\chi^2 = 649.8$, $p = 0.001$ and $\chi^2 = 87.32$, $p < 0.001$).

A disadvantage of RBL is that no pathologic specimen is obtained. Therefore, some cases of anal carcinoma may be overseen. The above-mentioned risk is minimized when careful examination, performed by an experienced surgeon, takes place prior to the procedure. Apart from that, the probability of finding an unexpected anal cancer is very low (one case out of 21,257 hemorrhoidectomy specimens) according to Cataldo and MacKeigan [43].

Established facts

The existing literature suggests that RBL is an effective method for the treatment of 2nd and 3rd degree hemorrhoids. On the

other hand, pain is the most frequent complication and most of the existing studies show that multiple banding is related to increased pain incidence [9, 12, 15, 16, 19–21].

Furthermore, there were no significant data regarding the application of RBL to 4th degree hemorrhoids and cirrhotic patients.

Novel insights

In our study, pain remained the most frequent complication but appeared to a significantly lower proportion of patients (16.16%). We also identified, via multiple regression analysis, multiple banding, young age, male sex, and external hemorrhoids as significant risk factors for pain ($p < 0.05$).

Finally, we showed that RBL can be applied safely in cirrhotic patients and in selected cases of 4th degree hemorrhoids.

Conclusion

RBL of symptomatic hemorrhoids is a safe, simple, effective, low-cost method with good results regarding the treatment of second and third degree hemorrhoids. It can also be applied in selected cases of fourth degree hemorrhoids such as patients with only one or two 4th degree piles, or patients that are not fit for surgery, due to severe comorbidities, with transient and less satisfactory results though. It also seems to be safe for patients with liver cirrhosis and portal hypertension.

Code availability Not applicable

Author contributions Vasilios Komporozos: method application and composing the “Discussion” section

Antonia Papazoglou: coordination, editing, and correspondence

Vasiliki Ziozia: collection of material and results and writing

Aikaterini Komporozou: statistical analysis

George Stravodimos: collection of material and results and writing

Ageliki Kolinioti: collection of material and results and writing

Data Availability Not applicable

Declarations The current study regards an already approved technique and not an experimental procedure. Therefore, no ethical approval was required.

Consent to participate Not applicable

Consent for publication Not applicable

Conflict of interest Nothing to declare

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